 <p>MARQUETTE UNIVERSITY Office of Research Compliance</p>	SOP	Title	Date	Page
	IRB-140	Expedited Review	July 2018	1 of 3

1. PURPOSE

1.1. Certain types of research protocols may be eligible for review under expedited review procedures. This policy establishes the criteria and process for Expedited Review.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. MU will use the most recent list of categories of research that may be reviewed by the IRB through an expedited review procedure available from the Office for Human Research Protections, HHS, or any successor office.

3.2. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. If the designated reviewer determines that the research involves more than minimal risk, additional input may be sought by the Chair or other members of the IRB committee prior to being referred for review by the convened IRB.


3.3. The limited IRB review that is required for certain exempt research may be conducted using expedited review procedures.

3.4. The research must involve no more than minimal risk and fit one or more of the categories for expedited review procedures as specified in the regulations (45 C.F.R. § 46.110 and 21 C.F.R. § 56.110).


3.5. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 C.F.R. § 46.102(i)).

3.6. Expedited Review Procedures

3.6.1. Federally funded research activities that meet all applicable criteria set forth by the federal regulations and involve no greater than “minimal risk” may qualify for expedited review from IRB review. Non-federally funded research activities that meet all applicable criteria set forth by the MU IRB may qualify for expedited review from the IRB.

	SOP	Title	Date	Page
	IRB-140	Expedited Review	July 2018	2 of 3

- 3.6.2. Research protocols meeting the criteria for expedited review may be determined by the IRB to pose ethical or other concerns and may be referred to the Chair and or Vice-Chair for guidance and/or referred to the convened IRB.
- 3.6.3. Upon submission of new IRB application by the investigator, IRB staff will enter the submission into the database system. IRB staff will conduct an administrative review of the research proposal to verify completeness, accuracy, and may request revisions, clarifications, or additional documentation.
- 3.6.4. At least one member of the IRB is assigned as a primary reviewer. The IRB Chair designates which experienced members from the IRB are eligible to conduct these reviews. The ORC performs an initial review of all expedited protocol submissions for completeness and to determine an appropriate IRB reviewer based on expertise.
- 3.6.5. All assigned IRB members review the research applications to determine if the research meets the definition of minimal risk and the criteria of one or more of the eligible categories using the IRB checklist.
- 3.6.6. IRB members assigned to review expedited research protocols may request clarification, require modification, or request that one or more additional IRB members also review the protocol. IRB members may request that a protocol be reviewed by the full board, but may not disapprove a research protocol under expedited procedures (45 C.F.R. 46 110(b)).
- 3.6.7. Under expedited review procedures, the determination options are:
1. Approved: Approve as is, no additional changes necessary.
 2. Approved with changes/clarifications. If instructed by the reviewer, the revisions/clarifications may be reviewed by the IRB staff. If PI does not wish to submit the revisions/clarifications, the protocol may be reviewed at a convened IRB.
 3. Request additional IRB member or members to review.
 4. Refer to the IRB Chair or Full Board: for review at a full board meeting of the IRB.
- 3.6.8. The IRB staff communicates the determinations of the IRB via email or in writing to the PI, and in the case of student investigators, also to the student's faculty advisor.

 MARQUETTE UNIVERSITY Office of Research Compliance	SOP	Title	Date	Page
	IRB-140	Expedited Review	July 2018	3 of 3

- 3.7. The PI may be required to make revisions, clarifications, or other requests before IRB approval is granted.
- 3.8. If a research protocol is given expedited approval, the approval is communicated to the investigator and includes the applicable category(ies) justifying the approval.
- 3.9. Once an expedited approval is granted, proposed changes to a research protocol must be submitted to the IRB for review prior to the change being carried out unless the changes to the research protocol initiated by the investigator prior to obtaining IRB approval is to eliminate apparent immediate hazards to subjects
- 3.10. An approval of research by expedited procedures is complete by itself and does not require any ratification by the convened IRB. However, the IRB does have the opportunity and the authority to raise questions about any research that was previously approved under expedited procedures.