# COMPLETE THIS FORM USING MICROSOFT WORD ONLY.

Do not use programs such as Google Docs to complete this form.

# LIPSCOMB UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB) RESEARCH PROPOSAL FORM

*Instructions:* Please do not modify this form in any way prior to completing it. To fill out the various sections of this proposal, click on the areas highlighted in gray or type in the boxes provided. Please note that researchers fill out the columns on the left side of this form. Institutional Review Board members fill out columns on the right side of this form (highlighted in purple). THIS DOCUMENT NEEDS TO BE COMPLETED USING MICROSOFT WORD.

If this proposal has been previously approved by this committee and is being resubmitted with any modifications, please make note of the modifications by highlighting the revisions (make sure that the information is updated on Section 1 of this form).

#### A NOTE ON CLASSROOM PROJECTS

Class research assignments that involve the use of human subjects do not require IRB review if they are not going to be published and have no connection with research conducted or presented outside the classroom. Course instructors are responsible for ensuring that class projects do not propose more than a minimal risk to participants and must make sure their students understand and abide by ethical obligations in carrying out their class research assignments. We suggest that, at a minimum, students be required to complete the training modules available through CITI at www.citiprogram.org.

Additionally, instructors are responsible for reviewing student class research assignment proposals and should review research methods and procedures to ensure they are ethical and appropriate. Course instructors are responsible for monitoring student research activities to ensure the rights and welfare of human subjects are adequately protected. Instructors who have any questions are encouraged to consult with the IRB Chair.

#### APPROVAL TIMELINES AND SUBMISSION DEADLINES

It is not uncommon for the approval of research proposals to be delayed due to missing information or issues with the research proposal itself (e.g., confusing and poorly written responses). Review timelines depend, in part, on the type of research proposal. Exempt and expedited proposals are normally approved in 2-4 weeks. For full review proposals, we highly suggest considering the following timeline in order to avoid delaying the desired data collection start date:

- 90 days prior to data collection = excellent chance of IRB approval
- 60 days prior to data collection = good chance of IRB approval
- **30 days prior to data collection = fair chance of IRB approval**

Convened meetings of the Committee shall occur once per month or on a called basis when the Chairperson judges a meeting to be necessary. To be considered at a given meeting, completed Research Proposal Forms must be submitted to the Office of Sponsored Programs not later than **ten days** prior to the scheduled meetings. The schedule for submissions and meetings is posted on the Research and Sponsored Programs web site at <a href="https://www.lipscomb.edu/research/irb/irb-meeting-schedule">https://www.lipscomb.edu/research/irb/irb-meeting-schedule</a>.

Human Subjects Research Training Requirements

Human Subjects Research training courses are available at <u>www.citiprogram.org</u>. Once at the CITI Program website, click on "My Courses" and "Log In" if you already have an account or "Register" an account in the system if you do not have an account. Select "Lipscomb University" as the Organization Affiliation.

Lipscomb provides the campus community with three CITI training courses in Human Subject Research. Researchers (and faculty advisors, as appropriate) must earn a CITI Certificate of Completion in one course which is most closely aligned to the type of Research being conducted. The three available Human Subject Research courses are as follows:

### **Option 1: Social-Behavioral-Education (SBE) Human Subjects Research**

Researchers shall take this course if the proposed Research focuses only on social, behavioral, or educational subjects and **DOES NOT** involve research of physical health, mental health, biomedical topics, blood draws, investigational drugs or devices; randomized clinical trials; research on medical records; and research using existing pathological specimens, discarded tissue, or secretions.

### **Option 2: Health Sciences, Biomedical, or Pharmaceutical Human Subjects Research**

Researchers shall take this course if the Research involves physical health, mental health, biomedical topics, blood draws, investigational drugs or devices; randomized clinical trials; research on medical records; and research using existing pathological specimens, discarded tissue, or secretions.

