Institutional Review Board Policy Manual

Human Research Policy and Procedures

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I. The History 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.

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.) People requesting research access who have had their research approved at another institution do need to send it through the IRB process.

III. Structure of the Limestone University IRB

Mission

The 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 (via e-mail, hybrid, Blackboard, or WebCT).

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 **membership** of the IRB shall consist of

Chair; Authorized Institutional Officer
Chair, Department of Psychology
Dean/Director of the Social Work Program
Chair, Department of Criminal Justice, Political Science, and Sociology
Chair, Institutional Animal Care and Use Committee (in development)
Chair, Department of Business, Economics, and International Studies
Chair, Department of Education or member
Chair, Department of Nursing
Member, A.J. Eastwood Library Staff
One member from outside of Limestone University (invited for 1-year terms)

Any Departments where research is conducted may have representation on the IRB. At least one member must be an online faculty member. Members of other departments may join as their research needs require.
Department Chairs may send a request for IRB representation to the Chair. Members will be added to the official roll .

Records of IRB applications, minutes, IRB Certificates, Protocol Completion certificates, and abstracts will be filed in the office of the Chair, who will serve as the Authorized Institutional Officer (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 . The chairmanship will be voted on at the first meeting of each fall semester (or by e-mail). The chair reserves the right to delete members from the IRB roster if they fail to vote for at least 50% of the protocol

vote requests. The Chair may request a vote on a Vice-Chairmanship position in the event that the Chair wants to request voting on a research protocol.

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

Procedures

Student Research

Research at Limestone University is typically conducted in conjunction with a class research project. Student researchers must be advised of research ethics by their faculty sponsor. Professors teaching research methods are responsible for advising students about the IRB and are responsible for testing students on the proper use of human subjects in research and IRB protocol.

The student or faculty member completes the online IRB application form located in the Halo and submits it to the IRB.
A hard copy of the application is in the appendix. (Copies of the Manual and IRB brochure are located on the Halo.)

The IRB receives the application via e-mail with a due date. Discussion of the research proceeds. IRB members vote to approve, not approve, or to approve with modifications. Research that is considered **Expedited** receive their IRB decision by e-mail.
The IRB approval is typically for the period of one semester. Students are requested to update the IRB with the results of their research.

Members of the IRB will respond to requests for feedback regarding research protocol by e-mail. In the event that a research protocol requires **full IRB review**, the IRB must meet within 10 days to fulfill that need. Materials will be submitted to members by e-mail or through campus mail.

Faculty/Staff Research; Research from Off-Campus

Exempt research from off-campus, research by faculty members or staff, including research for master's degrees or doctorates do not need a full IRB review if it has been previously approved.. Some research, then, will require IRB approval from both Limestone University and the institution where a faculty member or staff member is attending graduate school.

No IRB member may vote on research in which he or she has a conflicting interest, such as a student's research supported by that IRB member. Research proposed by an IRB member will be circulated without that person's inclusion on the e-mail list. He/she will just be informed of the IRB's final decision.

Non-voting consultants may be invited to IRB meetings or online discussions to lend their expertise on matters of importance.

IRB meetings and electronic meetings must be conducted by a quorum of at least 51% of the membership, including at least 1 scientist (Social/Behavioral/Biological sciences) and at least 1 non-scientist (Business/Honors) among the representatives, as well as a professional from the community.

Approval of research requires a simple majority (51%).
The IRB has the right to require changes in the design of the study in order for that study to be approved. If a study is not approved, then the IRB will provide written feedback to the applicants.

Decisions

IRB applications fall into three categories, exempt, expedited, and full IRB review.

Exempt research (46.104) is commonly used in classroom experiments. A survey is passed out, students respond, and the papers are collected. As long as the topic is non-controversial and the participation is anonymous, then the research is considered exempt. In this case, the IRB Chair may send the application via e-mail to the IRB with a due date for comments regarding the application.. If none, then an approval letter is sent to the student and faculty member by e-mail.

Research may be classified as **expedited** research 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 (e.g., a survey on sexuality or addiction) would require expedited review. Insuring confidentiality is critical here. This kind of research requires dissemination of the application materials and a vote of the IRB by e-mail or in person. The IRB may require changes in the research protocol if they are considered necessary.

