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INSTITUTIONAL REVIEW BOARD
FOR THE PROTECTION OF HUMAN SUBJECTS

Section VII.

IRB MEMBERSHIP, RESPONSIBILITIES AND PROCEDURES

Selection of IRB Members
Responsibilities of the Chair
Meeting Dates and Corresponding Application Deadlines for Submitting Protocols to the IRB (see below)
Procedures for IRB Meetings
Records

IRB Meetings and Corresponding Application Deadlines:

The IRB will hold its meetings the first week of every month unless there is no scheduled business.

All IRB research proposals must be submitted to the Chair of the IRB Committee by the **15th day of each month** in order to be considered at the next schedule meeting of the IRB.

Chair of the IRB: Theodore Wasserman Ph.D
Associate Dean, Institute for Achievement and Learning
International Building Suite 202,
Phone: 561-271-3489, E-mail: Twasserman@Lynn.edu

Section VIII. IRB RESOURCES

IRB Guidebook http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
Review: Ch. 3 IRB Review in the Guidebook, paying attention to Risk/Benefit Assessment
http://www.hhs.gov/ohrp/irb/irb_chapter3.htm

CFR (Code of Federal Regulations, **TITLE 45 PUBLIC WELFARE, PART 46 PROTECTION OF HUMAN SUBJECTS** Effective June 25, 2005): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Institutional Review Boards and the HIPAA Privacy Rule (Protected Health Information, and De-Identifiers)
http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp
-IRB requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research (alteration of the Authorization requirement are in section 164.512(i) of the Privacy Rule) http://privacyruleandresearch.nih.gov/pr_02.asp

Sample Forms Permitted Use of PHI:
http://www.irb.pitt.edu/hipaa/HIP_Auth_2.doc
http://www.irb.umn.edu/guidance/hipaa/hipaaforms.cfm
(or of relatives, employers, or household member of the individual) must be removed **Identifiers**

Informed Consent (*Make sure required and other elements are present).* Lynn University Required Language for Elements of your Informed Consent. Use language where appropriate. Last revision posted Oct. 14, 2006. This generic consent includes consent elements for adult (18+) interviews including audio (or tape) recordings and surveys. Use this form and adapt to your project, maintaining required language.

ATTENTION: For Child Assent, Parental Consent, Questionable Capacity etc. add additional language to comply with IRB.

Tips (Include USDHHS and APA) http://www.socialpsychology.org/consent.htm
Consent Short Form (you need to include script of oral information):
http://www.research.umn.edu/irb/consent/shortforms.cfm

Guidelines for Child Assent:
http://www.usm.maine.edu/orc/irb/pdf/child_assent.pdf
Sample Consent Forms and Information (Review HIPAA and De-Identification above):
http://www.augsburg.edu/irb/sample.html

Research Involving Individuals with Questionable Capacity to Consent:
http://grants.nih.gov/grants/policy/questionablecapacity.htm

Research with Human Subjects from a Foreign Country
Become familiar with the CFR. The Application tells explains what is needed - and it will vary with the country and the type of research. See Application Form 1, Part C. (5) Human Subjects in a Foreign Country http://www.irb.umn.edu/guide/humanGuide2.cfm#2_9 (review paragraph 2.9)

International Compilation of Human Subject Research Protection (2005) of many countries.
http://www.hhs.gov/ohrp/international/HSPCompilation.pdf

Internet Surveys:

Ethical and Legal Aspects of Human Subjects Research on the Internet
http://www.aaas.org/spp/sfrl/projects/intres/report.pdf

Examples on Minimal Risk (Important)
http://www.research.umn.edu/irb/applying/minrisk.cfm
http://darkwing.uoregon.edu/~humansub/examples.html

UMI Publishing Agreement and Submission Forms for Dissertations and Theses:
www.il.proquest.com/dissertationagree
login - dissertations
password - publish

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Required IRB Training
Lynn University offers an IRB training course through the *http://phrp.nihtraining.com/users/login.php For The Protection of Human Research Subjects.* This training is up-to-date and meets the federal requirements for training in human subjects protections. Completion of this training is required for individuals participating in the IRB process.

Section IX. LYNN UNIVERSITY IRB FORMS

Examples with Permission of Students:
Full Board Review (Form 1 only) 12-6-06 Andrew Huang
Exempt (Form 1 and Form 2) 12-14-06 Martha Pang (Secondary analysis of data, no human subjects)
IRB FORM 1 - *(Last Revised **1-12-07**)* Application and Research Protocol for Review of Research Involving Human Subjects in a New Project Application and Research Protocol for Review of Research Involving Human Subjects in a New Project ***(This Application is Required for all new research projects)***
11-7-05: IRB requests that all permissions provided via e-mail, for use of instruments, agencies, figures or tables, etc, are communicated using your Lynn-email (rather than a personal address. Furthermore, the contact information of the provider of the permission must be included in the e-mail).
IRB FORM 2 - *(Revised 3-21-07)* Request for Exemption
IRB FORM 3 - *(Revised 3-21-07*) Request for Expedited Review
IRB FORM 4 - *(Revised 3-21-07*) Application to Continue (Renew) a Previously Approved IRB Project (***Must be submitted annually)***
IRB FORM 5 - *(Revised 3-21-07*) Application for Procedural Revisions of or Changes in Research Protocol and/or Informed Consent Form I of a Previously Approved Project
IRB FORM 6 - *(Revised 3-21-07*) Report of Unexpected Adverse Event
IRB FORM 7 - *(Revised 3-21-07*) Request for Approval of Advertisements to Recruit Subjects
IRB FORM 8 - *(Revised 3-21-07*) Report of Termination of Project (***Must be submitted by All researchers)***

Section I.

HISTORY OF INSTITUTIONAL REVIEW BOARDS AND/OR HUMAN SUBJECTS REVIEW COMMITTEES and PROFESSIONAL CODES OF ETHICS

I. HISTORY OF INSTITUTIONAL REVIEW BOARDS AND/OR HUMAN SUBJECTS REVIEW COMMITTEES and PROFESSIONAL CODES OF ETHICS

To gain an understanding of why *Institutional Review Boards* and/or *Human Subjects Review Committees* are of necessity a brief history follows of the development of international codes, federal laws and regulations, State statutes and policies and procedures in institutions and agencies involved in human subjects in research. "Prior to 1906, when the **Pure Food and Drug Act** was passed, there were no regulations regarding the ethical use of human subjects in research. There were no consumer regulations, no Food and Drug Administration (FDA), no Common Rule, and no Institutional Review Board (IRB)." http://www.iupui.edu/~resgrad/Human%20Subjects/ethics3A.html (8-5-01)

Ethical concerns with the use of human subjects for research was dramatically addressed with the **Nuremberg Code**. This Code was developed for the *Trials of War Criminals Before the Nuremberg Military Tribunals* (October 1946–April 1949) to judge the human experimentation conducted by against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. Among the charges were that German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. Most of the subjects of these experiments died or were permanently crippled as a result. On December 9, 1946, the American military tribunal opened. After almost 140 days of proceedings, including the testimony of 85 witnesses and the submission of almost 1,500 documents, the American judges pronounced their verdict on August 20, 1947. Sixteen of the doctors were found guilty. Seven were sentenced to death. They were executed on June 2, 1948 (http://www.ushmm.org/research/doctors/index.html (8-5-01)).

While it did not have the force of law, the Nuremberg Code was the first international document that advocated voluntary participation and informed consent. The Nuremberg Code encompassed many ethical principles governing research with human subjects today, including:

1. the voluntary consent of the human subject is absolutely essential,
2. avoid all unnecessary physical and mental suffering and injury,
3. assess the degree of risk, and
4. the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible. (See http://ecco.bsee.swin.edu.au/studes/ethics/Nuremberg.html and http://www.ushmm.org/research/doctors/Nuremberg_Code.htm, 8-5-01)

In the late 1950s, while not approved in the United States by the FDA, thalidomide was approved as a sedative in Europe. The drug was prescribed to control sleep and nausea throughout pregnancy, but it was soon found that taking this drug during pregnancy caused severe deformities in the fetus. Many patients did not know they were taking a drug that was not approved for use by the FDA, nor did they give informed consent. Some 12,000 babies were born with severe deformities due to thalidomide. After the thalidomide disaster, legislators recognized that the drug approval process had to be more tightly controlled. Congress bolstered the FDA's regulatory powers by passing the **Kefauver-Harris Drug Amendments Act in October 1962**. As a result of this ruling, scientists had to prove that a drug was safe and effective before it could be sold to the American public. (http://science-education.nih.gov/nihHTML/ose/snapshots/multimedia/ritn/Thalidomide/fda.html http://www.fda.gov/fdac/special/newdrug/benlaw.html 8-5-01)

Declaration of Helsinki (http://www.wma.net/e/policy/17-c_e.html 8-5-01). In 1964, the World Medical Association established recommendations guiding medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki was revised in 1975, 1983, 1989,1996 and 2000 and is the basis for Good Clinical Practices used today. Issues addressed in the Declaration of Helsinki include:

1. Research with humans should be based on the results from laboratory and animal experimentation
2. Research protocols should be reviewed by an independent committee prior to initiation
3. Informed consent from research participants is necessary
4. Research should be conducted by medically/scientifically qualified individuals
5. Risks should not exceed benefits

In the United States, and due to the publicity from the Tuskegee Syphilis Study, the **National Research Act of 1974** (Pub. L. 93-348) was passed. For 40 years (1932-1972), there were 399 African males that were denied treatment for syphilis and were deceived by officials of the United States Public Health Service. http://www.dc.peachnet.edu/~shale/humanities/composition/assignments/experiment/tuskegee.html. "In 1932 the American Government promised 400 men - all residents of Macon County, Alabama, all poor, all African American - free treatment for Bad Blood, a euphemism for syphilis which was epidemic in the county. Treatment for syphilis was never given to the men and was in fact withheld. The men became unwitting subjects for a government sanctioned medical investigation, The Tuskegee Study of Untreated Syphilis in the Negro Male. The Tuskegee Study, which lasted for 4 decades, until 1972, had nothing to do with treatment. No new drugs were tested; neither was any effort made to establish the efficacy of old forms of treatment. It was a nontherapeutic experiment, aimed at compiling data on the effects of the spontaneous evolution of syphilis on black males. What has become clear since the story was broken by Jean Heller in 1972 was that the Public Health Service (PHS) was interested in using Macon County and its black inhabitants as a laboratory for studying the long-term effects of untreated syphilis, not in treating this deadly disease. From the moment the experiment begun, the immorality of the experiment was blatantly apparent. Many critics of The Tuskegee Study draw comparisons to the similar degradation of human indignity in inhumane medical experiments on humans living under the Third Reich. How could such callousness happen outside Nazi Germany? To deny that race played a role in The Tuskegee Study is naive. All 600 subjects (399 experimentals and 201 controls) were black; the PHS directors and most of the doctors who studied them were white. Was The Tuskegee Study government sanctioned, premeditated genocide? In July 1972, Jean Heller broke the story."

The National Research Act created the **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.** One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects, and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. The Commission was directed to consider

(i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine,
(ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects,
(iii) appropriate guidelines for the selection of human subjects for participation in such research and
(iv) the nature and definition of informed consent in various research settings.
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm, 8-6-01)

The National Research Act codified the requirement that human subjects in research must be protected and set the stage for the issuance of the **Belmont Report**.

> The basic ethical principles that we still use to guide research with human subjects were described in the Belmont Report and underlie all of the regulations: respect for persons, beneficence, and justice. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects. Respect for persons involves recognizing the personal dignity and autonomy of individuals, and special protection of those with diminished autonomy. It requires that all people involved in research give Informed Consent that contains the elements of (1) information, (2) comprehension, and (3) voluntariness. Beneficence is the obligation to protect people from harm by maximizing anticipated benefits and minimizing possible risks of harm. Justice requires that the benefits and burdens of research be distributed fairly" http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm and http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm#xethical, 8-5-01)

Since the Belmont Report, the Department of Health and Human Services (DHHS) and the Federal Drug Administration (FDA) set up their own guidelines that became **the Code of Federal Regulations (CFR).** These have been revised several times, and in 1991 the Federal Policy for the protection of Human Subjects was adopted (typically known as the "Common Rule"). Other protections have been added at various time -- these are always printed in the Federal Register. To facilitate education and the development of curricula, the NIH launched a **website on bioethics** in 1999. (See http://www.nih.gov/sigs/bioethics/). Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html 8-3-01) These guidelines are administrative requirements, not yet within the federal regulations, "The Common Rule." This **mandatory training** can be accessed on the web site of the NIH Office of Human Subjects Research at http://ohsr.od.nih.gov/ (8-3-01).

Each State establishes its own policies, and in the state of Florida statute; the State of Florida including Florida Statute Title XXIX PUBLIC HEALTH, Chapter 381 Public Health: General Provisions, 381.85 Biomedical and Social Research **("Florida Biomedical and Social Research Act.").**

> http://www.leg.state.fl.us/Statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=&URL=CH0381/SEC85.HTM

Professional Associations. Since the 1970's many professional associations developed professional codes of ethics, and researchers should adhere to standards for research with human subjects established by professional associations to which they are members, including the APA Ethical Principles of Psychologists and Code of Conduct http://www.apa.org/ethics/code.html, The American Sociological Association's (ASA's) Code of Ethics http://www.asanet.org/ecoderev.htmSociological, organization of university professors (http://www.aaup.org/repirb.htm) and the The National Education Association http://www.nea.org/aboutnea/code.html. **The Center for Ethics** (Illinois Institute of Technology) received a grant from the National Science Foundation to put their collection of codes of ethics on the World-Wide Web. This on-line source contains over 850 codes of ethics of professional societies, corporations, government, and academic institutions http://csep.iit.edu/codes.

Section II.

INSTITUTIONAL OVERSIGHT OF HUMAN SUBJECT RESEARCH AT LYNN UNIVERSITY

II. INSTITUTIONAL OVERIGHT OF HUMAN SUBJECT RESEARCH AT LYNN UNIVERSITY

The Vice-President for Academic Affairs (VPAA) is the institutional official responsible for ensuring compliance with Human Subject Research regulations, statutes and institutional policies.

Responsibilities:

(1) The VPAA shall supervise the overall execution of this policy and procedures.

(2) The VPAA or designee shall periodically review federal and state regulations and maintain this procedure accordingly.

(3) The VPAA shall review and approve appointments to the *Lynn University Institutional Review Board for the Protection of Human Subjects in Research (IRB)* to ensure compliance with federal and state requirements and institutional policies.

(4) The VPAA or designee shall make required compliance reports to external reports.

(5) The VPAA may initiate the promulgation of implementing policies supporting this procedure such as Filing Assurances of Protection for Human Subjects for federally funded research.

(6) The VPAA or designee shall review, supervise and approve *"Annual Review of Research Committees"* assigned in academic units ("The Colleges and Schools") for periodic review of research with approved IRB exempt status.

Section III.

OVERVIEW: INSTITUTIONAL POLICIES, LAWS, REGULATIONS AND STATUTES, AND DEFINITIONS

IRB: Institutional Review Board for the Protection of Human Subjects in Research
Compliance: Laws, Regulations, Statutes and Professional Codes of Ethics
Definitions
Research and Human Subject Research
Research in Foreign Countries
Cooperative Research
Informed Consent
Investigator and Researcher
Updating (if Changes in Regulations/Laws/Statutes)
Levels of IRB Review (Convened Full-Board, Expedited, Exempted Research)

III. OVERVIEW INSTITUTIONAL POLICIES, LAWS, REGULATIONS AND STATUTES, AND DEFINITIONS

Institutional Review Board for the Protection of Human Subjects in Research (IRB).

All human subject research and research-related activities involving human subjects conducted within or under the auspices of Lynn University by any faculty, employees or students, is subject to the Institutional Review Board **(IRB)** review, recommendations if warranted, and final approval. The IRB is responsible for review all applications and research protocols for new projects, continuation (renewal), advertisements for recruitment of subjects, procedural revisions and reports of unexpected adverse events and project termination (See Purview of the IRB).

The IRB conducts **continuing reviews** of research at intervals appropriate to the degree of risk, but at least once per year. The IRB conducts reviews on all non-exempt and exempt research.

Compliance

Researchers bear the primary responsibility for compliance with all applicable laws, statues and regulations. This IRB policy of Lynn University is designed to ensure compliance with laws, rules, regulations, statutes and professional codes of ethics associated with:

(1) the State of Florida including Florida Statute Title XXIX PUBLIC HEALTH, Chapter 381 Public Health: General Provisions, 381.85 Biomedical and Social Research ("Florida Biomedical and Social Research Act."). The website is:

http://www.leg.state.fl.us/Statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=&URL=CH0381/SEC85.HTM

Section 381 § (c)3 States: It is the intent of the Legislature that: The rules to be adopted by the department and the procedures and criteria to be adopted by the Review Council for Biomedical and Social Research be guided by the ethical standards for human research set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

(2) The guidelines established by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the ethical principles applicable to such research as summarized in the Belmont Report, the Code of Federal Regulation Title 45 Part 46 (known as 45CFR §C46), and the Office of Protection from Research Risks (HHS). The web site) is: http://ohrp.osophs.dhhs.gov/polasur.htm.

A variety of federal agencies are authorized to issue their own human subject research regulations. The most well-known is the Food and Drug Administration's regulation of clinical investigations involving new drugs or food additions, 21 CFR § 50 (http://www.fda.gov/oc/ohrt/irbs/default.htm). Many agencies have sought consistency with Human Subject Research regulation by adopting the "**common rule**" or "federal policy" that is described in the HHS regulations (45CFR §§ 46).

Human Subjects Research Regulated by FDA. Investigators conducting human subject research involving products regulated by the Food and Drug Administration (FDA) are subject to FDA regulations in Title 45 of the Code of Federal Regulations, Parts 50 and 56. There are some differences in FDA and PHS regulations, and investigators should become familiar with those that may apply to their research. A summary of the differences in the two sets of regulations is available at www.fda.gov/oc/ohrt/irbs/. The most significant difference involves the FDA exception from informed consent requirements for emergency research (45 CFR §50.24).

Human Subjects Education Training is required for federally supported research and is further required by Lynn University for non-federally supported research. In addition to training that may be obtained through course work, training programs may be found in:

Investigator: http://cme.nci.nih.gov/

IRB Members/Administration (Human Subject Assurance Training): http://137.187.172.201/cbttng_ohrp/default.asp?CBTID=2

Lynn University offers an IRB training course through the *http://phrp.nihtraining.com/users/login.php For The Protection of Human Research Subjects.* This training is up-to-date and meets the federal requirements for training in human subjects protections. Completion of this training is required for individuals participating in the IRB process.

(3) standards for research with human subjects established by professional associations pertinent to their discipline (Codes of Ethics).

(4) all other applicable Lynn University policies.

While Federal and State regulations apply to institutions that receive Federal or State research funds, it is the intent of Lynn University to apply the principles found in these regulations to research conducted at Lynn University, for the purpose of protection of Human Subjects. Lynn University is committed to the general principles embodied in the Belmont Report.

Typically an *Institutional Review Board* means a federally required committee that reviews research, using federal standards, for the protection of human subjects. A *Human Subjects Review Committee* means a committee, similar to the federally required Institutional Review Board, that reviews research under state standards for the protection of human subjects. At Lynn University, **the *Institutional Review Board for the Protection of Human Subjects in Research* (IRB)** satisfies dual roles for both federal and state standards.

Section IV.

IRB APPLICATION INSTRUCTIONS AND LEVELS OF IRB REVIEW

New Research Projects
Application and Research Protocol **(*Required for all new research projects)***
Convened Full Board Review of New Research Projects
Expedited Review of New Research Projects
Exemption Procedures for Review of New Projects

Other IRB Reviews
Training or Center Grants
Preliminary/Indefinite Plans
Application to Continue or Renew a Previously Approved Project
Application for a Procedural Revision for a Previously Approved Project
Report of Unexpected Adverse Event
Request for Approval of Advertisements to Recruit Subjects
Report of Project Termination

IV. IRB APPLICATION INSTRUCTIONS AND LEVELS OF IRB REVIEW

A submission for review by the IRB must be prepared for each research study using human subjects or human materials. All of the appropriate forms must be neatly typed and accurately completed. The IRB review cannot be accomplished unless all of the sections are completed. Any application that is not completed properly will be returned, possibly resulting in a delay in the review process.

Application materials **(IRB FORMS)** are available online. Simply click on the appropriate form listed on the IRB website. Submissions to the IRB are accepted in electronic format. Please follow the instructions for completing the forms that are in PDF format.

New Research Projects

All new research projects require an **IRB APPLICATION AND RESEARCH PROTOCOL FOR REVIEW OF A NEW PROJECT (FORM 1).** For new applications and research protocols, there are three levels of review: Full Board Review, Expedited Review and Exempt

FORM 2 (Request for Exemption) **or FORM 3 (Expedited Review)** is to be completed and submitted along with the IRB application and Research Protocol (FORM 1) if the investigator believes the proposal qualifies for:

- An exemption from Federal Regulations as noted in 45 CFR §46.101(b), exempt from full board or expedited review.
- An expedited review as noted in CFR 45 §46.110, for certain kinds of research involving no more than minimal risk

Convened Full Board Review of New Research Projects

A Convened Full-Board Review occurs when the application and research protocols (FORM 1) involve more than minimal risk to research participants or vulnerable populations of research participants (other than minors when the protocol qualifies for expedited review) and are reviewed by the IRB at a convened meeting. Formal IRB meetings are held monthly during the academic year. Researchers intending to conduct research which will require full IRB review/discussion should submit their research protocols to the Chair, IRB, at least two weeks prior to the board's monthly meeting. All submissions to the IRB are done electronically and are immediately distributed to the committee for review. Therefore IRB notifications are rolling. Only those proposals that do not obtain consensus votes or have an IRB member indicate that they wish a formal discussion would be held for the full board meeting. Notification from the IRB will also occur in an electronic format.

- Submit all material electronically
- Electronically signed IRB Application and Research Protocol (FORM 1); all pages must be completed.
- Consent Form and other requested materials and attachments
- Advertisement for Subject Recruitment, if applicable (FORM 7)

Expedited Review of New Research Projects

Under expedited review procedures, reviews may be carried out by the IRB Chairperson, or at the discretion of the Chairperson, by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45 §46.108(b).

- Submit all materials to the IRB electronically.
- Signed IRB Application and Research Protocol (FORM 1), all pages must be completed
- Consent Form when applicable and other requested materials and attachments (please collate with Application and Research Protocol copies)
- Completed Request for Expedited Review (FORM 3) An expedited review as noted in CFR 45 §46.110, for certain kinds of research involving no more than minimal risk
- Advertisement for Subject Recruitment, if applicable (FORM 7)
- Under normal circumstances, the Chair and generally not exceeding 5 IRB members, is able to review protocols in this category within 10 business days after receipt of a substantively complete protocol.

Exemption Procedures for Review of New Projects

Under request for IRB exemption procedures, reviews may be carried out by the IRB Chairperson, or at the discretion of the Chairperson, by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45§46.108(b).