### **Option 3: Interdisciplinary-SBE and Health Sciences+**

Researchers shall take this course if the Research focuses upon a **combination** of social, behavioral, or education subjects **and** involves physical health, mental health, biomedical topics, blood draws, investigational drugs or devices; randomized clinical trials; research on medical records; and research using existing pathological specimens, discarded tissue, or secretions. **The Interdisciplinary-SBE and Health Sciences+ course should be taken if there is doubt regarding the applicability of the other courses.** 

#### **Required and Supplemental Modules**

Each training course contains both required and supplemental training modules. All required modules must be successfully completed. Furthermore, researchers must take any and all supplemental modules directly related to the research or activity(ies) being performed. Failing to take appropriate supplemental modules may cause significant delays to the IRB review process. Supplemental modules may include, but not be limited to:

- Prisoners (ID: 8 or ID: 506)
- Children (ID: 9 or ID: 507)
- Pregnant women, fetuses, and neonates (ID: 10)
- International research (ID: 14081 or ID: 509 or ID: 971)
- Public elementary and secondary schools (ID: 805)
- Internet research (ID: 510)

- Non-English speakers (ID: 17260)
- Gender and sexuality diversity (ID: 16556)
- Undocumented status (ID: 16656)
- Critically ill (ID: 16592)
- Decisionally impaired (ID: 16610)
- Older adults (ID: 16502)
- Socially or economically disadvantaged (ID: 16539)
- Physical disabilities and impairments (ID: 16657)
- Students in research (ID: 1321)
- Workers and employees (ID: 483)
- Public health (ID: 17637, 17638, 17639, 17640)

In addition, a CITI Certificates of Completion may be required for one or more of the following courses, depending upon the circumstance of the research:

#### Supplemental Courses:

# Information Privacy and Security (IPS)

This course is required if a Research study includes data from medical records or other health-related information.

#### Good Clinical Practice (GCP) Social/Behavioral Research Best Practices for Clinical Research

This course is required for any individual engaged in Research regulated by the U.S. Food and Drug Administration (FDA). This type of research typically involves drug, device, or biologic agents or products. This course is recommended for any beginning researcher learning the steps involved in high-quality research and participant safety, and may also be included in research methodology courses.

#### **Responsible Conduct of Research (RCR)**

Completion of this course **does not** meet requirements for Human Subject Research; however, completion of a Human Subject Research course and RCR may be required in certain externally funded research and sponsored programs. The Office of Research and Grants will notify all researchers if this course is required as a condition of any award.

#### Supplemental Course and In-Person Training:

Responsible Conduct of Research (RCR), plus 8-Hours of Face-to-Face Training

Virtual **and** face-to-face training is required for certain categories of research funded by the National Institutes of Health (NIH), and potentially other funding agencies. The Office of Research and Grants will notify all researchers if this course is required as a condition of any award.

#### **Research Training Completion Submission for Proposal Review**

Researchers are required to submit proof of their completion of the appropriate training for their type of study (i.e., required courses and any necessary supplementary modules). To submit proof of research training completion, researchers are required to submit their CITI completion report, not their CITI completion certificate. The completion report shows which modules were completed, the date they were completed, and the quiz score for each module. The completion report allows research proposal reviewers (e.g., IRB members) to verify that the required course and any necessary supplemental modules (e.g., "Research with Children") were completed by the researcher/s.

Section 1.		
IDENTIFICATION INFORMATION		
<i>This proposal is (check where applicable):</i> Dissertation Research  Grant Proposal  Faculty Research	This column is for Institutional Review Board N	Member Use only
$\Box$ Master's Thesis Research $\Box$ Undergraduate Research $\Box$ Project Continuation		
Request for Amendment to Approved Research D Other:		
Funding Agency:	Reviewer Name:	Date: MM-DD-YY
Complete all items. Use "N/A" if necessary		
<ol> <li>Title of Proposal:</li> <li>Research Proposal Submission Date:</li> <li>Anticipated Research Project Data Collection Start Date:</li> <li>Anticipated Research Project Data Collection End Date:</li> <li>CITI Training expiration date (for each researcher involved, provide name and expiration date):</li> <li>Does each researchers' CITI training extend to the length of the proposed study?</li> <li>Principal Researcher:         <ul> <li>E-mail Address:</li> <li>College/Department:</li> <li>Campus Address:</li> <li>Telephone Number:</li> </ul> </li> </ol>	Is the identification information complete?	□Yes □No
<ol> <li>Other Researchers &amp; Affiliations:</li> <li>Faculty Advisor (if applicable):</li> <li>E-mail Address:</li> <li>Has your faculty advisor read this research proposal form?  Yes  No</li> <li>Dean:</li> <li>E-mail Address:</li> <li>Identify any other previous committee reviews, dates and results:</li> <li>This proposal is:  New  An Amendment</li> <li>Former proposal title (if applicable):</li> </ol>	If the proposal is student research, is the advisor copied to the emailed proposal submission?	□Yes □No □N/A
PROPOSAL TYPE To determine the category of the proposed research, visit the website to review types: www.lipscomb.edu/irb Check one and state the reason/s why you believe the proposal fits into this category:	Is the proposal accurately identified by type?	□Yes □No

