LIMESTONE
UNIVERSITY

Institutional Review Board Policy Manual

Human Research Policy and Procedures

Michelle Phillips-Meek, Ph.D.
IRB Co-Chair

Fred Lux, DCJ
IRB Co-Chair

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I. The History of the IRB

Establishment of the IRB

The National Research Act of 1974 established the IRB system for monitoring and approving research. The IRB regulations now come from the U.S. Department of Health and Human Services (45 CFR 46). Researchers requesting grant money are required to certify that their protocol has received IRB approval. The full text of the current regulation (7/19/2018 revisions) may be found at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1114.

Amdur and Bankert (2007) give several examples of research from the 1930's through 1973 which is now recognized as unethical for several reasons. **The Belmont Report** (1978) describes the main ethical principles of research. http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

The three basic principles of the Belmont Report include **respect for persons, beneficence,** and **justice.** The principle of respect for persons is the mandate that research participants must be able to give their informed consent to participation.
Participation is voluntary, and they must have the freedom to withdraw their consent without penalty. The principle of beneficence means that research participants must be kept free from harm. The principle of justice is about treating research participants equally.

Registration of the Limestone University IRB

The Limestone University IRB was officially registered with DHHS/OHRP on October 14, 2019 (as Limestone College).

II. Research Ethics in Practice

Common Guidelines

The practical application of the Belmont Report yields these common guidelines:

- The research participant must be able to give informed consent, and has the right to withdraw consent during the course of the research (i.e., "I quit").
- The research participant must be kept free from harm.
- The research participant has the right to confidentiality. His or her participation must be kept anonymous, so that names may not be associated with data.
- At the conclusion of the study, the research participant has the right to debriefing, as well as the right to ask questions about the study and his or her participation in that study.

Research Not Needing IRB Approval

Research for classroom use only, including anonymous tests, surveys and program evaluation, does NOT require IRB approval. Any professor may request IRB approval for class research if he or she so desires to do so.

III. Structure of the Limestone University IRB

Mission

The Limestone University IRB serves to support the research of Limestone University faculty and students. The policy is meant to serve the current needs of faculty and students. It may be modified as their needs change and programs expand.

The IRB may approve, request revisions or deny research conducted on the Limestone University campus, or through the Limestone University Internet programs in keeping with the terms of this handbook.

If the IRB does not approve a particular research protocol, then no one else may approve that research. The research protocol may, however, be resubmitted to the IRB with modifications for reconsideration.

Membership

The Limestone University IRB shall consist of:

- Two Co-Chairs; Authorized Institutional Officers (AIOs)
- A membership as follows:
    - Members from each of the following Academic Programs as appointed or reappointed annually by their respective Program Coordinators and approved by their respective Department Chairs:
        - Psychology
        - Social Work
        - Criminal Justice and Political Science
        - Business
        - Education and Kinesiology
        - Nursing
        - Biology and Chemistry
        - A member of Library Services personnel
        - One member from outside of Limestone University, invited for a 1-year term

The membership composition will be such that the number of IRB members, not including the Co-Chairs, is not divisible by thee (3).

The chairmanship will be voted on at the first meeting of each fall semester. The chair reserves the right to delete members from the IRB roster if they fail to participate in review of more than two of their assigned protocols.

Any Program where research is conducted may have representation on the IRB. Members of other programs may join as their research needs require. Department Chairs may send a request for IRB representation to the Co-Chairs and, upon consideration, members may be added to the official roll at the discretion of the sitting IRB Membership.

Current Membership (2022/2023 Academic Year)

IRB Member	Academic Program	Email	Phone Number
Co-Chairs			
Fred Lux, DCJ	Criminal Justice	flux@limestone.edu	(864) 488-4594
Michelle Phillips-Meek, Ph.D.	Psychology	mphillips@limestone.edu	(864) 488-4524
Membership			
Justin Bailey, Ph.D.	Psychology	jbailey@limestone.edu	(864) 488-8269
Beverley Burn-Turnage, D.M.D.	Community Rep	toogoodoo@hotmail.com	(864) 491-0814
Felicia Cavallini, Ed.D	Kinesiology	fcavallini@limestone.edu	(864) 488-8357
Theresa Coates, Ph.D.	Business	tcoates@limestone.edu	(864) 488-4375
Justin Davis, M.A., MLIS	Library	jdavis@limestone.edu	(864) 488-4450
Heather Harvey, Ph.D	Health Sciences	hharvey@limestone.edu	(864) 488-4067
Henry Hiott, MSW	Social Work	hhiott@limestone.edu	(864) 488-0450
Jackie Puckett, MSW	Social Work	jpuckett@limestone.edu	(864) 488-4585
Matthew Talbert, Ph.D.	Biology	mtalbert@limestone.edu	(864) 488-4520
Amber Williams, D.N.P.	Nursing	apwilliams@limestone.edu	(864) 488-4045

Obligations of the Membership

Records of certification of completion of ethical training, IRB Applications to Conduct Research, minutes, IRB Certificates, Protocol Completion certificates, and abstracts will be maintained in digital files by the Co-Chairs, who will serve as the Authorized Institutional Officers (AIO).

