		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	Expedited Review of Human Subject Research	Effective: 1/7/2019
		Approved: 2/19/2018
Policy ID		Last Revised: 12/4/2018
IRB-SOP-303		Expiration: n/a

PURPOSE

This procedure establishes the process for conducting expedited review, including the criteria and process for determining eligibility for expedited review.

SCOPE

This procedure applies to non-exempt human subject research conducted at Ascension Wisconsin and all researchers, study teams and RI&P staff.

DEFINITIONS

Expedited Review An IRB review procedure through which certain kinds of research, and changes to research, may be reviewed and approved without convening a meeting of the full IRB

Minimal Risk The probability and magnitude of harm or discomfort anticipated in the research that 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.

- Prisoners: Minimal risk is defined by federal regulation as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of a healthy person.
- Research involving the Department of Defense (funding, subjects, facilities, resources): Per DOD regulations, the phrase "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" must not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

Minor Change A minor change is one that:

- Does not meaningfully increase risk, or meaningfully decreases benefit, when considered in light of any changes proposed to mitigate risk and improve benefit;
- Does not meaningfully decrease scientific merit; and
- Does not adversely affect the assessment of the research with respect to the regulatory criteria for approval (45 CFR 46.111).

PROCESS

1. **Eligibility for Expedited Review**
   - **1.1.** Researchers are expected to use available IRB forms and guidance and to provide sufficient information to RI&P so that specific required determinations can be made and it can be determined, as appropriate, the kind of review is required and whether the applicable criteria

for IRB approval have been met. This may be achieved by submitting the IRB application and study materials as described in SOP: Materials for IRB Review (SOP-105).

1.1. Research is eligible for expedited review if it meets criteria specified in federal regulations and/or SOP: Review Standards for Research Not Covered by Federalwide Assurance- Flexibility Policy and Procedures (SOP-208). Activities that do not meet these criteria must be reviewed by the full IRB at a convened meeting.

1.1.1. Newly submitted research: The proposed research must be no more than minimal risk, as defined above, and qualify for one or more categories of research eligible for expedited review referenced in 45 CFR 46.110, 21 CFR 56.110 and 46 FR 8392

1.1.2. Continuing review of research previously approved by the convened IRB: The research must has met the applicability criteria set forth in 45 CFR 46.110(a) (categories (8) or (9)) and 45 CFR 46.110(b).

1.1.2.1. Category 8(c) may be used for continuing review of research beginning at the time when the researcher first identifies the remaining activities as consisting solely of data analysis.

1.1.2.2. Category (9) may be used for continuing review of research at any time after initial review and under the following conditions:

- The research is not conducted under an IND or IDE; and
- Expedited review categories 2 through 8 do not apply; and
- The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk (during initial review or later); and
- No additional risks have been identified.

1.1.3. Minor changes to previously approved research: Must be minor changes, as described above, which do not affect the rights and welfare of subjects, and in which all added procedures fall into categories of research that can be reviewed using the expedited procedure.

1.1.3.1. The IRB may require specific changes or clarifications to secure IRB approval; these do not require expedited Review. No other changes may be made to the study prior to final approval. Any additional changes must be submitted as an amendment after final approval is issued.

2. Expedited Review Process

2.1. Research Integrity and Protection (RI&P) staff are responsible for determining whether an item is eligible for expedited review. They may consult with other senior staff and management, IRB chairs or members as needed, particularly with respect to assessments of risks and benefits. If there is disagreement, the item will be reviewed by the full convened IRB.

2.1.1. If expedited review was requested, but research is not eligible for expedited review, staff assign the appropriate level of review and notify the Investigator.

2.2. Staff assigns the Designated Reviewer in Mentor, as described in SOP: IRB Pre-Review (SOP-202).

2.2.1. Experienced RI&P staff who are also members of an IRB have the expertise and knowledge to perform a majority of the expedited reviews. If an expedited review requires other expertise staff assigns the review to be completed by the IRB Chair and/or a Designated Reviewer with appropriate expertise.

2.3. The Designated Reviewer completes the applicable reviewer checklist in Mentor and may reference WORKSHEET: Expedited Review (WRK-1101)

2.3.1. The expedited review process uses the same criteria for approval as reviews conducted by a full convened IRB. For example, the standard regulatory requirements for informed consent (or its waiver or alteration) apply whether the review is performed by the expedited process or by the full convened IRB.

2.3.2. The reviewer checklist documents the review including the following:

- Determination that the criteria for approval are met

Frequency of review. The reviewer may consider factors such as complexity of the study, related risks, vulnerability of population, investigator experience, etc. when making this determination.

- If there is a need to verify from someone other than the Investigator that no material changes have occurred. The reviewer may consider factors such as the complexity of the study, previous compliance issues with the PI/study team, etc. when making this determination.
- Any minor or prescriptive changes or requirements (revisions required to secure approval).

2.3.3. An expedited reviewer may exercise all of the authority of the full IRB Committee except disapproval, suspension or termination of the research.

2.3.4. If the reviewer identifies changes to the research that would allow the research to qualify for expedited review, and the investigator cannot agree on the changes, the expedited reviewer obtains consultation. If agreement can still not be reached, the item will be reviewed by the full IRB.

2.4. The Investigator is notified through Mentor and informed of the nature of the review (expedited or full IRB) in the IRB approval letter or IRB review letter.

3. Notification of the IRB

IRB members are informed of completed expedited reviews for any research activity (i.e. new submissions, modification, continuing review) through an Expedited Item report attached to the IRB meeting agenda/minutes.

REFERENCES

- 21 CFR §56.110(b)
- 45 CFR §46.110(b)
- SOP: IRB Pre-Review (SOP-202)
- SOP: Review Standards for Research Not Covered by Federalwide Assurance- Flexibility Policy and Procedures (SOP-208)
- WORKSHEET: Expedited Review (WRK-1101)

RELATED MATERIAL

- SOP: Materials for IRB Review (SOP-105)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	2/13/2018	New- Initial Integration Update	J. Blundon
02	12/4/2018	2.3 updated to explicitly state the checklist is documentation of the determination that approval criteria are met, frequency	J. Blundon-Kirchen