 $\Box$  Exempt.  $\Box$  Expedited  $\Box$  Full Review

If the proposal is student research, is the advisor copied to the emailed proposal submission?	□Yes □No □N/A
Is the proposal accurately identified by type?	□Yes □No

Please state your reason/s for choosing this category in the box below	Type any Section 1 reviewer comments here

Section 2.	This column is for Institutional Devious Decard M	ombor lies only
ATTACHMENTS REQUIRED:	This column is for Institutional Review Board M	ember Use only
Please submit the forms below via email as <u>separate attachments</u> from this research proposal form (i.e., do not combine forms into one document).	Are all of the required attachments listed here included in the submitted proposal?	□Yes □No
Informed Consent Form	Is the scientific design adequately described in the informed consent?	□Yes □No □N/A
Recruitment Materials (if applicable; e.g., flyers, recruitment script, recruitment email text, etc.)	Are all of the following elements of informed consent contained in the consent document?	
□ Assent Form (if minors included)	Required Elements	
If your study will include participants who are age 11 and younger, please include an	□Research Purpose & Procedures	
example of a script you will use to obtain oral assent. For participants ages 12-17, assent	□Risks & Discomforts	
forms should be written at the appropriate grade level.	Potential Benefits	
□ All Instruments/Tests/Questionnaires to be given to subjects	□Provisions for Confidentiality	
□ CITI Training Completion Report (i.e., <b>not</b> the CITI Training Completion Certificate) for	Contacts for Additional Information	
each researcher & faculty advisor involved in the study (Training course available at	□Voluntary Participation	
www.citiprogram.org; Lipscomb has a subscription to CITI trainings). All required modules	□Right to Discontinue Participation Without Penalty	□Yes □No □N/A
must be successfully completed. Furthermore, researchers must take any and all	Required When Applicable	
supplemental modules directly related to the research or activity(ies) being performed.	□Unforeseeable Risks	
Letters of Cooperation from participating institutions (if applicable)	□Termination of Participation by the Investigator	
Letters should indicate that the authorized official of the organization (school, clinic,	□Additional Costs	
church) is fully apprised of the study activities described in the application and is supportive of project.	□Consequences of Discontinuing Research Participation	
supportive of project.	□Notification of Significant New Findings	
IRB Research Study Multimedia Release (if applicable)	□Approximate Number of Subjects	
This form is required whenever participants' likeness, voice, name and/or identity is	□Alternative Procedures or Treatments	
recorded on a video, audio, photographic, digital, electronic, Internet or other medium.	□Handling of Research-Related Injury	
The researcher should give this form to participants with the principle investigator's	Is the assent form acceptable (assent is not required if	
name, research study title, and type/s of recording (i.e., audio, video, photo) identified on	any of the parameters below are met)?	
the form itself. This form can be accessed by clicking this link:	□The child is not capable of assent □The research offers a prospect of direct benefit not	□Yes □No □N/A
	available outside of the research	
https://www.lipscomb.edu/sites/default/files/2019-	□Parental permission is not required by law in this	
01/Multimedia%20Release%20Form.docx	context and is not necessary to protect subjects	

Are all materials meant to be read by participants written in a clear and comprehensible manner?          \[             \Yes \]No \]N/A          Are all materials meant to be read by participants consistent with what is described in the research proposal and informed consent/assent forms?          \[             Yes \]No \]N/A	Section 2. Continued	Are all materials meant to be read by participants written at the appropriate grade level	□Yes □No □N/A
consistent with what is described in the research □Yes □No □N/A		, · · · ·	□Yes □No □N/A
		, · · · ·	□Yes □No □N/A