Members need to be familiar with the U.S. Department of Health and Human Services Code of Federal Regulations https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1114. All IRB Membership will be required to participate in ethical research training annually. The training materials and/or platform will be provided to the membership by the co-chairs at the start of the academic term and must be completed no later than the close of business the third Friday after day-campus classes have begun. Certification will be valid for the remainder of that academic year.

Service on the Limestone University IRB will suffice as *service to the University* as required by faculty contract. Co-Chairs for the IRB are exempt from serving on standing faculty committees unless serving at their own pleasure. Membership may be exempt from serving on standing faculty committees at the discretion of their Department Chair and the University Coordinating Committee; if serving on a standing faculty committee, membership is exempt from chairing a committee unless doing so at their own pleasure.

Procedures

Student Research

Research at Limestone University conducted by students is typically conducted in conjunction with a class research project. All student-conducted research must be conducted with the oversite of a faculty advisor. Student researchers must be advised of research ethics by their faculty advisor and participate in the mandatory ethical research training. Faculty advisors are responsible for advising students about the IRB, and are responsible for ensuring compliance with all standards of ethical research and Limestone University IRB protocols.

Any student conducting research requiring IRB approval will, in collaboration with their faculty advisor, complete the online IRB *Application to Conduct Research* (see Appendix A) form located on the Limestone University IRB website and as an appendix to this manual. Upon completing and signing the application, it must be reviewed and approved by their faculty advisor before submitting to the IRB. Upon completion of the application by the student, the student will submit the application via the University *Formstack* workflow for consideration. This application will then be work-flowed to the faculty advisor for review and signature before being presented to the IRB for consideration.

The role of the faculty advisor in the review process is to ascertain the application and all supporting documents are written in a competent, academic manner and free of any grammatical or ethical issues. Further, should the application be remitted back to the student for revisions, the faculty advisor is responsible for ensuring all revisions are completed properly and will re-review the document before resubmitting to the IRB for consideration. While this is a student learning process and work product, the faculty advisor does play a role in ensuring the quality of the learning process and the work product. The IRB may request revisions but it is the faculty advisor's role to ensure those revisions are appropriately made.

Faculty/Staff Research; Research from Off-Campus

Limestone University faculty and staff conducting research subject to the purview of the Limestone University IRB will be subject to the same application and approval process as student research.

For research conducted by faculty staff as part of an external institution or organization (including research for master's degrees or doctorates sponsored by other academic institutions) on Limestone University campus, IRB approval may be required from an external IRB as well as the Limestone University IRB:

- Research from an external institution or organization that has been deemed ***Exempt*** by an external IRB do not need an IRB review if it has been previously approved by an external IRB.
- Research from an external institution or organization that has been deemed ***Expedited***, or having been subject to a ***Full Review***, by an external IRB will be required to apply for review by the Limestone University IRB.

IRB Decisions and Workflow (see Appendix B)

IRB applications fall into three categories, ***Exempt***, ***Expedited***, or ***Full Review***. These designations are determined based upon guidance provided by *The Office of Human Research Protections* (OHRP) and found on their website: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exempt-research-and-research-expedited-review/index.html.

- ***Exempt*** research (46.104) is commonly used in classroom experiments and undergraduate research, but some more robust research studies may warrant this designation as well. As long as participation results in no greater risk than that incurred by the participant's every-day life it may be considered for ***Exempt*** status and workflow through the IRB process. Research falling into this category are generally those in which the topic is non-controversial and the participation is anonymous.
- ***Expedited*** research may be classified as such if there are questions about anonymity or the nature of the dependent variable. Research involving a pre- and posttest design or

research of a sensitive nature (i.e., a survey on sexuality or addiction), for instance, would require ***Expedited*** review. Insuring confidentiality is critical in this designation.

- ***Full Review*** designation is required if the research involves a vulnerable population (i.e., children or prisoners), if there is deception involved, if it is not possible to obtain informed consent, if there is considerable risk to the confidentiality of the participant (i.e. the use of video recording), considerable risk to emotional or physical health, or consensus cannot be reached as to ***Exempt*** or ***Expedited*** status.

