Office of Research Compliance

AAMU-IRB Review Process

The AAMU Institutional Review Board (AAMU-IRB) fulfill their goals to protect human research participants and support the design and conduct of sound research by reviewing and approving IRB submissions for new applications, amendments, and continuing reviews.

All projects that meet the definition of research with human subjects (45 CFR 46.102) must be reviewed and approved by an IRB, or receive an exempt determination, **prior** to beginning the research. The IRB staff initially screens submissions to determine the completeness and the appropriate type of review. Submissions may be returned to the study team for changes before the review type is assigned. The review type may be reassessed at any time during the review process. Researchers making submissions to the AAMU-IRB are required to complete the Human Subject Training provided online (CITI Program) at no charge to all AAMU faculty, students and staff. A completion certificate should be submitted as part of the IRB submission package.

Types of IRB Review

The basic types of IRB Review are: Comprehensive, Exempt, and Not Regulated. The type of IRB review and the associated review process (e.g., full board, expedited, limited IRB review) are determined by the:

- Level of risk to research participants
- Type of research being conducted (e.g., an educational intervention, a survey, an ethnographic observation, etc.)
- Sensitivity of the research questions or complexity of the research design
- Involvement of vulnerable populations as research participants
- Use of identifiable information
- Applicability of one or more of the criteria for exempt or expedited review

RESEARCH REQUIRING COMPREHENSIVE IRB REVIEW

The IRB may conduct either an **expedited** or **full board review** for IRB-regulated research proposed in the *Interaction/Intervention* or *Secondary Use* application types to ensure:

1. Risks to the subjects are minimal, and are reasonable in relation to anticipated benefits
2. The subject selection is equitable
3. Privacy and confidentiality are protected
4. Informed consent processes meet **federal** regulatory and AAMU requirements

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Full Board Review

Federal regulations and institutional policy require a review by the IRB Full Board for applications where the research involves **more than minimal risk** to human subjects, does not meet the criteria for one of the categories of expedited review, or has been referred to the committee by an expedited reviewer or the Chair. Regardless of risk level, IRB submission may require full board review when the research involves:

- Vulnerable populations, particularly prisoners
- Sensitive topics, including illegal behaviors which may require an NIH *Certificate of Confidentiality* (CoC) to protect subject data from compelled disclosure
- Research involving genetic/genomic analyses
- A complex research design requiring expertise of multiple board members.

The IRB posts submission deadlines for upcoming IRB meeting dates. If an application is "board ready", meaning that it contains all of the information and materials necessary for the full board to conduct its review, the application will be assigned to the next IRB meeting date, except where the agenda is already full or a reviewer with the necessary expertise is not available for that meeting. IRB staff assign submissions to a primary and secondary IRB reviewer for presentation at the full board meeting. Investigators may be invited to attend the meeting to answer questions from the board. At the conclusion of the meeting, the board votes and issues a determination for the submission.

IRB Full Board Determinations

Approved: the application is approved as submitted. The approval date is the date of the IRB review.

Approved with Contingencies: the application is approved, contingent on submission of specified changes to the protocol, informed consent document(s) and/or other supporting materials. Final approval status is granted when the IRB has reviewed and approved all requested changes. The date "approved with contingencies" determination is deemed the date of approval.

Action Deferred: the IRB needs additional information from the investigator before the IRB can make all of the determinations found at 45 CFR 46.111 necessary to approve the study. The principal investigator must submit the requested additional information before the IRB will consider the application for further review.

Disapproved: the protocol does not provide adequate protection to human participants, and it is unlikely that it can be modified to provide such protection. The IRB notifies the principal investigator of the disapproval in writing, including a statement of the reasons for its decision, and provides the opportunity for the investigator to respond to the IRB in person or in writing.

Tabled: the IRB full board did not have time to review the application at the convened board meeting. The application is placed on the agenda for the next convened meeting.

Expedited Review

Federal regulations (45 CFR 46.110) authorize the use of an expedited review process for:

- **Minimal risk** human research that meets one or more of the OHRP Expedited Review Categories
- Minor ***changes to research*** previously approved by the full board

Applications qualifying for expedited review are assigned to an expediting reviewer, an experienced IRB member appointed to the role by the IRB Chair. The expediting reviewer has the authority to make a determination or to refer a submission for full board review for multiple purposes (e.g., clarification, expertise), including in cases of disapproval. Only the full board has the authority to disapprove a study. Most studies that qualify for the expedited review process do not require annual Continuing Review.

Continued Review: Per federal regulations outlined in 45 CFR 46.109(e) an approved, federally-sponsored human subjects study must be reviewed, ***at least annually***, by the IRB. For this continuing review, the IRB reviews the: Study protocol; Informed consent and other documentation or materials; and any adverse events (AEs) or other reportable events (ORIOs) that occurred during the current approval period.

IRB Expedited Review Determinations

In addition to the *Approved* and *Approved with Contingencies* determinations, reviewer may issue a *Changes Requested* determination, when substantial changes to the application and/or materials are required before the expediting reviewer can approve the study.

EXEMPT RESEARCH REVIEW

Per university policy, investigators must submit an IRB application for determination of exemption before research begins. Applications are routed for exempt review through the *Interaction/Intervention* application or the *Secondary Use* application types. AAMU-IRB recommends using the Brief Protocol for Exempt Research Projects to provide an overview of exempt project or as a data entry guide when completing the IRB application.

Projects that meet the criteria for a federal exemption category *(45 CFR 46.104)* may be granted a **determination of exemption** by the AAMU-IRB. The review determination is limited in scope to the information necessary to determine if the proposed exemption applies. The IRB does not review informed consent documentation or recruitment materials for proposed exempt studies. Exemptions may be granted by the IRB Chair, expedited reviewers, or (in most cases) qualified IRB staff members.

Projects receiving an exempt determination are not subject to the *Continuing Review process*. Amendments are required only if the changes to the project would alter the exemption criteria. An exempt determination does not lessen the researcher's **ethical obligations** to participants as articulated in the Belmont Report or to the codes of conduct for specific disciplines.

NOTE: *Research involving prisoners or certain types of research with children (e.g. surveys, interviews/observations of public behavior where the investigator interacts with the children) does not qualify for exemption.*

Limited IRB Review

The Common Rule provides a **Limited IRB Review** process, which is a required expedited review of recruitment and consent materials as well as plans to maintain participant privacy and data confidentiality for exempt 2 and 3 projects *that collect or use sensitive and identifiable data*. An exempt determination is issued once the expediting reviewer confirms that these protections are acceptable.

NOT REGULATED REVIEW

Not all research-related activities that involve people, or their data are covered by the regulations governing human research. However, investigators may wish to submit a brief Research IRB application for a formal "not regulated" determination for funding or publication purposes. Submission to the IRB is not required for the following activities:

- Case studies
- Class activities
- Journalism/documentary activities
- Oral history
- Quality assurance and quality improvement activities
- Research on organizations
- Research using publicly available data sets.