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IRB FORM 1

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD APPLICATION AND PROTOCOL FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS IN A NEW PROJECT

The following information must be submitted in typed or word processed format. Fill in all information lines. If information is not applicable, indicate by answering "N/A."

Policy and Procedure

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. Under no conditions can proposed research begin prior to IRB review and written approval). If the application 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 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 the approval status and the level of review.

FORM 1 is to be typewritten. Paginate ALL PAGES. Precede each Appendix with a separate page, providing the Appendix letter (A, B, etc.), and the title of the Appendix. Do not put the Appendix letter on the actual appendix. Follow APA. Complete the cover page, with a table of contents of FORM 1, (Part A, B, C, D), required Appendixes, and other Forms as needed. Complete all parts of FORM 1 if the category of research is "new project." For an application to continue (renew) a previously approved project, complete FORM 4. For a procedural revision to a previously approved project, complete FORM 5.

FORM 1, Part A. Application for Review of Research Involving Human Subjects

Project IRB Number:
Principal Investigator: (Full name and educational credentials)
Principal Investigator Address:
Project Title:
Students: Specify Degree Program (Employees enrolled in degree programs, complete this item.
Employees: (Specify position and employment unit)
Phone number (work):
Phone number (home):
Phone number (mobile):
Fax number:
E-mail:
Faculty sponsor (if applicable):
Phone number (work):
E-mail:
Co-Investigators (Associate or Collaborating Investigators): Names, titles and addresses. If list exceeds this space, submit on a separate page.
Proposed starting date of research:
Expected duration of research activity and project end date:

Is project periodically implemented at Lynn University, such as a survey or assessment tool?	
Yes ☐	If yes, please describe typical dates for implementation and survey or assessment tool.
No ☐	

Type of IRB review requested (Check one of the following)	
☐	Full Board (Submit electronic copy of IRB FORM 1)
☐	Exempt (Complete IRB FORM 2: Request for Exemption from Full Board or Expedited Review and include with IRB FORM 1) (Submit electronic of IRB FORM 1.)
☐	Expedited (Complete IRB FORM 3: Request for Expedited Review by the IRB and include with IRB FORM 1.)

Location of project implementation:	
Is research activity being conducted in a country other than the U.S.?	
Yes ☐	If yes, specify the foreign country below and provide requested information in FORM 1, Part C.
No ☐	

If another agency is used, has permission been obtained from the agency or institution?	
Yes ☐	If yes, please describe and include approval communication as an attachment. If no, please describe plans to obtain approval.
No ☐	
N/A ☐	
Is this a Cooperative Project with another Institution or Agency?	
Yes ☐	If yes, specify the other institutions or agencies and provide requested information in FORM 1, Part C.
No ☐	
Has the research activity been reviewed and approved by another review board for the protection of human subjects elsewhere?	
Yes ☐	If yes, provide requested information in FORM 1, Part C.
No ☐	
Human Subject Participants (Check all that apply.)	
☐	Children/Adolescents (Persons who are minors, under age 18)
☐	Males
☐	Females
☐	Inpatients
☐	Outpatients
☐	Pregnant Women
☐	Mentally Handicapped or Disabled
☐	Physically Handicapped or Disabled
☐	Fetuses
☐	Abortuses
☐	Prisoners
☐	Non-English Speaking
☐	Lynn University Students or Other Students
☐	Lynn University Alumni
☐	Lynn University Employees
☐	Other vulnerable subjects (persons who are at risk (physically, socially, legally, emotionally, economically, or whose reputation could be at risk). Specify.
Are participants drawn from a classroom or special program?	
Yes ☐	If yes, provide requested information in FORM 1, Part C.
No ☐	
Number of subjects:	
Age range of human subjects:	
Where are the subjects of this research activity located?	
What kind of human samples (e.g., blood) or data (e.g., private information, surveys) will be involved?	
Does the research activity involve the use of an investigational new drug (IND)?	
Yes ☐	If yes, provide requested information in FORM 1, Part C.
No ☐	
Does the research activity involve the use of an Investigational Device (IDE)?	
Yes ☐	If yes, provide requested information in FORM 1, Part C.
No ☐	
Is there a Written Informed Consent form that is signed by participants/parents/guardians?	
Yes ☐	If yes, please attach Written Consent Form to be Signed in an Appendix. (Fully discuss in Form 1, Part C. (The Research Protocol, J. Consent and Assent Processes and Documents)
No ☐	