Applications submitted through the *Formstack* workflow will be automatically forwarded to both Co-Chairs of the Limestone University IRB. Upon receipt, the Co-Chairs will review the application within 72 working hours. In doing so, they will:

- Assign an IRB *Protocol ID* to the application, formatted as a four-digit year, two-letter semester, and three digit sequential designator (i.e. 2022-FA-001).
- Verify that both signature pages are completed, and all approvals have been attained.
- Verify that ethical research training has been completed by all parties involved in the research process, and a valid and current certification of this training is on file with the Limestone University IRB.
- Review the protocol for appropriate decision and the need for further IRB review.

Exempt Status Workflow

In the case that a submitted protocol meets standards established for ***Exempt*** status, the Co-Chairs will sign the application indicating so. They will then notify the applicant of this decision and advise them of permission to begin research and data collection. This decision will be provided to the researcher(s) via the email(s) provided by the applicant in their application. In the case of an ***Exempt*** decision, no further review by the Limestone University IRB will be necessary.

Expedited Status Workflow

If the Co-Chairs determine an ***Expedited*** review is necessary, they will forward the application and contained documents to a subpanel of three (3) members of the Limestone University IRB. The make-up of the three-person panel will be determined by the Co-Chairs using a rotating assignment schedule by which the membership are listed in alphabetical order by last name and the first three in the roster will be selected. Proceeding to future protocols, the next three are selected until the list cycles through. If a member must recuse themselves from review for any reason, the next member in the roster will be selected for the panel. Upon receipt of the application, the panel will schedule a time to convene a face-to-face meeting (virtual meetings are acceptable should circumstances dictate) to review and provide a decision regarding the protocol within seven (7) working days of receipt of the application. Decisions of the subpanel may result in:

- Approval to begin research.
- The need for the researcher to make necessary revisions to the protocol and/or application and resubmit directly to the assigned subpanel.
- The need for further review by the full Limestone University IRB.

All decisions by the subpanel will be noted and certified by the signature of all three members in the appropriate location of the research application. In the case of approval or the need for revisions, a member of the subpanel will notify the researcher(s) via the email(s) provided by the applicant in their application. Upon approval of the research, the subpanel will return the signed application to the Co-Chairs for record retention. In the case of needing further review, the

application will be returned to the Co-Chairs who will convene the full IRB in a face-to-face meeting for review and decision within five (5) workings days of return of the application.

Full Review Status and Workflow

If the Co-Chairs (or an expedited committee) determine a ***Full Review*** by the Limestone University IRB is necessary, they will notify the membership and schedule a face-to-face meeting for review and decision. The first Tuesday of each month at 3pm will serve as a standing meeting time for all ***Full Review*** discussions. Any protocol needing ***Full Review*** will be brought before the IRB at the next standing meeting. Decisions stemming from such a review may result in:

- Approval to begin research.
- The need for the researcher to make necessary revisions to the protocol and/or application and resubmit directly to the assigned subpanel.
- The research not being approved.

This decision of the full Limestone IRB will be provided to the researcher(s) via the email(s) provided by the applicant in their application.

IRB Member Recusal from Workflow

No IRB member may vote on research in which he or she has a conflicting interest, such as serving as faculty advisor. Research proposed or advised by a member of the Limestone University IRB will be processed without that person's inclusion in any aspect of the workflow. He/she will just be informed of the IRB's final decision the same as any non-member researcher. Should the researcher or faculty advisor to a research study be serving as a Co-Chair to the IRB, they will nominate a member of the IRB to serve as Co-Chair in their stead.

Seeking Expert Consultations during Review Process

Non-voting consultants may be invited to participate in IRB reviews to lend their expertise on matters as those conducting the review see fit. Members of the IRB involved in the review process should, first, attempt to garner consultation from a member of the IRB who has the requisite expertise (the roster notes the academic discipline of each member). If that member cannot provide sufficient consultation, or there is not an IRB member possessing the requisite expertise, the reviewers may seek external consultations upon notifying the Co-Chairs of their need to do so.

Quorum and Consensus

Initial review of all applications for research, and decision by the Co-Chairs must be made by consensus of both Co-Chairs. If the two cannot come to unanimous consensus, the initial review will automatically be assigned to a three-person subpanel for initial review to be completed within 72 working hours of it being assigned to them. Any decision by the subpanel shall be binding as it would be on the part of the Co-Chairs. Once the decision is rendered by the subpanel, facilitation of the workflow will be returned to the Co-Chairs to complete the process (should the decision result in ***Expedited*** review, a new subpanel will be selected).

For ***Expedited*** reviews, a quorum of two-thirds majority is necessary for discussion, but all three members are still required to vote for decision. A two-thirds majority consensus is necessary for a biding decision.