A **full IRB review** is required ~~if~~ the research involves a "vulnerable" population (e.g., children or prisoners), if there is deception involved, or if it is not possible to obtain informed consent.

At the end of the semester the researchers fill out an **IRB Protocol Completion** form (see appendix) to indicate that the research has been completed. An abstract of the research is to be attached.

The application, approval, and IRB Protocol Completion form are all kept on file in the office of the Chair (AIO) for at least 3 years, according to Federal standards.

Problems and Changes to Research Protocol

If the researcher with an IRB-approved study experiences problems or needs to change part of the research protocol, then the IRB needs to be informed in writing immediately.

The IRB Chair needs to be informed if a researcher needs extended time for the completion of his or her IRB-approved research. Exempt research may be granted an immediate extension.

The IRB has the authority to suspend research or to terminate a research protocol if the protocol is violated and/or the research participants experience any harm.

If a faculty member wants to continue research that has been previously approved, he or she just needs to make the request to the IRB Chair via e-mail

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 on the Limestone campus.
- For a serious infraction, the IRB may recommend expulsion to the Academic Dean or Provost.

In the event that the IRB supports penalizing a student, a letter will be sent from the Chair to the Academic Dean/Provost to the student, his or her advisor, and the student's professor (if the research was in conjunction with a class). 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 Academic Dean/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. IRB Assessment in WEAVE

The IRB will be formally assessed in WEAVE starting in 2016-2017 (under "IRB"). The outcomes and measures will be as follows:

1. Track all research protocols.
    a. Department sponsoring the research?
    b. IRB voting decisions?

2. Track research results
    a. Research presentations?
    b. Problems?

3. Publications
    a. Keep the IRB brochure and Policy Manual updated.
    b. Create and update a training module for students and faculty.
    c. Develop a new training module for students.
    d. Discuss recommendations for formalizing the Limestone University IRB.
    http://www.hhs.gov/ohrp/irbs-and-assurances.html

Limestone College faculty members have access to WEAVE and can view the assessment.

V. Resources and Further Reading

Amdur, R.J. & Bankert, E.A. (2007). Institutional review board member handbook (2nd ed). Boston: Jones & Bartlett Publishers.

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 library has a copy of Protecting Human Subjects (2001), which is the video from the Office of Human Research Protection. The video contains segments of "Evolving Concern", "Balancing Society's Mandates", and "The Belmont Report".

VI. Appendix

Application for conducting research at Limestone University(original version)

Sample Informed Consent Form

IRB Flow Chart

Limestone College

Institutional Review Board

Application to Conduct Research with Human Research Participants

Researchers:

_____

Address_____

Phone_____

Department _____

Class/Professor_____

Title of research project_____

What is the research hypothesis?

_____

How many research participants will be used? How will they be obtained? Will incentives be used?

What is your research methodology? Attach any tests/references to this form.

Describe the research procedure. Attach a copy of the consent form and debriefing statement. How will you protect their rights to NOT participate? How will you protect their right to confidentiality?

Are there any risks at all to the research participants? Describe how they will be protected.
Is any deception involved?

Will the results of the research be reported? Describe how, when, and where this should be accomplished.

If there are changes to this research protocol, please contact the IRB with an update. If the research results are published, please forward the abstract to the IRB.

When do you expect to complete the data collection?

Are there any outside sponsors /grants for your research? If so, explain.

Sample Consent Form

Date_____ Researcher_____

I, _____ (name) give

My consent to participate in the study titled _____

_____.

I understand that I will be asked to_____

_____.

I understand that any risks to my participation involve

_____

_____

.

I understand that my participation is voluntary. My results will be kept Anonymous and confidential. I may at any time withdraw my consent and discontinue participation without any penalty.

I understand that I will be debriefed at the conclusion of the study, and that I will have the opportunity to ask questions.

_____

Research participant

_____

Witness

(Note: Research involving children requires parental consent in addition to the minor's consent. Research involving public school also requires the principal and classroom teacher's consent.)

IRB Flow Chart:
From Application to IRB Approval