Is there a Written Informed Consent but a request is being made to the IRB to waive the documentation requirement (waive the signature as consent documentation)?	
Yes ☐ No ☐	If yes, please attach Written Consent Form in an Appendix. Include justification as to why the request for waiving the documentation requirement (Fully discuss in Form 1, Part C.)
Is there a short form, oral consent, IRB request for waiver of informed consent or other alteration in informed consent?	
Yes ☐ No ☐	If yes, please attach short form for Written Consent with script, or Oral Consent script in an Appendix. (Fully discuss in Form 1, Part C.)
Are participants to be minors?	
Yes ☐ No ☐	If yes, include a child assent script and Assent Form if applicable in FORM 1, Part C
Is deception involved?	
Yes ☐ No ☐	If deception is major, (intentional deception), provide requested information in FORM 1, Part C.
Funding (Check one of the following.)	
☐	Currently funded
☐	Pending funding decision
☐	Funding proposal in process of development
☐	Not funded
For Funded Research Activity: -Funding Agency or Research Sponsor	
☐	Grant/Contract Project Title:
☐	Please submit one complete copy of all externally funded proposals with form.
☐	Federal Agency Grant/Contract #
☐	Industry
☐	Extramural (other)
☐	Internal
Name of agency official, if any, to be notified of IRB approval:	
Title:	
Address:	
Phone Number (work):	
Fax Number:	
E-mail:	

FORM 1, Part B. Certifications and Signatures

CERTIFICATIONS

1. I am knowledgeable about the IRB policies and procedures and I will adhere to the policies and procedures explained therein.
2. I understand that I must seek IRB approval to advertise to recruit subjects.
3. I certify that the method of obtaining informed consent as approved by the Lynn University IRB will be followed during the period covered by this research project. Consent forms will bear the research protocol expiration date. Any future changes will be submitted to the IRB for review and approval prior to implementation. Should I wish to make changes in the approved human subjects protocol for this project, I will submit them for review prior to initiating the changes.

4. If any problems involving human subjects occur, I will adhere to the policies and procedures for emergencies and reporting of adverse events explained therein. Problems include unanticipated side effects or adverse reactions from participation in the project and any injuries. If any emergency occurs I 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. I will promptly notify (verbally first, then in writing) my sponsor and Chair of the Institutional Review Board.
6. I understand that I must seek review for continuation of projects that last longer than one year or earlier if specified by the IRB. I will seek review for continuation no later than one month prior to the anniversary of initial approval or earlier if requested by the IRB. I further agree to have a third party observe the consent process and the research should that be requested by the IRB.
7. I will prepare a summary report of the project results, to include identification of any adverse effects occurring to human subjects in this study within 30 days of the conclusion of data collection (termination of study).
8. I understand that a copy of the IRB approval letter must appear in the Appendix of the final document (professional publications or report, project, thesis or dissertation). IRB procedures and approval process will be described in the dissertation/thesis/ or other professional publication or report. This is typically the "Methods" section of the report. I will maintain appropriate records.
9. I understand that applications and research protocols and other IRB requests for review that are submitted without all requested information and materials will be returned to me without IRB review.

SIGNATURES (To sign the document, click on the pink tab below and follow the computer prompts)

_____

Signature of Applicant Date

Prior to submission to the IRB, the Research Application and the Research Proposal (FORM 1, Part C.) must be approved: (1) by a faculty sponsor in the case of student research, (2) by a faculty sponsor in the case of research by an employee without a doctorate, (3) by the supervisory Vice-President in the case of staff employee research, and (4) by the College Dean in the case of faculty research.

