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

Expedited and Full Board Review Worksheet

Dear investigator,

Read the information in this worksheet carefully, as our policies and procedures are updated regularly to reflect federal regulations and guidance. This worksheet is for **expedited or full board status** proposals only. Complete the worksheet and supply the required attachments in accordance with the instructions provided. Questions and inquiries should be directed via email to the IRB Director, Dr. Sharon Foreman-Kready.

About Expedited and Full Board Review Categories:

Under some circumstances, research involving "minimal risk" and no more than "minimal risk" may qualify for expedited review. "Minimal risk," according to 45 CFR 46.012(i), means that the "probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." As discussed in the LC IRB policy and procedure manual, there are many factors that may increase risk level beyond the "minimal risk" threshold. Proposal that address illegal behavior by subjects (such as underage drinking or drug use) are more than minimal risk because they may expose subjects to criminal liability. Other examples of factors that could increase the risk level beyond minimal risk include threats to reputation, financial standing, or employability. Stating that a data collection instrument is anonymous or confidential does not negate or counterbalance potential for risk or discomfort. In many instances, knowing that one's identity is protected is not sufficient to completely minimize risk. Questions or other study dynamics to which subjects are exposed that elicit responses to life events that are so upsetting that they may cause significant distress might also increase level of risk.

Typically, an expedited review consists of review by the IRB Director and/or other members of the IRB. Research cannot be disapproved using the expedited process. However, review may be delayed until a proposal can be reviewed by a full IRB meeting. If required revisions are not made and/or if the proposal revisions are not approvable after the first IRB request for revisions, then the research study will be placed, 'as is' at time of revision submission, on the agenda for the next full board meeting of the IRB. Additional information (including clarifications) can be requested as part of an expedited review; communication regarding proposals becomes a part of the official IRB records. Researchers at Lynchburg College should be cognizant of the fact that the LC IRB does not meet as a full board in the summer term and during the winter term. Consequently, proposals should be submitted in a manner that acknowledges this schedule. If a study is submitted for expedited or full board review during these terms, the timeline for review will be impacted.

Studies eligible for expedited review must present no more than minimal risk to subjects and fall into one of nine federally defined research categories. Persons doing no more than minimal risk research

must be aware that their research cannot be expedited unless it is minimal risk *and* falls into one of these nine categories. Numbers six through nine are most applicable at Lynchburg College. See Section Three to review the nine categories. There are three determinations that may occur at the expedited review level: (1) Approved; (2) Conditional Approval (minor revisions required within 30 days of letter of determination); and (3) Not Approved and referred for a review by full Board. As previously stated, there is one opportunity for revisions to be submitted for review at the expedited level of review; if revisions or other issues remain, then the determination will be to refer for a review by the full Board at the next convened meeting of the Board.

Studies that do not meet the criteria for an expedited review must be reviewed by the full Board at a convened meeting. If in doubt about the form of review required, the Director will most often bring a proposal to the full Board for its review. Factors taken into consideration in making such a decision will include the level of risk to subjects, the nature of the proposal, and the subject population. For example, a study that might otherwise be expeditible would likely be taken to the full Board if it involved vulnerable populations as subjects, such as children, prisoners, or persons who are considered to be at a diminished decision-making capacity (frequently referred to as 'mentally impaired'). As explained in Section 4.3 of the policy and procedure manual, revised study proposals that are submitted incompletely or otherwise non-approvable after the revision request will be reviewed at a convened full Board meeting. In appropriate circumstances, the Board may convene by some form of conferencing technology. Such a convening would have to involve agreement in advance by a majority of Board members either by a meeting vote or email consensus. There are three determinations for a full Board level of review: (1) Approved; (2) Conditional Approval (minor revisions required within 30 days of letter of determination); and (3) Not Approved.

Additional Information Regarding Human Subjects Research at Lynchburg College:
A complete list of policies and procedures are found on the LC IRB website and in the LC IRB Policy and Procedure Manual, which is available on the website.
- All research activities involving the use of human beings as research subjects must be reviewed and approved by the LC IRB, unless the IRB Director determines that the activity does not qualify as human subjects research and is thereby non-reviewable.
- Members of the research team **are not permitted to recruit or begin data collection until approval has been provided by the Director of the IRB.**
- Undergraduate students are not permitted to serve as Principal Investigator (PI) for a research study and must have a faculty mentor as the study PI; graduate students may serve as Co-Principal Investigator (Co-PI) along with a faculty member.
- Federal regulations and guidance are seen as a "floor," not a "ceiling," for the protection of human subjects.

