



<b>TITLE: ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS</b>	<b>SOP NO.: IRB 302</b>
<b>EFFECTIVE DATE: 3/24/2025</b>	<b>REVISION NO.: 01</b>

## **1. PURPOSE**

1.1. The efficiency and effectiveness of the UMBC Institutional Review Board (IRB) must be supported by administrative procedures that ensure that UMBC IRB members have adequate time for thorough assessment of each proposed study, and the documentation received is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

1.2. SCOPE: This SOP applies to the UMBC IRB and IRB Staff.

## **2. DEFINITIONS**

2.1. IRB – Institutional Review Board

2.2. ORPC – Office of Research Protection and Compliance

2.3. PI – Principal Investigator. Typically the lead researcher responsible for submitting an IRB protocol application and communicating on its behalf. At UMBC, an IRB PI may have a faculty, staff, graduate student or undergraduate student affiliation. Student PIs are required to include a faculty advisor as personnel on their IRB protocol.

2.4. IRB Admin. – IRB administrators are in staff positions within the ORPC and include IRB compliance specialists, senior compliance specialists, managers, and (in some cases) the Director(s) of ORPC.



## POLICY

An administrative pre-review occurs with new study, continuing review, and amendment applications by an IRB staff member using checklists in the UMBC Quali system. Checklists help IRB staff determine if sufficient information has been provided for IRB review. An IRB staff member is assigned as the administrative reviewer based upon the type of application (i.e., new study application, continuing review, or amendment, etc.) and an initial assessment of the level of review the application is likely to receive (e.g., full board, expedited review, etc.).

## PROCEDURES

### 1. Administrative Review

The assigned administrative reviewer may request revisions of the investigator(s) (i.e., PI, etc.) to ensure sufficient information for the IRB review.

#### 1.1 New Studies

Upon receipt of new study applications, the IRB manager (or designated IRB Admin.) assigns an administrative reviewer. The assigned administrative reviewer makes a primary risk assessment after their pre-review. Based on the primary risk assessment, the administrative reviewer proceeds with the appropriate action as described below.

Primary Risk Assessment	Review Requirements
Non-Research/Non-Human Subject	Review and determination completed by the IRB Chair, as outlined in IRB SOP 401a: Non-Human Subjects Research.



Research	
Exempt	Administrative review by IRB Admin. and determination completed by the IRB Chair or Vice Chair (who must be an IRB member) as outlined in IRB SOP 401b: Research Activities Exempt from IRB Review.
Minimal (Expedited)	<p>Assigned to a primary IRB reviewer for expedited review (see IRB SOP 403: Initial Review – Criteria for IRB Approval; IRB SOP 402: Expedited Review). Secondary reviewers are assigned at the discretion of the IRB administrator or at the request of the primary reviewer. The assigned IRB Admin. may complete their administrative review concurrently.</p> <p>Student IRB members may be assigned a secondary faculty reviewer as a mentor when completing Expedited Review.</p>
Greater than Minimal Risk (Full Board)	<p>Assigned to primary and secondary reviewers for convened board review (see IRB SOP 403: Initial Review – Criteria for IRB Review). The assigned IRB Admin. may complete their administrative review concurrently.</p> <p>The Primary reviewer will be assigned as the Presenting member during the respective convened committee meeting.</p>

## 1.2 Continuing Reviews



An IRB administrator (Admin.) is assigned to complete the administrative pre-review for continuing review applications. Priority for assigning administrative reviewer is the staff member who previously worked on the protocol. If the prior IRB Admin. is unavailable for timely review, then another IRB Admin. may be assigned. The IRB Admin. proceeds with the appropriate action based upon the determined risk assessment and the current status of the study. 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](#). Protocols that are determined as Exempt from review do not receive continued review.