_____

Signature of Sponsor (required for students) Date

_____

Name Position Academic Unit/Department

_____

Signature of Sponsor (for non-doctoral employees) Date

_____

Name Position Academic Unit/Department

_____

Signature of Vice President (for staff employee) Date

_____

Name Position Academic Unit/Department

_____

Signature of College Dean (for faculty) Date

_____

Name Position Academic Unit/Department

FORM 1, Part C. Continue Application with Completion of Research Protocol

Principal Investigator:
Project Title:

DO NOT WRITE BELOW THIS LINE: FOR IRB USE ONLY

APPLICATION AND PROTOCOL FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS OF A NEW PROJECT
IRB Project Number
Request for Exempt Status ☐ Expedited Review ☐ Convened Full-Board ☐
IRB ACTION BY IRB CHAIR OR ANOTHER MEMBER OR MEMBERS DESIGNATED BY THE CHAIR
Exemption Status (See FORM 2): Approved ☐ Approved w/provision(s) ☐
Expedited Review (See FORM 3): Approved ☐ Approved w/provision(s) ☐
Complete FORM 2 (Exempt Status, including categories for exempt status) and Resubmit ☐
Complete FORM 3 (Expedited Review, including categories for expedited review) and Resubmit ☐
Referred For Convened Full-Board Review ☐
Comments:
Consent Required: No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐
Consent forms must bear the research protocol expiration date of _____.
Application to Continue/Renew is due: (1) For an Expedited IRB Review, one month prior to the due date for renewal ☐ (2) For review of research with exempt status, by a College or School Annual Review of Research Committee ☐.
Other Comments:
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____

Name of IRB Chair (Print) _____

Signature of IRB Chair_____ Date:_____

IRB ACTION by the CONVENED FULL BOARD *If Applicable*
Date of IRB Review of Application and Research Protocol _____
IRB ACTION: Approved☐ Approved w/provision(s)☐ Not Approved☐ Other☐
Comments:
Consent Required: No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐
Consent forms must bear the research protocol expiration date of _____.
Application to Continue/Renew including an updated consent, is due: (1) For a Convened Full-Board Review, two months prior to the due date for renewal _____ (2) For an Expedited IRB Review, one month prior to the due date for renewal _____ (3) For review of research with exempt status, one month prior to the due date for renewal _____.
Other Comments:

Name of IRB Chair (Print) _____

Signature of IRB Chair_____ Date: _____

FORM 1, Part C. The Research Protocol

Complete all applicable information. Type (font size 10-12). Single Space, with double spacing between paragraphs. Organize presentation by headings and subheadings beginning with **a. Abstract.** Please refer to IRB policies and procedures in developing the protocol. The outline for this research protocol is adapted from: GUIDELINES FOR WRITING RESEARCH PROTOCOLS and GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS

a. Abstract

This abstract is meant to serve as a complete description of the proposed study and should be 400 words or less.

(1) It should contain a clear and succinct description of specific aims (purpose), objectives and outcomes (variables) of this project.

(2) It should also include an accurate description of the study population, experimental or non-experimental design and methods of achieving these goals.

b. Introduction

(1) Describe the background, including human subject or animal research and references that are relevant to the design and conduct of the study.

(2) Where new techniques or procedures are to be used, a description of preliminary or early work should be provided in depth.

(3) Investigational New Drug (IND) and Investigational Device (IDE) (if applicable)

(a) Research activity involving the use of an investigational new drug (IND).
Specify Name and # of IND. Specify Sponsor. Specify Cooperating Institution. *Discuss whether the* Investigator has, or has applied for, Investigational New Drug certification by the FDA for the use of drugs included in this project. If yes, provide copy of the FDA form. If an FDA Investigational New Drug (IND) is to be used, animal data on the drug should be included. If the study is one for which a Clinical Investigator's Brochure (CIB) is provided, one copy of the CIB must be available to the IRB when the protocol is reviewed. A summary of the relevant features of the CIB should be included in the protocol.

(b) Research activity involving the use of an Investigational Device (IDE)?
Specify Name and # of the IDE. Specify Sponsor. Specify Cooperating Institution. Discuss whether the Investigator has or has applied for an Investigational Device Exemption (IDE) from FDA for the use of a significant risk medical device in this project. If yes, provide copy of the FDA form.

(c) Research Activities involving use of Radiation or Radioisotopes
Specify Sponsor and Cooperating Institution
If yes, prior to IRB submission, approval must be obtained from the Vice President for Administration and the approval letter must be attached to this application (See I. Research Protocol Appendix).

c. Objectives: State the objectives of the study as research questions and/or hypotheses.

d. Study Design and Methods

(1) Describe the involvement of human subjects (see section (h), below) including initial evaluation procedures and screening tests, phases, procedures and sequence of the study. Separate standard (non-experimental) and experimental aspects of the study as much as possible.

