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IRB FORM 4

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD APPLICATION TO CONTINUE (RENEW) A PREVIOUSLY APPROVED 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."

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

> 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 all copies of FORM 4 and updated consent forms 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 all copies of FORM 4 and updated consent forms to the IRB 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 3 copies of FORM 4 and updated consent forms to the IRB, no later than one month prior to the due date of the anniversary of initial approval.

The IRB reserves the right to request the investigator to provide additional information concerning the application for continuation. After review, the IRB will send the applicant formal notification of IRB actions.

Complete FORM 4 Parts: A. IRB Review Level Requested, B. Checklist for Continuing Review of Research and C. Progress Report.

FORM 4 A. IRB Review Level Requested (Check One of the Following)

☐ A Convened Full-Board Review is requested to continue/renew a project previously approved by Full-Board Review.

☐ An Expedited Review is requested to continue/renew a project previously approved by Expedited Review or Exemption Status.

☐ An Expedited Review is requested to continue/renew a project previously approved by the convened (Full Board Review). This may be requested if the IRB, during initial review a convened full Board Review indicated Continuation (Renewal) may be by expedited review.

☐ An Expedited Review is requested to continue/renew a project previously approved by the convened (Full Board Review). This request is made in accordance with 45 CFR§46.110(8-9) *(Categories of Research That May Be Reviewed by the Institutional Review Board (IRB)* in a continuing review of research. If this review level is requested, please identify the category (s) for expedited review this applies:

☐ (8) Continuing review of research previously approved by the convened IRB as follows:

- ☐ (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- ☐ (b) where no subjects have been enrolled and no additional risks have been identified; or
- ☐ (c) where the remaining research activities are limited to data analysis.

☐ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. **Please review FORM 3 (Expedited Review) which identified categories** two (2) through eight (8).

Source: IRB (45 CFR§46.110.)

FORM 4, Part B: Checklist for Continuing Review of Research

(Assessing the Degree of Risk and Monitoring Data Collected to Ensure the Safety of Subjects)

1.	Has the research project been initiated?	Yes ☐ No ☐
2.	How many subjects have been studied since last renewal approval?	
3.	How many subjects have been studied since study initiation?	
4.	Has there been a change in Principal Investigators or other key professional personnel which has not been submitted on FORM 5 (Procedural Revisions)?	Yes* ☐ No ☐
5.	Have there been any changes in the experimental protocol or the consent form which have not been submitted on FORM 5 (Procedural Revisions)?	Yes* ☐ No ☐
6.	Consent Required (Check as applicable): No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐	
7.	Has informed consent been properly obtained and are the consent documents securely stored?	Yes ☐ No* ☐
8.	Has all information pertaining to the identity of the subjects been securely stored?	Yes ☐ No* ☐
9.	Have the results of your research thus far or of similar studies by other investigators changed your estimate of the risk/benefit ratio?	Yes* ☐ No ☐
10.	Are there any significant new findings which may alter the risk/benefit ratio?	Yes ☐ No ☐
11.	If yes to item 10, were these significant new findings provided to the research subjects?	Yes ☐ No* ☐ N/A ☐
12.	If yes to item 10, were these significant new findings submitted to the IRB?	Yes ☐ No* ☐ N/A ☐
13.	Have your studies or similar studies by other investigators resulted in any undesirable consequences that have not yet been reported on FORM 6 to the IRB?	Yes ☐ No* ☐
14.	Did any subjects withdraw from the study? (State the number of withdrawals and the reason(s) in FORM 4 Part C.)	Yes* ☐ No ☐
15.	Were there any problems or complications in the study that affected the subject or others which have not been submitted to the IRB?	Yes* ☐ No ☐
16.	Did any subject experience unexpected adverse reactions, serious injuries or death during the study which have (has) not been submitted on FORM 6?	Yes* ☐ No ☐
17.	What is the estimated completion date of the study?	

(* If this response has been circled, explain in FORM 4, Part C where applicable)

Continue to FORM 4, Part C, next page

FORM 4, Part C Progress Report, Risk/Benefits and Explanations

Preliminary Results
Provide a brief summary of any research results to date in the space below. Do not exceed 250 words.

Current Assessment of the Risks Versus the Benefits

1. Provide information as to the number and type of expected (anticipated) adverse events.

2. Provide information as to the number and type of unanticipated adverse events; such as injuries or deaths.

3. Has there been any significant change in the risk benefit ratio? Yes ☐ No ☐ If yes, explain.
   See starred (*) responses in FORM 4 Part B, items 9, 10, 11, 12, and 13

Procedural Issues and Other Explanations
See starred (*) responses in FORM 4 Part B), items 4, 5, 7, 8, 14, 15, 16

Additional Comments

Additional Materials Required
Submit a copy of informed consent form(s) currently in use.

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 TO CONTINUE (RENEW) 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
Expedited Review for Continuation: Approved ☐ Approved w/provision(s) ☐
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 _____.
For an Expedited and Exempt Status Review, the Application to Continue/Renew is due, one month prior to the due date for 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 for Continuation _____
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 _____
Other Comments:

Name of IRB Chair (Print) _____

Signature of IRB Chair_____Date:_____