- Submit all materials to the IRB electronically.
- Signed IRB Application and Research Protocol (FORM 1), all pages must be completed
- Consent Form when applicable and other requested materials and attachments
- Completed Request for Exemption (FORM 2) An exemption from Federal Regulations as noted in 45 CFR §46.101(b), exempt from full board or expedited review.
- Advertisement for Subject Recruitment, if applicable
- Under normal circumstances, the Chair or another member, and generally not exceeding 3 IRB members, is able to review protocols in this category within 10 business days after receipt of a substantively complete protocol.

Other IRB Reviews

Reviews may be carried out by the IRB Chairperson, or at the discretion of the Chairperson, convened Full-Board Review or expedited by one or more experienced reviewers designated by the chairperson from among members of the IRB. The IRB reserves the right to request the investigator to provide additional information concerning applications or reports. After review, the IRB will send the applicant formal notification of IRB actions.

Training or Center Grants

When training grants are submitted and some projects are expected to involve human subjects, the training grant will be reviewed by the IRB Chairperson, or at the discretion of the Chairperson, by the full board or by one or more experienced reviewers designated by the chairperson from among members of the IRB. A certification of IRB review and approval will be sent to the funding agency.

(Note: Training and Center grants will be reviewed even though specific research projects for trainees or sub-projects are not fully described in the application. When IRB approval is provided for such applications, it will be contingent upon each project director submitting a complete or updated application and research proposal (FORM 1) to the IRB prior to the initiation of their particular project.)

The principal investigator is responsible for ensuring that all subprojects supported by the training grant are also submitted for full IRB review prior to initiation. The annual continuing review of the training grant requires submission of a list of subprojects that involve human subjects and documentation that they have been reviewed by the IRB.

- Submit a complete proposal/grant as it was submitted to funding agency
- Signed IRB Application and Research Protocol (FORM 1), FORM 2 (Request for Exemption) or FORM 3 (Expedited Review) if applicable, all pages must be completed
- Consent Form when applicable and other requested materials and attachments
- Advertisement for Subject Recruitment, if applicable (FORM 7)

Preliminary/Indefinite Plans

In instances where there is no immediate involvement of human participants, such as grant proposals planned for submission or where the research Application and Research Protocol (FORM 1) is not complete and a preliminary review is desired, proposals fall into this category. Generally, the review is conducted by the IRB Chairperson, or at the discretion of the Chairperson, by the full board or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

Upon completion of the review, a letter advising to proceed with the funding request, request for further information or further development of the proposal will be sent to the Principal Investigator. In cases of a funded project, upon funding, a detailed protocol describing the research (including the informed consent process and research instruments) must be reviewed and approved by the IRB (as a full, expedited or exempt study), pending the nature of the investigation.

- Cover Letter requesting a Preliminary Review and Purpose
- Signed IRB Application and Research Protocol (FORM 1), all pages must be completed
- Signed IRB Application and Research Protocol (FORM 1), FORM 2 (Request for Exemption) or FORM 3 (Expedited Review) if applicable, all pages must be completed
- Advertisement for Subject Recruitment, if applicable (FORM 7)

Application to Continue or Renew a Previously Approved Project

> An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research CFR 45 §46.109)(e).

The Lynn University IRB determines that adequate provisions are in place for monitoring the data collected to ensure the safety of subjects. Following initial approval, the researcher must seek review for projects at the intervals mandated by the IRB, not to exceed one year. The researcher is expected to forward FORM 4 in a timely manner, allowing the IRB to review the project well before it expires, thus avoiding an interruption in research. Failure to seek continuing review may jeopardize present and future projects.

(1) For projects that require a Convened Full-Board Review, the researcher forwards FORM 4 and an updated consent form to the IRB no later than two months prior to the due date for renewal.

(2) If a research proposal was authorized by expedited review, or the researcher believes the renewal qualifies for expedited review, the researcher forwards FORM 4 and an updated consent no later than one month prior to the due date for renewal.

(3) If a research proposal was authorized for exempt status, the researcher forwards FORM 4 and an updated consent no later than one month prior to the due date of the anniversary of initial approval.

IRB FORM 4 - LYNN UNIVERSITY IRB APPLICATION TO CONTINUE (RENEW) A PREVIOUSLY APPROVED PROJECT

Application for a Procedural Revision for a Previously Approved Project

The principal investigator is responsible for obtaining prior approval for changes in accordance with policies. Expedited review procedures may be used for certain kinds of research involving no more than minimal risk, and for minor changes in approved research CFR 45 §46.110. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45 §46.108(b). If the procedural change is judged to involve more than minimal risk, intentional deception, or questions pertaining to a protected population and does not meet the categories for exempt or expedited review it must be presented to for a convened full-board review board for discussion and consideration of approval or non-approval. The IRB reserves the right to request the investigator to provide additional information concerning the application for a procedural change. After review, the IRB will send the applicant formal notification of IRB actions.

IRB FORM 5 - LYNN UNIVERSITY IRB APPLICATION FOR PROCEDURAL REVISIONS OF OR CHANGES IN RESEARCH PROTOCOL AND/OR INFORMED CONSENT FORM 1 OF A PREVIOUSLY APPROVED PROJECT

Report of Unexpected Adverse Event

The responsible project investigator must promptly notify the sponsor (when applicable), supervising Vice-President and IRB Chair of any problems involving human subjects that arise during the course of the research project (See FORM 6). Problems include unanticipated side effects or adverse reactions from participation in the project and, of course, any injuries. If any emergency occurs during a research project, investigators should first call 911 and be prepared to provide the following information to the dispatcher: (1) type of injury and what assistance is needed, (2) number of victims, (3) the location and instructions on how to get there, and (4) their name and telephone number.

For students, if the accident is minor, they must go to Health Center if open. The Health Center is authorized to refer them elsewhere if necessary. For research projects at more than minimal risk, the consent form should include information on available medical treatment if injury should occur and whether any compensation is available for treatment of injuries.

IRB FORM 6 - LYNN UNIVERSITY IRB REPORT OF UNEXPECTED ADVERSE EVENT, SERIOUS INJURY, OR DEATH

Request for Approval of Advertisements to Recruit Subjects

It is the policy of Lynn University that the IRB review and approve all advertising or other forms of solicitation for subject recruitment and approval must be granted by the IRB prior to implementation of recruitment strategy.

IRB FORM 7 - LYNN UNIVERSITY IRB REQUEST FOR APPROVAL OF ADVERTISEMENTS TO RECRUIT SUBJECTS

Report of Project Termination

The IRB conducts review of reports of project termination on all non-exempt and exempt research.

One month after the conclusion of data collection (termination of study), the principal investigator submits 3 copies of IRB FORM 8, unless otherwise requested. This allows the IRB to monitor the status of all human subject research. Failure to submit an IRB report of project termination may jeopardize future projects. The IRB reserves the right to request the investigator to provide additional information concerning the report of project termination. After review, the IRB will send the applicant formal notification of IRB actions.

IRB FORM 8 - LYNN UNIVERSITY IRB REPORT OF TERMINATION OF PROJECT

Section V.

PURVIEW OF LYNN UNIVERSITY'S INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH (IRB)

V. PURVIEW OF LYNN UNIVERSITY'S INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH (IRB)

The purpose of the IRB is to safeguard the safety, privacy, health, and welfare of the human subjects involved in research and research-related activities. The IRB reviews three categories of research: new projects, periodic review on a continuing project, or a procedural revision to a previously approved project.

Vested with this ethical imperative to safeguard the rights and welfare of human subjects in research studies, the IRB peer-reviews protocols to assure protection of human subjects in three major areas:

(a) the procedures do not place the subject at risk, include no unnecessary risks and minimize potential risks to subjects,

(b) the subject is informed about the purpose and intent of the research along with the necessary and sufficient details, including description of the risks or discomforts and the anticipated benefits, to assure voluntary and informed consent, and

(c) privacy of the subjects and confidentiality of subject data are adequately protected.

Where the participants are members of a vulnerable population, the IRB determines whether appropriate additional safeguards are in place to protect the rights and welfare of these research participants.

Furthermore, the **benefits of the research must outweigh the risks** to the subjects. The IRB measures the importance and significance of the scientific knowledge potentially gained against risks to study subjects. The researcher is required to provide the supporting documentation. For Lynn University, the IRB is the only authorized University committee to make this determination.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval includes a statement of the reasons for the IRB's action and is reported promptly to the investigator, appropriate institutional officials, and pertinent external bodies.

The IRB is responsible for review of Applications and Research Protocols required for all new research. The IRB determines intervals of periodic review (continuation/renewal), and, where appropriate, determines that adequate provisions are in place for monitoring the data collected to ensure the safety of subjects. The IRB is responsible for review of procedural revisions, advertisements to recruit subjects, and reports of adverse events and project termination.

In reviewing Human Subject Research applications, protocols and reports, the IRB implements full board review or expedited and exempt procedures. The IRB is responsible for adhering to the Code of Federal Regulations (CFR 45 §46) which serves as the preeminent guide in approval of research at Lynn University. CFR 45 §46.111 specifies Criteria for IRB Approval of Research (See Section VI of IRB guidelines) and these are summarized below:

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits
3. Selection of subjects is equitable.
4. Informed consent will be sought
5. Informed consent will be appropriately documented,
6. Ensure the safety of subjects
7. Protect the privacy of subjects and to maintain the confidentiality of data.

Section VI.

CRITERIA FOR IRB APPROVAL OF RESEARCH (CFR 45 §46.111)

VI. CRITERIA FOR IRB APPROVAL OF RESEARCH (CFR 45 §46.111).

(a) In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

(1) **Risks to subjects are minimized**:
(i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. (CFR 45 §46.111).

Subject Risk
Minimal Risk means that the probability and magnitude of harm or discomfort in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This definition may vary for vulnerable classes of human subjects. (CFR 45 §46.102)

The potential for physical risk is most obvious in procedures requiring medical intervention or involving strenuous exertion.

There is a wide range of medical, social, and behavioral research that may pose no immediate physical risk to the subject, but may involve varying degrees of emotional stress, deceit, invasion of privacy, etc. (http://www.uiuc.edu/unit/vcres/irb/hbsec3.html#C4 Univ. of Illinois, 7-25-01)

Investigators have many obligations, including designing the study so that the incidence of risk and stress are minimized to the greatest degree possible and that these risks are accurately described in the protocol. Investigators must also make appropriate provisions for the over-all care of the subjects where applicable. The Investigator bears responsibility for terminating the study when hazards or risks to the subject become apparent or may be incompatible with the benefits of the study; further, investigators must report any adverse reactions associated with the study to the IRB.

(2) **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (CFR 45 §46.111).

It is the investigator's responsibility to minimize the risks associated with any research and to make clear to the research subjects any benefits that may result to them directly or more generally to society. Direct payments or other forms of remuneration to the research subject are not considered to be benefits of participation. Evaluation of the risk/benefit ratio is a primary consideration in the IRB review of research protocols (http://www.uiuc.edu/unit/vcres/irb/hbsec3.html#C4 Univ. of Illinois, 7-25-01)

(3) **Selection of subjects is equitable.** In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons. (CFR 45 §46.111).

(4) **Informed consent** will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

General requirements for informed consent. (CFR 45 §46.116). **See (a)-(f)**

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) **Basic elements of informed consent**. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so,

what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) **additional elements of informed consent**. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, **State,** or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(5) **Informed consent will be appropriately documented**, in accordance with, and to the extent required by §46.117.

Documentation of informed consent. CFR 45 §46.117

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in

any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Common Problems with Consent Forms:
http://rgp.ufl.edu/irb/irb02/ifcprob.html (University of Florida 7-30-01)
Internet Sources (Examples of Consent Forms)
http://rgp.ufl.edu/irb/irb02/samples.html

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to **ensure the safety of subjects**. (CFR 45 §46.111).

(7) When appropriate, there are adequate provisions to **protect the privacy of subjects and to maintain the confidentiality of data.** (CFR 45 §46.111).

Issues of Confidentiality: Source of Information University of Illinois: http://www.uiuc.edu/unit/vcres/irb/hbsec3.html#C4 (7-27-01)

In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. The more sensitive the material, the greater the care that must be exercised. Ordinarily, the following requirements must be met:

(1) Questionnaires, inventories, interview schedules, and other data-gathering instruments and procedures should be carefully designed to limit the personal information to be acquired to that which is essential.
(2) Data that could reveal a subject's identity should be stored in files accessible only to the project investigator and authorized staff.
(3) As early as feasible, the data should be coded to remove identifying information.
(4) The identity of subjects must not be released except with their express permission.
(5) Use of existing data that were originally obtained for different purposes and that involve identifiable subject information, requires examination of the risk involved. There should be a determination of whether the new use is within the scope of the original consent or whether it is necessary or feasible to obtain additional consent. Anonymity of the subjects must be preserved in these cases.
(6) Some research protocols use audio or video taping of research subjects. Subjects should always be told in the informed consent that taping will occur. Explicit consent must be obtained for any public use of the tapes such as use in the classroom or as part of a public presentation of the research results, since this constitutes a waiver of the normal confidentiality of research data.

(b) **When some or all of the subjects are likely to be vulnerable** to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. (CFR 45 §46.111).

Pregnant Women, The Fetus and Human in vitro fertilization: See CFR 45 46.201-§46.211 Subpart B
Prisoners: CFR 45 §46.301-306 Subpart C
Children: CFR 45 §46.401- §46.409. Subpart D

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. CFR 45§46.402. The age of majority in the State of Florida is 18 years of age.

Veterans: See Title 38 CFR Part 16
http://www.access.gpo.gov/nara/cfr/waisidx_98/38cfr16_98.html
Research Involving Special Subject Groups (see
http://www.uiuc.edu/unit/vcres/irb/hbcontents.html)

Deception in Research:

In most investigations the subject should be made aware of the major purposes of the research. Usually **minor deception** consists of merely failing to tell the subject what the specific points of interest are in an attempt to prevent biasing the results. Deception of this kind is reasonable and acceptable as long as the investigator provides justification for its use, and debriefs the subjects after their participation, when appropriate. http://ohrp.osophs.dhhs.gov/irb/irb_chapter3.htm More frequently, however, IRBs will confront the possibility of psychological harm when reviewing behavioral research that involves an element of deception, particularly if the deception includes false feedback to the subjects about their own performance. **IRB Guidebook:** http://ohrp.osophs.dhhs.gov/irb/irb_chapter5.htm

The IRB Committees take any use of **intentional deception** in research seriously, because it puts subjects at risk because they have not been able to give fully informed consent. The research must satisfy the IRB that deception, when acceptable is unavoidably required by the research to be done and

the benefits outweigh the risks. When deception is involved in research, the IRB may request that the subjects be **debriefed** when appropriate. In some instances, debriefing may be inappropriate such as when the debriefing may itself be an unreasonable risk of harm without a countervailing benefit.), the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the subjects will be debriefed. The IRB should also make sure that the proposed subject population is suitable. [See Guidebook Chapter 3, Section A, "Risk/Benefit Analysis."] **IRB Guidebook:** http://ohrp.osophs.dhhs.gov/irb/irb_chapter5.htm

Debriefing "after deception has several goals: to repair the breach of informed consent entailed by the deception, to remove any confusions or defuse any tensions that might have been generated by the deception, to make it clear especially to younger subjects that deception is permissible only in exceptional circumstances, and to repair (as much as possible) the breach of trust that has occurred not only between the investigator and the subject, but (potentially) between all researchers and all subjects" http://depts.washington.edu/hsd/INFO/deception.htm.

The following is adapted from The University of Washington provides the following http://depts.washington.edu/hsd/INFO/deception.htm

Debriefing usually has two components. One is a debriefing protocol; the other is an accompanying written debriefing statement.

The debriefing protocol constitutes a guideline for in-person interaction between subjects and investigators. It should indicate how you will review and explain the nature of, and reasons for, the deception with the subjects, should express regret for the necessity of deceiving the subjects, and should offer the subjects a chance to ask questions or work through any confusion they might have.

The written debriefing statement should present the same information in summary form, and should include a contact telephone number and name for subjects to call if they should have further questions or concerns. The written debriefing statement should express regret for the necessity of deceiving the subjects, should explain what the deception was and why it was necessary, should offer the subjects a chance to ask questions or work through any confusion they might have, and should (if there is a significant risk of such reactions) offer information about sources of further support, counseling, or other assistance subjects may need as a result of the deception. It is also important, especially when students have served as subjects, to present this material in a way that introduces the subjects to the broader conceptual and research issues involved. http://depts.washington.edu/hsd/INFO/deception.htm

In order to monitor the IRB's approval of use of major deception in research, the IRB may review the study in relation to the following Ethics Monitoring Questionnaire developed by the University of Alabama http://bama.ua.edu/~sprentic/607%20outline-deception%20methodology.html

A. Take-home questionnaire, stamped envelope--distributed after the debriefing. Returned by mail to someone other than the experimenter.
B. Items (Yes-No format with space provide for comments)
   (1) Now that the purpose of the experiment has been completely explained to you, do you think we were justified in telling you that the study was about (fill in cover story).
   (2) Do you believe that you were forced to participate in the study?
   (3) Do you believe that you received a fair explanation of the risks involved in the experiment?
   (4) Do you think that the study was set up so as to prevent you from experiencing unjustified injury or harm?
   (5) Should this experiment be allowed to continue?
   (6) If you had it to do over again, would you be willing to participate in a similar study?

Section VII. Rev. 11-06-03

IRB MEMBERSHIP, RESPONSIBILITIES AND PROCEDURES

Selection of IRB Members
Responsibilities of the Chair
Meeting Dates and Corresponding Application Deadlines for Submitting Protocols to the IRB (see below)
Procedures for IRB Meetings
Records

IRB Meetings and Corresponding Application Deadlines:

The IRB will hold its meetings the first week of every month unless there is no scheduled business.

All IRB research proposals must be submitted to the Chair of the IRB Committee by the **15th day of each month** in order to be considered at the next schedule meeting of the IRB.

VII. IRB MEMBERSHIP (45 CFR §46.107), RESPONSIBILITIES AND PROCEDURES

Selection of IRB Members

IRB members are selected for their experience, expertise, diversity and breadth in backgrounds and represent individuals with primary concerns in both scientific and non-scientific areas.

The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The VPAA shall review and approve all appointments to the Lynn University Institutional Review Board for the Protection of Human Subjects in Research (IRB) to ensure compliance with federal and state requirements and institutional policies.

Nine Members constitute the committee and a Chair is elected annually (first meeting in Fall) from among the committee members. Members include:

Deans of the Colleges in the University (or their designated representatives)
Coordinators of the Ph.D. Programs
General Counsel (*non-scientific area)*
One non-affiliated University member from the community at-large (3-year Term)

> A non-affiliated member means an IRB member who is not affiliated with or employed by the University, nor part of the immediate family of a person who is affiliated or employed by the University.

Five full-time, doctorally prepared faculty", representing each one of the following discipline areas: (1) Arts and Humanities, (2) Business Management and Hospitality Administration, (3) Education, (4) Health and Human Services and (5) Natural, Social and Behavioral Sciences. Representatives are elected by members of the discipline areas for a 3-year term** and must be approved by the VPAA. A member may not serve more than two consecutive terms.

**In order to promote continuity among members from year to year, the cycle of 3-year terms for the discipline representatives will be phased in as shown on the next page. The first years of the cycle is indicated and then the cycle repeats as indicated:

Disciplines	**Cycle Year One**	**Cycle Year Two**	**Cycle Year Three**	**Cycle Year Four**
Arts and Humanities (ADS, COA, COM, ENG, HUM, LAN, MUS)	X (F2001, 2002, 2003) 3-year Term	X	X	Elect Rep for 3-year term (F2004, 2005, 2006)
Business and Hospitality	X (F2001, 2002, 2003) 3-year Term	X	X	Elect Rep for 3-year term (F2004, 2005, 2006)
Education	X (F2001, 2002) 2-year Term	X	Elect Rep for 3-year term (F 2003, 2004, 2005)	
Health and Human Services (CRJ, CJA, EMA, HS, BMT, HCA, NUR)	X (F2001, 2002) 2-year Term	X	Elect Rep for 3-year term (F 2003, 2004, 2005)	
Natural, Social and Behavioral Sciences (IRPS, HIS, IR, PSY, SCI, SOC)	X (F2001) 1-year Term	Elect Rep for 3-year term (F 2002, 2003, 2004)		

Responsibilities of the Chair

The Chair shall preside over meetings of the IRB.

Each application, request or report pertaining to a research proposal shall be identified by an IRB Number that begins with the year of initial submission, followed by three digits. For example, the first application submitted in the year 2001, has the seven digit assigned IRB number of: 2001001 and the second application has the IRB number of 2001002. A record is maintained on each IRB project, appropriately labeled with an IRB number.

Assign review to IRB members for applications and research proposals and other requests or reports that do not require a convened full-board review.

The Chair shall forward all applications and IRB report forms to the Office for Academic Affairs for records maintenance at the end of the Calendar year (June 30). (See Records maintenance)

All formal correspondence, decisions and recommendations in the name of the IRB shall include the IRB number and bear the signature of the Chair. The Chair shall forward all communications to the Office for Academic Affairs for records maintenance at the end of the Calendar year (June 30).

The Chair shall maintain a list of IRB members for each academic year and include the following:

A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. (45 CFR §46.103) A form may be created.

> *In instances where a project is funded or sponsored by the Federal Government: changes in IRB membership shall be reported to the Department or Agency head, unless in accord with §46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.*

The IRB Chair shall receive all IRB Applications two weeks prior to the scheduled IRB meeting. The Chair shall forward all proposals to each IRB member no later than one week prior to convened meetings. Communications to investigators shall be made in writing, within 5 working days of the IRB meeting.

An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. (45 CFR § 46.109)

The Chair shall keep all IRB members advised of actions which use the expedited review procedure and applications through regular reporting at convened meetings for approved expedited reviews, exemptions, continuation, procedural revisions, advertisements to recruit subjects, and reports of adverse events and project termination.

Meeting Dates and Corresponding Application Deadlines for Submitting Protocols to the IRB

The IRB meets once a month. Applications for IRB review of protocols are due the 15th day of each month prior to the next meeting.

Procedures for IRB Meetings

The IRB shall meet and conduct business at least twice a year, or more often at the call of the chairperson.

The Chair of the IRB shall be elected at the first meeting of the calendar year (first meeting in Fall) by members of the IRB. If the position of Chair becomes vacant, a new Chair shall be elected at the next scheduled meeting.

At the option of the IRB, a Vice-Chair may be elected from among the IRB members to assist the Chair in performance of duties.

A rotating secretary shall be appointed for each meeting.

Principal Investigators and Co-Principal Investigators may attend the IRB meeting to provide information to the members, but they may not be present during the final discussions and vote.

IRB members may not participate in the review and approval process of their own protocols.