For ***Full Review***, a quorum of two-thirds majority of the membership of the IRB and one Co-Chair is necessary for discussion. A simple majority (51%) consensus is necessary for any binding decision. One Co-Chair will preside over any discussion and deliberation, and will be assigned to each review in a sequential manner on a rotating basis (every other review). The Co-Chair may participate in all discussions but will only vote in the event of a tied vote.

All approvals for research will be valid and binding for a period of one calendar-year from the date of decision.

Revisions to Research Protocol

The Limestone University IRB has the right to require revisions in the design of or application for research in any study whether while or under review or after approval.

Revisions at the Direction of the IRB

Revisions may be explicitly advised by the IRB allowing for immediate resubmission of the protocol within the immediate workflow process if the IRB deems this appropriate. If issues with research design are so extensive that a revision process is not possible, the application to conduct research may simply not be approved. If a study is not approved, then the IRB will provide written feedback to the researcher(s) as to why and allow for resubmission at a later date.

Revisions to Protocol after Approval by IRB

If the researcher with an IRB-approved study experiences problems or needs to change part of the research protocol, then the IRB Co-Chairs need to be informed in writing immediately. A new application for research is not necessary. Rather, the Co-Chairs should be notified of problems or necessary changes via email. This includes changes to data collection dates, research dates, or research being conducted beyond the one-year certification of the IRB. Extensions on dates may be granted at the discretion of the IRB but will be reviewed and addressed on a case-by-case basis.

Suspension of IRB Approval and Research

The IRB has the authority to suspend research or to terminate a research protocol at any time if the protocol, as approved by the IRB, is violated and/or the IRB becomes of research participants experiencing any harm.

Records Retention

At the end of the semester in which research has been approved and/or conducted the applicant for research must fill out the *IRB Protocol Completion* form (see Appendix C) to indicate whether the research has been completed or not. Upon completion of the research and submission of the *IRB Protocol Completion* indicating so, an abstract of the research is to be attached. The *IRB Protocol Completion* form(s) and abstract should be emailed to the currently sitting IRB Co-Chairs. Upon completion of the research it is the responsibility of the current Co-Chairs to ensure the original *Application for Research* and approval documents, the *IRB Protocol Completion* form, and any supporting documents are all placed in the appropriate digital file maintained by the Co-Chairs as the AIOs. All files submitted to the Limestone University IRB must be maintained for at least 3 years, according to Federal standards.

Penalties

Use of the IRB to approve research must be monitored by the IRB, faculty, and administration of Limestone University. Any concerns may be addressed to any IRB member.

If a student conducts research without IRB approval:

- The IRB may recommend failure of the research project **or** failure of the class.
- The IRB may recommend banning the student from future research sponsored by or facilitated at Limestone University.
- For a serious infraction, the IRB may recommend expulsion from Limestone University to the Provost.

In the event that the IRB supports penalizing a student, a letter will be sent from the Co-Chairs to the Provost the student, his or her advisor, and the student's faculty advisor. The letter will describe the suggested penalty.

If a Limestone University faculty or staff member conducts research without IRB approval

- The IRB may recommend placing a letter in that person's file from the Provost. A copy goes to the faculty or staff member and to the Executive Vice President
- The IRB may bar that faculty or staff member from conducting future research at Limestone University.

IV. Resources and Further Reading

Bankert, E.A. & Amdur, R.J. (2006). Institutional review board: Management and Function (2nd ed). Boston: Jones & Bartlett Publishers.

National Research Council (2011). Guide for the care and use of laboratory animals (8th Ed.) . Washington, DC: The National Academies Press.

Penslar, R.L. & Porter, J.P. (2001). Office for Human Research Participants: IRB guidebook. http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

Sparks, J. (2002). Timeline of laws related to the protection of human subjects. http://history.nih.gov/01Docs/historical/2020b.htm

Sparks, J. (2002). Timeline of laws related to the protection of animal subjects. http://history.nih.gov/01Docs/historical/2020d.htm

Stark, L. (2012). Behind closed doors: IRBs and the making of ethical research. Chicago: The University of Chicago Press.

The Limestone University Library maintains a copy of the video, *Protecting Human Subjects* (2001), provided for academic and classroom use by *The Office of Human Research Protection*. The video contains segments of "Evolving Concern", "Balancing Society's Mandates", and "The Belmont Report".

V. Appendixes

Appendix A: Application to Conduct Research

Limestone University Institutional Review Board
Application to Conduct Research

Applicants checking any items marked with *(* must complete part 2)* in part 1 of this application, MUST complete both parts 1 and 2 of this application in their entirety.

