IRB Procedure

Proposals seeking participants from vulnerable populations (minors, pregnant women, or prisoners, etc.) must be submitted for review by the 15th of each month by an MSU Faculty or Staff member.

Student Principal Investigators

- The principal investigator prepares the IRB application with the assistance and approval of their faculty mentor.
- Appendices labeled PI first initial last name_appendicies title_first initial last name of mentor_vdate of creation (ex. RKemp_online consent_JBrogan_v08292023)
- CITI certificates labeled First initial last name_CITI_date of completion (RKemp_CITI_08292023)
- All files should be put into one folder titled PI first initial last name_faculty first initial last name (RKemp_JBrogan)
- *The complete application packet is submitted by email to msu.irb@murraystate.edu* by the ***Faculty Mentor only***. Application materials are to be found on the Murray State IRB website.
    - Email Subject: Student IRB Submission, first initial last name
    - Email Body:
        - Principal Investigator
        - Faculty Mentor
        - Department
        - Project title
        - Project period
- The principal investigator and faculty mentor will be notified via e-mail of the identification number and receipt of the IRB application, within 48 business hours.
- The Compliance Coordinator conducts an Initial Review to determine that the IRB application is complete and contains the following:
    - Completed Application
    - CITI Certifications for all researchers
    - The final format for online/electronic tests. Questionnaires, etc.
    - Proposed consent (or assent) forms, including text of oral explanations/scripts
    - Letter (or email) from agency granting permission to use their name
    - Letter (or email) of approval from participating organizations on official letterhead or with official title.
    - Copyrighted tests, questionnaires, etc.… and include evidence of permission to use.
    - All other specially designed or public domain tests. Questionnaires, interview protocols, debriefing, etc.

Faculty IRB Submission

- The principal investigator prepares the IRB application
- Appendices labeled PI first initial last name_appendecie title_vdate of creation (ex. JBrogan_online consent_v08292023)
- CITI certificates labeled First initial last name_CITI_date of completion (RKemp_CITI_08292023)
- All files should be put into one folder titled PI first initial last name_date of submission (JBrogan_08292023)

- *The complete application packet is submitted by email to msu.irb@murraystate.edu*. Application materials are to be found on the Murray State IRB website.
    - Email Subject: Student IRB Submission, first initial last name
    - Email Body:
        - Principal Investigator
        - Department
        - Project title
        - Project period
- The principal investigator and faculty mentor will be notified via e-mail of the identification number and receipt of the IRB application, within 48 business hours.
- The Compliance Coordinator conducts an Initial Review to determine that the IRB application is complete and contains the following:
    - Completed Application
    - CITI Certifications for all researchers
    - The final format for online/electronic tests. Questionnaires, etc.
    - Proposed consent (or assent) forms, including text of oral explanations/scripts
    - Letter (or email) from agency granting permission to use their name
    - Letter (or email) of approval from participating organizations on official letterhead or with official title.
    - Copyrighted tests, questionnaires, etc.… and include evidence of permission to use.
    - All other specially designed or public domain tests. Questionnaires, interview protocols, debriefing, etc.

Incomplete application packets will be returned to the principal investigator, with a memo stating deficiencies. Once corrected, these applications may be resubmitted for review.

- Complete IRB applications will receive an Initial Evaluation by the Compliance Coordinator to determine the content and impact of the project on human subjects. The Compliance Coordinator recommends to an IRB Member one of the following categories:

Exempt from further Review - The Compliance Coordinator provides written reasons for the exemption to the IRB Committee

Expedited Review - the Compliance Coordinator provides written reasons for expedited review to the IRB Chair, Vice Chair, or appointed IRB committee member (only recommended if there is minimal risk to human subjects).

Full Board Review Required - The Human Protections Administrator and Compliance Coordinator provide copies of the application to all members of the IRB for review at the next Human Subjects Review Board meeting.

- The full board meets once per month. If an application requires full board review, the principal investigator will be asked to make a brief verbal presentation of the application at the meeting and to respond to IRB inquiries. A summary of projects approved for exempted or expedited review is reviewed by the full board at the monthly meeting and recorded in the minutes.
- In all cases, the disposition of the IRB application is forwarded to the applicant by the Compliance Manager within two weeks following the decision. Depending upon the type of review required,

and whether or not any revisions must be made by the principal investigator, the decision may take from one day to one month or more.

Special Considerations

- All student-initiated research projects which are conducted outside of the classroom require IRB review.
- All Training Programs, regardless of source of funding (or unfunded), with a research component require IRB review.
- All dissertation or thesis projects using human subjects require IRB review.

Continuing Review

- Within a year following approval, the principal investigator will receive an email from IRBNet.org at 60, 30, and on the day of expiration. The principal investigator should complete the Continuing Review Form as soon as possible and return it to the IRB Office.
- If changes *(other than an extension of time)* need to occur the principal investigator should complete the Continuing Review Form as soon as possible and return it to the IRB Office.
- The IRB may observe the project at any time.

Expedited and Exempt Reviews*:

- Allow 2-3 weeks (business days) for Exempt from further review certifications.
- Allow 2-3 weeks (business days) for Expedited approvals.*
- Allow 2-3 weeks for renewals and amendments to expedite and exempt studies.
- Exempt and expedited complete application packets are reviewed in the order received. (If not complete, your application will not be placed in the queue until the complete packet is received.)

Full Board Review*:

- Allow a minimum of 6-8 weeks for Full Committee approvals of initial submissions and amendments.*
- Allow 4 weeks for Full Committee approval of continuing review submissions.

Completed Protocols

- Following data completion researchers are responsible for completing a protocol closure form
- All protocols will be closed 365 days following their approval if a continuation is not filed and approved.
- Any data collected post-closure will be considered misconduct and require data to be destroyed and a formal complaint to be filed.

Allow extra time during holiday and vacation periods. • Note: The IRB Committee does not convene during Fall Break, Winter Break, Spring Break, or Summer.