(2) Describe alternatives to experimental therapy if they exist. Give detailed procedures for treatment, dose adjustments, etc if applicable. Describe the randomization procedure, if applicable.

(3) Address the experience of investigators if procedures are to be performed for which the investigators have not been specifically credentialed.

(4) In the space below, provide outline of the experimental design of the investigation focusing on those aspects that involve human subjects and emphasizing the specific time sequence of the procedures to be performed.

(5) If paid healthy volunteers are involved, or if subjects are to be paid, specify the amount of compensation. (include all payment arrangements, including reimbursement of expenses, free medication, etc.) Direct payments or other forms of remuneration to the research subject are not considered to be benefits of participation

(6) Describe any costs related to the research procedures that are over and above those incurred by standard treatment, and indicate who will be responsible for them.

(7) The **Methods Section** of the study (Chapter 3 in the dissertation) and one copy of the Research instrument should be included as an **attachment (See I. Research Protocol Appendix).** Insert into this Form 1, with continued pagination).

e. Inclusion and Exclusion Criteria

These must be included in the protocol. List specific eligibility requirements for subjects, including those criteria which would exclude otherwise acceptable subjects.

f. Monitoring Subjects and Criteria for Withdrawal of Subjects from the Study

(1) Describe the types, frequency and duration of tests, admissions (inpatient) outpatient visits. Consider specifying a monitor if the study involves a blinded design.

(2) Define stop points and criteria for withdrawing subjects from the study.

g. Analysis of the Study

(1) Delineate the precise outcomes (variables) to be measured.

(2) Describe how data will be analyzed, including statistical analysis.

(3) Describe methods used to estimate the required number of subjects.

(4) Describe power calculations if the study involves comparisons (optional).

h. Human Subject Protections Protocols without this section will not be accepted for IRB review.

(1) Rationale for Subject Selection

The protocol must include:

(a) Rationale for research subject selection. If a health related study, provide a rational for subject selection based on a review of gender/ethnic/race categories at risk for the disease/condition being studied;

(b) Strategies/procedures for recruitment (including advertising, if applicable); and

(c) Justification for exclusions, if any. If the protocol is a Phase III or IV clinical trial, a discussion of how the trial will be carried out to conduct valid results analyses of differences by gender and ethnicity must be included.

(d) Rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, cognitively impaired individuals, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. Reference the Code of Federal Regulations Subparts (CFR) as necessary when discussing the research involvement of these subjects. Discuss what, if any, procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risks (physical, psychological, etc.) as research subjects.

(e) Students: If the protocol involves participants drawn from a classroom or special program, respond to the following: Is the procedure part of the regular curriculum of a class or program? If yes, describe. Will the participant miss any regularly scheduled work/class? If so, will s/he be allowed to make up this work? Describe whether participation or non-participation will affect the participant's grade or status in a program? In what way(s) is participation linked to the grading policies announced for the course? How is the requirement for "student participation" presented to the student (in the course description, in the syllabus, as an assignment)? Will non-participation affect course grades adversely? How are these consequences announced to students? What will non-participants do while the experimental procedure is taking place?

(f) Multiple Sites: If the protocol involves subject enrollment at multiple sites, describe plans for ensuring appropriate IRB review and approval at each site.

(2) Evaluation of Benefits and Risks/Discomforts:

(a) **Potential Benefits**

Describe the potential benefits to subjects or to others (benefits to society) that may reasonably be expected from the research.

-1- Subjects: may include evaluation of a procedure that may benefit the subject by ameliorating that condition or providing a better understanding of the disorder.

-2- Society: increase our understanding and knowledge about human physiology and behavior that may benefit society as a whole in the form of increased knowledge, improved safety, technological advances, and better health.

(b) **Potential Risks**

-1- Describe any potential risks -- physical, psychological, social, legal, drug toxicity or other associated with the proposed procedures and assess their likelihood and seriousness.

-2- When appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

-3- Describe the procedures for protecting against or minimizing any potential risks and assess their likely effectiveness. Describe precautions, safeguards and alternatives that can be incorporated into the research to reduce the probability of harm or limit its severity or duration and prevent violations of confidentiality or anonymity.

-4- Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

(c) Risk/Benefit

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result. Consider the following in your discussion:

-1- When participants are members of a vulnerable population, appropriate additional safeguards are in place to protect the rights and welfare of these research participants.