On behalf of the IRB, I look forward to review of your proposal materials.
- Dr. Sharon Foreman-Kready, Director and Chair, LC IRB

Instructions:
All submissions must follow the instructions found on the Lynchburg College (LC) Institutional Review Board (IRB) Submission Instructions and Forms web page. Incomplete or improperly completed/submitted worksheets and supporting materials will experience a delay in the review process.

Checklist and submission instructions for *expedited and full board review status* submissions:

Online submission materials (hardcopy also permitted): Submit all electronically in .pdf or .docx format to IRB-HS@lynchburg.edu. In the body of the email, include the name(s) of researcher(s) and title of the research study. It is preferred that all documents be scanned into one file; however, separate files are also accepted. In the subject of the email, indicate level of review (expedited or full board). In the body of the email, include the name(s) of investigator(s) and the title of the research study.

- ☐ This worksheet, filled out completely (Expedited and Full Board Review Worksheet).
- ☐ Responses to questions in Sections Two.
- ☐ Explanation(s) for qualifications under expedited review category/categories listed in Sections Three, if applicable, or indication of full board review.
- ☐ Scanned copy of the Research Team Signature Page signed by all research team members.
- ☐ Data collection instrument(s) or comparable item(s).
- ☐ Invitation to participate in study or oral script to introduce study, if applicable.

At least one of the following (no witness necessary):

- ☐ Consent form (for participants over the age of 18 years old, if applicable). Please access template on our website. Witness signature block only for full board review proposals.
- ☐ Assent form (for participants under the age of 18 years old, if applicable) and Parental Consent Form, if applicable. Please access template on our website. Witness signature block only for full board review proposals.

☐ Additional support materials (add as many appendices as necessary; check this box ONLY if you have submitted additional support materials).

☐ Per record keeping requirements, an original hard copy document with real signatures for all researchers must be submitted using the Research Team Member Signature Page. Submit within 3 business days of email submission; exempt status acknowledgement cannot be made without this item. Indicate below which of the three methods you will use to submit the signature page; see Submission Instructions and Forms page for location/address details.

- ☐ Send via campus mail (preferred) to IRB Director;
- ☐ Hand deliver to faculty mailbox of IRB Director; **OR**
- ☐ Mail (USPS) to IRB Director.

What is the name of the person who will be responsible for submitting the proposal materials to the IRB Director? _____

What is the name of the person completing this worksheet? _____

Section One: Basic information about the research study and research team

Per institutional policy, undergraduate students are not permitted to serve as PI on the research team. They may; however, be listed as the lead researcher. Graduate students who wish to serve as a Co-PI with their faculty mentors/advisors are permitted to do so.

Title of the Research Study: _____

Per the LC IRB Ethical Research Practices Policy, all members of the research team must complete the CITI training appropriate for their learner group (either faculty/staff or students).

☐ Check this box once you have confirmed that all members of the research team have completed the appropriate CITI training course. Do not submit materials without confirmation of this requirement.

Principal Investigator (PI) or Co-Principal Investigators (Co-PIs): _____
PI Department or Office (list for Co-PIs, if applicable): _____
PI Email Address (list for Co-PIs, if applicable): _____

Additional research team members and their roles*:

Name of researcher	Role of researcher**	Affiliation, if not LC	Student Researcher***

*If there are more than five additional research team members, then the research team must submit a complete list of research team members with necessary explanations of researcher roles.
**Examples: Research assistant; student investigator; statistician/data analyst; consultant; co investigator
*** Yes or No. If yes, list undergraduate or graduate student.

☐ Check this box if this study is being conducted (in full or in part) to meet requirements for course credit, class assignment, thesis, dissertation, or other similar pursuit.
If you did not check this box, then you can proceed to Section Two. If you did check the box, then fill out the following fields:
[If there are more than one student and/or courses for which this study will meet requirements, separate with a semi-colon and (if applicable) clarify which course is for which student.]