Applicants NOT checking any of those items, only fill out Part 1.

PART 1 – TO BE FILLED BY ALL APPLICANTS

1. Principal Researcher's (PR) Full Name (**ONE full name only**): Click or tap here to enter text.

2. Institution or Organization: Click or tap here to enter text.

3. Department: Click or tap here to enter text. **4.** Program: Click or tap here to enter text.

5. Program level: ☐ Undergraduate ☐ Graduate ☐ N/A

6. Email address: Click or tap here to enter text. **7.** Phone number: Click or tap here to enter text.

8. Co-Researcher(s): Click or tap here to enter text.

9. Faculty Advisor (if student research; **ONE advisor's name only**): Click or tap here to enter text.

10. Faculty Advisor's Email Address: Click or tap here to enter text.

11. Project Title: Click or tap here to enter text.

12. Anticipated Project Start Date: Click or tap to enter a date.

13. Anticipated Projected End Date: Click or tap to enter a date.

14. Please describe the purpose(s) or goal(s) of your study. Include your research question(s) or hypothesis(es) if applicable:
Click or tap here to enter text.

15. Research Methods (Mark all that apply)

- ☐ Survey *(attach questionnaire)*
- ☐ Interviews *(attach interview schedule)*
- ☐ Focus Group(s)
- ☐ Participant observation
- ☐ Unobtrusive observation
- ☐ Experiment
- ☐ Analysis of existing data (i.e., "archival" data; *provide Letter of Cooperation)*
- ☐ Other, specify: Click or tap here to enter text.

16. Type of instrument used:

- ☐ Paper questionnaire, Survey, interview guide
- ☐ Online questionnaire or Survey
- ☐ Pre-post survey
- ☐ Experimental design
- ☐ None (note-taking)
- ☐ Not applicable (existing data)
- ☐ Other, specify: Click or tap here to enter text.

17. How long do you anticipate that it will take the participants to complete the research procedure(s)?
Click or tap here to enter text.

18. Anticipated Number of participants: Click or tap here to enter text.

19. Types of participants (Mark all that apply):

- ☐ Adults (18 and older)
- ☐ Elected officials
- ☐ Limestone University students *(attach a copy of your Recruitment Letter)*
- ☐ Limestone University personnel
- ☐ Minors (under 18)**must complete part 2 of application (attach Letter of Cooperation)*
- ☐ Individuals diagnosed with a mental disorder or illness* *must complete part 2 of application (attach Letter of Cooperation)*
- ☐ Terminally-ill patients* *must complete part 2 of application (attach Letter of Cooperation if institutionalized)*
- ☐ Incarcerated individuals* *must complete part 2 of application (attach Letter of Cooperation)*
- ☐ Undocumented immigrants* *must complete part 2 of application*
- ☐ Convicted felons* *must complete part 2 of application*

20. Please briefly describe your participants, including the social categories you are drawing from or targeting or any other relevant characteristics of your sample. Be sure to include any demographic information, such as age, gender, ethnicity, and any other social categories or groups that your research involves:
Click or tap here to enter text.

21. Sampling strategy:

- ☐ Convenience/availability
- ☐ Random/probability
- ☐ Snow-ball
- ☐ Purposive/judgmental/theoretical
- ☐ Other, specify: Click or tap here to enter text.

22. Recruitment strategy (Mark all that apply):

- ☐ Individual contacts (in person, by phone, or by mail)
- ☐ Email announcements *(attach email graphics and/or message)*
- ☐ Public announcements (including social media; *attach announcement*)
- ☐ Flyers *(attach flyer)*
- ☐ Other, specify *(attach any pertinent documents)*: Click or tap here to enter text.

23. Indicate the agencies who give approval for the recruitment or data collection *(attach Letter(s) of Cooperation)*; indicate any funders or organizations from which you obtain participants or their data:
Click or tap here to enter text.

24. What type of consent process will you use? (Mark all that apply)

- ☐ Implied consent * *must complete part 2 of application (attach implied consent statement)*
- ☐ Consent form * *must complete part 2 of application (attach consent form)*
- ☐ Assent form * *must complete part 2 of application (attach assent form or statement)*
- ☐ Not applicable *(research on publicly available data)*
- ☐ Other, specify* *must complete part 2 of application*: Click or tap here to enter text.

25. Data recording method (Mark all that apply):

- ☐ Written (includes notes, questionnaires or surveys)* *must complete part 2 of application*
- ☐ Electronic (online survey, email, blog, etc.)* *must complete part 2 of application*
- ☐ Audio* *must complete part 2 of application*
- ☐ Video* *must complete part 2 of application*
- ☐ Photo* *must complete part 2 of application*
- ☐ Use of existing data
- ☐ Other, specify* *must complete part 2 of application*: Click or tap here to enter text.

