# IRB Process Synopsis

## Table of Contents

# DOES MY PROJECT REQUIRE IRB REVIEW?

All projects that meet the definition of research with human subjects **(5 CFR 46.102)** must be reviewed and approved by the Morgan State University Institutional Review Board (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. Applications may be returned to the Principal Investigator(s) for changes before the review type is assigned. Under MSU policy, students are not allowed to serve as the Principal Investigator on a human subjects research study.

The MSU Institutional Review Board (IRB) fulfills its functions to protect human research participants and support the design and conduct of ethical research at the University by reviewing and approving IRB applications for new studies, amendments/modifications, and continuing reviews. The review type may be reassessed at any time during the review process.

If you can answer "yes" to the following three (3) questions, you need to submit an IRB protocol for IRB review to: irb.research@morgan.edu.

## 1. Is It Research?

Research is a **systematic investigation** (including research development, testing, and evaluation) designed to develop or contribute to **generalizable knowledge** ~ Federal definition, **45 CFR 46.102**

- *Systematic investigation* is an activity designed to test a hypothesis and to draw conclusions as described in a formal protocol that sets forth an objective and procedures to reach that objective.
    - Activities such as the **practice** of public health, medicine, counseling, or social work are not research.
- *Generalizable knowledge* is information expressed in theories, principles, and statements of relationships that can be widely applied (e.g., by publishing findings or presenting findings at a professional meeting).
    - Studies for internal management purposes (e.g., program evaluation, quality assurance, or quality improvement) are not research because the intent is not to provide generalizable knowledge but to apply findings only to the program or activity.

## 2. Is It Human Subjects Research?

Human subjects research is a project that involves a living individual about whom the investigator (whether student or professional)

(1.) obtains information or bio-specimens through interaction/intervention with the individual, and uses, studies, or analyzes the information or bio-specimens; or

(2.) obtains, uses studies, analyzes, or generates identifiable private information or identifiable bio-specimens. ~ Federal definition **(45 CFR 46.102(e)(1))**

## 3. Is the University Engaged in the Research?

The University is "**engaged**" when the research is conducted by MSU faculty, staff, trainee, or other agent acting under the auspices the University.

# IRB REVIEW TYPES

The basic types of IRB Review are: **Full Board, Expedited, Exempt**. The type of IRB review and the associated review process (e.g., Full Board, Expedited, or Exempt) is 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 or identifiable bio-specimens
- 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 to ensure:

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

## 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 Board by an Expedited Reviewer or the Chairperson. ***Regardless of risk level, IRB 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* to protect subject data from compelled disclosure
- A complex research design requiring the expertise of multiple board members for evaluation
- Research involving genetic/genomic analyses

## IRB Full Board Determinations

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

*Deferred Approval*: the IRB needs additional information from the investigator before the IRB can make all of the determinations found under **45 CFR 46.111** necessary to approve the study. The Principal Investigator(s) must submit the requested additional information before the IRB will consider the application for further review.

In some cases, the protocol may be *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.

*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(s) 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

## IRB Expedited Review Determinations

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 previously approved by the full board

***Only the Full Board has the authority to disapprove a study***.

## 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.

## Exempt Research Review

Per university policy, principal investigators must submit an IRB application for Determination of Exemption before research begins.

Projects that meet the criteria for a federal exemption category **(45 CFR 46.104)** may be granted a **Determination of Exemption** by the 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 Administrator (or designated qualified IRB staff member).

Projects that receive 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.

***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***.

## Exemption Categories

- ***Exemption #1*: Educational Exemption**
- ***Exemption #2*: Surveys, Interviews, Educational Tests, & Observation of Public Behavior**
- ***Exemption #3:* Benign Behavioral Intervention**
- ***Exemption #4*: Secondary Research (Identifiable Private Information / Bio-specimens**
- ***Exemption #5*: Public Benefit / Service Program Research (Federal Demonstration Projects)**
- ***Exemption #6:* Taste/Food Quality Evaluation & Consumer Acceptance**
- ***Exemption #7:* Storage / Maintenance of Identifiable Bio-specimens with Broad Consent**
- ***Exemption #8:* Use of Identifiable Data / Bio-specimens Obtained with Broad Consent**

### Not Regulated Review

Not all research-related activities that involve people, their data, or their bio-specimens are covered by the regulations governing human research. However, investigators may wish to submit an IRB application for a formal "not regulated" determination for funding or publication purposes.

Submission to the IRB is not required for the following activities:

- Oral history
- Research on organizations
- Research using de-identified data or bio-specimens
- Research using publicly available data sets
- Quality assurance and quality improvement activities
- Case studies
- Journalism/documentary activities

## DATA RETENTION

Federal regulations require that research records be retained for at least **3 years** after completion of the study. If a study uses records that fall under HIPAA, records should be retained for **6 years** after the last subject completed the study activity. When University, state, and local policies have more stringent policies on records retention, the investigator must follow the most stringent policy.

The IRB records can be retained securely in hard-copy, electronic, or other media form. They must be accessible for inspection and copying by the IRB and authorized representatives of HHS when necessary.

## IRB AUTHORIZATION AGREEMENTS/RELIANCE AGREEMENTS

The University has regulatory oversight responsibility for human subjects research activities conducted by its researchers. However, the 2018 Common Rule recommends the designation of a single IRB to review a multi-site research study with multiple collaborating domestic sites. Consequently, for such studies MSU uses an IRB Authorization Agreement (IAA), also known as a Reliance Agreement, executed by the collaborating institutions to designate a single IRB as the IRB of record.

The IAA is a formal written agreement that documents respective authorities, roles, responsibilities, and communication between the single IRB serving as the IRB of record reviewing the research, and the collaborating IRB(s) relying on the single IRB. In most cases, an IAA is for a particular study; however, it can be used to cover multiple studies.

Regardless of which IRB is designated as the IRB of record, the MSU researcher must still have the research protocol approved and entered into the MSU IRB database. Before any research activities can begin, the IRB of record must approve the study, and the relying IRB must acknowledge that approval. The MSU researcher is responsible for ensuring that all MSU requirements are met throughout the course of the research activities.