Submit by Email | Print Form

IRB FORM 3

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD
REQUEST FOR EXPEDITED REVIEW

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."

Principal Investigator:
IRB Project Number (if previously assigned for exempt application):
Project Title:
Today's Date:

Policy and Procedure

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).

In general, research may qualify for expedited review if it is judged to involve no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures.

In studies qualifying for expedited review, the description of subject's performance should not be misleading or untruthful. However, there are times when full disclosure would jeopardize the procedure. For example, subjects might not be informed of the actual purpose of certain procedures. No more than such mild deception can be tolerated in an experiment or research study submitted for expedited review. Any intentional deception involving misleading or untruthful information provided to the subjects must be considered in a full IRB review.

If a project meets any of the *Research Activities Eligible for Expedited Review* specified in 45 CFR 46.110 (and related CFR), and is not excluded by the limitations for the specific categories, it may qualify for IRB review through the expedited review procedure. The research activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB. The IRB reserves the right to request the investigator to provide additional information concerning the proposal. After review, the IRB will send the applicant formal notification of whether or not the proposal qualifies for expedited review.

Complete Part A *Checklist for Expedited Review Level (Limitations*) and indicate the appropriate *Research Activities Eligible for Expedited Review* in Part B. Submit FORM 3 along with the IRB Application and Research Protocol (FORM 1) when the investigator considers that the proposal may qualify for Research Activities Eligible for Expedited Review as noted in 45 CFR 46.110 and 21 CFR 56.110.

FORM 3, Part A. Checklist for Expedited Review Level

1.	It is clear that the nature of the proposed research fits among the examples listed in FORM 3, Part B (Categories of Research That May Be Reviewed by the IRB through an Expedited Review 45 CFR 46.110 and 21 CFR 56.110)	Yes ☐ No ☐
2.	No implications for criminal or civil liability, employability, or damage to subjects' financial standing, insurability or reputation would exist if data (subjects and/or their responses) were known outside of the study. (Risks related to invasion of privacy and breach of confidentiality are no greater than minimal.)	Yes ☐ No ☐
3.	The research does not employ a protected group as subjects (e.g., fetuses, pregnant women, prisoners, mentally handicapped, or minors).	Yes ☐ No ☐
4.	The study does not present more than a MINIMAL RISK to subjects.	Yes ☐ No ☐
5.	The study does not involve INTENTIONAL DECEPTION such that misleading or untruthful information is provided to subjects.	Yes ☐ No ☐
6.	Appropriate informed consent procedures will be followed.	Yes ☐ No ☐
7.	The study will not be conducted in a foreign country.	Yes ☐ No ☐
8.	The study will not be used for classified research involving human subjects.	Yes ☐ No ☐

"Yes" answers to all of the above are required to qualify for a recommendation for expedited review. If the answer to one or more of these questions is "no," then a convened full IRB review is required.

FORM 3, Part B.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review 45 CFR 46.110 and 21 CFR 56.110

Please indicate into which of the Expedited Review Categories your research falls by providing a checkmark **(√).** Check all that apply.

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

☐ (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

☐ (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

☐ (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

☐ (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- ☐ (a) hair and nail clippings in a nondisfiguring manner;
- ☐ (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- ☐ (c) permanent teeth if routine patient care indicates a need for extraction;
- ☐ (d) excreta and external secretions (including sweat);
- ☐ (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- ☐ (f) placenta removed at delivery;
- ☐ (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- ☐ (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- ☐ (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- ☐ (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- ☐ (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- ☐ (b) weighing or testing sensory acuity;
- ☐ (c) magnetic resonance imaging;
- ☐ (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Source: IRB (45 CFR 46.110.)

In the space below (or attachment), please explain how your project fits into the indicated category(s) for Expedited Review.

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

_____

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

NOTE: Applications without all requested information will be returned without IRB review.

Principal Investigator:
Project Title:

DO NOT WRITE BELOW THIS LINE: FOR IRB USE ONLY

REQUEST FOR EXPEDITED REVIEW OF APPLICATION AND RESEARCH PROTOCOL FOR NEW PROJECT
IRB Project Number:
IRB ACTION BY IRB CHAIR OR ANOTHER MEMBER OR MEMBERS DESIGNATED BY THE CHAIR
Expedited Review of Application and Research Protocol and Request for Expedited Review: Approved ☐ Approved w/provision(s) ☐
Complete FORM 2 (Exempt Status, including categories for exempt status) 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, <u>one month</u> prior to the due date for renewal_____ (2) Other:
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 _____
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 _____.
Other Comments:

Name of IRB Chair (Print) _____

Signature of IRB Chair_____Date:_____

Last revision: March 2010.