26. How long do you anticipate it will take you to collect all your data for this project?
Click or tap here to enter text.

27. Will the data be linked to the individual participants' identifying information (such as name, email address, social security number, video, picture, etc.)? This may include identifying information on the data collection instrument, or keeping a list of names matched to codes used in the data.

☐ No ☐ Yes* *must complete part 2 of application*

28. For how long do you plan to keep your data and why?
Click or tap here to enter text.

28. How will you store your data? (Check all that apply):

- ☐ Locked file cabinet ☐ Password-protected computer
- ☐ Locked office ☐ Locked safe
- ☐ Other, specify: Click or tap here to enter text.

30. How will you report your research? (Mark all that apply)

- ☐ Report for an outside organization ☐ Master's thesis or dissertation
- ☐ Senior thesis project ☐ Class paper
- ☐ In-class presentation ☐ Publication
- ☐ Public presentation (i.e. conference) ☐ Limestone University Symposium
- ☐ Other, specify: Click or tap here to enter text.

31. Does the research involve any deception of the participants?

☐ No ☐ Yes* *must complete part 2 of application*

32. Does the research involve any cost to participants?

☐ No ☐ Yes, specify: Click or tap here to enter text.

33. Is participation in this research study incentivized in any way?

☐ No ☐ Yes, specify: Click or tap here to enter text.

34. Risk involved in participating in this research (Mark all that apply):

☐ None above those incurred in daily life
☐ Physical injury, illness, exposure to toxic/noxious substance* *must complete part 2*
☐ Emotional or psychological harm* *must complete part 2 of application*
☐ Social (i.e. embarrassment, damage reputation, etc.)* *must complete part 2 of application*
☐ Legal* *must complete part 2 of application*
☐ Financial* *must complete part 2 of application*
☐ Other, specify* *must complete part 2 of application*: Click or tap here to enter text.

35. Describe fully how you will collect, store, manage, analyze, and report your data. Include information regarding paper or electronic copies. If your data is linked or identifiable in any way, you must also describe how you will securely store your data and procedures for de-identification and study close out. If your data is collected electronically then you must also describe the program and security features that you will use.
Click or tap here to enter text.

PART 2 – TO BE FILLED BY APPLICANTS WHO CHECKED ANY ITEMS REQUIRING PART 2

Applicants NOT checking any of those items marked with (* *must complete part 2 of application)* **are not required to complete this part of the application.**

Please provide ***detailed*** answers to the questions below.

1. Describe the objective(s) of your study. What do you hope to accomplish?
Click or tap here to enter text.

2. What are the expected benefit(s) of your research to the participants themselves, to society, and/or to the academic community?
Click or tap here to enter text.

3. How will you secure informed consent from your participants?
Click or tap here to enter text.

4. How will you ensure participant anonymity or the confidentiality of the data during data collection, storage, analysis, and reporting? Please note that anonymity means that no information that can identify participants is collected in the data, while confidentiality means that such information is collected, but access to it is restricted.
Click or tap here to enter text.

5. Who will have access to the data? For what purposes?
Click or tap here to enter text.

6. Describe fully any and all risks beyond those of daily life to which participants may be exposed as a result of participation in your study (legal, social, emotional, etc.).
Click or tap here to enter text.

7. How will you minimize the existing risk(s)? What debriefing process will be employed *(attach any debriefing documents that will be utilized)*?
Click or tap here to enter text.

Principle Researcher Statement of Responsibility

I, the Principal Researcher, certify that I have followed the guidelines as outlined in this application and in the instructions available on the IRB webpage including (initial all that apply):

___ I have provided an answer to each question in Part 1 of the application, leaving none blank.
___ I checked one or more items followed with an asterisk ***** *must complete part 2 of application* and I have answered each question in Part 2 of the application, leaving none blank.
___ I have answered all questions truthfully. I understand that failure to do so will result in immediate revocation of any IRB approval, with the potential for further disciplinary action.
___ I have obtained the required ethics training certification, as described on the IRB webpage and uploaded oof of completion along with this application.
___ If a student, I have received guidance from my faculty advisor and obtained their approval.

