SOP 2.1.1 Types of RDIA/IRB Decisions

General Description:

Research as defined by DHHS regulations at 45 CFR 46.102 is "a systematic investigation designed to develop or contribute to generalizable knowledge." A human subject is defined as "a living individual about whom a researcher gathers data or biospecimens either through interaction or intervention or from whom a researcher obtains personal private information or identifiable biospecimens." Upon receipt of any submission through IRBNet, the IRB staff will determine if the research is human subjects research and, if so, the review level and category. The review levels include: exempt, expedited, and full board. IRB staff will base the determination of review category on study activities, participant population, and risks to participants.

Procedures:

1. When reviewing an IRB submission, the IRB staff will first determine whether or not the proposed research meets the regulatory definition of human subjects research. IRB staff will create a determination letter for proposed research that is not human subjects research. For research that meets the definition of human subjects research, the IRB staff will then determine the level of review in consultation with the IRB Chair as needed.
2. Some research may be exempt from IRB review. There are eight categories of exempt research specified by DHHS. The IRB staff will determine if the proposed research is exempt based on the activities and procedures described in the IRB application. Because of possible conflicts of interest, the Office for Human Research Protections (OHRP) recommends that researchers not make the determination that the proposed research is exempt for themselves. Therefore, at Mason exempt research is reviewed and categorized by the IRB staff. The research must fit into at least one of the eight exempt categories and may not pose any more than minimal risk to study participants to meet this review category.
3. Certain research projects that collect information which is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, may still qualify for exemption so long as a designated IRB member conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. For these projects, IRB staff will ensure IRB review of the necessary details of the project prior to exemption.
4. If the research does not meet the criteria for exempt review, the IRB staff may determine that expedited review is needed. There are nine categories of expedited research specified by DHHS. Expedited research is reviewed by one or more experienced members of the IRB designated by the IRB Chair as eligible to provide expedited reviews. The IRB staff, in consultation with the IRB Chair as needed, will determine which IRB member will review the research based on the following: the member's time on the IRB; his/her experience conducting expedited reviews; and/or his/her level of expertise with the proposed study activities. Expedited research must fit into at least one of the nine expedited categories and may pose no more than minimal risk to study participants.
5. Research that does not meet the criteria for exempt or expedited review and/or poses more than minimal risk to study participants will be reviewed by the full board at a regularly scheduled meeting.

6. An amendment to existing research may change the review level of that study. The IRB staff, in consultation with the IRB Chair as needed, will determine whether or not an amendment changes the review level.

Related Forms, Guidance, and SOPs:

- 2.1.2 Study intake and triage
- 2.5.1 Full board review
- 2.5.2 Expedited and exempt review
- 2.5.3 Non-human subjects research review procedures

Responsibility:

IRB Staff/Research Development, Integrity and Assurance
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	January 21, 2019
Laurie Meamber	IRB Chairperson	January 21, 2019