Type any comments here	Section 2 reviewer comments here

Section 3.	This column is for Institutional Review Board m	ember use only
	Are the specific aims/objectives clearly specified?	□Yes □No □N/A
<b>Research Plan – What is the purpose of the research study?</b> ( <i>please give a paragraph</i>	Are the objectives likely to be achievable within the given time period?	□Yes □No □N/A
overview of the proposed research study and be sure to specify any objectives)	Is there appropriate justification for this research protocol?	□Yes □No □N/A

Type response here	Section 3 reviewer comments here

Section 4.	This column is for Institutional Review Board m	ember use only
Describe types, numbers, age and sources of subjects to be studied (From where will the	Are the methods for recruiting potential subjects acceptable and well defined in the proposal?	□Yes □No □N/A
subjects be recruited? How will subjects be recruited?).	If vulnerable groups (e.g., children, minorities) are included or excluded, is this justified?	□Yes □No □N/A

Type response here	Section 4, part 1, reviewer comments here

	Are inclusion and exclusion criteria clearly specified and appropriate?	□Yes □No □N/A
	Is the choice of subjects appropriate for the question being asked?	□Yes □No □N/A
Please indicate any exclusion criteria needed when screening subjects for inclusion in the study.	Is the principle of distributive justice (i.e., risk is spread evenly among those who may benefit from the research) adequately incorporated into the inclusion and exclusion criteria for the research protocol?	□Yes □No □N/A
	Is the selection process equitable (i.e., people groups are not unnecessarily favored or excluded)?	□Yes □No □N/A
	Is the individual performing the recruitment appropriate for the process?	□Yes □No □N/A

Type response here	Section 4, part 2, reviewer comments here

Section 5.	This column is for Institutional Review Board member use only	
	Is the process of obtaining consent adequately described in the research proposal?	□Yes □No □N/A
	Are there adequate provisions to avoid out-of-pocket expenses by the research subject, or is there sufficient justification to allow subjects to pay?	□Yes □No □N/A
	Are the rationale and details of the research procedures accurately described and acceptable?	□Yes □No □N/A
	If an intervention/procedure is being investigated, is there a clear differentiation between research procedures and standard care?	□Yes □No □N/A
	Are the individuals performing the interventions/procedures appropriately qualified?	□Yes □No □N/A
Identify all procedures that will be carried out with each type of subject in chronological, step-by-step order. This description should make it clear how the	Is the location of where the intervention/procedure will be performed acceptable?	□Yes □No □N/A
researchers plan to recruit, obtain consent, and collect data from participants.	Are there adequate plans to inform subjects about the specific research results if necessary?	□Yes □No □N/A
	When a project involves drugs, biologics, and devices:	
	Is the status of the drug/biologic/device(s) described and appropriate?	□Yes □No □N/A
	Are the drug/biologic/device(s) dosage and route of administration appropriate?	□Yes □No □N/A
	The drug/biologic/device(s) safety and efficacy data are sufficient to warrant the proposed phase of testing.	□Yes □No □N/A
	Is the significant risk or non-significant risk status of the drug/biologic/device(s) described and appropriate?	□Yes □No □N/A

Type response here	Section 5 reviewer comments here

Section 6.	This column is for Institutional Review Board member use only	
Does the project offer a direct benefit to each type of subject, inclusive of but not limited to monetary compensation? (it need not) $\Box$ Yes $\Box$ No	Is the amount or type of compensation or reimbursement reasonable?	□Yes □No □N/A
	Are there adequate provisions to avoid out-of-pocket expenses by the research subject, or is there sufficient justification to allow subjects to pay?	□Yes □No □N/A
	If children or adolescents are involved, is the person receiving the compensation appropriate?	□Yes □No □N/A

Type any comments here	Section 6 reviewer comments here

Section 7.	This column is for Institutional Review Board m	ember use only
	Are the risks and benefits adequately identified, evaluated, and described?	□Yes □No □N/A
	Is the risk/benefit ratio acceptable for proceeding with research?	□Yes □No □N/A
Describe anticipated risks, discomforts, or inconveniences that might be associated with the procedures (that are beyond what subjects typically encounter in everyday life).	If children are involved, which regulatory category of risk/benefit below does the protocol fall within, and are all the criteria within the category adequately addressed? Research presenting no greater than minimal risk to children Research involving an intervention/procedure presenting more than minimal risk that offers the prospect of direct benefit or may contribute to the well-being of the individual child Research involving an intervention or procedure that presents only a minor increase over minimal risk, yet does not offer any prospect of direct benefit or contribute to the well-being of the child	□Yes □No □N/A