I also certify that I have included all necessary supplemental documentation, as applicable to my research (initial all that apply):

___ Data collection instrument(s), such as survey, interview questionnaire(s), or protocols for experiments
___ Consent form(s)
___ Assent form(s)
___ Implied consent statement(s)
___ Letter(s) of Cooperation to conduct the specific research from outside agency
___ Proof of approval from any necessary external IRB
___ Proof of completion of ethical training with at least 6 months validity, to be renewed if the study extends beyond that date.
___ If I am submitting this application as a student, proof of completion of ethical training for my faculty advisor

I accept the following responsibilities (please initial each after reviewing):

___ I will not start collecting any data for this project before obtaining IRB approval of the proposal.
___ I will obtain approval from the Limestone University IRB prior to instituting any change in the project protocol.
___ I will bring to the attention of the Limestone University IRB the development of any unexpected risks or ethical concerns.
___ I understand that the IRB approval period is for exactly one year, and that all study activities will either cease prior to expiration, or I will submit a request for an extension prior to the expiration date.
___ I will keep signed informed consent forms (if required by the project) from each participant for five years after the completion of the project and will ensure proper storage.
___ I have fully read the Limestone University IRB Policy Manual, and this application adheres to the expectations outlined in it.
___ I agree to further review of this application by the IRB, in keeping with the protocols outlined in the Limestone University IRB Policy Manual.

Principle Researcher's signature: _____ Date _____

Faculty Advisor Statement of Responsibility and Approval of Protocol

*(Necessary Only for **Student Research**)*

I, the Faculty Advisor for this research project, certify the following (initial all that apply):

___ I have fully read the Limestone University IRB Policy Manual, and this application adheres to the expectations outlined in it.

___ I agree to further review of this application by the IRB, in keeping with the protocols outlined in the Limestone University IRB Policy Manual.

___ I have reviewed and assisted the PR in designing this research project.

___ I have ensured that the PR has followed all instructions to fill out this application according to the guidelines provided by the Limestone University IRB

___ I will assist the PR in making any revisions requested by the Limestone University IRB.

___ I will assist the PR in the completion of the research and will continuously monitor all study related activities for the duration of IRB approval.

___ I will ensure that the PR submits a modified application for review, should any modifications to the research plan occur.

___ I will ensure that the PR submits a request for continuation in a timely fashion, should the research be extended beyond the one-year IRB approval.

___ My ethics certification is valid for at least another 6 months and has been provided to the IRB; in the case proof of my ethics certification has not been pre3viously provided, it has been uploaded along with this application.

___ I will renew my ethics certification at expiration, if it expires before the PR's research project is completed.

___ **I understand that I can be held legally responsible in case of any violation of any law or the IRB regulations by the research team.**

Faculty Advisor's Signature: _____ Date _____

I, the Faculty Advisor for this research project, approve the protocol as outline in this application and authorize the Principle Researcher to proceed with this research project.

Faculty Advisor's Signature: _____ Date _____

****

FOR IRB USE ONLY

Application and Protocol Information

Protocol ID: Click or tap here to enter text.

Date Received: Click or tap to enter a date. Date Assigned for Review:Click or tap to enter a date.

Verification of Ethics Training Certification

PR: ☐ Certification (Expiration date: Click or tap to enter a date.) ☐ No/expired certification

Faculty Advisor: ☐ N/A ☐ Valid certification (Expiration date:Click or tap to enter a date.)

☐ Certification expired ☐ No certification

Type of review: ☐ Exempt ☐ Expedited ☐ Full Review

Decision: ☐ Approved

☐ Revise and Resubmit

Revisions required:
Click or tap here to enter text.

☐ Requires Further Review by Full IRB (decision made my sub-panel)

Justification for further review: Click or tap here to enter text.

☐ Not approved

Justification for non-approval: Click or tap here to enter text.

