Lynchburg College (LC) Institutional Review Board (IRB) for Human Subjects Research

Renewal Request Form – annual renewal for studies necessitating continuing review and renewal

Dear investigator,

All research that has been approved by the IRB must be reviewed annually (if the study has not been completed), and closed once the study has been completed. The LC IRB considers a study to be completed once the Principal Investigator (PI) determines that there will be no further contact with human subjects – for many studies, this means that the study is completed once data are collected.

The renewal review requirement at LC includes studies approved at all levels of review (exempt, expedited, and full board review status). **This is the form to use for annual renewal review, and this form must be submitted to the IRB Director following the instructions provided below at least 30 days before the end date of the approval period as stated in the most recent approval letter for the study.** While the LC IRB makes an effort to send reminder correspondence 60-90 days before the end of the approval period, it is ultimately the responsibility of the PI and research team, not the LC IRB, to ensure that this deadline is met. This deadline will allow adequate time for the IRB to review the form so that a decision can be made before the research proposal approval expires. Research studies approved at the exempt status level will be reviewed by the IRB Director; expedited level either by the IRB Director or members of the Board; full board level by the full Board.

The principal investigator or his/her designee shall complete this form. Read the instructions carefully and contact the IRB Director with any questions about the renewal and closure process (IRB-HS@lynchburg.edu).

Failure to complete the Renewal Form or the Closure Form in the stated time frame will result in the automatic closure of the study due to noncompliance with stated policy and the IRB will no longer accept any responsibility for the research; noncompliance with stated policy will serve as a barrier for approval of future research at LC as it is a violation of the Research Integrity & Misconduct Policy.

Per IRB policy, any **adverse events** must be reported to the IRB in writing immediately following any such occurrence and should not be held for notification until the renewal review. This form requires the reporting of all adverse events; the information provided here will be compared to previously submitted written reports.

The closure form is a separate form; see the LC IRB website for the closure form.

Submit the hard copy original with real signature(s) to the IRB Director[1]. A review of the annual renewal form will be made if sent via email, but determination and official review cannot be made until original form is submitted.

[1] See Submission Instructions and Forms webpage for delivery/mailing instructions.

Project Title: _____

Proposal Approval Date[2]: _____

IRB Approval Number[3]: _____

Name of Person Completing This Form: _____

Role on Research Team: ☐ Principal Investigator ☐ Co-Principal Investigator
☐ Other (specify:_____)

Name of Principal Investigator, if different than person completing this form:

_____

By signing this form, I agree to the following statement: "To the best of my knowledge, the research being considered for annual review complies with the applicable federal, state, and institutional regulations and guidance on the ethical conduct of research and protection of human subjects. I hereby agree to comply with the parameters for the responsible conduct of research and protection of human subjects; and have read, understand, and agree to abide by the LC Research Misconduct Policy. Per the LC IRB Ethical Research Practices Policy, all members of the research team have successfully completed the appropriate CITI training."

_____

Signature of Principal Investigator (or Co-PIs, if applicable; if Co-PI is an LC graduate student, faculty member must sign here as the lead PI)

Date: _____

Level of review at which this study was approved: ☐ Exempt ☐ Expedited ☐ Full Board

The following attachments are being submitted with this completed and signed form, in accordance with the instructions provided in this form:

☐ Status Report
☐ Copy of signed consent, parental consent, and/or assent agreement(s) OR blank copy (see instructions).
☐ Adverse Events and Unanticipated Problems Summary
☐ Implications of Recent Findings
☐ Modification Summary
☐ Other attachment(s). Specify: _____

_____

[2] Initial approval and all subsequent annual revisions, if applicable.
[3] Available for studies approved September 2013 and forward.

Data Collection and Data Analysis

Has data collection begun? ☐ Yes ☐ No

If *yes*:

a) Number of participants accrued to-date: _____

b) What was the maximum number of participants needed as identified in the original proposal application or in the most recent modification approved by the IRB? _____

If *no*:

a) Number of participants planned for next twelve months: _____

b) What was the maximum number of participants needed as identified in the original proposal application or in the most recent modification approved by the IRB? _____

Has data analysis been completed? ☐ Yes ☐ No

If *yes*, do you plan to accrue participants in the next twelve months? ☐ Yes ☐ No ☐ Unsure

If *yes*, how many additional participants do you plan to accrue? _____

If *no*, will analysis begin in the next twelve months? ☐ Yes ☐ No ☐ Unsure

Status of the Research Study

Attach a short status report on the progress of the research to date. Label this item, "Status Report." A status report should include more than a summary of the information included above regarding number of participants. If appropriate, the status report should include rationale for continuing the study beyond the one year approval period.

Copy of Informed Consent, Parental Consent, and Assent Agreement(s)

Per policy, we must retain documentation to confirm that the informed consent agreements (inclusive of all forms such as parental consent or child assent; and the introduction or invitation to participate) being provided to the participants are the same as those approved by the IRB.

Attach one *copy* of the approved consent, parental consent, and/or assent form(s), signed by a research participant, and one *copy* of the cover letter used in this research (or other introductory script/text). *Cross out participant's signature so that the actual signature cannot be read. We recommend drawing a thick line through with a permanent marker.*
If there has been no accrual of participants, then submit a blank form.

Is the consent form or cover letter identical to the one approved by the IRB? ☐ Yes ☐ No

If *no*, (a) List the modification reference number _____

(b) Date of the approval of the modification _____

Adverse Events and Unanticipated Problems Summary

Attach a brief summary of all adverse events and unanticipated problems related to this study. Label this attachment, "Adverse Events and Unanticipated Problems Summary." For each of the adverse events listed in your attached summary, a detailed report should have been submitted to the IRB promptly following any such occurrence. As such, this summary only need be comprised of basic participant demographics (as allowable to collect based on the approved research study's protocol), date(s) of adverse event, and a short description of adverse event and outcome (e.g., was upset by images of child abuse, voluntarily left experiment, completed a debriefing with PI, and received referral to Counseling Center). View the IRB Policy and Procedure Manual and the LC IRB policy web page for additional information and guidance on Adverse Events and Unanticipated Problems.
If none, state that here by checking this box: ☐ there are no adverse events or unanticipated problems.

Implications of Recent Findings

Attach a summary of any recent literature, findings, or other relevant information about risks associated with this research. Label this, "Implications of Recent Findings." If none are known, state that here by checking this box: ☐ there are no recent findings, literature, or other relevant information about risks associated with this research.

Modifications to Initial Protocol Approved by IRB

Modifications to research projects may not be initiated until IRB approval has been obtained.

Is the research project currently being conducted identical to that previously approved by the IRB?
☐ Yes ☐ No
If *no*, attach a summary of modifications including (a) modification reference number(s), (b) summary of modifications associated with that reference number, and (c) date(s) of approval for these modifications. Label this attachment, "Modification Summary."

If you wish to submit modifications for review by the IRB in connection with the annual review request form, then you must attach a completed Modification Form (see website for form and instructions).