Meetings (and Records: 45 CFR §46.115 IRB records)

Attendance shall be recorded
Agenda Items Include:

1. Approval of Minutes
2. Approval of Agenda
3. Old Business
4. New Business: Reports or IRB Committee Review and Action
   Include Assigned IRB Number, title, and author.
   Provide Records of Actions, Discussion and Resolution of Controverted Issues

4.1 Application and Protocol for Review of Research Involving Human Subjects for a New Project (IRB Form 1)
4.2 Application to Continue (renew) a Previously Approved IRB Project (Form 2)
4.3 Application for Procedural Revisions of or Changes in Research Protocol and/or Informed Consent for IRB Form 1 of a Previously Approved Project (IRB Form 3)
4.4 Report on Unexpected Adverse Event, Serious Injury, or Death (IRB Form 4)
4.5 Applications and Protocol for Requests for Exemptions (IRB Form 5)
4.6 Applications and Protocol for Expedited Reviews (IRB Form 6)
4.7 Request for Approval of Advertisements to Recruit Subjects (IRB Form 7)
4.8 Report of Termination of IRB Projects (IRB Form 8)
4.9 Other Business

5. Adjournment and Announcement of Next Meeting Date

Rules of Order: parliamentary procedures follow Robert's Rules of Order

Quorum:
A quorum of the IRB shall consist of at least 1/2 of the current membership. Furthermore, it shall consist of at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

Voting: Voting on matters shall be by viva voce (by the voice), or "show of hands," general (unanimous) consent unless some one objects, or by request for a secret (written) ballot by any single member of the committee.

Proxy Voting. A proxy is a power of attorney given by one member of the committee to another to vote in his/her behalf.

All actions shall require affirmation of a majority of a quorum of the current membership except in the following instances where two-thirds of the majority is required.

Motions Requiring a Two-thirds of the majority include but are not limited to the following:
Amend any part of the these By-laws, or Rules of Order, previously adopted;
Suspending the Rules
Expelling a member from Membership:

In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

The IRB may consult outside experts, target populations, and others to assist in decision-making during the review process when deemed necessary.

Records (45 CFR §46.115)

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5). *CFR 45*§46.116(b)(5) *(Informed Consent). This is: a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;*

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research, which is conducted, shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the [Federal] Department or Agency at reasonable times and in a reasonable manner [when applicable] (Approved by the Office of Management and Budget under Control Number 9999-0020.)

Section VIII.

IRB RESOURCES

PART I

IRB Guidebook http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
Review: Ch. 3 IRB Review in the Guidebook, paying attention to Risk/Benefit Assessment
http://www.hhs.gov/ohrp/irb/irb_chapter3.htm

CFR (Code of Federal Regulations, **TITLE 45 PUBLIC WELFARE, PART 46 PROTECTION OF HUMAN SUBJECTS** Effective June 25, 2005): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Institutional Review Boards and the HIPAA Privacy Rule (Protected Health Information, and De-Identifyers) http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp
-IRB requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research (alteration of the Authorization requirement are in section 164.512(i) of the Privacy Rule) http://privacyruleandresearch.nih.gov/pr_02.asp

Sample Forms Permitted Use of PHI:
http://www.irb.pitt.edu/hipaa/HIP_Auth_2.doc
http://www.irb.umn.edu/guidance/hipaa/hipaaforms.cfm

Certification of De-identification:
http://www.policies.uchc.edu/policies/HIPAADeidentifiedCertification.pdf
For information to be de-identified the following identifiers of the individual (or of relatives, employers, or household member of the individual) must be removed Identifiers

Institutional Review Board Guidebook

* CHAPTER III *
BASIC IRB REVIEW

A. RISK/BENEFIT ANALYSIS

INTRODUCTION

Risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. This requirement is clearly stated in all codes of research ethics, and is central to the federal regulations. One of the major responsibilities of the IRB, therefore, is to assess the risks and benefits of proposed research.

DEFINITIONS

Benefit: A valued or desired outcome; an advantage.

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §___.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. [*See* 45 CFR 303(d) and Guidebook Chapter 6, Section E, "Prisoners."]

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

OVERVIEW

There are two sources of confusion in the assessment of risks and benefits. One arises from the language employed in the discussion: "Risk" is a word expressing probabilities; "benefits" is a word expressing a fact or state of affairs. It is more accurate to speak as if both were in the realm of probability: *i.e.*, risks and expected or anticipated benefits. Another confusion may arise because "risks" can refer to two quite different things: (1) those chances that specific individuals are willing to undertake for some desired goal; or (2) the conditions that make a situation dangerous *per se*. The IRB is responsible for evaluating risk only in the second sense. It must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies inviting any person to undertake the

risks. The IRB should disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits. [*See also* Guidebook Chapter 5, Section A, "Overview: Social Policy Experimentation."]

IRB CONSIDERATIONS

The IRB's assessment of risks and anticipated benefits involves a series of steps. The IRB must: (1) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research; (2) determine that the risks will be minimized to the extent possible [*see* Guidebook Chapter 3, Section A, "Risk/Benefit Analysis," and Chapter 3, Section E, "Monitoring and Observation"]; (3) identify the probable benefits to be derived from the research; (4) determine that the risks are reasonable in relation to be benefits to subjects, if any, and the importance of the knowledge to be gained; (5) assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits [*see* Guidebook Chapter 3, Section B, "Informed Consent"]; and (6) determine intervals of periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected [*see* Guidebook Chapter 3, Section E, "Monitoring and Observation," and Chapter 3, Section H, "Continuing Review"]. In addition, IRBs should determine the adequacy of the provisions to protect the **privacy** of subjects and to maintain the **confidentiality** of the data [*see* Guidebook Chapter 3, Section D, "Privacy and Confidentiality"], and, where the subjects are likely to be members of a vulnerable population (*e.g.*, mentally disabled), determine that appropriate additional safeguards are in place to protect the rights and welfare of these subjects. [*See* Guidebook Chapter 6, "Special Classes of Subjects."] Research to which DHHS regulations apply that involves fetuses or pregnant women, prisoners, or children is governed by special provisions [45 CFR 46 Subpart B, 45 CFR 46 Subpart C, and 45 CFR 46 Subpart D, respectively]. [*See also*, Guidebook Chapter 6, "Special Classes of Subjects."]

Identification and Assessment of Risks. In the process of determining what constitutes a risk, only those risks that may result from the research, as distinguished from those associated with **therapies** subjects would undergo even if not participating in research, should be considered. For example, if the research is designed to measure the behavioral results of physical interventions performed for therapeutic reasons (*e.g.*, effects on memory of brain surgery performed for the relief of epilepsy), then only the risks presented by the memory tests should be considered when the IRB performs its risk/benefit analysis. It is possible for the risks of the research to be minimal even when the therapeutic procedure presents more than minimal risk. IRBs should recognize, however, that distinguishing therapeutic from research activities can sometimes require very fine line drawing. Before eliminating an activity from consideration in its risk/benefit analysis, the IRB should be certain that the activity truly constitutes therapy and not research.

It is important to recognize that the potential risks faced by research subjects may be posed by design features employed to assure valid results as well as by the particular interventions or maneuvers that may be performed in the course of the research. Subjects participating in a study whose research design involves **random assignment** to treatment groups face the chance that they may not receive the treatment that turns out to be more efficacious. Subjects participating in a **double-masked** study take the risk that the information necessary for individual treatment might not be available to the proper persons when needed. In behavioral, social, and some biomedical research, the methods for gathering information may pose the added risk of invasion of **privacy** and possible violations of **confidentiality**. Many risks of research are the risks inherent in the methodologies of gathering and analyzing data, although the more obvious risks may be those posed by particular interventions and procedures performed during the course of research.

A final potential risk to subjects is the possible long-range effect of applying the knowledge gained through research. For example, information gained about associative memory may enable advertising companies to develop new techniques for encouraging arguably harmful consumer behaviors; associations between race or gender and intelligence may have profound effects on public policy. The regulations specifically provide, however, that IRBs should not consider such effects "as among those research risks that fall within the purview of its responsibility" [Federal Policy §___.111].

The risks to which research subjects may be exposed have been classified as physical, psychological, social, and economic [Levine (1986), p. 42].

Physical Harms. Medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. All of these should be considered "risks" for

purposes of IRB review. Some of the adverse effects that result from medical procedures or drugs can be permanent, but most are transient. Procedures commonly used in medical research usually result in no more than minor discomfort (*e.g.*, temporary dizziness, the pain associated with venipuncture). Some medical research is designed only to measure more carefully the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness. Such research may not entail any significant risks beyond those presented by medically indicated interventions. On the other hand, research designed to evaluate new drugs or procedures may present more than minimal risk, and, on occasion, can cause serious or disabling injuries.

Psychological Harms. Participation in research may result in undesired changes in thought processes and emotion (*e.g.*, episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be either transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but IRBs should be aware that some research has the potential for causing serious psychological harm.

Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence. These feelings may be aroused when the subject is being interviewed or filling out a questionnaire. Stress may also be induced when the researchers manipulate the subjects' environment - as when "emergencies" or fake "assaults" are staged to observe how passersby respond. More frequently, however, IRBs will confront the possibility of psychological harm when reviewing behavioral research that involves an element of deception, particularly if the deception includes false feedback to the subjects about their own performance. Some examples from the American Psychological Association's guidebook, *Ethical Principles in the Conduct of Research with Human Subjects* (1973), illustrate the kinds of research - and the types of psychological risks - IRBs may encounter:

A social psychologist attached a psycho-galvanometer to subjects (male college students). The participants were told that the needle would be deflected if they were aroused, and that if the needle deflected when they viewed photographs of nude males, it would indicate latent homosexuality. Then false feedback was given so that the subjects were led to believe incorrectly that they were latent homosexuals. After the experiment, the ruse was explained.

Students in a school of education were told by the experimenter that questionnaires revealed that they were unsuited for the teaching profession, although this was untrue. The expectation was that students with such evaluations would do poorly in their course work because these negative appraisals would lower their self-esteem. Many of the students were upset with the "results" of the questionnaire and considered abandoning the teaching profession.

The work which seems to me to raise ethical questions of the most serious type occurred in a military setting. It involved taking untrained soldiers, disorienting them, placing them in an isolated situation, giving them false instructions, and leading them, as individuals, to believe that they had caused artillery to fire on their own troops and that heavy casualties had occurred. The subjects ran, cried, and behaved in what they could only consider an unsoldierly way, and no amount of debriefing could remove the knowledge that they had done so.

Invasion of privacy is a risk of a somewhat different character. In the research context, it usually involves either covert observation or "participant" observation of behavior that the subjects consider private. [*See* Guidebook Chapter 3, Section D, "Privacy and Confidentiality."] The IRB must make two determinations: (1) is the invasion of privacy involved acceptable in light of the subjects' reasonable expectations of privacy in the situation under study; and (2) is the research question of sufficient importance to justify the intrusion? The IRB should also consider whether the research design could be modified so that the study can be conducted without invading the privacy of the subjects.

Breach of confidentiality is sometimes confused with invasion of privacy, but it is really a different problem. Invasion of privacy concerns access to a person's body or behavior without consent; confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another. [*See* Guidebook Chapter 3, Section D, "Privacy and Confidentiality."]

Some research requires the use of a subject's hospital, school, or employment records. Access to such records for legitimate research purposes is generally acceptable, as long as the researcher protects the confidentiality of that information. The IRB must be aware, however, that a breach of confidentiality may result in psychological harm to individuals (in the form of embarrassment, guilt, stress, and so forth) or in social harm (see below).

Social and Economic Harms. Some invasions of privacy and breaches of confidentiality may result in embarrassment within one's business or social group, loss of employment, or criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Some social and behavioral research may yield information about individuals that could "label" or "stigmatize" the subjects. (*e.g.*, as actual or potential delinquents or schizophrenics). Confidentiality safeguards must be strong in these instances. The fact that a person has participated in HIV-related drug trials or has been hospitalized for treatment of mental illness could adversely affect present or future employment, eligibility for insurance, political campaigns, and standing in the community. A researcher's plans to contact such individuals for follow-up studies should be reviewed with care.

Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective subjects during the consent process.

Minimal Risk vs. Greater Than Minimal Risk. Once the risks have been identified, the IRB must assess whether the research presents greater than minimal risk. The regulations allow IRBs to provide **expedited review** of proposals if certain conditions exist (the research must present no more than minimal risk, and the involvement of human subjects must fall into one or more categories approved by DHHS) [Federal Policy §___.110]. Alternatively, when the proposed research presents no more than minimal risk, waiver or modification of consent requirements may be available (if certain other conditions are met) [Federal Policy §___.116(d); note, however: FDA does not provide for waiver of consent requirements].

In research presenting more than minimal risk, potential subjects must be informed of the availability of medical treatment and compensation in the case of research-related injury, including who will pay for the treatment and the availability of other financial **compensation** [Federal Policy §___.116(a)(6); 21 CFR 50.25(a)(6)]. Although institutions are not required to provide care or payment for research injuries, many have procedures for reducing the cost of research-related injuries by providing hospitalization and necessary medical care, at least in emergency situations. A few institutions have formal insurance programs to cover lost income, as well as the direct costs of hospitalization and medical care.

Minimal Risk and Especially Vulnerable Populations. DHHS regulations on research involving fetuses and pregnant women [45 CFR 46 Subpart B], research involving prisoners [45 CFR 46 Subpart C], and research involving children [45 CFR 46 Subpart D] strictly limit research presenting more than minimal risk. **The National Commission for the Protection of Human Subjects** recommended special limitations on research presenting more than minimal risk to persons institutionalized as mentally disabled. For such subjects, the Commission recommended that minimal risk be defined in terms of the risks normally encountered in the daily lives or the routine medical and psychological examination of healthy subjects. IRBs should therefore determine whether the proposed subject population would be more sensitive or vulnerable to the risks posed by the research as a result of their general condition or disabilities. If so, the procedures would constitute more than minimal risk for those subjects.

These concerns are equally applicable to other subjects. Taking a blood sample or pulling a tooth may represent significant risk to a hemophiliac; outdoor exercises might be dangerous to persons with asthma if the air is polluted or saturated with allergens; modest changes in diet might be dangerous to diabetics; and over-the-counter drugs, normally taken for minor ailments, might pose more than minimal risk to pregnant women. Deciding whether or not research procedures will present more than minimal risk to the proposed subject population is a matter requiring careful consideration and case-by-case review. [*See also* Guidebook Chapter 6, "Special Classes of Subjects."]

Determination That Risks Are Minimized. Risks, even when unavoidable, can be reduced or managed. Precautions, safeguards, and alternatives can be incorporated into the research activity to reduce the probability of harm or limit its severity or duration. IRBs are responsible for assuring that risks are minimized to the extent possible.

In reviewing any protocol, IRBs should obtain complete information regarding experimental design and the scientific rationale (including the results of previous animal and human studies) underlying the proposed research, and the statistical basis for the structure of the investigation. IRBs should analyze the beneficial and harmful effects anticipated in the research, as well as the effects of any treatments that might be administered in ordinary practice, and those associated with receiving no treatment at all. In addition, they should consider whether potentially harmful

effects can be adequately detected, prevented, or treated. The risks and complications of any underlying disease that may be present must also be assessed.

IRBs should determine whether the investigators are competent in the area being studied, and whether they serve dual roles (*e.g.*, treating physician, teacher, or employer in addition to researcher) that might complicate their interactions with subjects. For example, an investigator's eagerness for a subject to continue in a research project (to obtain as much data as possible) may conflict with the responsibility, as a treating physician, to discontinue a therapy that is not helpful or that results in significant adverse effects without countervailing benefit. Likewise, teachers or supervisors who conduct research could (wittingly or unwittingly) coerce student- or employee-subjects into participating. Thus any potential conflicts of interest must be identified and resolved before IRB approval is granted.

Another way for IRBs to meet this responsibility is to assess whether the research design will yield useful data. When the sample size is too small to yield valid conclusions or an hypothesis is imprecisely formulated, subjects may be exposed to risk without sufficient justification. While good research design may not itself reduce or eradicate risks to subjects, poor or faulty research design means that the risks are not likely to be reasonable in relation to the benefits. To help assess the research design, some IRBs include a biostatistician as a member; others consult with statisticians when the need arises. Not all procedures designed to increase the statistical validity of a study may be justified. Procedures, even those included for purposes of good research design, that add disproportionate risks to subjects may be unacceptable. [*See* Guidebook Chapter 4, "Considerations of Research Design."]

A useful method of minimizing risk is to assure that adequate safeguards are incorporated into the research design. Frequent monitoring, the presence of trained personnel who can respond to emergencies, or coding of data to protect confidentiality are examples. It may be necessary to exclude individuals or classes of subjects (*e.g.*, pregnant women, diabetics, people with high blood pressure) whose vulnerability to a drug or procedure may increase with the risks to them. In certain types of clinical trials, special provisions need to be made for monitoring the data as they accumulate to assure the safety of patients, or to assure that no group or subgroup in a trial is compromised by a less effective treatment. Data monitoring should also be used to ensure that the trial does not continue after reliable results have been obtained. In large-scale drug trials, this often requires establishing a specialized **data and safety monitoring board** or committee to review the incoming data at stated intervals. [*See* Guidebook Chapter 3, Section E, "Monitoring and Observation," Chapter 4, "Considerations of Research Design," and Chapter 5, Section B, "Drug Trials."]

A subject's symptoms or condition may worsen during the course of a study, and medical problems caused by an adverse reaction to experimental therapy or an unrelated illness may arise. If the study design is such that the investigators do not know which treatment individual subjects are receiving, there should be a mechanism permitting someone else to break the code so that appropriate treatment can be provided to a subject experiencing such difficulty. In a medical emergency, individuals in **single-** or **double-masked** studies may require treatment by physicians unfamiliar with the research. In such cases, providing the subject with a card or bracelet identifying someone who can provide the necessary information is a wise precaution.

The investigator can often obtain research data from the procedures performed for diagnosis or treatment of a patient's condition, thus avoiding unnecessary risks to the subjects. Research should always be designed to avoid exposing participants to unnecessary risks, particularly if invasive or risky procedures (*e.g.*, spinal tap, cardiac catheterization) are involved.

In behavioral research involving deception or incomplete disclosure, especially if the research may induce psychological stress, guilt, or embarrassment, it is often suggested that subjects be "**debriefed**" after their participation. Debriefing gives the investigator an opportunity to explain any deception involved and to help the subjects deal with any distress occasioned by the research. In rare instances, such debriefing may not be helpful C it may even be harmful. Some subjects may not benefit from being told that the research found them to be willing to inflict serious harm to others, have homosexual tendencies, or possess a borderline personality. Again, the IRB must be sensitive to possible harms, and use good judgment, evaluating the potential risks on a case-by-case basis. [*See* Guidebook Chapter 3, Section B, "Informed Consent."]

Assessment of Anticipated Benefits. The benefits of research fall into two major categories: benefits to subjects and benefits to society. Frequently, the research subjects are undergoing treatment, diagnosis, or examination for an illness or abnormal condition. This kind of research often involves evaluation of a procedure that may benefit the subjects by ameliorating their conditions or providing a better understanding of their disorders. Patients and healthy individuals may also agree to participate in research that is either not related to any illnesses they might have or that is related to their conditions but not designed to provide any diagnostic or **therapeutic** benefit. Such research is designed principally to increase our understanding and store of knowledge about human physiology and behavior. Research that has no immediate therapeutic intent may, nonetheless, benefit society as a whole. These benefits take the form of increased knowledge, improved safety, technological advances, and better health. The IRB should assure that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

Direct payments or other forms of **remuneration** offered to potential subjects as an incentive or reward for participation should not be considered a "benefit" to be gained from research. [*See* Guidebook Chapter 3, Section G, "Incentives for Participation."] Although participation in research may be a personally rewarding activity or a humanitarian contribution, these subjective benefits should not enter into the IRB's analysis of benefits and risks.

Determination That the Risks Are Reasonable in Relation to Anticipated Benefits. Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals. The risk/benefit assessment is not a technical one valid under all circumstances; rather, it is a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit. Consequently, different IRBs may arrive at different assessments of a particular risk/benefit ratio.

Determining whether the risks are reasonable in relation to the benefits depends on a number of factors, and each case must be reviewed individually. An IRB's decision depends not only on currently available information about the risks and benefits of the interventions involved in the research, but also on the degree of confidence about this knowledge. Although information drawn from animal research may be highly suggestive of the risks and benefits to be expected for humans, it is not conclusive (because human responses may differ from those of animals). Similarly, absence of data concerning risks does not necessarily mean that no risks exist.

An IRB's assessment of risks and benefits must also take into account the proposed subjects of the research (*e.g.*, children, pregnant women, terminally ill). [*See* Guidebook Chapter 3, Section C, "Selection of Subjects."] In addition, IRBs should be sensitive to the different feelings individuals may have about risks and benefits. Some subjects may view surgery (and thus avoiding chronic illness or prolonged medication) as a benefit while others would consider it a significant risk (and instead view chronic medication as a benefit because they can avoid the need for surgery). An elderly person might consider hair loss or a small scar an insignificant risk, whereas a teenager could well be concerned about it. IRB members should remember that their appraisals of risks and benefits are also subjective. Finally, risk/benefit assessments will depend on whether the research: (1) involves the use of interventions that have the intent and reasonable probability of providing benefit for the individual subjects; or (2) only involves procedures performed for research purposes.

In research involving an intervention expected to provide direct benefit to the subjects, a certain amount of risk is justifiable. In studies designed to evaluate therapies for life-threatening illness, risk of serious adverse effects may be acceptable. However, in any trial of a new or not-yet-validated treatment, the ratio of benefits to risks should be similar to those presented by any available alternative therapy.

In research where no direct benefits to the subject are anticipated, the IRB must evaluate whether the risks presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable. There should be a limit to the risks society (through the government and research institutions) asks individuals to accept for the benefit of others, but IRBs should not be overprotective. While the IRB must consider the importance of the knowledge that may result from the research, the IRB's appreciation of that importance may, at times, be limited. If only minimal risks are involved IRBs do not need to protect competent adult subjects from participating in research considered unlikely to yield any benefit.

Disclosure of Risks and Benefits. *See* Guidebook Chapter 3, Section B, "Informed Consent."

Continuing Review and Monitoring of Data. The Federal Policy requires that IRBs continue to reevaluate research projects at intervals appropriate to the degree of risk but not less than once a year [Federal Policy §___.108(e)]. Periodic review of the research activity is necessary to determine whether the risk/benefit ratio has shifted, whether there are unanticipated findings involving risks to subjects, and whether any new information regarding the risks and benefits should be provided to subjects. It is important to note that the risk/benefit ratio may change over time. At the time of initial review, the IRB should determine whether an independent **data and safety monitoring board** or committee is required, and should also set a date for reevaluating the research project. The issue of continuing review by the IRB is addressed more fully in Guidebook Chapter 3, Section H, "Continuing Review."