Course prefix and number _____
Course title _____
Semester(s) and year(s) of enrollment _____
Course instructor/professor _____
If these or dissertation, provide details here on your degree program (for undergraduate honors, list Westover or department honors, or both), and name of thesis director or dissertation chair:

_____

_____

Section Two: Background information on the proposed research study

Submit responses to these sixteen items in a separate document that is either in Word (.doc or .docx) or PDF format. Include all items, and number each item the same as it is numbered here. At the top of the document, clearly state the title of the research study and the name of the PI and (if applicable) additional researcher(s). Make sure you label the section number as well, as additional information may be added to your document from Section Three.

Researchers are encouraged to provide as much detail as they would provide in describing to a faculty member or other academic professional who is not in their discipline/profession. In other words one can assume that the review will understand the methodological and analysis references, but not necessarily technical jargon, acronyms, or devices.

Special note for student research projects: Be mindful that you are engaging in a review process focused on the assessment of the protection of human subjects and responsible conduct of research; this is very different than assessment of your completion of an assignment – be careful to separate your course assignment requirements from the information requested on this worksheet. All researchers are held to the same standards for rigor and responsibility. Students are encouraged to take the time to read the information found on the LC IRB website as it may help them better understand the significance of an IRB review.

1. Provide a description of the purpose of your study. The purpose of a study is different than a topic statement; make sure that your response to this item focuses on the purpose of the study as it relates to the conduct of research with human subjects toward the goal of creating or contributing to generalizable knowledge. *Note for student researchers: Be mindful that completion of a course assignment or project is not an acceptable study purpose. In order to be in compliance with recordkeeping requirements, the researcher must present a cogent statement regarding the purpose of the study as it relates to creating or contributing to generalizable knowledge.*
2. Provide a detailed description of how you will collect data for your study. Be specific about your procedures for data collection (including if you will distribute online, in-person, etc.) and the data collection instrument itself (standardized, created by researchers, etc.) This is not a question about recruitment or access to your sample (see question 3, below, for that); instead, this is a question about what type of data collection instrument(s) you will utilize. Attach/include in your proposal packet all of the data collection instruments that you will use.
3. Provide a detailed description of how you will recruit subjects. No individual, office, program, or division at LC holds the responsibility for or expressed authorization to distribute recruitment statements and/or links to data collection instruments among those in the LC community. It is the responsibility of the PI and the research team to make arrangements for these tasks and then to clearly explain the recruitment and data collection methods for the study within this proposal. If your study protocol incorporates procedures for electronic recruitment and/or collection of data among faculty, staff, and/or students at LC, then your proposal submission materials must include explicit reference to the methods used to recruit and collect data (e.g., who will send recruitment email, to whom it will be sent, how many emails will be sent and at what frequency). Indicate in the proposal if arrangements have already been made or if the

arrangements are in the planning stage. For studies involving recruitment through sign-up sheets: Researchers are to explain the sign-up sheet protocol using explicit details regarding location/placement, duration of posting, who will have access to the building/location (reasonable expectations of privacy for potential subjects who sign up), and include a copy of the sign-up sheet itself; researchers are encouraged to utilize electronic means (e.g., Google forms) to facilitate the sign-up process as this reduces risk for privacy concerns.