-2- Potential risks, minimizing risks, and adequate protection of privacy of the subjects and confidentiality of subject data protected

-3- In research involving an intervention expected to provide direct benefit to the subject, a certain amount of risk is justifiable.

-4- In a trial of a new or not-yet-validated treatment the ratio of benefits to risks should be similar to those presented by any alternative treatment.

-5- In research where no direct benefit to the subjects is anticipated, consider whether the risks presented by procedures performed solely to gain generalizable knowledge are ethically acceptable. (There should be a limit to the risks society asks individuals to accept for the benefit of others.)

-6- When **intentional deception** is involved, the IRB requests an expanded discussion of the following.

-a- information sufficient to understand why deception is needed,

-b- a clear description of the deception

-c clear delineation of the risks

-d- how the potential benefits justify its use, and

-e- how debriefing will be done (debriefing protocol and debriefing statement).

(3) **Cooperative Project with Another Institution or Agency**

If this is a cooperative project, specify and describe whether this is (1) a joint IRB Review arrangement, (2) Independent IRB review or (3) reliance is upon the review of another qualified IRB (45 CFR §46.114).

(4) **Involvement of Another IRB**

Has the research activity been reviewed and approved by another review board for the protection of human subjects elsewhere? If "Yes", specify which IRB, when reviewed and the outcome. If there are plans for review by another IRB, please describe?

(5) **Human Subjects in a Foreign Country**

If this research involves human subjects in a foreign country, please answer the following: What are the special issues related to cultural differences? What are the regulatory requirements pertaining to human subjects research protection is the foreign country? *[For example, complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.]*

Are these requirements equivalent at least to those in the United States (see Title 45 Code of Federal Regulations Part 46, Section 101 (h))? What are key differences? *The researcher may be required to establish a special IRB in the foreign country to review the proposed research, or to take other steps to ensure that human subjects receive the same protection they would in the United States, and that any special cultural factors are taken into consideration.*

i. Adverse Event Reporting and Data Monitoring

(1) Provide a plan for reporting adverse events to the IRB.

(2) Describe the provisions for monitoring the data collected to ensure the safety of subjects.

j. Consent and Assent Processes and Documents

(1) Consent Procedures

(a) Describe the consent procedures to be followed, including the circumstances in which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

(b) Non-English Speaking Subjects:
Where informed consent is documented in accordance with §46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them, and, in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117).

(c) Minors and the Consent/Assent Procedures
"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(a). The age of majority in the State of Florida is 18 years of age. Children are generally not legally empowered to give consent, but depending on their age, they may have the ability to give assent ("assent" means a child's affirmative agreement to participate in research). If participants are minors, include a child assent script and Assent Form if applicable. Include a discussion of how assent will be obtained for the particular study. http://www.cirp.org/library/ethics/AAP/ (Resource on "Assent")

(d) The proposed consent document must be **attached (See l. Research Protocol Appendix).** It should be written in the second person, in language understandable to someone who has not completed high school.

(2) Waiver, Short form, Oral Consent or Request for Waiver or Alteration

(a) If using a short form, oral consent, or request for IRB waiver or alteration, provide justification and supporting regulation (CFR).

(b) Please attach the short form written consent (if applicable) and other documentation.

(c) A Waiver of the informed consent process is limited to research involving the collection or study of existing data, publicly available information, and observation of unmanipulated public behavior where data are recorded in such a manner that identifiers cannot be linked to individuals. CFR 45 § 46.116-117.

(d) 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. If applicable, please provide the written statement.

(3) Vulnerable Subjects

(a) If subjects are members of special classes or likely to be vulnerable, explain any additional human subjects safeguards pertinent to the consent and assent process and documents.

(b) Reference the specific Code of Federal Regulations Subparts (CFR) as necessary when discussing the research involvement of these subjects.

(4) Protection of Participants through Anonymity or Confidentiality
Describe the manner in which names and other identifiers and information about the subjects or their responses, are protected by either anonymity or confidentiality.

k. References.
Include selected references which highlight methods, controversies, and study outcomes in APA format, or other approved by an academic unit. .

l. Research Protocol Appendix: Include all required attachments or documentation requested. Include curriculum vitae (résumé) of Principal Investigator**.** (Paginate consecutively)

Last revision: March 2010.