During the course of a study, unexpected side effects may occur or knowledge resulting from another research project may become available. The IRB may then need to reassess the balance of risks to benefits. In light of the reassessment, the IRB may require that the research be modified or halted altogether. Alternatively, special precautions or criteria for inclusion may be relaxed. Between IRB reviews, it is largely the researchers' responsibility to keep the IRB informed of significant findings that affect the risk/benefit ratio. In larger studies or clinical trials, a data and safety monitoring committee may be responsible for keeping the IRB up-to-date. Even isolated incidents of unanticipated adverse reactions must be reported to the IRB. The IRB must then decide whether the research should be modified. In addition, a report from one research activity may sometimes be relevant to the evaluation of another.

Federal policy also requires that investigators inform subjects of any important new information that might affect their willingness to continue participating in the research [Federal Policy §___. 116]. [*See* Guidebook Chapter 3, Section B, "Informed Consent."]

POINTS TO CONSIDER

1. Are both risks and anticipated benefits accurately identified, evaluated, and described?

2. Are the risks greater than minimal risk? Has the IRB taken into account any special vulnerabilities among prospective subjects that might be relevant to evaluating the risk of participation?

3. If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?

4. Has due care been used to minimize risks and maximize the likelihood of benefits?

5. Are there adequate provisions for a continuing reassessment of the balance between risks and benefits? Should there be a data and safety monitoring committee?

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B. INFORMED CONSENT

INTRODUCTION

Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of **respect for persons**. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. This assurance protects all parties C both the subject, whose **autonomy** is respected, and the investigator, who otherwise faces legal hazards. The "proxy consent" of someone other than the subject is not the same as the subject's own consent, although it may be an acceptable substitute when a subject is unable to give informed consent. [*See* Guidebook Chapter 6, "Special Classes of Subjects."] Federal Policy consent requirements are provided in §§___.116 and ___.117; FDA consent requirements are provided in 21 CFR 50.20-27 and 21 CFR 56.109.

OVERVIEW

The **Nuremberg Code**, developed by the International Military Tribunal that tried Nazi physicians for the "experiments" they performed on unconsenting inmates of concentration camps, was the first widely recognized document to deal explicitly with the issue of informed consent and experimentation on human subjects. The first principle of the code states:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

All subsequent codes and regulations, insofar as they pertain to competent, adult subjects, follow these principles closely.

Although the elements of informed consent (*i.e.*, full disclosure, adequate comprehension, voluntary choice) are easy to enumerate, recent empirical studies suggest they are not so easy to achieve. Even the best intentions do not ensure against failures of communication C information may be poorly conveyed or subjects may forget (if indeed they ever understood) that they are involved in a research project. Enhancing the likelihood that informed consent will take place is a challenge to which IRBs should respond with imagination and good judgment. When the proposed research will involve vulnerable subjects or the research design involves incomplete disclosure or deception, the challenges to the IRB are even greater. Certain populations (*e.g.*, children or mentally retarded individuals) may not be able to understand the required information, whereas other populations (e.g., prisoners or institutionalized individuals) are so situated that the voluntariness of their consent may be in doubt. Hospitalized patients, particularly those who are seriously ill or undergoing emergency treatment, may also need special protection. Problems raised by the involvement of some vulnerable populations are discussed in other sections of this Guidebook. [*See* Chapter 6, "Special Classes of Subjects."]

IRB CONSIDERATIONS

The issues discussed in this section are general IRB considerations regarding informed consent, and they apply generally to the review of research that involves human subjects. Problems surrounding the use of deception or incomplete disclosure are discussed near the end of this section under the headings "Exceptions," "Deception and Incomplete Disclosure," and "Placebos, Randomization, and Double-Masked Clinical Trials."

The Regulations. The federal regulations require that certain information must be provided to each subject [Federal Policy §___.116(a)]:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The regulations further provide that the following additional information be provided to subjects, where appropriate [Federal Policy §___.116(b)]:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

Investigators may seek consent only under circumstances that provide the prospective subject or his or her representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the subject or representative. The consent process may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence [Federal Policy §___.116].

Adequacy of the Content. One of the IRB's most important activities is evaluating the information to be provided to potential subjects in light of the risks and benefits of the proposed research procedures. Each IRB member brings a different perspective to this review. Certain expert members may be able to correct the technical information or identify omissions in the consent documents provided by the investigators. Other members may add their reactions to the way information is provided or question the adequacy of the information. Whether or not the information is deemed "adequate" depends partly on the impression being conveyed (*e.g.*, whether it is clear that a procedure is to be done for research purposes).

In making a judgment concerning what information should be disclosed in the informed consent process, the IRB should attempt to view the matter from the subject's perspective by asking what facts the subjects might want to know before deciding whether or not to participate in the research. Information could be deemed "material" if it might influence the decision of any reasonable person. For example, the risk of death from cardiac catheterization might be statistically small, and, therefore, seem unimportant to an investigator, but the risk may loom large for people invited to undergo the procedure for the benefit of others. Research in sensitive areas such as child abuse, illegal activities such as drug or alcohol abuse, or reportable communicable diseases such as HIV, also may pose

risks to subjects about which they should be informed. Where the potential for the need to report such information to authorities exists, subjects should be so informed before agreeing to participate in the study. Depending on the circumstances, potential subjects may also feel it is "material" to be informed about additional costs that might arise during the course of the research, the identity of the research sponsor, any circumstances that would make it difficult or dangerous to withdraw from the research, or the amount or kind of inconvenience involved.

Expression. IRBs must ensure that information will be presented to prospective subjects in language they can understand. How well subjects understand that information will vary according to the population from which subjects will be drawn. For example, if all the subjects will be registered nurses, they will probably understand most medical terms, but if the population consists of college students, an intermediate level of understanding can be anticipated. If English is not the subject population's primary language, the explanations and the forms should be translated into the subjects' native language.

The medical terms and complex sentences in oral presentations and consent forms often need to be presented in simpler terms C even for the educated layperson. If the prospective subjects include children, persons whose primary language is not English, or populations with the average of a sixth grade education, the IRB should take special care to ensure that both oral presentations and consent forms are comprehensible to all subjects. In these cases, ordinary language should replace technical terms (*e.g.*, upper extremities are better referred to as arms, hematoma as a bruise, venipuncture as taking blood from your arm with a needle, and so forth).

Some IRBs find that their lay members are particularly helpful in suggesting necessary modifications. Others ask members of the proposed subject population (*e.g.*, children, clinic patients) to review consent forms and indicate what parts they do not understand.

In addition, **the informed consent may not contain any exculpatory language**: Subjects may not be asked to waive (or appear to waive) any of their legal rights, nor may they be asked to release the investigator, sponsor, or institution (or its agents) from liability for negligence.

Process. It is essential that IRB members think of informed consent not as a form that must be signed, but as an educational process that takes place between the investigator and the prospective subject. No one can guarantee that another person has understood the information presented; one can only inform prospective subjects as clearly as possible. No one can guarantee that another's choice is voluntary; one can only attempt to remove obvious impediments to free choice by being alert to coercive aspects of the consent procedure. In cases where there is reason for special concern about pressure (*e.g.*, when patients are invited to participate in research conducted by their physician, or when students, military personnel, employees, etc., are asked to participate in research conducted by their supervisors), the IRB may require some form of monitoring (such as the presence of an impartial observer). If the research presents significant risk, or if subjects are likely to have difficulty understanding the information to be provided, the IRB may suggest that investigators employ devices such as audiovisual aids, tests of the information presented, or consent advisors.

Because obtaining informed consent is an educational process, the IRB should do what it can to enhance the prospective subject's comprehension of the information presented. It should consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved). After answering these questions, the IRB may want to suggest changes in the timing or location of an investigator's first contact with potential subjects, or changes in how others will contact subjects during or following the study. For example, some investigators may plan to release their data to a "data broker" who will in turn make the data available to other researchers. IRBs should review the appropriateness of making the data available in this way, and should ensure that subjects will be informed about who will have access to the data and who might contact them.

Sometimes the information to be imparted to prospective subjects is so complex or possibly disturbing that it may require some time for it to be absorbed and appreciated. In these circumstances, the IRB might suggest that the investigator either present the information and discuss the issues with prospective subjects on more than one occasion, or that a period of time elapse between imparting the information and requesting a signature on the consent form. During this waiting period, prospective subjects might be encouraged to discuss their possible

participation with family members, close friends, or trusted advisors. Other approaches to communicating complex information include the use of audio-visual materials and brochures.

Documentation. In most cases the federal regulations require that informed consent be documented [Federal Policy §___.117; FDA regulations 21 CFR 50.27], but they also provide for some important exceptions. Documentation usually involves the use of a written consent form containing all the information to be disclosed and signed by the subject or the subject's legal representative. It should be reiterated, however, that these documents are not substitutes for discussion. The person who signed the consent form must be given a copy as a reference and reminder of the information conveyed. A "short form" may sometimes be used [Federal Policy §___.117(b)(2); FDA regulations 21 CFR 50.27(b)(2)]. The use of a short form means that the information is presented without benefit of a written version of the consent document. Before a short form can be used, the IRB must first review and approve a written summary of what will be presented. Each oral presentation must be witnessed by a third person, who must sign both the consent form and a copy of the written summary of the presentation. A copy of the summary must be provided to those who sign the consent form so that they have the information available for future reference [Federal Policy §___.117(b)(2)].

The IRB may waive the regulatory requirement for written documentation of consent in cases where: (1) the principal risks are those associated with a breach of **confidentiality** concerning the subject's participation in the research (*e.g*., studies on sensitive topics such as drug abuse or sexual deviance); and (2) the consent document is the only record linking the subject with the research [Federal Policy §___.117(c)(1)]. Written documentation of consent may also be waived when the research presents no more than **minimal risk** and involves procedures that do not require written consent when they are performed outside of a research setting [Federal Policy §___.117(c)(2); FDA regulations on IRB review, 21 CFR 56.109(c)]. [*See* Guidebook Chapter 3, Section A, "Risk/Benefit Analysis."]

At institutions that require IRB review of all research involving human subjects (including research exempt from the federal regulations), the IRB may decide to waive consent documentation requirements for research that would be exempt from the federal regulations (*e.g*., most **survey** and observational research). IRBs taking such an approach should be careful, however, to make sure that the subjects will be provided adequate information about the research. The IRB may decide that, in some cases, subjects should be provided written copies of the information conveyed despite the fact that they are not asked to sign a consent form.

Exceptions. Federal regulations on informed consent specify the information that must be disclosed to prospective subjects [Federal Policy §___.116; FDA regulations on consent, 21 CFR 50.25]. The regulations do permit modifications in the consent procedure, and, under certain circumstances, informed consent may be waived entirely if the research meets certain conditions [Federal Policy §___.116(c)-(d)]. Such modifications and waivers are not allowed under FDA regulations. [*But see* 21 CFR 50.23, which sets out conditions under which the obtaining of informed consent for use of a test article can be deemed infeasible]. Situations in which modification or waiver of consent may be indicated call for careful consideration by the IRB. Decisions to waive informed consent or documentation of informed consent should be clearly documented in the IRB's minutes. [*See* also Guidebook Chapter 6, Section F, "Traumatized and Comatose Patients."]

The IRB may approve a waiver of some or all of the consent requirements provided that: (1) the research involves no more than **minimal risk** to subjects [*see* Guidebook Chapter 3, Section A, "Risk/Benefit Analysis"]; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study [Federal Policy §__.116(d)]. Most commentators suggest that the IRB also determine whether the knowledge being sought is important enough to justify whatever invasion of privacy may be required either to obtain information about unconsenting (or unaware) subjects or to involve them in research under false pretenses. [*See* Guidebook Chapter 3, Section D, "Privacy and Confidentiality."]

Under the Federal Policy (but not FDA regulations), if the research is designed to evaluate or demonstrate possible changes in (or alternatives to) provision of benefits or services provided for under federal, state, or local programs, an IRB may approve alteration or waiver of the consent requirements [Federal Policy §___.116(c)]. If the research could not practicably be carried out without the waiver or alteration of the consent requirements, the IRB may

approve such a waiver. Both the **National Commission for the Protection of Human Subjects and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research** recommended that such waivers be granted only if subjects will not be denied benefits or services to which they are otherwise legally entitled.

Record Reviews. Sometimes, especially in epidemiological studies, scientists need to review thousands of records to identify appropriate subjects for their study. (Consent is not an issue for record reviews of deceased individuals because federal regulations apply only to research involving living human subjects [Federal Policy §___.102(f)].) It is often difficult, if not impossible, to obtain the permission of everyone whose records are contained in the files. For this preliminary part of the research, IRBs will generally waive the consent requirement if: (1) they are satisfied that the information contained in the files is not particularly sensitive; (2) the investigator has devised procedures to protect the confidentiality of the information to be collected; and (3) the study could not practicably be carried out if consent were required. Some university hospitals notify all incoming patients that their records may be reviewed for research purposes; others provide an opportunity to consent (or refuse to consent) to such use.

Contacting potential subjects to obtain further information is a more sensitive phase of the research. IRBs should consider how the investigator proposes to make the initial contact with potential subjects (*e.g.*, through employer, physician, institution having custody of the records, or directly by the investigator) and what information will be conveyed at that time. [*See* Guidebook Chapter 3, Section D, "Privacy and Confidentiality," and Chapter 4, Section E, "Epidemiologic Studies."]

In making decisions regarding record reviews and plans for contacting individuals thus identified, IRBs should consider the importance of the research, the extent to which privacy will be invaded, the sensitivity of the information to which the investigators will have access, plans for further contact of the subjects, and the feasibility of obtaining consent from all prospective subjects.

For further discussion of records research, including consent issues, *see* Guidebook Chapter 4, Section E, "Epidemiologic Studies."

Observation in which Subject's Identity will be Recorded. Behavioral scientists sometimes need to observe the behavior of people who either are not aware that they are being observed or who are unaware that their behavior is being recorded for research purposes. Because subjects might behave differently if they knew they were being observed, researchers may request that the consent requirements be waived (if subjects must be unaware of their involvement, they will not have the opportunity to consent or refuse to participate in the research). Videotaping of the responses of passersby to staged emergencies (*e.g.*, heart attacks or criminal assaults), observing the interaction between patients and staff in mental hospitals, and studying homosexual activities in public rest rooms are three examples of this kind of study.

In the first case, the subjects have no knowledge of (and, therefore, have not consented to) the presence of an observer or recording equipment. When the behavior observed may be embarrassing, or when the staged conditions are stressful, this kind of study poses ethical problems for the investigator and the IRB. In the second example, although the patients and staff of the mental hospital may be aware that someone is observing their behavior, they may not be aware of why they are being observed. In the study, "On Being Sane in Insane Places," social scientists disguised themselves as mental patients and made important observations of the behavior patterns of both patients and staff in mental hospitals. This kind of research presents ethical problems, because the subjects might not consent to the pseudo-patient's presence if they were aware of the real purpose.

In the "Tea Room Trade" study, a social scientist adopted the role of "watch queen" (*i.e.*, lookout) for homosexuals engaged in sexual acts in public rest rooms. Although his subjects obviously knew of his presence, they did not know (at least until after publication of his results) that they were being studied. The unwitting subjects also did not know that the investigator recorded their license plate numbers and searched motor vehicle registration files for their names and addresses. A year later, he disguised his appearance and interviewed these subjects, purportedly for a different kind of study, thus obtaining information about their family and social life. Commentators have suggested that the subjects would neither have consented to the researcher's presence in the rest room nor responded to his later survey questionnaire had they known his real purpose.

The "Tea Room Trade" study raises many of the same ethical questions as the other two examples, but the problems are compounded because the investigator identified the subjects, and, through further deception, obtained possibly private information about their family and social life. (Identifying the subjects placed them at risk of serious legal, social, and economic harm since the behavior being studied was illegal.)

The last two studies illustrate another sensitive problem IRBs must consider when reviewing research involving covert observation. Although consent requirements can be waived if the IRB determines that the knowledge to be gained is important, this decision can easily be influenced by the extent to which IRB members approve of either the subject matter or what they expect may be the findings of the research. IRB members should guard against the inclination to approve or disapprove research based upon their personal feelings about the possible outcome of a research proposal. Drawing the line between judgments about the social or scientific value of a particular study and personal attitudes towards the subject matter of that study is admittedly difficult. IRB members should try to distinguish between qualms they may have about the subject matter (*e.g.*, homosexuality or drug abuse) and qualms they may have about the research methods (*e.g*., covert observation, staged events, and so forth).

Deception and Incomplete Disclosure. Sometimes, particularly in behavioral research, investigators plan to withhold information about the real purpose of the research or even to give subjects false information about some aspect of the research. This means that the subject's consent may not be fully informed. For example, to discover whether certain kinds of background music are more distracting than others in a learning situation, an investigator might recruit subjects and explain that certain aspects of learning and memory are being studied. If the research is to be conducted, some of the consent requirements must be waived. Subjects would be told that they would be required to learn sets of words and then be tested on how well they remember those words, but they would be deceived about the purpose of the research and certain elements of the study design.

A contrasting example, much discussed in the literature, is the Milgram study of obedience. Subjects of this study were told that, as part of a learning study, they were to give electric shocks each time a "student" made an error in learning. Although they consented to participate in a study of learning, they were unwittingly involved in a study of their own obedience and willingness to inflict pain. Subjects were told about the true nature and purpose of the research after they had participated. This research has been criticized for the emotional stress it caused and the "inflicted insight" provided to the subjects about their own behavior (neither of which they had consented to). Although Milgram's follow-up studies indicated that few if any subjects reported that they had misgivings about participating in the research, many commentators argue that such deception is wrong *per se*. [*See* Guidebook Chapter 3, Section D, "Privacy and Confidentiality."]

IRBs reviewing research involving incomplete disclosure or outright deception must apply common sense and sensitivity to the problem. They must first decide whether the information to be withheld would influence the decision of prospective subjects about participating in the research. In the case of the research about the effects of background music on learning and memory, this determination would be relatively easy. IRB members might well disagree among themselves, however, about the Milgram study. (Scholars and commentators have disagreed about it for years.) According to the regulations, research should not be permitted at all if the risk to subjects is more than minimal and the subjects are not being informed of things they would consider material to a decision to participate.

In deciding whether to waive or alter consent requirements, IRBs must consider the risks to which subjects will be exposed. To receive a waiver of consent requirements, the study must present no more than minimal risk. Further, the waiver must not adversely affect the rights and welfare of subjects, and must be essential to the ability to carry out the research.

A final condition for waiving some or all of the elements of informed consent is that, whenever appropriate, subjects will be given additional pertinent information after they have participated in such a study. The IRB must decide if subjects should be **debriefed** either after participating in research unwittingly or after knowingly participating in research that involved some form of deception. It is clear that debriefing is appropriate when it contributes to the subject's welfare (*i.e*., when it corrects painful or stressful misperceptions, or when it reduces pain, stress, or anxiety concerning the subject's performance). There is greater uncertainty over whether it is appropriate to debrief subjects when such a debriefing could itself produce pain, stress, or anxiety (*i.e*., IRBs must be concerned with cases where debriefing subjects might harm them but failure to debrief subjects would wrong them).

Further descriptions of risks encountered in research involving deception are included in the discussion of psychological harms in the Guidebook Chapter 3, Section A, "Risk/Benefit Analysis."

Placebos, Randomization, and Double-Masked Clinical Trials. Involving subjects in clinical trials where they may receive a **placebo** instead of the experimental therapy or where they may not be told which of several treatments they will receive could be said to entail an element of deception. Most commentators now believe that if subjects are told they may receive a placebo, and if the design of the clinical trial is explained to them, no deception is involved.

When the particular therapy a subject receives will be assigned on a scientifically **random** basis, this selection process must be explained to prospective subjects in language they can understand. Merely telling them that the assignment to treatment will be done randomly, mathematically, or by lottery may not be sufficient. Instead, more of an explanation should be given. In a two-arm trial, for example, subjects should be told that there is a 50 percent chance of receiving one of two treatments thought to be beneficial for patients with their particular kind of disease; that one is the standard treatment and the other is the experimental treatment; that the experimental treatment is thought to be at least as good as the standard treatment; and that their physician will not be the person who decides which treatment they receive. If the study involves the use of placebos, subjects should be told the chances of receiving the various possible treatments, including the chance of receiving a placebo.

It is important that prospective subjects understand that a **double-masked** design means that neither they, their physicians, nor the investigators treating and evaluating them will know which treatment they have received. If it is important to the research design that neither the investigators nor the subjects know about developing trends in the data, the fact that such developments will not affect their assignment during the course of the study should be communicated to prospective subjects prior to enrollment. [*See* Guidebook Chapter 4, "Considerations of Research Design."]

Subjects should understand that although they may withdraw from the study at any time, they will not be given any information about which treatment(s) seem to be better or worse until the study is completed. The significance of developing trends in the data has played an important role in placebo trials involving experimental AIDS drugs. When sufficient data showed the drug AZT to be effective in slowing the progress of the disease, the status of subjects receiving the placebos was revealed, and they were offered the drug. Continued provision of placebos once the experimental drug was shown to be effective was considered unethical. IRBs should consider the relevance of developing trends in the data to continued consent.

In double-masked clinical trials, there should be a mechanism for someone other than the investigator to break the code to discover which treatment a particular subject has been given in case the subject experiences a worsening of his or her condition or an adverse effect that requires medical intervention. This procedural safeguard should also be explained to prospective subjects.

Consent as a Continuing Process. Consent is not a single event; rather, it is a process. Since subjects always retain the right to withdraw from a research project, their continuing consent is important. IRBs should be aware that subjects often seem to forget they are involved in research or have difficulty distinguishing research interventions from diagnostic and therapeutic interventions. When a research proposal is first approved, the IRB should determine whether consent should be renegotiated as a formal matter during the course of the research. If renegotiation is required, the frequency and/or events that will trigger this process should be decided upon and made clear to the investigators.

Federal policy also requires that investigators inform subjects of any important new information that might affect their willingness to continue participating in the research [Federal Policy §___. 116]. For instance, a totally independent study might find an unanticipated adverse effect (*e.g.*, birth defects or carcinogenicity) in a drug or substance being used in research. IRBs should determine whether any new findings or reports of adverse effects (in the present study or other studies) should be communicated to subjects. The IRB should also receive copies of any such information conveyed to the subjects.

When the proposed subjects are seriously ill, or, for some other reason, might not be able to make decisions about continuing in the research (*e.g.*, children or cognitively impaired individuals), the IRB may suggest that family

members be closely involved with the research to evaluate its impact on the subject and to request that the subject be withdrawn from the study if conditions warrant.

POINTS TO CONSIDER

l. Do the investigators plan to involve a particularly vulnerable subject population?

2. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?

3. Is the language and presentation of the information to be conveyed appropriate to the subject population? (Consider the level of complexity and the need for translation into a language other than English.)

4. Are the timing of and setting for the explanation of the research conducive to good decision making? Can anything more be done to enhance the prospective subjects' comprehension of the information and their ability to make a choice?

5. Who will be explaining the research to potential subjects? Should someone in addition to or other than the investigator be present?