4. Provide a detailed description of what will happen to or be required of the subjects in your research study. Answer the following questions, in complete sentences: (a) Will deception be involved in this study?; (b) Will an experimental or quasi-experimental design be used?; and (c) Will participants be asked to disclose information about illegal activity?
5. Will data collected include personally identifiable information, including multiple demographics? Provide a statement in which you clearly state the personally identifiable information, actual or potential, which will be collected.
6. What is the maximum number of participants in your study? Answer in a complete sentence.
7. How long will participation last? Provide duration for individual sessions and duration over time if multiple sessions are required. Answer in complete sentences.
8. Provide a statement in which you clearly state the level of involvement of vulnerable populations in your study. While the federal regulations do not provide a definitive list of vulnerable populations, the study of the following groups is generally accepted as the study of vulnerable populations: Pregnant women, human fetuses, and neonates; prisoners; children (anyone under the age of 18 years); cognitively impaired persons; students and employees; minorities; economically and/or educationally disadvantaged; AIDS/HIV+ subjects; terminally ill subjects. There are special regulations for the study of fetuses; pregnant women and in vitro fertilization, prisoners, and children.
9. What are the foreseeable risks or discomforts to the subjects? Describe the nature and magnitude of these risks or discomforts. Then, discuss what steps have been taken to minimize the risks or discomfort. For risk of physical or psychological harm/discomfort that exists, describe any medical or mental health (or other professional treatment) and compensation, if any, that will be provided or referrals that will be provided. It is not permitted to incorporate exculpatory language releasing the researcher, institution, etc. from costs associated with any harm caused during the subject's participation in the study.
10. What are the potential benefits of this study? Note that compensation for participation, including extra credit for students, is not considered a potential benefit; proposals indicating that there is 'no potential benefit' will not be approved. Benefit relates to how the subjects, society, science, etc. will potentially benefit from the findings. List direct, indirect, and potential benefits.
11. Describe any circumstances under which a participant's participation may be ended by the researcher.
12. How will consent be obtained? Will the standard consent template (see website) be used or is the research team requesting waiver of documentation of consent? If requesting waiver of

documentation of consent, provide a reason for why obtaining signed consent is not appropriate. Contact the IRB Director at irb-hs@lynchburg.edu for more information.

13. Will any of the participants be minors? If so, how will the assent be obtained from the minor? How will consent by obtained from the parent(s) or guardian? Provide a synopsis of the process and procedures here; make sure that appropriate documents are attached as appendices. Be advised that while school districts and other academic entities might provide "opt-out" forms for their students' participation in activities, that process is not acceptable for human subjects research activities and as such will not be approved by the IRB.
14. What is the data storage and protection plan? This is also known as a data safety plan. Be advised that federal guidance states that these items be maintained in a locked location (locked room with limited access by those without a key/card or locked filing cabinet) for at least three years after which point in time they must be destroyed. List location as specifically as possible. For electronic files, describe the password or other system in place to limit access and protect data.
15. Describe all foreseeable plans for dissemination, including print and oral. Include venues that are private (e.g., classroom dissemination or paper that will only be read by professor) and those that are public (e.g., Student Scholar Showcase, academic journal, conference).
16. Provide additional information that you feel will be helpful to the reviewer(s) and/or Board.

Section Three: Regulatory categories for consideration of expedited status classification

Select as many as apply and provide, in the separate document directly underneath your responses to Section Two items, an explanation for how your study qualifies for that specific parameter. Clearly label the category for which each explanation is provided. Note that simply stating "this is a survey" or "this is anonymous" is not acceptable – researchers should note that items in italics, below, have been added by the LC IRB in an effort to provide additional clarification. The language here in regular font *is taken directly from 45 CFR 46; contact the IRB Director with questions about interpretation of material found in the Code.* ***If you do not check any boxes next to these categories, then your study will be reviewed at the full board review level.***

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

☐ This study might qualify for expedited review under **CATEGORY ONE, as explained further in the attached document.**

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (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[2], 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.

    ☐ This study might qualify for expedited review under **CATEGORY TWO, as explained further in the attached document.**

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.

    ☐ This study might qualify for expedited review under **CATEGORY THREE, as explained further in the attached document.**

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.

    ☐ This study might qualify for expedited review under **CATEGORY FOUR, as explained further in the attached document.**

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.)

   ☐ This study might qualify for expedited review under **CATEGORY FIVE, as explained further in the attached document.**

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

   ☐ This study might qualify for expedited review under **CATEGORY SIX, as explained further in the attached document.**

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.)

   ☐ This study might qualify for expedited review under **CATEGORY SEVEN, as explained further in the attached document.**

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.

   ☐ This study might qualify for expedited review under **CATEGORY EIGHT, as explained further in the attached document.**

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.

   ☐ This study might qualify for expedited review under **CATEGORY NINE, as explained further in the attached document.**

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "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." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.

☐ This study does not appear to qualify for expedited review under the nine categories outlined above. This study appears to qualify for full board review.