<b>Determined Risk Assessment</b>	<b>Review Requirements</b>
Minimal (Expedited)	Unless determined otherwise, continuing review is not required for a study eligible for expedited review if the study was approved on or after the implementation of the 2018 Common Rule (January 21, 2019), or the study was transitioned to the Common Rule (see IRB SOP 404: Continuing Review). If continued Expedited Review is appropriate it is assigned to IRB Chair review and approval (see IRB SOP 402: Expedited Review). Otherwise, the assigned IRB Admin. may review and administratively approve protocols with unremarkable continuation request forms.
Greater than Minimal Risk (Full Board)	Assigned to primary reviewer for convened board review (IRB SOP 404: Continuing Review) unless eligible for expedited review. If eligible for expedited review (see IRB SOP 402: Expedited Review), assigned to IRB Chair or a designated expedited reviewer for review.



### 1.3 Amendments

An IRB administrator (Admin.) is assigned to complete the administrative pre-review for continuing review applications. Priority for assigning administrative reviewer is the staff member who previously worked on the protocol. If the prior IRB Admin. is unavailable for timely review, then another IRB Admin. may be assigned. The IRB Admin. proceeds with the appropriate action based upon whether the amendment proposes minor changes and involves no more than minimal risk to the participant. Amendments to exempt studies will be reviewed to determine whether the changes alter the initial exempt determination.

Amendment Type	Review Requirements
Amendments that alter exempt eligibility	Substantial changes which alter exempt status will be reviewed using initial review procedures.
Amendments proposing minor administrative changes and involve <i>no additional risk</i> to participants	Assigned to an IRB Admin. for review and approval.
Amendments proposing changes which have been requested by a convened board.	Assigned to a designated expedited reviewer for review. Convened board discussion is not required for these submissions.
Amendments proposing minor changes and involves <i>no more than minimal risks</i> to the	Assigned to designated expedited reviewer or IRB Chair for review. Convened board discussion is not required for these submissions.



participant	
Amendments proposing substantial changes or may represent a <i>greater than minimal risk</i> to the participant	Assigned to primary reviewer for convened board Review (see IRB SOP 405: Review of Amendments to Research Studies) regardless of the determined risk assessment of the study (i.e., minimal, greater than minimal).

## 2. Assignment of Reviewers and Preparation of an Agenda

2.1 The assignment of designated expedited reviewers, primary reviewers and secondary reviewers is the responsibility of the IRB administrator. The IRB administrator makes assignments informed by the IRB membership roster. The IRB administrator assigns reviewers with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol. Based upon the research proposal, the IRB administrator assigns reviewers who are knowledgeable about or experienced in working with vulnerable participants, if necessary. If the IRB administrator finds there is no IRB member with appropriate scientific and scholarly expertise to conduct an in-depth review, IRB administrator will consult with the IRB manager and IRB Chair for assistance in obtaining consultation (i.e. ancillary review, etc.) or whether deferral to another IRB meeting will be required.

2.2 The assignment of designated expedited reviewers is made concurrently with the assignment of convened board reviewers (see 2.3) or upon completion of the pre-review. Applications approved using expedited procedures are available to all board members in Kuali on the agenda and minutes.

2.3 The assignment of convened board reviewers (primary and secondary reviewers) is made at least 30 calendar days in advance of the convened board meeting. If the assignment is made less than 30 calendar days before



a convened meeting, extenuating circumstances must exist, and the assignment must be made no less than five working days prior to the meeting. Reviewers receive an e-mail automatically generated by Kuali stating the assignment.

- 2.4 Kuali creates an electronic agenda for convened meetings. The assigned IRB administrator is responsible for the accuracy of the agenda and for completing any other components of the agenda in Kuali. A copy of the agenda and attached materials is maintained with the meeting minutes within Kuali.
- 2.5 Complete applications as described in IRB SOP 301: Research Submission Requirements are available to all IRB members, via the electronic agenda beginning at least seven calendar days in advance of the convened meeting. Complete applications are made available to any alternate members attending the meeting in place of a regular member. Ad hoc consultant reviewers receive copies of material that pertain to their requested input.