TITLE: EXPEDITED REVIEW	SOP NO.: IRB 402
EFFECTIVE DATE: 10-6-2025	REVISION NO.: 01

1. **PURPOSE**

1.1. The UMBC Institutional Review Board (IRB) uses an expedited procedure to review human subject research, when eligible. This policy describes when the expedited review procedure may be used and the procedures for expedited review.

1.2. SCOPE: This policy applies to human subject research conducted at UMBC.

2. **DEFINITIONS**

2.1. ***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.

2.2. In this policy, a ***minor modification*** does not involve greater than minimal risk to the participant and it does not have a significant impact on the (1) risk level of the study, (2) risk-to-benefit ratio of the study, or (3) a participant's willingness to participate in the study.

2.3. A ***substantive modification*** is any modification that cannot be considered a minor modification as defined in this policy.

3. **POLICY**

Expedited review procedures consist of a review of research involving human subjects by an experienced reviewer designated by the IRB Chair (or designated HRPI staff) from among IRB members (see IRB SOP 202: Duties of IRB Members for a full

description of the procedure used to designate expedited reviewers). In some cases, the IRB Chair or IRB Vice-Chair may provide the primary expedited review of a protocol. In this policy, the IRB Chair's designee refers to an IRB Vice-Chair or a designated expedited reviewer. For day-to-day functions, reviewer protocol assignments are delegated to a HRPI staff member (i.e., Senior Compliance Specialist) who will match protocols to expedited reviewers with relevant experience and expertise.

The designated reviewer may exercise all the authorities of the IRB, except that they may not table or disapprove the research. A research proposal may be tabled or disapproved only after review by the convened IRB.

The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register (FR) Volume 63, No 216 and (3) the research is not classified. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.

HRPI staff and IRB members follow the Office for Human Research Protections (OHRP) guidance concerning expedited review procedures of a continuing review application. The IRB is permitted to use expedited review for initial and continuing review of research that involves solely one or more of the activities published at 63 FR 60364-60367. If research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review except in limited circumstances as described in expedited categories (8) and (9) of 63 FR 60364-60367.

Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review if:

- The study was approved on or after the implementation of the Final Rule (January 21, 2019).
- The study was transitioned to the Final Rule.

The designated reviewer may use the expedited review procedure to review minor modifications to previously approved research during the period for which approval is authorized if the following conditions are met:

1. The proposed modifications are administrative changes or similar minor changes; or

2. The research was previously determined to be eligible for expedited review under FR categories 1-7 and/or 9, and the proposed modifications do not change the study's expedited determination; or

3. The research was previously determined to be exempt and the proposed modifications do not change the study's exempt status.

Any modification that possibly entails more than a minimal risk to the participants must be reviewed by the full IRB at a convened meeting.

The designated reviewer may use the expedited review procedure to review amendments proposing changes which have been requested by a convened board. In such cases, changes must be stipulated by the convened board and no additional changes may be added to the amendment that would require convened board review.

When the expedited review procedure is used, all IRB members shall be informed of actions taken by the IRB at each convened meeting. A report is generated by way of the UMBC Kuali Protocols system and made available to all voting members of the IRB for their review. This report is included with the IRB agenda or minutes within Kuali, for the respective meeting event.

4. PROCEDURES

4.1. Procedures for Expedited Review

4.1.1. The HRPI staff member conducts an administrative review of the new study, continuing review, or amendment application using the IRB internal checklist within Kuali. The HRPI staff member determines whether the application may qualify for expedited review using the internal checklist. The internal checklist also serves as documentation of the determination. Please see IRB SOP 302: Administrative Review and Distribution of Materials, for the full description of the procedure for administrative review.

4.1.2. The designated reviewer is assigned as an expedited reviewer. Assigned expedited reviewers perform an in-depth review of pertinent documentation and materials submitted by the investigator (see IRB SOP 301: Research Submission Requirements) and HRPI staff.

- For new study and continuing review applications, the assigned expedited reviewer completes a board reviewer checklist documenting whether the application meets one or more of the expedited categories and whether the study meets the criteria for IRB approval. The reviewer documents the applicable expedited category.

- For amendment applications, the assigned expedited reviewer completes a board reviewer checklist documenting whether the amendment to the previously approved research is eligible for expedited review and that the modification involves no more than minimal risk to participants. Amendment applications requesting minor changes to a protocol may also be administratively reviewed and approved by HRPI staff.

4.1.3. If the expedited reviewer determines the application does not qualify for an expedited review, the reviewer notifies the HRPI staff, who will assign the study for the next available convened IRB meeting.

4.1.4. If the expedited reviewer recommends that the study be tabled or disapproved, the reviewer notifies the HRPI staff, who will move the item to the agenda for discussion at a convened IRB meeting. The research may only be tabled or disapproved by the convened IRB.

4.1.5. If the expedited reviewer determines that the criteria for approval of the application have been met, the reviewer may approve the application.