6. Should subjects be reeducated and their consent required periodically?

7. Should the IRB monitor incoming data to determine whether new information should be conveyed to participating subjects? How often should this occur? Who is responsible for bringing new information to the attention of the IRB between scheduled reviews?

8. If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver? Is more than minimal risk involved? Can the research design be modified to eliminate the need for deception or incomplete disclosure? Will subjects be given more information after completing their participation? Would the information to be withheld be something prospective subjects might reasonably want to know in making their decision about participation?

APPLICABLE LAWS AND REGULATIONS

Federal Policy for the protection of human subjects
Federal Policy §___.116 [General requirements for informed consent]
Federal Policy §___.117 [Documentation of informed consent]
21 CFR 50 [FDA: Informed consent]
21 CFR 50.20 [FDA: General requirements for informed consent]
21 CFR 50.23 [FDA: Exception from general requirement]
21 CFR 50.25 [FDA: Elements of informed consent]
21 CFR 50.27 [FDA: Documentation of informed consent]
21 CFR 56 [FDA: IRB review and approval]

Local laws: Federal requirements for informed consent do not necessarily meet all the requirements of local laws. Therefore, IRBs should be aware of any state and local requirements regarding informed consent.

C. SELECTION OF SUBJECTS

INTRODUCTION

Defining the appropriate group of subjects for a research project involves a variety of factors - requirements of scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. IRBs are required to make a specific determination that the selection of subjects is **equitable** [Federal Policy §___.111(a)(3)].

OVERVIEW

The requirement for an equitable selection of subjects helps ensure that the burdens and benefits of research will be fairly distributed. When the **National Commission for the Protection of Human Subjects** recommended that IRBs be required to make this determination, they noted that questions of equity have only recently been associated with scientific research. In the 19th and early 20th centuries, the burdens of research fell largely upon poor patients in hospital wards, while the benefits flowed primarily to private patients. This inequity was starkly revealed in the Tuskegee syphilis study, in which disadvantaged blacks in the rural south were recruited for studies of the untreated course of a disease that was by no means confined to that population. Such unjustified overutilization of certain segments of the population led the National Commission to recommend that selection of research subjects be scrutinized to determine "whether some classes (*e.g.*, welfare patients, racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position or their manipulability, rather than for reasons directly related to the problem being studied."

Easy availability, compromised position, and susceptibility to manipulation often overlap. For example, psychology students are readily available for psychological research, medical students are readily available for medical research, prisoners, patients in mental institutions, and military personnel are readily available for a variety of research activities, and employees of drug manufacturing companies are readily available for pharmaceutical research. Subjects selected from these populations are also compromised to the extent that their jobs, promotions, grades, etc., are dependent upon those who might be recruiting them for research. This circumstance makes them susceptible to manipulation.

Prisoners and patients in mental institutions are confined under the strict control of people whom they must please and to whom they must appear cooperative and rational if they are to earn their release. These potential subjects may believe, probably as a result of their dependent situation, that agreeing to participate in research will be viewed positively by their wardens, psychiatrists, or social workers. They are also readily available in large numbers, and, therefore, have historically been involved as subjects of drug research that is totally unrelated to the basis of their confinement. Mental patients and prisoners have accepted the risks of research in disproportionate numbers, while the benefits of the research in which they participated went to all segments of the population. This situation led the National Commission to suggest that investigators be required to justify any proposed involvement of hospital patients, other institutionalized persons, disproportionate numbers of racial or ethnic minorities, or persons at the lower end of the socioeconomic scale.

Patients may also be susceptible to real or imaginary pressure to participate. If an investigator also serves as a patient's primary physician, he or she may feel obliged to participate in the research out of a desire to please, gratitude, or fear that failure to do so will result in hostility or abandonment. Patients who are dependent upon a particular facility for their care (*e.g.*, Veterans Hospitals, Indian Health Service Hospitals, or community health clinics) may feel that they will be treated less well or with less favor if they refuse to participate in research.

With these caveats in mind, investigators and IRBs must be careful not to *overprotect* vulnerable populations so that they are excluded from participating in research in which they wish to participate, particularly where the research involves therapies for conditions with no available treatments (such as HIV). So too, patients with serious or poorly understood disorders may want to participate frequently in research designed to provide a better understanding of their condition. The fact that the subject may be either a patient of the principal investigator or a patient in the clinic or hospital where the investigator conducts the research should not preclude them from the opportunity to choose to participate as often as they wish. [*See* Guidebook Chapter 6, "Special Classes of Subjects."]

Just as the inclusion of disproportionate numbers of racial or ethnic minorities in research studies might overburden these groups without affording them the benefits that will result from the research, so will underrepresentation of these groups in study populations ensure that they will not benefit from the research. The National Institutes of Health (NIH) requires that its research grantees include minorities and women in study populations "so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study." If a proposed project includes a study population in which women and minorities are not appropriately represented, the investigator must provide "a clear compelling rationale for their exclusion or inadequate representation" [Application for PHS Grants, form PHS 398, pp. 21-22, and NIH Requests for Proposals (RFPs)]. *See* Guidebook Chapter 6, Section B, "Women," and Chapter 6, Section I, "Minorities," for further discussion of this issue.

IRB CONSIDERATIONS

The **National Commission** recommended that, as a matter of social justice, there should be an order of preference in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and noninstitutionalized persons before institutionalized persons. In addition, the Commission believed that those who are already burdened (*e.g.*, by disabilities or institutionalization) should not be asked to accept the burdens of research unless other appropriate subjects cannot be found (*i.e.*, if the research concerns their particular disability or circumstance). IRBs should consider the extent to which a proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities in deciding whether they are a suitable subject population.

When determining whether the burdens of research are being distributed equitably, it is appropriate for an IRB to consider more than the risks associated with the research procedures. It may be appropriate to consider such things as inconvenience (*i.e.*, the time required, travel involved, restrictions on diet, or other activities), discomfort, and embarrassment as burdens of participating in research.

To encourage a broad cross-section of research subjects, IRBs might consider the manner in which subjects will be recruited. Will notices appear only on the bulletin boards of the psychology department or the medical school? Will investigators personally recruit subjects only in community health clinics? If a new treatment is available only in the research context, and it is a scarce resource (in that only a small proportion of those who could benefit from the therapy can be accepted as research subjects), the IRB should try to devise procedures to ensure that subjects from a variety of locations and circumstances have an equal chance of being selected. This becomes particularly important when the intervention is a life-saving procedure (*e.g.*, organ transplant or germ-free environment).

IRBs should consider means for reducing the pressures on certain classes of subjects to participate in research. Patients should be reassured during the consent process that no benefits to which they are otherwise entitled, and no care or concern on the part of the health care providers, will be jeopardized by a decision not to participate in research. In cases where the principal investigator is the potential subject's physician, the IRB might find it preferable for someone other than the physician-investigator to discuss participation with the potential subject or to solicit the patient's consent. In other cases, the possibility of pressure may be reduced by consulting beforehand with representatives of the proposed subject group.

Some IRBs have guidelines that prohibit professors from soliciting their students as subjects and supervisors from including their employees in research. A scientist's proposal to involve students, technicians, and junior members of the laboratory in his or research should be examined with care. The line between protecting the vulnerable and being unduly **paternalistic** is difficult to draw. This is one of the IRB's recurrent challenges. But avoiding the use of a group of subjects repeatedly on the grounds of mere convenience must not prevent free and **competent** adults from volunteering to be subjects of research as often as they wish.

Those who accept the risks or burdens of being research subjects should be the ones who share in its benefits whenever possible. One group of subjects should not be asked always to bear the risks of research for the benefit of others. Those who have participated as research subjects should have the first opportunity to receive a therapy that the research has demonstrated to be safe and effective (*e.g.*, subjects of clinical trials who were either in a control group or recipients of a therapy that proved not to be superior should be offered the treatment that the trial demonstrated to be preferable). The study design should provide for the adequate representation of women and minorities in the study population so that the findings will be meaningful for those groups and they can, therefore, share in the benefits of the research. Adequate representation of women and minorities is particularly important in studies of diseases, disorders, and conditions that disproportionately affect them. Note that risk/benefit assessments are relevant to subject selection [*see, e.g.*, Guidebook Chapter 5, Section B, "Women"].

POINTS TO CONSIDER

l. Will the burdens of participating in the research fall on those most likely to benefit from the research?

2. Will the solicitation of subjects avoid placing a disproportionate share of the burdens of research on any single group?

3. Does the nature of the research require or justify using the proposed subject population?

4. Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?

5. To the extent that benefits to the subjects are anticipated, are they distributed fairly? Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?

6. To the extent that participation in the study is burdensome, are these burdens distributed fairly? Is the proposed subject population already so burdened that it would be unfair to ask them to accept an extra burden?

7. Will any special physiological, psychological, or social characteristics of the subject group pose special risks for them?

8. Would it be possible to conduct the study with other, less vulnerable subjects? What additional expense or inconvenience would that entail? Does the convenience of the researcher or possible improvement in the quality of the research justify the involvement of subjects who may either be susceptible to pressure or who are already burdened?

9. Has the selection process *overprotected* potential subjects who are considered vulnerable (*e.g.*, children, cognitively impaired, economically or educationally disadvantaged persons, patients of researchers, seriously ill persons) so that they are denied opportunities to participate in research?

10. If the subjects are susceptible to pressures, are there mechanisms that might be used to reduce the pressures or minimize their impact?

APPLICABLE LAWS AND REGULATIONS

Federal Policy §___.111(a)(3) [Criteria for IRB approval of research]
21 CFR 56.111(a)(3) [FDA: Criteria for IRB approval of research]

NIH policy concerning inclusion of women and minorities in study populations. *NIH Guide for Grants and Contracts* 20 (No. 32, August 23, 1991): 1-3. The policy also appears in the application packet for PHS Grants, form PHS 398, pp. 21-22, and in NIH Requests for Proposals (RFPs).

D. PRIVACY AND CONFIDENTIALITY

INTRODUCTION

The possibility that research may invade the privacy of individuals or result in a breach of confidentiality sometimes arises in biomedical and behavioral research. Under certain circumstances, an invasion of privacy or breach of confidentiality may even present a risk of serious harm to subjects (*e.g.*, as when the researcher obtains information about subjects that would, if disclosed by the researcher, jeopardize their jobs or lead to their prosecution for criminal behavior). Under less dramatic circumstances, an invasion of privacy or breach of confidentiality can be a moral wrong, or, at least in theory, provide cause for legal action against a researcher or institution.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Privacy and Research. In the context of research, concerns about privacy pertain primarily to the methods used to obtain information about subjects. Objections to the nature of information being sought in research are sometimes couched in the language of privacy (*i.e.*, that it would be an invasion of a subject's privacy even to inquire about

certain matters of a personal nature). IRBs are often reluctant to accept these arguments, which tend to preclude research on such topics. In any event, the issue of whether there may be harm in asking certain questions is less a matter of privacy than one of risks versus benefits, and is, therefore, not discussed in this Section.

Researchers ordinarily use information that subjects have disclosed or provided voluntarily for research purposes (*i.e.*, with their informed consent). Under these circumstances, there is little reason for concern about privacy, other than to assure that appropriate confidentiality of research data is maintained. Where privacy issues do arise is in regard to information obtained for research purposes without the consent of subjects. Although serious privacy questions arise with relatively few protocols reviewed by IRBs, the questions that do arise can involve difficult and subjective judgments about matters of propriety.

Concerns about the privacy interests of research subjects may arise in several different contexts.

Privacy Issues in the Use of Personally Identifiable Records. Identifying suitable subjects often presents no ethical problems. Physicians studying a particular disease may be able to identify subjects from among their own patients, and the sociologist interested in studying people who have recently been married can identify their subjects through public records. Privacy concerns may arise when potential subjects cannot be identified from public records or from sources to which the researcher's work provides access.

To identify suitable subjects, researchers must sometimes approach institutions (*e.g.*, hospitals or schools) seeking information generally regarded as confidential (*e.g.*, the identity of patients treated for a particular condition or students meeting a particular criterion). In some circumstances, the researcher needs information that would make it possible to contact suitable subjects to obtain further data. In other circumstances, no contact with subjects is contemplated because the information to be obtained from the records is sufficient (or will be combined with data from other sources). In these cases, personal identifiers may not need to be recorded by the researchers, or, if recorded, can be destroyed at some stage of the research. All of these factors are relevant to IRB assessments of privacy and confidentiality issues in research.

When patients give information about themselves to a doctor or hospital for the purpose of facilitating diagnosis or treatment of disease, they do so in a relationship of trust. They generally expect that the information will be shared only as necessary for their health care or reimbursement by their insurance company or other third party payer; patients would not expect information that identifies them to be passed on in casual conversations at cocktail parties or made available to journalists or to university students writing papers. Nor do they necessarily intend that the information will be shared with even their closest family members. Health care providers should respect the patient's trust. They should not betray the confidence placed in them. (The same may be said of educators with regard to students, and of employers with regard to employees.) Yet such confidences are not absolute; patient records are commonly used for a variety of purposes other than the care of a particular patient C for the management of the organization through quality assurance programs and for utilization review. To say that an organization has an obligation to keep certain patient information confidential does not resolve the question of what uses are appropriate for those records.

Clearly, some important research cannot be conducted unless an investigator gains access to many records (sometimes thousands). In epidemiological studies, scientists may seek to determine, for example, whether certain industrial or environmental contaminants are associated with an increase in birth defects or deaths from cancer. In their search they might wish to review thousands of hospital or employment records to identify infants born with a defect, patients suffering from a particular form of cancer, or workers exposed to a particular substance. Without access to such records, an investigator cannot identify potential subjects or match the relevant records. [*See* Guidebook Chapter 4, Section E, "Epidemiologic Studies."]

It is not possible to specify precisely when an institution should honor a researcher's request to examine records or when an IRB should approve this potential invasion of privacy. In 1977, the Privacy Protection Study Commission concluded that medical records can legitimately be used for biomedical or epidemiological research without the individual's explicit authorization, provided that the medical care provider maintaining the record:

(i) determines that such use or disclosure does not violate any limitations under which the record or information was collected;

(ii) ascertains that use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which use or disclosure is to be made;

(iii) determines that the importance of the research or statistical purpose for which any use or disclosure is to be made is such as to warrant the risk to the individual from additional exposure of the record or information contained therein;

(iv) requires that adequate safeguards to protect the record or information from unauthorized disclosure be established and maintained by the user or recipient, including a program for removal or destruction of identifiers; and

(v) obtains consent in writing before any further use or redisclosure of the record or information in individually identifiable form is permitted.

The **National Commission** endorsed this recommendation, and concluded that in studies of documents, records, or pathological specimens where the subjects are identified, informed consent may be waived if the IRB determines that the subject's interests are adequately protected and the importance of the research justifies the invasion of privacy. Unless otherwise required by the head of the department or agency funding or conducting the research, federal regulations (except those promulgated by the FDA) exempt from review all research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from IRB review if the sources are publicly available or if the information is recorded by the investigator in a manner that does not allow subjects to be identified, either directly or through identifiers that are linked to them [Federal Policy §___.101(b)(4)]. [*See* also Guidebook Chapter 1, Section A, "Jurisdiction of the Institutional Review Board," and Chapter 4, Section A, "Considerations of Research Design C Introduction."]

In cases where researchers gain access to identified records without the individual's explicit permission, methods for reducing the associated privacy problems should be considered. For instance, an institution possessing records on suitable subjects may be willing to contact them and ask their permission to release their names to the researcher. Depending on the purpose of the research, the possible biases that this approach would create may be unacceptable, but in other studies it may prove feasible. Another approach is for institutions to make known the uses to which its records may be put in advance, so that individuals will be aware that their records may be used in research. Some institutions provide an opportunity for people to consent (or withhold consent) to use at the time of the initial creation of the record. Other institutions have been reluctant to do this because of either logistical difficulties or systematic biases that might be built into subsequent research. Still another approach, which may be feasible on occasion, is for the researcher to become an employee of, or consultant to, the institution and thereby gain proper access to the records. Various other creative solutions may be negotiated among researchers, institutions, and IRBs. No firm rule can be stated; this is one of many areas in which IRBs must exercise common sense and sound judgment.

Observational Studies. Of all the methods used to locate suitable subjects and obtain data, covert observation and participant observation are especially likely to raise concerns about privacy. Covert observation includes the use of concealed devices to record information for later analysis (*e.g.*, tape recording conversations or videotaping personal interactions) and concealment of the researcher (*e.g.*, behind a one-way mirror) as the behavior of subjects is observed and recorded. In participant observation, the researcher assumes a role in the setting or group being studied. When the purpose of these methods is to gain access to information not ordinarily available to "outsiders," questions of privacy arise. (Similar issues about obtaining information not intended to be disclosed can be raised about many other forms of research that involve deception.)

Several factors may be relevant to an IRB's evaluation of such privacy questions. One is the extent to which the behavior in question is public. Covert observation of public behavior (*e.g.*, observing pedestrians on the street) raises little if any concern about privacy; concealed observation of people in their homes would be quite another matter. Some behavior that occurs in public places may not really be public behavior C the individuals involved have a reasonable expectation of privacy. Research involving covert recording of conversations in public parks or filming of activities in public rest rooms clearly raises invasion of privacy questions. Observational studies in quasi-public places (*e.g.*, hospital emergency rooms or state mental hospital wards) may also raise such concerns.

A question sometimes raised about the use of covert observation in research is whether an ethical issue exists if the subjects never become aware of the invasion of privacy. That is, if subjects are never aware that their behavior has been observed or recorded for research purposes, they can hardly feel embarrassed, guilty, or that their rights have been violated. On the other hand, it can be argued that an invasion of privacy is wrong, whether or not the subjects

are ever aware of it. In some cases, subjects may inadvertently learn of their involvement in the research, perhaps when the study is published, and feel that they have been harmed.

Most observational research, except that involving children and minors, is exempt from federal regulations. For studies involving adults, current regulations require IRB review only for the most risky observational investigations C those in which two conditions exist: (1) the observations are recorded in a manner that allows the subjects to be identified, directly or through identifiers linked to them; and (2) the observations recorded, if they became known outside the research, could reasonably place the subject either at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or reputation [Federal Policy §___.101(b)(2)]. Clearly, in such studies one of the IRB's major concerns should be to determine if it is necessary to record information in a way that entails such risk, and, if so, whether the provisions for maintaining confidentiality of the data are adequate. Observational research involving children and minors must be reviewed by the IRB unless the research involves observations of public behavior when the investigator(s) do not participate in the activities being observed; IRB review is also required where the two conditions described above obtain (*i.e.*, identifiers will be recorded and the observations could place the subjects at risk).

Confidentiality of Research Data. A major set of concerns about confidentiality pertains to the methods used to ensure that information obtained by researchers about their subjects is not improperly divulged. Perhaps because the creation and handling of confidential records is routine in medical institutions, discussions of confidentiality as a special ethical responsibility of researchers have been more prominent in the social sciences than in the biomedical sciences. Nevertheless, the need for confidentiality exists in virtually all studies in which data are collected about identified subjects. It is in the interest of researchers C and essential to the conduct of research on sensitive topics C that researchers be able to offer subjects some assurance of confidentiality. These assurances should be given honestly, which sometimes requires the researcher and the IRB to make explicit provisions for preventing breaches of confidentiality.

In most research, assuring confidentiality is only a matter of following some routine practices: substituting codes for identifiers, removing face sheets (containing such items as names and addresses) from survey instruments containing data, properly disposing of computer sheets and other papers, limiting access to identified data, impressing on the research staff the importance of confidentiality, and storing research records in locked cabinets. Most researchers are familiar with the routine precautions that should be taken to maintain the confidentiality of data. More elaborate procedures may be needed in some studies, either to give subjects the confidence they need to participate and answer questions honestly, or to enable researchers to offer strong, truthful assurances of confidentiality. Such elaborate procedures may be particularly necessary for studies in which data are collected on sensitive matters such as sexual behavior or criminal activities.

In studies where subjects are selected because of a sensitive, stigmatizing, or illegal characteristic (*e.g.*, persons who have sexually abused children, sought treatment in a drug abuse program, or who have tested positive for HIV), keeping the identity of participants confidential may be as or more important than keeping the data obtained about the participants confidential. In such instances, any written record linking subjects to the study can create a threat to confidentiality. Having the subjects of these studies sign consent forms may increase the risk of a breach of confidentiality, because the consent form itself constitutes a record, complete with signature, that identifies particular individuals of the group studied. The Federal Policy allows IRBs to waive the requirement for the investigator to obtain a signed consent form where it will be the only record linking subjects to the research, and where a breach of confidentiality presents the principal risk of harm that might result from the research [Federal Policy §___.117(c)]. FDA regulations allow IRBs to waive the signed consent form requirement only when the research presents no more than minimal risk and involves procedures that do not normally require consent when performed outside the research context [21 CFR 56.109(c)]. If both FDA regulations and the Federal Policy apply to a protocol, the IRB must meet the requirements of both. In this instance, documentation of informed consent can be waived only if the consent form is the sole record linking subjects to the research, the research involves minimal risk, breach of confidentiality is the principal risk of harm and the procedure involved in the research is one that does not normally require consent when performed outside the research context. (Note that the foregoing waiver provisions apply to documentation of informed consent and not waiver of the requirement to obtain informed consent.)

Where data are being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) protection of confidentiality consists of more than preventing accidental disclosures. There

have been instances where the identities of subjects or research data about particular subjects have been sought by law enforcement agencies, sometimes under subpoena, and with the threat of incarceration of the uncooperative researcher. Under federal law (and some state laws), researchers can obtain an advance grant of confidentiality that will provide protection even against a subpoena for research data [Public Health Service Act §301(d)]. Although regulations implementing §301(d) are not in place as of this writing, the PHS has issued an Interim Policy Statement [also called the "Interim Guidance" (May 22, 1989)] that sets forth PHS policy exercising the its authority to grant certificates of confidentiality. Section 301(d) extends to "biomedical, behavioral, clinical, or other research" an earlier authority (in '303 of the Public Health Service Act) that was available only for "research on mental health, including research on the use and effect of alcohol and other psychoactive drugs."

To take advantage of §301(d), the investigator must request a grant of confidentiality from the appropriate official. Protection for research on mental disorders or the use and effects of alcohol and other psychoactive drugs can be obtained from the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), or the National Institute of Mental Health (NIMH), which, in 1991, became components of NIH. Certificates of confidentiality for biomedical, behavioral, clinical, or other research that does not fall into these categories are issued by the Assistant Secretary for Health. Protection is available for: (1) direct federal activities (*i.e.*, intramural research); (2) federally-funded activities; and (3) research in the United States that has no federal funding. Under the Interim Policy, protection will be granted "sparingly," and only "when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives." The Policy defines "sensitive" research as involving the collection of information falling into any of the following categories:

(a) Information relating to sexual attitudes, preferences, or practices;

(b) Information relating to the use of alcohol, drugs, or other addictive products;

(c) Information pertaining to illegal conduct;

(d) Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;

(e) Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;

(f) Information pertaining to an individual's psychological well-being or mental health.