For Exempt Approval

IRB Co-Chair Signature (not approved unless signed by both):_____ Date: _____

IRB Co-Chair Signature (not approved unless signed by both):_____ Date: _____

For Expedited Decisions

IRB Sub-Panel Member (signatures of all three required): _____ Date: _____

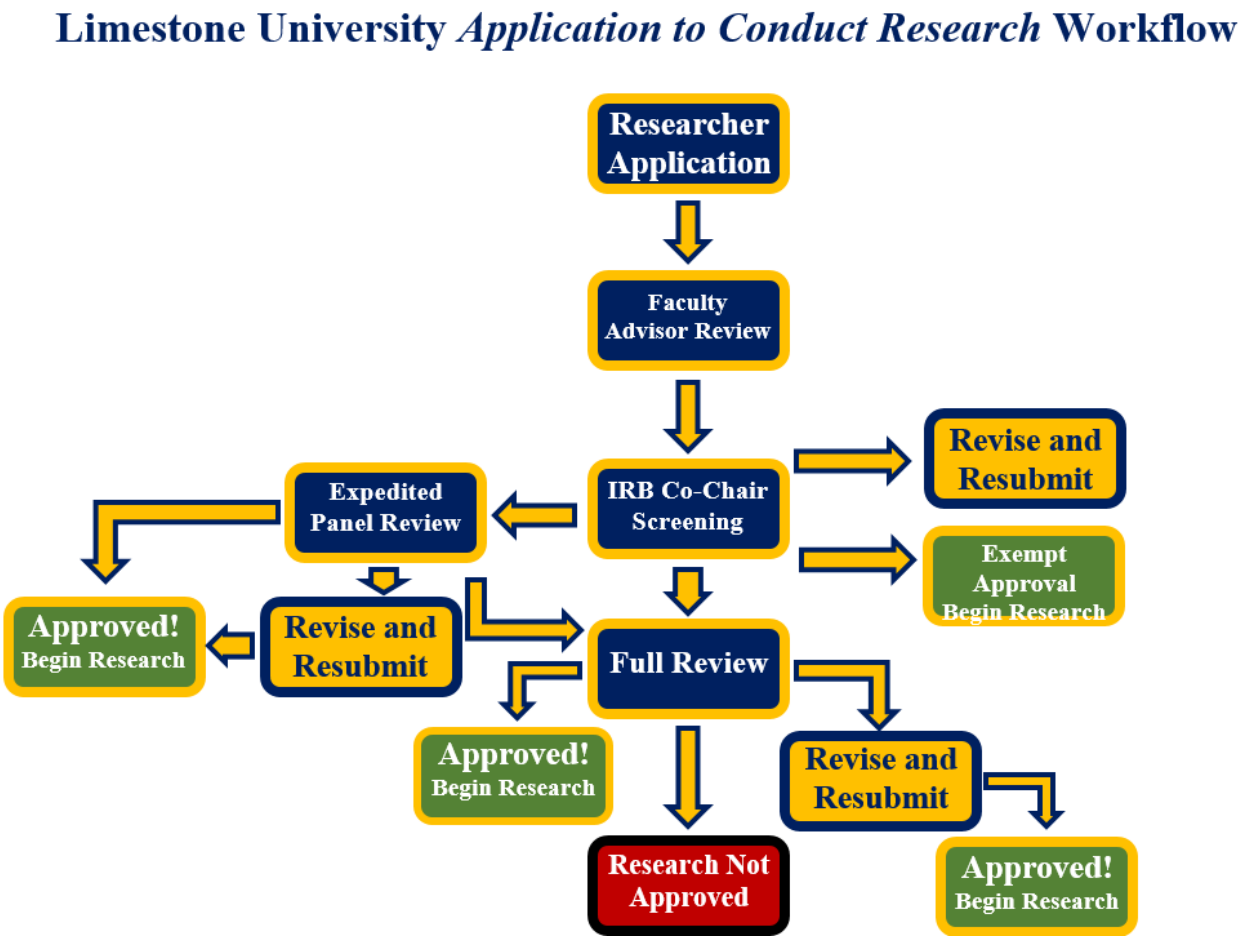
IRB Sub-Panel Member (signatures of all three required): _____ Date: _____

IRB Sub-Panel Member (signatures of all three required): _____ Date: _____

For Decisions Made Upon Full Review

IRB Co-Chair Signature (presiding co-chair only): _____ Date: _____

Appendix B: Workflow Chart



Appendix C: Protocol Completion Form

Limestone University Institutional Review Board
Protocol Completion Form

PART 1 – TO BE COMPLETED AT THE END OF EACH SEMESTER

1. Principal Researcher's (PR) Full Name (**ONE full name only**): Click or tap here to enter text.

2. Email address: Click or tap here to enter text. **3.** Local phone number: Click or tap here to enter text.

4. Project Title: Click or tap here to enter text.

5. Protocol ID: Click or tap here to enter text. **6.** Protocol Approval Date: Click or tap to enter a date.

7. Protocol Start Date: Click or tap to enter a date. **8.** Anticipated End Date: Click or tap to enter a date.

9. Does the research involve any deception of the participants?

☐ No ☐ Yes* *please complete part 2 of application*

PART 2 – TO BE COMPLETED AT CONCLUSION OF RESEARCH PROTOCOL

1. Protocol End Date: Click or tap to enter a date. **2.** Number of Participants: Click or tap here to enter text.

3. Provide a summary of the overall conduct of the study, and proper assurance that there are no active participants or potential risks to prior participants. **Please include a statement to indicate all identifiable data has been de-identified and how all links to identifiable data have been destroyed or will be securely maintained until destroyed.*
Click or tap here to enter text.

Principle Researcher's signature: _____ Date _____

****

FOR IRB USE ONLY

IRB Co-Chair Signature: _____ Date: _____

IRB Co-Chair Signature:_____ Date: _____