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IRB FORM 5

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD APPLICATION FOR PROCEDURAL REVISIONS OF OR CHANGES IN RESEARCH PROTOCOL AND/OR INFORMED CONSENT FORM 1 OF A PREVIOUSLY APPROVED PROJECT

Initial Review: Full ☐ Expedited ☐ Exempt ☐
Principal Investigator:
IRB Project Number:
Date of initial approval:
Date of most recent continuing (renewal) approval:
Today's Date:
Project Title:

Report changes only to items listed below since last IRB review (initial or continuing).

Principal Investigator: (*Full name and educational credentials)*	
Principal Investigator: Address	
Project Title:	
Students: *Specify Degree Program* Employees enrolled in degree programs, complete this item	
Employee: *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 Investigator(s): Names, titles and address. If list is extensive, insert on a separate page.	

Policy and Procedure

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 a convened full 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.

Complete the information below.

1. DESCRIPTION AND JUSTIFICATION OF PROPOSED REVISIONS IN RESEARCH PROTOCOL (the revised protocol must be submitted with the items representing revisions highlighted):
2. DESCRIPTION OF AND JUSTIFICATION FOR PROPOSED CHANGES IN INFORMED CONSENT FORM (if revisions to the consent form are proposed, a copy of both the revised consent and the original consent must be submitted with the requested revisions highlighted on both forms, if applicable):
3. OTHER CHANGES (i.e., changes in investigator status, funding sources, etc.):
4. LIST ATTACHMENTS (i.e., research protocol, consent form, correspondence, etc.):

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

APPLICATION FOR PROCEDURAL REVISIONS OF OR CHANGES IN RESEARCH PROTOCOL AND/OR INFORMED CONSENT FORM 1 OF A PREVIOUSLY APPROVED PROJECT
IRB Project Number:
Initial Review: Full ☐ Expedited ☐ Exempt ☐ Date of most recent continuation approval: _____
IRB ACTION BY IRB CHAIR OR ANOTHER MEMBER OR MEMBERS DESIGNATED BY THE CHAIR
Procedural Revision(s): Approved ☐ Approved w/provision(s) ☐
Referred For Convened Full-Board Review _____
Comments:
Consent Required: No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐
Consent Form Revised: No ☐ Yes ☐. If yes, the Consent forms must bear the research protocol expiration date of _____. Date for Application to Continue/Renew is as noted on initial application or most recent renewal
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 Procedural Revision _____
IRB ACTION: Approved_____ Approved w/provision(s)_____ Not Approved_____ Other_____
Comments:
Consent Required: No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐
Consent Form Revised: No ☐ Yes ☐. If yes, the Consent forms must bear the research protocol expiration date of _____. Date for Application to Continue/Renew is as noted on initial application or most recent renewal
Other Comments:

Name of IRB Chair (Print) _____

Signature of IRB Chair_____Date:_____

Last revision: March 2010.