Information in other categories, not listed here, might also be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation.

Additional policy considerations apply to research that involves the collection of data that relates to communicable diseases. The Assistant Secretary for Health has, therefore, issued a further PHS policy on the granting of certificates of confidentiality to projects that "intend routinely to determine whether its subjects have communicable diseases and that are required to report them under State law" [Memorandum, James O. Mason, "Certificates of ConfidentialityC Disease Reporting," August 9, 1991]. Certificates will be issued: (1) where the referring treating physicians assure the project that they have complied with reporting requirements; or (2) where there is no referring physician, the investigator has reached an agreement with the health department about how he or she will cooperate with the department to help serve the purposes of the reporting requirements (unless the investigator can show why such cooperation is precluded); and (3) only where disclosures of identifiable information about subjects comply with regulations on subject protection and are explained clearly to subjects prior to their participation.

For further information concerning PHS certificates of confidentiality under '301(d) of the Public Health Service Act and the Interim Guidance, contact:

Ms. Olga Boikess
National Institute of Mental Health
17C-02 Parklawn Building
5600 Fishers Lane

Rockville, MD 20857
Tel: (301) 443-3877

In addition to certificates of confidentiality available under §301(d), the U.S. Attorney General is authorized to grant protection for research concerning drug abuse under the Controlled Substance Act. For more information write to the Drug Enforcement Administration, 14501 I St., N.W., Washington, D.C. 20537.

For studies in which the data to be obtained concern illegal or stigmatizing activities but which are not eligible for these statutory shields against subpoena, careful attention should be given to a series of decisions related to confidentiality: (1) whether the researcher will record subject identifiers at all (including on consent forms); (2) if identifiers are to be collected, whether they will be retained after the data are coded; (3) if identifiers are not destroyed, how are they to be maintained; and (4) what subjects should be told about these matters as part of the informed consent process. Some researchers enlist a third party (sometimes in another country) to act as a custodian of keys to coded identifiers or lists of participants. This approach may provide some protection for the data, but may expose the researcher to legal risks. Where such steps are contemplated, investigators should seek competent legal advice regarding the advisability of such arrangements.

Clearly, different types of studies entail different confidentiality problems. A variety of methods for protecting confidentiality are available for different situations, including situations in which there is a danger of deductive identification of otherwise anonymous subjects on the basis of separate elements of data (*e.g.*, birthdate, occupation, and zip code). A substantial and highly specialized literature has developed on methods for safeguarding confidentiality. Among the available methods for assuring confidentiality are statistical techniques and physical or computerized methods for maintaining the security of stored data. The more sensitive the data being collected, the more important it is for the researcher and the IRB to be familiar with the state of the art in protecting confidentiality.

IRB CONSIDERATIONS

Privacy. In reviewing some protocols, an IRB may have to consider whether an invasion of privacy is involved. No ready and clear criteria are available for evaluating this question. IRBs must base decisions on their members' sense of propriety and the particular circumstances of the study. Among the relevant factors are: the private nature of the information sought, the likelihood the subjects would regard the release of information as an invasion of privacy, the importance of the research, and the availability of alternative ways to do the study.

Much research in which privacy concerns may be relevant will not necessarily come to the attention of the IRB. Under federal regulations, IRBs need not even review proposed research involving observation unless someone (*e.g.*, the investigator or department head) determines that it falls in the category of research that requires IRB review, as discussed above [Federal Policy §--___.101(b)(2)]. Some institutions review all observational research, as a matter of policy, to ensure that the IRB sees those few protocols for which review is required. Although the Federal Policy exempts from IRB review most research involving access to existing records, data, and surgical and diagnostic specimens, some institutions require review of the protocols to assure that the information is sought for a legitimate purpose and that research involving a record of individually identifiable information receives regular IRB review.

Investigators sometimes want access to existing records to identify people suitable for inclusion in a study. If the subjects' names will be recorded by the investigator for follow-up (either for further record reviews or for personal contact), this research requires IRB review. In such instances, the IRB must determine whether the consent of subjects should be sought (*e.g.*, by the institution holding the records) before the researcher gains access to the records. Factors to consider in deciding if consent must be sought include the sensitivity of the information to be reviewed, the vulnerability of the subject population, and the purpose for which the investigator wants access to the information. The Buckley Amendment [the General Education Provisions Act (20 USC 1232)] requires parental consent for release of records or identifiable information about children in public schools; instructional materials to be used in connection with any research or experimental program must be open to inspection by the parents or guardians of the children to be involved.

Protection of Confidentiality. When information linked to individuals will be recorded as part of the research design, IRBs should assure that adequate precautions will be taken to safeguard the confidentiality of the information. Sensitive information is sometimes obtained in the course of behavioral research, research with the cognitively impaired, AIDS research, and research dealing with drug and alcohol abuse. Various specialized security methods have been developed to maintain the confidentiality of such information. IRBs that review research in which confidentiality of data is important should have at least one member (or consultant) familiar with the strengths and weaknesses of the different mechanisms available, including the statutory shields against subpoena that are available. IRBs should also be aware of the regulatory provision for waiving documentation of consent when a signed consent form would itself constitute a risk to the subjects [Federal Policy §___.117(c)(1)].

Finally, IRBs should be aware that federal officials have the right to inspect research records, including consent forms and individual medical records, to ensure compliance with the rules and standards of their programs. FDA rules require that information regarding this authority be included on the consent forms for all research regulated by that agency; the Federal Policy, which applies to DHHS, and FDA regulations require that subjects be informed of the extent to which confidentiality of research records can be maintained [Federal Policy §___.116(a)(5); 21 CFR 50.25(a)(5)]. Identifiable information obtained by federal officials during such inspections is protected by the provisions of the Privacy Act of 1974.

POINTS TO CONSIDER

1. Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion?

2. If privacy is to be invaded, does the importance of the research objective justify the intrusion? What if anything, will the subject be told later?

3. If the investigators want to review existing records to select subjects for further study, whose permission should be sought for access to those records (the physician, the institution maintaining the records, the subjects)? How should the subjects be approached (through their physician, the medical records department, the institution)?

4. Will the investigator(s) be collecting sensitive information about individuals? If so, have they made adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study? If the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, can a grant of confidentiality be sought from a federal or state agency to protect the research data and the identity of the subjects from subpoena or other legal process?

5. Are the investigator's disclosures to subjects about confidentiality adequate? Should documentation of consent be waived in order to protect confidentiality?

APPLICABLE LAWS AND REGULATIONS

The Public Health Service Act [§301(d)] permits the Secretary, HHS, to authorize persons conducting biomedical and behavioral research to protect the privacy of subjects, even against subpoena. Persons so authorized may not be compelled to testify in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Regulations that predate §301(d) and that are used for guidance in implementing '301(d) for research relating to mental health (including alcohol and drug abuse) are published at 42 CFR 2A. The "Interim Policy Statement" on protection of identity of research subjects dated May 22, 1989, sets forth the policy of the PHS in accordance with §301(d).

The Controlled Substance Act (21 USC 872) permits the U.S. Attorney General to authorize persons conducting educational or research programs concerning drug abuse to withhold the names and other identifying characteristics of the subjects of such research. This provision is implemented by FDA regulations published at 21 CFR 1315.21.

The Buckley Amendment to the General Education Provisions Act (20 USC 1232) requires parental permission for access to records or identifiable information of children in public schools.

The Privacy Act of 1974 [5 USC 552(a)] prohibits federal agencies from disclosing records maintained in a system of records to any person, with certain exceptions, or other agency except upon a written request by, or with the prior written consent of, the individual to whom the record pertains.

The Freedom of Information Act (5 USC 552) exempts information such as medical or personnel records the disclosure of which would constitute a clearly unwarranted invasion of personal privacy from mandatory release by federal agencies.

Federal Policy §___.101(b)(2) [To what does this policy apply?]
Federal Policy §___.101(b)(4) [To what does this policy apply?]
Federal Policy §___.115(a)(5) [IRB records]
Federal Policy §___.116(a)(5) [General requirements for informed consent]
Federal Policy §___.117 [Documentation of informed consent]
21 CFR 50.25 [FDA: Elements of informed consent]
21 CFR 50.27 [FDA: Documentation of informed consent]
21 CFR 56.109(c) [FDA: IRB review of research]

E. MONITORING AND OBSERVATION

INTRODUCTION

One of the areas to be reviewed in proposed research is the researcher's plan for collection, storage, and analysis of data. Monitoring of the research by the researcher is important because preliminary data may signal the need to change the research design, change the information presented to subjects, or even to terminate the project before the scheduled end date.

Both the timing and adequacy of the plan for analysis are important. If the data are not analyzed until the project is terminated, the chance to make mid-course corrections is lost. If the data are not properly analyzed, the research itself is not valid, and proper conclusions may not result.

DEFINITIONS

Monitoring: The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections.

Review: The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy §___.108(e)].

IRB CONSIDERATIONS

For an IRB to approve proposed research, the protocol must, when appropriate, include plans for monitoring the data collected to ensure the safety of subjects [Federal Policy §___.111(a)(6)]. Investigators sometimes misinterpret this requirement as calling for annual reports to the IRB so that the IRB can monitor the project. In fact, however, §___.111 requires that, when appropriate, researchers must provide the IRB with a description of their plans for analyzing the data during the collection process. Concurrent collection and analysis enables the researcher to identify flaws in the study design early in the project. At this point, researchers are to reevaluate the risks to human subjects to assure that they are no greater than initially predicted.

Like other considerations, the level of monitoring in the research plan should be related to the degree of risk posed by the research. Furthermore, where the research will be performed at foreign sites, the IRB at the United States institution may

want to require different monitoring and/or more frequent reporting than that required by the foreign institution. [*See* also Guidebook Chapter 3, Section A, "Risk/Benefit Analysis," and Chapter 6, Section K, "International Research."]

IRBs should assure themselves that the progress of clinical trials will be adequately monitored to determine if information generated from them (or other related trials) should be passed on to the subjects, affect recruitment of subjects, change the ratio of risks and benefits, or lead to modification or discontinuation of the treatments being evaluated. Under normal circumstances, it is neither necessary nor desirable for the IRB itself to undertake data monitoring. Because investigators may have strong interests in continuing a clinical trial, however (*e.g.*, to obtain a higher level of statistical significance to ensure publication of the results), it is important that other, independent persons be responsible for monitoring trials and for decisions about modification or discontinuation of trials. It is the IRB's responsibility to ensure that these functions are carried out by an appropriate group. The review group should be required to report its findings to the IRB on an appropriate schedule.

Many trials, especially multicentered or double-masked studies, have independent data monitoring boards that fulfill this function. The primary responsibility of these monitoring boards is to safeguard human subjects by analyzing accumulating data relevant to risks and benefits on a regular basis. Especially in long-term trials, where patient enrollment or follow-up occurs over a long period of time, the boards review data periodically to assess effectiveness and toxicity. They must decide if and when the data are sufficiently favorable to one treatment that the study should be ended, which sometimes occurs sooner than the investigators had planned. Similarly, monitoring boards must decide whether adverse effects are serious enough to warrant termination of the trial [Federal Policy §___.113]. [*See* also Guidebook Chapter 3, Section E, "Monitoring and Observation."]

IRBs may want to monitor not only the collection of data but also the informed consent process. The IRB should not delegate the monitoring of the informed consent process to others.

Finally, the regulations also require periodic IRB reviews of research [Federal Policy §___.109(e)]. Periodic IRB review is discussed in the Guidebook in Chapter 3, Section H, "Continuing Review."

POINTS TO CONSIDER

l. How will the research data be recorded and maintained?

2. Considering the degree of risk, is the plan for monitoring the research adequate in terms of timeliness and thoroughness?

3. If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?

4. Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? (Unexpected results may raise the possibility of unanticipated risks to subjects.)

5. Does the institution have a data and safety monitoring board? If so, should it be asked to monitor the project under review? If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?

APPLICABLE LAWS AND REGULATIONS

Federal Policy §___.111(a)(6) [Criteria for IRB approval of research]

F. ADDITIONAL SAFEGUARDS

INTRODUCTION

The protection of human subjects is the paramount consideration of the IRB. Each project should be reviewed to determine whether some or all of the subjects are likely to be vulnerable to coercion or undue influence to participate. These vulnerabilities may be subtle but may limit the ability of certain subjects to refuse to participate or to continue to

participate in the research. The IRB must assure that due consideration of this issue is addressed in the research plan. Additional safeguards may need to be included in the study to protect the rights and welfare of these subjects.

IRB CONSIDERATIONS

The federal regulations provide that additional safeguards to protect subjects' rights and welfare must be included in any study where "some or all of the subjects are likely to be vulnerable to coercion or undue influence" [Federal Policy §___.111(b)]. Examples of such vulnerable subjects are children, prisoners, pregnant women, mentally disabled persons, and persons who are economically or educationally disadvantaged. Provision of additional safeguards for three of these groups (children, prisoners, and pregnant women) is handled differently by DHHS. The DHHS regulations provide distinct rules (which differ from the Federal Policy) for research involving fetuses, pregnant women, and human in vitro fertilization (45 CFR 46 Subpart B), prisoners (Subpart C), and children (Subpart D).

The consent process must be conducted only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate. Research conditions must also minimize the possibility of coercion or undue influence to give consent.

Persons with acute and/or severe physical or mental illness may be overly compliant with requests to participate in research due to the effects of their illness or due to the prospect of relief from suffering. Clinical studies must be specially designed to assure that patients are able to consent freely. Additional safeguards may include such requirements as the co-consent of relatives, parents, or impartial observers. In acute illness, patients may need to be treated before being entered into research protocols as subjects. This may mean that subjects are sometimes lost to the research protocol.

Occasionally, the institutional setting in which the consent is sought will pose the possibility of coercion. Conducting research at institutions that provide services to subjects may be perceived as implying that continued service is dependent upon participation in the research. Students in the educational setting may be concerned that refusal to participate will affect their grades. These institutional pressures should be addressed in the research design. The protocol must adequately preserve the right to refuse participation.
There are many other examples of possible sources of undue influence on subjects. It may not be possible to remove all sources of influence, but the IRB must examine each project to assure the elimination of coercion and minimization of other influences.

The requirement to obtain informed consent should be seen as not only a legal obligation, but also as a moral obligation. The research design must adequately address how informed consent will be obtained and what information will be given to prospective subjects. IRBs must look at the coercion issue in each proposal and insist on experimental designs that protect against undue influence to participate. See Guidebook Chapter 3, Section B for a fuller description of informed consent requirements.

POINTS TO CONSIDER

1. Are recruitment procedures designed to assure that informed consent is freely given?

2. What special safeguards are included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (*e.g.*, children, prisoners, pregnant women, persons with physical or mental illness, and persons who are economically or educationally disadvantaged)?

3. Does the nature of the disease or behavioral issue to be studied permit free consent?

4. Are any incentives offered for participation likely to unduly influence a prospective subject's decision to participate?

5. Is there an adequate procedure for monitoring the consent process, and should the IRB or its representative observe the process?

APPLICABLE LAWS AND REGULATIONS

Federal Policy §___.111(b) [Criteria for IRB approval of research]
Federal Policy §___.116 [General requirements for consent]
Federal Policy §___.117 [Documentation of informed consent]

45 CFR 46.111(b) [DHHS: Criteria for IRB approval of research]

45 CFR 46 Subpart B [DHHS: Additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and human in vitro fertilization]

45 CFR 46 Subpart C [DHHS: Additional protections pertaining to biomedical and behavioral research involving prisoners as subjects]

45 CFR 46 Subpart D [DHHS: Additional protections for children involved as subjects in research]

G. INCENTIVES FOR PARTICIPATION

INTRODUCTION

Each year, thousands of individuals are paid for participating in biomedical and behavioral research funded either by federal departments and agencies or private institutions. Although payments are usually monetary, both patients and normal healthy volunteers may be offered other rewards in lieu of or in addition to money. Free medical care, extra vacation time, and academic rewards (in the form of a grade or a letter of recommendation) are examples of alternative rewards. Regardless of the form of remuneration, the issues for IRBs remain the same. IRBs must consider whether paid participants in research are recruited fairly, informed adequately, and paid appropriately. Taking into consideration the subjects' medical, employment, and educational status, and their financial, emotional and community resources, the IRB must determine whether the rewards offered for participation in research constitute undue inducement.

OVERVIEW

Federal regulations governing research with human subjects contain no specific guidance for IRB review of payment practices. One of the primary responsibilities of IRBs, however, is to ensure that a subject's decision to participate in research will be truly voluntary, and that consent will be sought "only under circumstances that provide the prospective subject...sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence" [Federal Policy ___.116; 21 CFR 50.20]. Incentives for participation in research are discussed in the FDA's Information Sheet, "Payment to Research Subjects" (February 1989).

Clear cases of coercion (*i.e.*, actual threats) are readily identifiable; it is more difficult to recognize undue inducement. An offer one could not refuse is essentially coercive (or "undue"). Undue inducements may be troublesome because: (1) offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and (2) they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling or continuing as participants in a research project.

IRB CONSIDERATIONS

IRBs must attempt to make sure that prospective subjects realize that their participation is voluntary, and that choosing not to participate will not adversely affect their relationship with the institution or its staff in any way. To make this determination, IRBs should know who the subjects will be, what incentives are being offered, and the conditions under which the offer will be made.

Some institutions have adopted policies regarding the recruitment and payment of volunteers. In general, they attempt to minimize the possibility of coercion or undue influence by requesting that subjects be recruited by open, written invitation rather than by personal solicitation. Institutions try to ensure that the consent document contains a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (for example, what will happen if they withdraw part way through the research).

Determining the appropriateness of the incentive is another matter. For research that requires subjects to undergo only minor inconvenience or discomfort, a modest payment will usually be adequate. Reimbursement for travel, babysitting, and so forth may also be provided. In more complex research projects, IRBs tend to base their assessment on the prevailing payment practices within their institution or general locale. Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Standard payments may be established for each tissue or fluid sample collected, depending on the type of sample (blood, urine, or saliva) and the time (day or evening) the sample is to be collected. Alternatively, subjects may be paid an hourly rate or a fixed amount, depending on the duration of the study and whether the study requires admission to research ward. Extra payments are usually provided for a variety of additional inconveniences (e.g., the imposition of dietary restrictions). Payments may vary according to a number of factors, and, therefore, IRBs may need to become familiar with the accepted standards within their community as well as the anticipated discomforts and inconveniences involved in a particular study to judge appropriateness of payments. Some institutions have a ceiling on the amount an individual may earn in any one study or during a given length of time (e.g., per year, per semester).

One of the most perplexing problems for IRBs is how to assess the appropriateness of payment offers for experiments that involve the assumption of risk or significant discomfort. On a practical level, it is probably impossible for an IRB to determine what amount of money or type of reward would unduly influence a particular individual to accept a given degree of risk. Although our society generally accepts the premise that those assuming risk deserve reward, the application of this rule in establishing payment for subjects in biomedical and behavioral experiments is still being debated. The appropriateness of proposed payments is a matter each institution must address in formulating its policies.

IRB members tend to approach the problem of assuming risk for pay from one of two positions. One side argues that normal healthy volunteers are able to exercise free choice, and that, since judging the acceptability of risk and weighing the benefits is a personal matter, IRBs should refrain from imposing their own views on potential subjects. On this view, IRB responsibility should be confined to ensuring that consent is properly informed. Other IRB members argue that the IRB should protect potential subjects from inducements that may affect their ability to make an informed, voluntary choice. It should be noted that, in this context, incentives need not be financial to cause problems. Free health care for persons with limited resources and major medical problems may be a significant inducement to participate in research (even if the research activity is nontherapeutic). There is no consensus as to whether this kind of inducement is unacceptable. In assessing this potential problem, IRBs might consider whether only the destitute agree to volunteer or if people who can obtain good medical care on their own agree to participate as well. IRBs may need to monitor subject recruitment to make such determinations.

POINTS TO CONSIDER

1. Are all conditions in keeping with standards for voluntary and informed consent?

2. Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular subject population?

3. Are there special standards that the IRB ought to apply to the review of research in which volunteers are asked to assume significant risk?

4. Should the IRB monitor subject recruitment to determine whether coercion or undue influence is a problem?

APPLICABLE LAWS AND REGULATIONS

Federal Policy ___.109(e) [IRB review of research]
Federal Policy ___.111 [Criteria for IRB approval of research]
Federal Policy ___.116 [General requirements for informed consent]

45 CFR 50.20 [FDA: General requirements for informed consent]

H. CONTINUING REVIEW

INTRODUCTION

It would be a mistake to see the IRB approval process as a one-time step in the life of a research project. IRB approval is a temporary authority that may be withdrawn at any time if warranted by the conduct of the research. The regulations authorize the IRB to establish procedures for the concurrent monitoring of research activities [Federal Policy ___.109(e)]. DHHS and FDA rules require reevaluation of approved research at intervals that are appropriate to the degree of risk [Federal Policy ___.109(e)]. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research must be reviewed at least annually.

IRB CONSIDERATIONS

The initial IRB review is based on the researcher's best assessment about anticipated results, risk, and procedures. The IRB uses its expertise to judge whether this estimate is reasonable and supportable. At the time of its initial review, the IRB must determine how often it should reevaluate the research project and set a date for its next review.

The responsibility for continued monitoring of approved research is as important as the initial review and approval. It is only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio; the IRB can then determine the correctness of the initial judgment. Some IRBs have set up a complaint procedure that allows subjects to indicate whether they believe that they were treated unfairly or that they were placed at more risk than was agreed upon at the beginning of the research. A report form available to all researchers and staff may be helpful for informing the IRB of unforeseen problems or accidents. The IRB may find that scheduled progress reports are an effective means of monitoring some research.

The risk/benefit ratio may change over time. Not only unexpected results and effects of the research project itself, but new knowledge resulting from other research may affect the balance. After reassessment, the IRB may require that the research be modified or halted altogether. The IRB may need to impose special precautions or relax special requirements it had previously imposed on the research protocol.

Federal policy requires that investigators inform subjects of any important new information that might affect their willingness to continue participating in the research [Federal Policy ___.116(b)(5)]. The IRB should make a determination whether any new findings, new knowledge, or adverse effects should be communicated to subjects. The IRB should receive copies of any such information conveyed to subjects. Any necessary changes to the consent document(s) must be reviewed and approved by the IRB. [*See* also Guidebook Chapter 3, Section B, "Informed Consent."]

The IRB has the authority to observe, or have a third party observe, the consent process and the research itself [Federal Policy ___.109(e)]. The researcher is obligated to keep the IRB informed of unexpected findings involving risks and to report any occurrence of serious harm to subjects [Federal Policy ___.103(b)(5)]. Reports of preliminary data analysis may be helpful to the researcher and the IRB in monitoring the need to continue the project. An open and cooperative effort between the researcher and the IRB protects everyone concerned.

IRBs have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects [Federal Policy ___.113]. If the IRB decides to suspend or terminate its approval of a research project, the IRB shall report its decision promptly to the investigator(s), appropriate institutional officials, and the department or agency head (or designated office, such as OPRR). The IRB's report must include a statement of the reasons for the suspension or termination.

