

# Lamar University

## IRB/Human Subjects Research Submission Checklist

Once you have your detailed research methods planned for your project involving human subjects, it is important that all steps are completed before submitting your application to the IRB or analyst. Participants for your research study cannot be recruited, nor the study implemented until IRB approval is received. For more info visit our **Institutional Review Board webpage under Research Compliance at [www.lamar.edu](http://www.lamar.edu)**.

Below is a checklist/list of steps that will assist you in submitting your IRB:

1. **Getting Set up in Cayuse** (the IRB Online Submission Platform):
  - A. Students and faculty: If this is the first time you are using Cayuse you will need to submit a request to [rspa@lamar.edu](mailto:rspa@lamar.edu) to create your account. Students must have a faculty member request their account on their behalf. Give the full name of requestor or student, LU email address, Campus Department, Campus P.O. Box, and contact Telephone number. Accounts may take up to 24 hours to activate. Once active, you will login using your LU credentials.
2. **Required CITI Training:**

Complete the appropriate training in CITI for all investigators. Go to [www.citiprogram.org](http://www.citiprogram.org) and register, and complete required courses listed under Human Subjects question#2. Most students and faculty will need the “**Social and Behavioral Research Investigators course**” or the “**Biomedical Research Basic Course**”. For more information view the CITI Human Subjects Training under the Related Information on the Institutional Review Board webpage at [www.lamar.edu](http://www.lamar.edu) for course specifics and detailed instructions.
3. **Get Site/Permission Letters if Applicable.** This may include School district permission, Collaborating University approval, Public Businesses, and many other off campus sites. The letter needs to include information found in the Off-Site Approval Template listed on the IRB webpage.
4. **Choose the appropriate level of IRB review required.** (The analyst will correct if necessary.) See the federal Office of Human Research Protections (OHRP) decision charts <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/> or contact the LU Office of Research and Sponsored Projects Administration (ORSPA) for assistance at [rspa@lamar.edu](mailto:rspa@lamar.edu).
5. **Complete each section of the IRB application in Cayuse.** Be sure to include all procedures in detail and written in a way that all reviewers from various areas will be able to understand. Be sure the purpose is clear and that all steps in the procedure are clearly listed. Attach all Investigators’ CITI training certificates (faculty sponsors and students included).
6. **Attach all surveys, forms, interview questions, etc.** in final form. Be sure if the participants get a copy, the IRB should get a copy attached in Cayuse. If electronic surveys will be used, Qualtrics is the platform LU recommends. Qualtrics information can be found at [www.lamar.edu](http://www.lamar.edu)

7. **Attach all recruitment material and flyers.** Flyers should have a statement that the study was approved by the IRB and list the IRB approval #. A recruitment method should be clear. If participants are recruited in person, attach the script that will be used.
8. **Attach informed consent documents: You may use and modify the sample consent form located on the IRB webpage or create your own. Be sure all elements are listed clearly in the form. The main elements should be:**
  - A statement that the study involves research. This includes but is not limited to:
    - An explanation of the purposes of the research
    - The expected duration of the subject's participation
    - A description of the procedures to be followed
    - A description of any foreseeable risks or discomforts to the subject
    - A description of any expected benefits to the subject or to others
    - When applicable, a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject
    - A statement describing how confidentiality of data will be managed
    - For research involving more than minimal risk: an explanation as to whether any compensation or medical treatments are available if injury occurs
  - List of whom to contact with questions about the research, research subjects' rights, or in the event of a research-related injury to the subject. This includes but is not limited to:
    - Principal Investigator's contact information
    - IRB Administrator's contact information (rspa@lamar.edu)
  - A statement that:
    - Participation is voluntary
    - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
    - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. **Be sure to Save the Cayuse application** itself within the Submission, **Certify** the information is correct, and **Submit**. All PIs and Co-PIs must certify the application. Your application will then be routed through your department approval and then to the IRB analyst.
10. **Wait for Review Correspondence or Approval Letter.** If your submission is returned, carefully view each comment and make comments and changes. Contact the ORSPA office if you have questions. **Re- Save, Certify, and Submit.**
11. Once you receive your letter of approval you may begin your research.  
Any changes to your approved IRB must be approved via Modification to your submission in Cayuse. Login and select the approve IRB. In the initial submission, click button pull down to modify.
12. If you have questions about this procedure contact the ORSPA office or the Research Compliance Specialist.

If IRB approval has been received for this investigation from another institution, LU's IRB will need a copy of the other institution's IRB approval letter. Contact the Research Compliance Specialist for what will be required at LU.