Type response here	Section 7 reviewer comments here

Section 8.	This column is for Institutional Review Board member use only	
What precautions will be taken in those procedures where potential risk may be	Are the potential risks minimized and the likelihood of	
involved?	benefits maximized?	□Yes □No □N/A

Type response here	Section 8 reviewer comments here

Section 9.	This column is for Institutional Review Board member use only	
What steps will be taken for maintaining the subjects' confidentiality, rights, privacy, and well -being? Include plans for maintaining confidentiality of documents and data, and access to such. Be specific.	Are the provisions to protect the privacy and confidentiality of the research subjects appropriate?	□Yes □No □N/A
	Is the use of identifiers or links to identifiers necessary and how is this information protected?	□Yes □No □N/A
	If the data has been de-identified, is the process through which the data was de-identified made clear?	□Yes □No □N/A
	Is it clear that all identifiable data will be stored securely?	□Yes □No □N/A

Type response here	- e	Section 9, part 1, reviewer comments here

Describe plans for data after study completion, (e.g., will it be destroyed)? If stored,	Are there adequate plans to store, secure, and de-	
will identifiers be removed?	identify data?	□Yes □No □N/A

Section 10.	This column is for Institutional Review Board member use only	
<b>Is any element of deception of the subjects necessary for this research?*</b> □Yes □No If the answer is "Yes" describe the nature of the deception and the procedures for the required debriefing of subjects.* Note that research requiring deception is unable to be verified as Exempt	Does the use of deception appear to be necessary?	□Yes □No □N/A

Type response here	Section 10 reviewer comments here

Section 11.	This column is for Institutional Review Board m	ember use only
<ul> <li>Please identify your procedure for obtaining the participants' informed consent/assent:</li> <li>A. □ Written consent form will be used</li> <li>B. □ An oral presentation will be made (required for participants ≤ age 11)</li> <li>C. □ Other</li> <li>Regardless of the method chosen, the researcher must <u>attach to this proposal the</u></li> </ul>	Is the waiver or modification of consent possible?	□Yes □No □N/A
planned consent form, assent form (if minors included), recruitment script, and/or a description of the alternate procedure. If consent is not considered necessary, please explain. Federal regulations specify the circumstances under which a waiver of consent can be granted by an IRB. Waiver of consent should be discussed prior to a committee review by contacting the chair.	Is the procedure for obtaining the participants' informed consent appropriate?	□Yes □No □N/A

Type any comments here	Section 11 reviewer comments here

Section 12.	This column is for Institutional Review Board member use only	
	Is the letter of cooperation signed and written on the appropriate letterhead?	□Yes □No □N/A

If other institutions' researchers are engaged in this research overseen by Lipscomb	Is the person who signed the letter of cooperation	
University, submit letters of cooperation from the administrative authority in these	authorized to speak for his or her particular	□Yes □No □N/A
institutions as well as IRB approvals from the investigators' committees.	organization?	

Type any comments here	Section 12 reviewer comments here

Section 13.	This column is for Institutional Review Board m	ember use only
Do any members of the research team or their immediate families have any financial interest in the sponsor of the research and/or in the results of this research?	Are the potential risks associated with any conflicts-of- interest minimized?	□Yes □No □N/A

Type any comments here	Section 13 reviewer comments here

Section 14.	This column is for Institutional Review Board m	ember use only
The researcher agrees to seek prior approval from the committee for any changes in title, experimental procedures, informed consent procedures or working of informed consent letter, or other aspects of this proposal, once approved. The researcher further agrees to notify the committee immediately of any adverse effects experienced by subjects participating in this study. I understand and agree to the parameters of this section statement. I DO NOT agree to the parameters of this section statement	Has the researcher agreed to abide by the IRB approval and proposal update process?	□Yes □No

Type any comments here	Section 14 reviewer comments here

# Submission Instructions Please submit the completed Research Proposal Form and all attachments to the Institutional Review Board via email at: irb@lipscomb.edu