POINTS TO CONSIDER

1. Are the actual risks and benefits as anticipated?

2. Have any subjects been seriously harmed?

3. Has the IRB been informed of any unforeseen problems or accidents that may have occurred?

4. Should the IRB request that the investigator(s) submit scheduled progress reports?

5. Should the investigator(s) submit progress reports more often than annually?

6. Since the last IRB review, have subjects been informed of any important new information that might affect their willingness to continue participating in the research?

7. Have any new findings, knowledge, or adverse effects come to light that should be, but have not been, communicated to subjects?

8. Does the progress of the project together with the results of other new research indicate that the IRB should either impose special precautions or relax special requirements it had previously imposed?

9. Do the consent documents need to be revised?

10. Has due care been used to reduce risks and increase the likelihood of benefit?

11. Are the procedures agreed upon at the beginning of the research still being used?

12. Does the protocol adequately provide for continuing assessment of the balance between risks and benefits?

13. Should IRB approval be continued, or should approval be suspended or terminated?

14. When should the IRB next review the project (taking into account what has been learned about the actual risk to subjects since the project first received IRB approval)?

APPLICABLE LAWS AND REGULATIONS

Federal Policy ___.103(b)(4)-(5) [Assuring compliance with this policy research conducted or supported by federal departments or agencies]
Federal Policy ___.109(e) [IRB review of research]
Federal Policy ___.110(b) [Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research]
Federal Policy ___.113 [Suspension or termination of IRB approval]
Federal Policy ___.116(b)(5) [General requirements for informed consent]
Federal Policy ___.117 [Documentation of informed consent]

SUGGESTIONS FOR FURTHER READING

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CFR (Code of Federal Regulations, **TITLE 45 PUBLIC WELFARE, PART 46 PROTECTION OF HUMAN SUBJECTS** Effective June 25, 2005):

http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf

Institutional Review Boards and the HIPAA Privacy Rule

(Protected Health Information, and De-Identifyers)

http://privacyruleandresearch.nih.gov/pdf/IRB_Factsheet.pdf

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule

http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf

HIPPA

CONSENT FORM ADDENDUM

http://www.irb.pitt.edu/hipaa/HIP_Auth_2.doc

AUTHORIZATION (CONSENT) TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES

(Division, Department, School, or Center Letterhead)

University of Pittsburgh
Institutional Review Board
IRB Number:
Approval Date:
Renewal Date:

TITLE:

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATORS:

SOURCE OF SUPPORT:

Why is my additional consent being requested?

You have previously given your consent to participate in the above-named research study. The purpose of this additional consent form is to provide you with specific knowledge regarding the use and disclosure of your identifiable medical record information for the purpose of this research study. While much of this knowledge was provided to you previously, recently enacted laws focused on the privacy of medical record information require that this knowledge be addressed in certain manner. Through the use of this additional consent form, we are seeking your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study as per the requirements addressed in these recently enacted laws.

What uses of my identifiable medical record information will this research study involve?

[Include if the research study involves the collection of the subjects' current or future identifiable medical record (i.e., hospital, health care provider) information:]

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (e.g., physician office) records. The information that will be recorded will be limited to information concerning *[specify the nature of the data that will be recorded].* This information will be used for the purpose of *[specify the purpose of the research use of the current and/or future identifiable medical record information]*.

[Include if the research study will involve the generation of information (e.g., diagnostic information, laboratory information, treatment or adverse event information) that will appear or be placed in the subjects' medical (i.e., hospital, health care provider) records:]

This research study will result in identifiable information that will be placed into your medical records held at *[specify the name of the applicable hospital or health care provider's office]*. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes *[specify the type research data which may or will be recorded in the subject's medical record]*.

Who will have access to my identifiable medical record information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to your identifiable medical record information related to your participation in this research study:

[Include routinely:]

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable medical record information for the purpose of monitoring the appropriate conduct of this research study.

[Include if an external sponsor of the research study will have access to the subjects identifiable medical record information for study monitoring or data analysis purposes:]

Authorized representatives of the sponsor of this research study, *[specify name of sponsor and/or contract research organization]*, will review and/or obtain your identifiable medical record information for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. *[Include if applicable - "Authorized representatives of the study sponsor may also be present during your participation in certain research procedures."]* While the study sponsor understands the importance of maintaining the confidentiality of your identifiable medical record information, the UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable medical record information related to your participation in the study.

[Include if research study involves an evaluation of any article (e.g., drug, device, electronic product, food additive) regulated by the U.S. Food and Drug Administration:]

Authorized representatives of the U.S. Food and Drug Administration may review and/or obtain your identifiable medical record information for the purpose of monitoring the accuracy of the research data. While the U.S. Food and Drug Administration understands the importance of maintaining the confidentiality of your identifiable medical record information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the U.S. Food and Drug Administration.

[Include if the research study (or any aspect of the research study) will involve the utilization of hospital or health care services (e.g., laboratory tests, diagnostic procedures); hospital or health provider care of the patient-subject; or hospital or health provider billing activities:]

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable medical record information for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

[Include if applicable:]

[Identify any other individuals who may or will have access to the participant's identifiable medical record information and the purpose of such access.]

[Include routinely:]

In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record information) in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

May I have access to my medical record information resulting from participation in this research study?

In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider unless otherwise specifically stated below.

[Include if you intend to restrict patient-subject access to medical record information generated as a result of the patient's-subject's participation in the research study:]

[Specify any restrictions on the patient's-subject's access to medical information generated as a result of research participation. Indicate that such access will be granted at the end of the research study. Note that the UPMC does not generally permit investigators to include restrictions on patient-subject access to medical record information held by the UPMC or affiliated health care providers. The principal investigator must petition the Privacy Officer, UPMC, on a study-specific basis, if s/he wishes to restrict respective patient-subject access to their own medical record information. If the Privacy Officer, UPMC, grants such restrictions, it will be the principal investigator's responsibility to clearly communicate to the involved UPMC hospital(s) or affiliated health care providers the restrictions that have been granted. This communication must include documentation of the Privacy Officer's permission along with a copy of this signed consent form/authorization.]

May I refuse to provide my authorization (consent) for the use of my identifiable medical record information for the purpose of this research study?

Your authorization (consent) to use and disclose your identifiable medical record information for the purpose of this research study is completely voluntary. However, if you do not provide your written authorization (consent) for the use and disclosure of your identifiable medical record information, you will not be allowed to participate or continue to participate in the research study.

Whether or not you provide your authorization (consent) for the research use and disclosure of your medical record information will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Whether or not you provide this written authorization (consent) will have no affect on your current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my authorization (consent) for the use of my identifiable medical record information for the purpose of this research study?

You may withdraw, at any time, your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study. However, if you withdraw your authorization (consent) for the use and disclosure of your identifiable medical record information, you will also be withdrawn from further participation in this research study. Any identifiable medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your authorization may continue to be used and disclosed by the investigators for the purposes described above *[or specify what other action will be taken with regard to the retention of previously collected identifiable medical record information upon subject withdrawal from study participation]*.

To formally withdraw your authorization (consent) you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your authorization (consent) for the research use and disclosure of your medical record information will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Your decision to withdraw this authorization will have no affect on your current or future relationship with the University of Pittsburgh.

For how long will the investigators be permitted to use my identifiable medical record information?

The investigators may continue to use and disclose your identifiable medical record information for the purposes described above for an indefinite period of time.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask any additional questions I may have about the research use and disclosure of my identifiable medical record information. Such future questions will be answered by the investigators listed on the first page of this form.

Any questions I have about my rights associated with the research use of my medical record information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to allow the use and disclosure of my medical record information for the purposes described above. A copy of this authorization (consent) form will be given to me.

_____ _____

Participant's Signature Date

[If applicable: For adults (age > 18 years old) determined to be decisionally impaired and thus unable to provide direct authorization for the use of their identifiable medical record information, incorporate the following standard statements and signature lines:]

_____

Participant's Name (Print)

The above-named individual is unable to provide direct authorization for the use and disclosure of his/her identifiable medical record information for the purpose of this research study because:

_____

_____.

Therefore, by signing this form, I give permission for the use and disclosure of his/her medical record information for the purpose of this research study.

_____ _____

Representative's Name (Print) Representative's Relationship to Participant

_____ _____

Representative's Signature Date

[If applicable: Incorporate the following statements if the potential patient-subject is capable of exercising some judgement concerning the use of his/her medical record information for the purpose of this research study.]

VERIFICATION OF EXPLANATION

I certify that I have explained the nature and purpose of the research use and disclosure of the above-named individual's identifiable medical record information in appropriate language. He/she has had an opportunity to discuss this with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to allow the use and disclosure of his/her identifiable medical record information for the purpose of this research study.

_____ _____

Investigator's Signature *Date*

[If applicable: For research studies wherein the nature of the subject population is such that an individual may not be capable of initially providing direct authorization for the research use of his/her identifiable medical record information but may recover adequate decision-making capability for direct authorization at a later time, also incorporate the following standard statements and signature lines:]

AUTHORIZATION (CONSENT) FOR THE CONTINUED RESEARCH USE OF IDENTIFIABLE MEDICAL RECORD INFORMATION

I understand that I am currently participating in a research study. I further understand that authorization (consent) for the research use and disclosure of my identifiable medical record information was initially obtained from my authorized representative as a result of my inability to provide direct authorization (consent) at the time that this initial authorization (consent) was requested. I have now recovered to the point where it is felt that I am able to provide direct authorization (consent) for the continued use and disclosure of my medical record information for the purpose of this research study.

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my continued participation in this research study, I am encouraged to ask additional questions I may have about the research use and disclosure of my identifiable medical record information. Such future questions will be answered by the investigators listed on the first page of this form. Any questions I have about my rights associated with the research use and disclosure of my identifiable medical record information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

By signing this form, I agree to allow the continued use and disclosure of my identifiable medical record information for the purposes described above. A copy of this authorization form will be given to me.

_____ _____

Participant's Signature Date

[If applicable: For children (age 0-17 years), incorporate the following standard statements and signature lines:]

_____

Participant's (Child's) Name (Print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to directly authorize the research use and disclosure of his/her identifiable medical record information. Therefore, by signing this form, I give my authorization (consent) for the use and disclosure of his/her identifiable medical record information for the purpose of this research study.

_____ _____

Parent's or Guardian's Name (Print) Relationship to Participant (Child)

_____ _____

Parent's or Guardian's Signature Date

HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

1. Purpose. As a research participant, I authorize [name of PI] and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled [title of study], [Human Subjects' Code].

2. Individual Health Information to be Used or Disclosed. My individual health information that may be used or disclosed to conduct this research includes: [List all of the individual health information to be collected for this protocol/study such as demographic information, results of physical exams, blood tests, x-rays, and other diagnostic and medical procedures as well as medical history].

3. Parties Who May Disclose My Individual Health Information.

The researcher and the researcher's staff may obtain my individual health information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals and/or clinics) for the purposes of carrying out this research study. I authorize these parties to disclose my individual health information to the researcher and the researcher's staff for the purposes of carrying out this research study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information disclosed by parties in item 3 and information disclosed by me during the course of the research may be received and used by [name of researcher] and the researcher's staff and [list any collaborators, other clinical sites involved in the research, sponsors if applicable, outside laboratories]. [OPTIONAL: Also, if I receive compensation for participating in this study, identifying information about me may be used or disclosed as necessary to provide compensation.]

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign the Authorization, I may not be allowed to participate in this study or receive any research related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to [researcher's name and address] to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this study and no longer covered by this authorization. However, the research team and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect your privacy and limit the disclosure of identifying information about you.

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

7A. Also, there are other laws that may require my individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities and public health measures.

8. [Optional Item] **Suspension of Access**. I may not be allowed to review the information collected for this study, including information recorded in my medical record, until after the study is completed. When the study is over, I will have the right to access the information again.

This authorization does not have an expiration date.

I am the research participant or personal representative authorized to act on behalf of the participant.

I have read this information, and I will receive a copy of this authorization form after it is signed.

_____ _____

signature of research participant or research participant's personal representative

date

_____ _____

printed name of research participant or research participant's personal representative

description of personal representative's authority to act on behalf of the research participant

HIPAA[2] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR *FUTURE RECRUITMENT* PURPOSES

1. Purpose. As a patient of a University of Minnesota Healthcare Provider and or a current participant in a University of Minnesota research study, I authorize [UMN Department or Unit, Fairview Staff] to collect and maintain my individual health information for the purposes of potential contact for recruitment into future research projects.

2. Individual Health Information to be Used or Disclosed. My individual health information that will be maintained for recruitment purposes includes: [List all the individual health information to be collected for this recruitment database/protocol, such as the subject's name, mailing address, telephone number, medical records, and any other identifiable information that will be maintained in the database. {*** Items listed in this section MUST coincide with parameters outlined in the recruitment database application***}.

3. Parties Who May Disclose My Individual Health Information.

The researcher and the researcher's staff may obtain my individual health information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals and/or clinics) for the purposes of carrying out this research study. I authorize these parties to disclose my individual health information to the researcher and the researcher's staff for the purposes of carrying out this research study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information maintained in this database may be disclosed by parties listed in item 3 may be received and used by [UMN Department or Unit, Fairview Staff] and their staff and [list any other researchers at the UMN and or external academic institutions, clinical sites, sponsors, collaborators, that may be given permission to access data from the recruitment database to initiate contact with subjects]. [***Note, persons who establish the recruitment database MUST clearly specify who may be allowed to access subjects' data for recruitment purposes. If one is unclear about who may be allowed access, then include a broad description of possible future researchers (e.g. researchers studying a specific type of disease, etc ***). [OPTIONAL: Also, if I receive compensation for participating in this study, identifying information about me may be used or disclosed as necessary to provide compensation.]

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign the Authorization, I may not be allowed to include my individual health information in this recruitment database. My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to [Unit/Department contact person's name and address] to inform them of my decision. If

[2] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

I withdraw this authorization, my name and individual health information will be removed from the recruitment database. No further health information about me will be collected by or disclosed to the staff for this recruitment database.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this recruitment database and no longer covered by this authorization. However, the [UMN Department or Unit, Fairview Staff] and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect your privacy and limit the disclosure of identifying information about you.

This authorization does not have an expiration date.

I am the patient and or research participant authorized to act on behalf of the participant.

I have read this information, and I will receive a copy of this authorization form after it is signed.

_____ _____

Signature of patient and or research participant date

_____

Printed name of patient and or research participant date

DATA USE AGREEMENT BETWEEN

[Insert Name of Holder of Protected Health Information]

and

[Insert Name of Data Set Recipient/Researcher]

This Data Use Agreement is made and entered into on [Insert Date] by and between [insert Holder name], hereafter "Holder" and [insert Recipient name], hereafter "Recipient."

This agreement sets forth the terms and conditions pursuant to which Holder will disclose certain protected health information, hereafter "PHI" in the form of a Limited Data Set to the Recipient.

Terms used, but not otherwise defined, in this Agreement shall have the meaning given the terms in the HIPAA Regulations at 45 CFR Part 160-164.

Permitted Uses and Disclosures

Except as otherwise specified herein, Recipient may make all uses and disclosures of the Limited Data Set necessary to conduct the research described herein: [include a brief description of the research and/or HSC protocol number] ("Research Project")

In addition to the Recipient, the individuals, or classes or individuals, who are permitted to use or receive the Limited Data Set for purposes of the Research Project include: [insert names or classes of persons who may use or receive the limited data set, e.g. the researcher's staff, any collaborators, other clinical sites involved in the research, sponsors if applicable, outside laboratories] To the extent that the classes of persons are not part of the Recipient's workforce who are directly involved in the Research Project, the Recipient shall enter into a data agreement with the other classes of persons before such release of the Limited Data Sets.

Recipient Responsibilities

1. **Recipient will not use or disclose the Limited Data Set for any purpose other than permitted by this Agreement pertaining to the Research Project or as required by law;**
2. **Recipient will use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement;**
3. **Recipient will report to the Holder any use or disclosure of the Limited Data Set not provided for by this Agreement of which the Recipient becomes aware within 15 days of becoming aware of such use or disclosure;**
4. **Recipient will ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Recipient with respect to the Limited Data Set;**
5. **Recipient will not identify the information contained in the Limited Data Set; and**
6. **Recipient will not contact the individuals who are the subject of the PHI contained in the Limited Data Set.**

Term and Termination

The terms of this Agreement shall be effective as of [insert effective date], and shall remain in effect until all PHI in the Limited Data Set provided to the Recipient is destroyed or returned to the Holder.

Upon the Holder's knowledge of a material breach of this Agreement by the Recipient, the Holder shall provide an opportunity for Recipient to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the reasonable time period specified by the Holder, the Holder shall discontinue disclosure of PHI to the Recipient and report the problem to the Secretary of the Department of Health and Human Services or its designee. The Holder shall immediately discontinue disclosure of the Limited Data Set to the Recipient if the Holder determines cure of the breach is not possible.

General Provisions

Recipient and Holder understand and agree that individuals who are the subject of Protected Health Information are not intended to be third party beneficiaries of this Agreement.

This Agreement shall not be assigned by Recipient without the prior written consent of the Holder.

Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof.

IN WITNESS WHEREOF, the parties hereto execute this agreement as follows:

[INSERT NAME OF HOLDER OF DATA]

Date: _____ By: _____

(Title person with authority to sign agreement for the holder of the data)

Date: _____ RECIPIENT

By: _____

(Title of recipient or person with authority to sign agreement for the recipient)

HIPAA[3] AUTHORIZATION TO MAINTAIN
INDIVIDUAL HEALTH INFORMATION FOR *FUTURE RESEARCH* PURPOSES

1. Purpose. As a patient of a University of Minnesota Healthcare Provider and or a current participant in a University of Minnesota research study, I authorize [UMN Department or Unit, Fairview Staff] to collect and maintain my individual health information for the purposes of possible use in future research projects.

2. Individual Health Information to be Maintained. My individual health information that may be maintained to conduct future research includes: [List all the individual health information to be collected for this recruitment database/protocol, such as the subject's name, mailing address, telephone number, medical records, and any other identifiable information that will be maintained in the database. {*** Items listed in this section MUST coincide with parameters outlined in the database application***}.

3. Parties Who May Disclose My Individual Health Information.

The researcher and the researcher's staff may obtain my individual health information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals and/or clinics) for the purposes of carrying out this research study. I authorize these parties to disclose my individual health information to the researcher and the researcher's staff for the purposes of carrying out this research study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information maintained in this database may be disclosed by parties listed in item 3 may be received and used by [UMN Department or Unit, Fairview Staff] and their staff and [list any other researchers at the UMN and or external academic institutions, clinical sites, sponsors, collaborators, that may be given permission to access data from the recruitment database to initiate contact with subjects]. [***Note, persons who establish the database MUST clearly specify who may be allowed to access subjects' data for future research purposes. If one is unclear about who may be allowed access, then include a broad description of possible future researchers (e.g. researchers studying a specific type of disease, researchers within a specific department, etc ***). I understand that before my individual health information may be used in any future research study, the Principal Investigator must obtain approval from the Institutional Review Board (The committee that reviews studies to be sure that the rights and safety of study participants are protected).

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign the Authorization, my individual health information will not be maintained for future research purposes. My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to [Unit/Department contact person's name and address] to inform them of my decision. If I withdraw this authorization, my name and individual health information will be removed from the database. No further health information about me will be collected or maintained for this database.

[3] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this recruitment database and no longer covered by this authorization. However, the [UMN Department or Unit, Fairview Staff] and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect your privacy and limit the disclosure of identifying information about you.

7A. Also, there are other laws that may require my individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities and public health measures.

This authorization does not have an expiration date.

I am the patient and or research participant authorized to act on behalf of the participant.

I have read this information, and I will receive a copy of this authorization form after it is signed.

_____ _____

Signature of patient and or research participant date

_____

Printed name of patient and or research participant date

IDENTIFIERS

1. Names
2. Address information smaller than a state, including street address, city, county, zip code (except if by combining all zip codes with the same initial three digits, there are more than 20,000 people)
3. Names of relatives and employers
4. All element of dates (except year), including DOB, admission date, discharge date, date of death; and all ages over 89 and all elements of dates including year indicative of such age except that such ages and elements may be aggregated into a single category of age 90 or older;
5. Telephone numbers
6. Fax numbers
7. Email addresses
8. Social Security Number (SSN)
9. number (health record number)
10. Health beneficiary plan number
11. Account numbers (any and all)
12. Certificate/License Number
13. Vehicle identifiers, including license plate numbers
14. Device ID and serial number
15. Uniform Resource Locator (URL) - Web address
16. Identifier Protocol (IP) addresses (Internet Protocol)
17. Biometric identifiers including finger and voice prints (identifiers such as age, race, gender, and ethnicity do not have to be removed; however, if the identifier is so unique to the consumer that it could reasonably be used to identify the consumer, then the identifier should be removed)
18. Full face photographic images and other comparable images
19. - Any other unique identifying number characteristic, or code.

PART II

Informed Consent (*Make sure required and other elements are present)*

Lynn University Required Language for Elements of your Informed Consent. Use language where appropriate.

****Last Revision Posted 10-14-06**
This generic consent includes consent elements for adult (18+) interviews including audio (or tape) recordings and surveys.
Use this form and adapt to your project, maintaining required language

ATTENTION: For Child Assent, Parental Consent, Questionable Capacity etc. add additional language to comply with IRB.

Tips (Include USDHHS and APA) http://www.socialpsychology.org/consent.htm
Consent Short Form (you need to include script of oral information):
http://www.research.umn.edu/irb/consent/shortforms.cfm

Guidelines for Child Assent:
http://www.usm.maine.edu/orc/irb/pdf/child_assent.pdf

Sample Consent Forms and Information (Review HIPAA and De-Identification above):
http://www.augsburg.edu/irb/sample.html

Research Involving Individuals with Questionable Capacity to Consent:
http://grants.nih.gov/grants/policy/questionablecapacity.htm

Research with Human Subjects from a Foreign Country
Become familiar with the CFR. The Application tells explains what is needed - and it will vary with the country and the type of research. See Application Form 1, Part C. (5) Human Subjects in a Foreign Country http://www.irb.umn.edu/guide/humanGuide2.cfm#2_9 (review paragraph 2.9)

International Compilation of Human Subject Research Protection (2005) of many countries.
http://www.hhs.gov/ohrp/international/HSPCompilation.pdf

Internet Surveys:
Ethical and Legal Aspects of Human Subjects Research on the Internet
http://www.aaas.org/spp/sfrl/projects/intres/report.pdf

Examples on Minimal Risk (Important)
http://www.research.umn.edu/irb/applying/minrisk.cfm
http://darkwing.uoregon.edu/~humansub/examples.html

www.il.proquest.com/dissertationagree
login - dissertations
password - publish

Observe this statement that ProQuest requests when seeking different types of permissions:

The requested permission extends to any future revisions and editions of my dissertation, including non-exclusive world rights in all languages, and to the prospective publication of my dissertation by ProQuest Information and Learning (ProQuest) through its UMI® Dissertation Publishing business. ProQuest may produce and sell copies of my dissertation on demand and may make my dissertation available for free internet download at my request. These rights will in no way restrict republication of the material in any other form by you or by others authorized by you. Your signing of this letter will also confirm that you own [or your company owns] the copyright to the above-described material.

This generic consent includes consent elements for adult (18+) interviews including audio (or tape) recordings and surveys.

Lynn University
THIS DOCUMENT SHALL ONLY BE USED TO PROVIDE AUTHORIZATION FOR VOLUNTARY CONSENT

PROJECT TITLE: _____
Project IRB Number: _____ Lynn University 3601 N. Military Trail Boca Raton, Florida 33431

I _____ , am a doctoral student at Lynn University. I am studying Global Leadership, with a specialization in _____. One of my degree requirements is to conduct a research study.

DIRECTIONS FOR THE PARTICIPANT:

You are being asked to participate in my research study. Please read this carefully. This form provides you with information about the study. The Principal Investigator (_____ or his/her representative if applicable) will answer all of your questions. Ask questions about anything you don't understand before deciding whether or not to participate. You are free to ask questions at any time before, during, or after your participation in this study. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled. *(include the following statement for adults, otherwise see Child Assent →* You acknowledge that you are at least 18 years of age, and that you do not have medical problems or language or educational barriers that precludes understanding of explanations contained in this authorization for voluntary consent.

PURPOSE OF THIS RESEARCH STUDY: The study is about_____. There will be approximately __ number of people invited to participate in this study. *Expand on some characteristics of participants such as where they are from such as a business, schools, organizations, etc).*

PROCEDURES:
Describe all procedures fully. Examples with survey, interview, and audio-tape recordings (delete what doesn't apply):

Experimental (varies)

If a Survey (Self-Report)
You will first complete a _____ (*such as a demographic survey*). Then you will be asked to complete a_____ (*some description or title*). These two surveys should take about ____ minutes to complete. *(Option - If the survey is conducted in presence of the researcher or other data collectors, you can add the following, survey will* ***no longer be anonymous*** →If necessary, the researcher, (_____), can help you in completing the surveys. *If the survey is conducted in the presence of a researcher or data collector, explain how anonymity will be maintained.* If *Mailed or Internet (what are plans for this)*

> ***If using an "Internet survey":*** ***Include*** *required statements* such as instructions to participants include a blind copy format so that the list of recipients will not appear in the header (this is particularly appropriate when using snowball sampling, or when using large "email addresses".) **Report** methods of protection of privacy of respondents include encryption, security, protection of IP addresses, etc.

If Interview and Self-Report
You will first complete a _____ (*such as a demographic survey)* and this is followed by an interview(s). In the interview, you will be asked to elaborate on questions that are relevant to this study and to provide insights about _____. There are __ (*insert # of questions*). The survey and interview should take about ___ minutes to complete. *If applicable*→A follow up interview may be necessary at a mutually agreed upon time and place, of approximately __ minutes in duration (*or a follow up by telephone call may be necessary).*

***If Interview only*→**
The interview begins with your response to demographic questions. Next you will be asked to elaborate on questions that are relevant to this study and to provide your insights about _____. The interview should take about ___ minutes to complete. *If applicable*→A follow up interview may be necessary at a mutually agreed upon time and place, of approximately __ minutes in duration (*or a telephone call may be necessary*).

If applicable→ The interview will be recorded on audio-tape to allow a more accurate transcription. This interview will be done _____(*in person, over the phone*) in response to questions provided by the researcher. You have the right to review all or any portion of the tape, and request that it be destroyed.
If applicable include Debriefing

POSSIBLE RISKS OR DISCOMFORT: This study involves minimal risk. You may find that some of the questions are sensitive in nature. In addition, participation in this study requires a minimal amount of your time and effort.

POSSIBLE BENEFITS: There may be no direct benefit to you in participating in this research. But knowledge may be gained which may help_____.

FINANCIAL CONSIDERATIONS: There is no financial compensation for your participation in this research. There are no costs to you as a result of your participation in this study.

CONFIDENTIALITY (or change to ANONYMITY)
(Explain how either anonymity or confidentiality will be assured. Describe the procedures by which any information obtained through this study, as it relates to a specific individual, will be kept private.

ANONYMITY

Secondary data sets: Unrestricted datasets have been sufficiently purged of identifying information that we believe they pose no significant threat to respondent **anonymity**. **...**

Surveys will be anonymous. You will not be identified and data will be reported as "group" responses. Participation in this survey is voluntary and return of the completed survey will constitute your informed consent to participate.

> *Use this statement for **Internet Surveys** where anonymity is planned instead of the above statement (revision 6-21-05):* Anonymity will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. The researcher will not identify you and data will be reported as "group" responses. Participation in this survey is voluntary and return of the completed survey will constitute your informed consent to participate. All information will be held in strict confidence and will not be disclosed unless required by law or regulation.
>
> **Note to researchers**: In survey based research, the answering of the survey and passing or mailing in of said survey instrument is evidence of consent and often preferable because the subject's name is never linked to the research data. The survey will be anonymous, and anonymity will be preserved. ***Anonymity*** means the researcher will collect NO identifying information from participants – no identifiers→ (e.g., no names, no social security numbers, no driver's license numbers, etc.). If participants can be assured anonymity, then this must be clearly explained in the Informed Consent Form.

CONFIDENTIALITY
Every effort will be made to maintain confidentiality. Your identity in this study will be treated as confidential. Only the researcher (_____) will know who you are. During the Interview you will be given a fictitious name (or code number). Data will be coded with that fictitious name.

> *Use the following instead of the above statement, for **Internet Surveys** where data are confidential (revision 6-21-05):* Every effort will be made to maintain confidentiality. Your identity in this study will be treated as confidential by the researcher (_____) who will know who you are. During the Interview you will be given a fictitious name (or code number). Data will be coded with that fictitious name. Confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

Interview data ___ *(including audio recorded or video if applicable)* will be coded so that there is no personally identifying information. They will be kept in a secure place (e.g., a locked file cabinet in the investigator's office). They will be heard (or viewed) only for research purposes by the investigator, _____ and his or her faculty advisor, ____. They will be transcribed and coded. *Adapt to what is applicable →*At the end of end of the study, all audio-tapes (or video-recordings) will be destroyed in a responsible manner.

ALL STUDIES must include these statements in the last two paragraphs under either anonymity or confidentiality:
Describe in what format the data results will be presented, (i.e. aggregate form only if possible?).
The results of this study may be published in a dissertation, scientific journals or presented at professional meetings. In addition, your individual privacy will be maintained in all publications or presentations resulting from this study.

All the data gathered during this study, which were previously described, will be kept strictly confidential by the researcher. Data will be stored in locked files and destroyed at the end of the research *(state how data are stored if other than locked files as well – such as password protected computers, and be specific as to when data will be destroyed.* All information will be held in strict confidence and will not be disclosed unless required by law or regulation.

RIGHT TO WITHDRAW: You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate.

CONTACTS FOR QUESTIONS/ACCESS TO CONSENT FORM: Any further questions you have about this study or your participation in it, either now or any time in the future, will be answered by _____ (Principal Investigator) who may be reached at: _____ and Dr._____, faculty advisor who may be reached at: (561) 237-_____. For any questions regarding your rights as a research subject, you may call Dr. _____, Chair of the Lynn University Institutional Review Board for the Protection of Human Subjects, at (561) 237-____. If any problems arise as a result of your participation in this study, please call the Principal Investigator (_____) and the faculty advisor (Dr._____) immediately.
A copy of this consent form will be given to you.

AUTHORIZATION FOR VOLUNTARY CONSENT:

> I have read and understand this consent form. I have been given the opportunity to ask questions, and all my questions have been answered to my satisfaction. I have been assured that any future questions that may arise will be answered. I understand that all aspects of this project will be carried out in the strictest of confidence, and in a manner in which my rights as a human subject are protected. I have been informed of the risks and benefits. I have been informed in advance as to what my task(s) will be and what procedures will be followed.

I voluntarily choose to participate. I know that I can withdraw this consent to participate at any time without penalty or prejudice. I understand that by signing this form I have not waived any of my legal rights. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws. I understand that I will receive a copy of this form.

_____
Participant's printed name

_____ _____
Participant's signature Date

I consent to be audio taped (include if applicable – if video-tape, include):

_____ _____
Participant's signature Date

ALL STUDIES REQUIRE AN AFFIDAVIT*:*
Use this Affidavit when there is face-to face or oral contact between the researcher (or assistants) and the subject to answer questions or explain the study
INVESTIGATOR'S AFFIDAVIT: I have carefully explained to the subject the nature of the above project. The person participating has represented to me that he/she is at least 18 years of age, and that he/she does not have a medical problem or language or educational barrier that precludes his/her understanding of my explanation. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits, and risks involved in his/her participation and his/her signature is legally valid.

_____
Signature of Investigator Date of IRB Approval: _____

Use this Affidavit for online or hard copy surveys, when there is no face-to face or oral contact between the researcher (or assistants) and the subject to answer questions or explain the study.
I hereby certify that a written explanation of the nature of the above project has been provided to the person participating in this project. A copy of the written documentation provided is attached hereto. By the person's consent to voluntary participate in this study, the person has represented that he/she is at least 18 years of age, and that he/she does not have a medical problem or language or educational barrier that precludes his/her understanding of my explanation. Therefore, I hereby certify that to the best of my knowledge the person participating in this project understands clearly the nature, demands, benefits, and risks involved in his/her participation.

_____ Date of IRB Approval: _____
Signature of Investigator

(Make sure the address of the IRB is in the "footer") as displayed in this authorization.

*If you are using an Internet survey **DO NOT** INCLUDE THE UNIVERSITY SEAL.*

Tips (Include USDHHS and APA)

http://www.socialpsychology.org/consent.htm#us

Consent Short Form (you need to include script of oral information)
http://cflegacy.research.umn.edu/irb/consent/shortForms/Short%20Form%20ENG.pdf

Guidelines for Child Assent:
http://www.usm.maine.edu/orc/irb/pdf/child_assent.pdf

Sample Consent Forms and Information (Review HIPAA and De-Identification above):
http://www.augsburg.edu/irb/downloads/Sample_Consent_Form.pdf

Research Involving Individuals with Questionable Capacity to Consent:

Research Involving Individuals with Questionable Capacity to Consent: Points to Consider

(March 11, 1999)

Importance of Research Involving Individuals with Impaired Decisionmaking Capacity.

Research is essential to improve our understanding of and ability to treat human diseases and disorders that place great burdens on individuals and their families. The quest for new knowledge, however, should never take precedence over the welfare of the research participant. Research may at times involve individuals with limited decisionmaking capacity. The NIH is committed to helping researchers and Institutional Review Boards (IRBs) carry out this research in an ethical manner, protecting the rights and welfare of research participants while advancing treatment opportunities and vital knowledge. Critical to this research process are appropriate safeguards that ensure legally effective[(1)] informed consent and protect the confidentiality and dignity of the individuals participating in research.

Individuals in a wide variety of situations may have impaired decisionmaking capacity. For example, impairment may occur at times of great stress. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems; conversely, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to be decisionally impaired. Some research questions may only be answered by research that involves persons with impaired decisionmaking capacity; precluding this research would contribute to needless suffering. The most severely impaired individuals have the greatest need for the benefits of research on etiology and treatment. While this area is controversial, limiting research to the least impaired individuals would hamper research on the underlying causes and potential therapies of many disorders. Not all research will directly benefit the individual participant but may offer future benefits to others who have or will develop the condition or disorder. For example, genetic studies, biochemical measures, or other non-therapeutic approaches may benefit subsequent generations.

Unlike research involving children, prisoners, pregnant women, and fetuses, no additional Department of Health and Human Services (DHHS) regulations specifically govern research involving persons who are cognitively impaired. While limited decisionmaking capacity should not prevent participation in research, it is important to keep in mind that additional scrutiny by IRBs and researchers is warranted for research involving this population.

In developing this statement, members of several NIH Institutes consulted a broad array of experts on clinical research, bioethics, mental health, substance abuse, and age-related conditions. The Office for Protection from Research Risks and representatives from professional and lay advocacy communities, former research participants and IRB members, and others concerned about clinical research and human subject protections also provided valuable perspectives. Together, we have carefully considered clinical research situations in which the additional safeguards described in the DHHS regulations for the protection of participants in research[(2)] might be used by IRBs and by clinical investigators to protect potentially vulnerable individuals.

The NIH offers the following *Points to Consider* to assist IRBs and clinical investigators in their effort to protect participants in research who are, or may be, or may become decisionally impaired:

Conflicting Roles and Potential Conflicts of Interest. Potential and actual research participants, especially those with permanent or transient cognitive impairments, may find it difficult to understand the difference between research and treatment, and to understand researchers' multiple roles, making "therapeutic misconceptions" particularly problematic, and possibly creating confusion among participants and their families.

- It is essential that the consent process (including consent documents) clearly indicate differences both between individualized treatment and research and between clinician and clinical investigator.

IRB Membership. IRBs that regularly review research involving vulnerable subjects (such as the decisionally impaired) are required by DHHS and FDA regulations to consider including one or more individuals who are knowledgeable about and experienced in working with these subjects (45 CFR 46.107; 21 CFR 56.107). When reviewing research involving individuals with questionable capacity to consent, additional options in the makeup of the IRB should be considered:

- Include at least one voting member, independent of the research and investigators, with appropriate professional background, knowledge and experience in working with individuals with questionable capacity;

- Include additional voting members from the community; these members may include representatives of patient advocacy groups and others not affiliated with the research institution.

Assessing Capacity to Consent. Individual's capacities, impairments, and needs must be taken into account, in order to develop practical and ethical approaches to enable them to participate in research. Since well-validated and practical methods to assess capacity to consent are clearly needed, the NIH is supporting and will continue to support research addressing these issues. A clear understanding of the implications of various cognitive impairments, along with a careful consideration of proposed clinical research methodology, is required. Assessment is complex; simply answering a certain number of factual questions about a protocol may not be an adequate assessment. A key factor in participants' decisionmaking is their appreciation of how the risks, benefits, and alternatives to participation in the study apply to them personally.

- Limited decision making capacity covers a broad spectrum. A healthy person in shock may be temporarily decisionally impaired. Another may have been severely mentally retarded since birth, while yet a third who has schizophrenia may have fluctuating capacity. Researchers should be sensitive to the differing levels of capacity and use assessment methods tailored to the specific situation. Further, researchers should carefully consider the timing of assessment to avoid periods of heightened vulnerability when individuals may not be able to provide valid informed consent.

- Both IRBs and clinical investigators must keep in mind that decisionmaking capacity may fluctuate, requiring ongoing assessment during the course of the research. The consent process should be ongoing.

Responsibilities of Investigators and IRBs:

Not all research projects proposing to involve decisionally impaired persons should be approved by IRBs, and indeed, not all such persons should be enabled to participate in research studies.

- Principal investigators and members of the research team bear primary responsibility for protecting research participants. Responsibilities of IRBs also are significant, including the review of the informed consent forms and processes and research design as presented in the research proposal. They should exercise heightened vigilance in the review of protocols involving individuals with questionable capacity in accordance with 45 CFR 46.111(b).[(3)]

- As impairment increases, along with risks and discomforts, safeguards should increase according to a sliding scale, i.e., protections should be proportional to the severity of capacity impairment, or to the magnitude of experimental risk, or both. Provisions for additional safeguards should be in place prior to involving individuals with questionable decisionmaking capacity in research that poses greater than minimal risk.

- Educational efforts should be ongoing to enhance research participants' understanding and appreciation of their role in the research.

Options for Additional Safeguards. A sliding scale involving assessment of risks, benefits, and capacity to consent should guide the IRB's decisions regarding additional safeguards. Many strategies are available as options for investigators as they develop their research protocols and for IRB members as they evaluate them. In considering increasing levels of risk and/or impairment, investigators should be creative in choosing appropriate protections, seeking strategies used successfully in other situations.

- **Use of an Independent Monitor.** When reviewing greater than minimal risk research involving individuals with questionable capacity to consent, IRBs should discuss and document the potential value of an independent monitor. A monitor can be appointed to be present when investigators invite individuals with impaired decisionmaking capacity to participate in a research study. The consent process should be visible throughout, and IRBs have a right to observe recruitment, assessment, the informed consent process, and debriefing of research participants (and/or their family/surrogates).

- **Use of a Surrogate.** Where permitted by law, individuals with impaired capacity may have a family member or other legally authorized representative serve as a surrogate for research decisions, with this role documented during the consent process. Surrogates should be informed of the risks, benefits, and alternatives to the research when they are providing permission for an individual to participate. Whenever possible, surrogates should make research decisions based on *substituted judgment*, reflecting the views of the individual expressed while decisionally capable. *Best interest standards* should be used if the values of the individual are not known. It is important that surrogates receive some education about their own role, the cognitive and health status of the research participant, as well as about the study in which the participant may be involved.

- **Use of Assent in Addition to Surrogate Permission.** The autonomy of individuals with impaired decisionmaking capacity should be respected. Their assent to participation in research should be obtained whenever possible and their decision to withdraw from a study at any time should be honored.

- **Use of an Advance Directive.** Where State or other applicable law permits, use of an advance directive for research may be considered.

- **Use of Informational/Educational Techniques.** Because informed consent is an ongoing process throughout the course of the protocol, assessing and enhancing comprehension at each stage is essential. Single sheet summaries of important information about key elements of a study may be useful when provided on a regular basis. Questions from potential participants and family members should be encouraged, and handouts of frequently asked questions and answers regarding specific human subject protections can be prepared. Model consent forms and procedures can be developed. Communication between members of the research team and participants and their families is key to successful research participation.

- **Use of Waiting Periods.** Individuals who are decisionally impaired may need more time to consider the information they are given about a research protocol. Information should be provided incrementally to facilitate understanding. Planning built-in waiting periods within the consent process also may be useful to allow potential participants time to consult with family members about whether or not to participate.

In conclusion, in all human research, varied degrees of research risk and decisional impairment call for varied levels of scrutiny and safeguards; additional protections (e.g., involvement of family surrogates where State or other applicable law permits and independent monitoring) may be highly advisable in certain circumstances. But treating all individuals who have cognitive deficits as incapable of understanding research is inaccurate and disrespectful of their autonomy. Many individuals, adequately

informed, may be willing to undertake certain risks so that they, or others, may benefit in the future. Researchers and IRBs must strive for a balance that maximizes potential benefits and opportunities, recognizes and extends individual autonomy, and minimizes risks associated with scientific inquiry.

ADDENDUM: The National Bioethics Advisory Commission (NBAC) has addressed related issues and published a comprehensive report: *Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity*. The full text of this report can be found on the NBAC web site.

The NIH *Points to Consider* document is generally consistent with the NBAC report, but is intended to provide practical guidance now for investigators and Institutional Review Boards (IRBs) working in these fields.

1. Legally effective refers to informed consent as specified in 45 CFR Part 46 and to applicable state and local law and regulation.

2. *Human Subject Protection Regulations* [45 CFR 46.109(b), 46.111(b) and 46.116]

3. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, including those with cognitive limitations, the IRB must be sure that additional safeguards have been included in the study to protect the rights and welfare of these subjects {45 CFR 46.111 (b); 21 CFR56.111 (b)}.

Research with Human Subjects from a Foreign Country

2.9 Research in foreign countries

Research conducted by University investigators in foreign countries remains under University purview and guidelines. While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct or consent process

While human subjects in foreign countries merit the same level of protection as subjects in the United States, acceptable practices vary from place to place. Different mores, traditions, and institutions may require different research protocols, particularly in informed consent, recruitment practices, and documentation. Special attention should be given to local customs and to local cultural and religious norms in drafting written consent documents.

Research projects must have been approved by the local equivalent of an IRB before they are presented to the University IRB. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval" before it gives approval. Researchers should describe what if any, knowledge or experience they possess regarding the language and culture of the country in question.

The Office for Human Research Protection (OHRP) can provide guidelines on procedures followed by foreign institutions which affords protections that are at least equivalent to U.S. regulations (45 CFR 46 101 [h]). Under this provision, OHRP reviews the foreign country's guidelines for human subjects research, and if the foreign guidelines are found to be equivalent to U.S. regulations, the investigator is permitted to substitute those foreign procedures.

Researchers proposing international research should allow additional time for this review process.

International Compilation of Human Subject Research Protection (2005) of many countries
http://www.hhs.gov/ohrp/international/HSPCompilation.pdf
Ethical and Legal Aspects of Human Subjects Research on the Internet
http://www.aaas.org/spp/sfrl/projects/intres/report.pdf

Examples on Minimal Risk (Important)

Minimal Risk

Minimal Risk: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (from *45 CFR 46.102(i)*).

When making a decision about minimal risk of research:

1. **Consider both magnitude and likelihood of risk**
   A more serious event may be permissible if its probability is extremely low;
   Example: Airplane flight carries a risk of death, but it occurs only once in some millions of passenger miles.
2. **Risks of ordinary, non-invasive diagnostic tests are OK**
   Examples: routine blood draws in adults, general physical exams, pen-and-paper tests, ultrasound exams(at accepted levels)
3. **Minimal risk may be age- or context- dependent**
   Example: Blood draw may be minimal risk for someone old enough to give consent, but not for a small and needle-shy child
4. **Remember that risks need not be "physical" in order to be "more than minimal"**
   Examples: A serious privacy risk, confidentiality risk, informational risk or risk of embarassment may be enough to push a study into the "greater than minimal risk" category and thus to full committee review

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If you have any questions, please feel free to contact us at 1.800.521.0600, ext. 7020.

Section IX. LYNN UNIVERSITY IRB FORMS

IRB FORM 1 - Application and Research Protocol for Review of Research Involving Human Subjects in a New Project Application and Research Protocol for Review of Research Involving Human Subjects in a New Project **(*This Application is Required for all new research projects)***
IRB requests that all permissions provided via e-mail, for use of instruments, agencies, figures or tables, etc, are communicated using your Lynn-email (rather than a personal address. Furthermore, the contact information of the provider of the permission must be included in the e-mail).

IRB FORM 2 - *(Revised March 2010)* Request for Exemption

IRB FORM 3 - (*Revised March 2010*) Request for Expedited Review

IRB FORM 4 - *(Revised March 2010*) Application to Continue (Renew) a Previously Approved IRB Project (***Must be submitted annually)***

IRB FORM 5 - *(Revised March 2010*) Application for Procedural Revisions of or Changes in Research Protocol and/or Informed Consent Form I of a Previously Approved Project

IRB FORM 6 - *(Revised March 2010*) Report of Unexpected Adverse Event

IRB FORM 7 - (*Revised March 2010*) Request for Approval of Advertisements to Recruit Subjects

IRB FORM 8 - *(Revised March 2010*) Report of Termination of Project (***Must be submitted by All researchers)***