



TITLE: IRB ANCILLARY REVIEWERS	SOP NO.: IRB 306
EFFECTIVE DATE: 4/2/2025	REVISION NO.: 01

1. PURPOSE

- 1.1. The UMBC Institutional Review Board (IRB) is composed of members in accordance with federal regulations. If the UMBC IRB lacks specific expertise among panel members, ancillary reviewers may be utilized.
- 1.2. SCOPE: This SOP applies to the UMBC IRB.

2. DEFINITIONS

- 2.1. IRB Admin. – IRB administrators are in staff positions within the Office of Research Protections & Compliance (ORPC) and include IRB compliance specialists, senior compliance specialists, managers, and (in some cases) the Director(s) of ORPC.
- 2.2. IRB member / Board member – A committee member serving on the IRB (as described in IRB SOP 201: IRB Membership Requirement and Responsibilities) that may be assigned as a Primary or Secondary reviewer of expedited or full board protocol applications.
- 2.3. Ancillary Reviewer – Individuals with competence in special areas who are invited to assist in the review of issues which require expertise beyond or in addition to that of available IRB panel members. These ad hoc consultants are not voting members of the Institutional Review Board.

POLICY



The UMBC IRB, at its discretion, may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond, or in addition to, that of available IRB panel members. Ancillary reviewers are not voting members of the IRB. These ad hoc consultants are subject to the IRB's policy regarding conflicts of interest and confidentiality (see IRB SOP 304: Convened IRB Meeting Administration). Ancillary reviewers may be requested regardless of the field of research being conducted.

PROCEDURES

1. Obtaining Additional Expertise

- 1.1** It is the responsibility of the primary reviewer to make the determination that a consultation for additional expertise is needed beyond the expertise available to the board. The primary reviewer contacts the secondary reviewer (if applicable) to notify him/her of the needed expertise and notifies the IRB staff or IRB Chair in a timely manner (i.e., before the convened meeting, if possible).
- 1.2** The primary reviewer may contact IRB staff for assistance in obtaining an ancillary reviewer. The IRB staff may contact department chairs of the appropriate discipline for references of qualified individuals. This will preferably be handled before the study is reviewed at a convened board meeting to allow for dissemination of any applicable information and/or comments from the ancillary reviewer.
- 1.3** If additional expertise is requested during the convened board review of a study, discussion will be deferred until an ancillary reviewer with additional expertise can provide more information. The study will be reviewed at the next available board meeting.



- 1.4** If there is no member with appropriate scientific and scholarly expertise to provide an in-depth review of a protocol and an ancillary reviewer is not available, the protocol must be deferred to another IRB meeting where the appropriate consultation or expertise is available for in-depth review of a protocol.
- 1.5** The primary or designated reviewer of a protocol subject to Expedited review, is similarly responsible for making the determination that a consultation for additional expertise is needed beyond the expertise available to the board. The primary expedited reviewer may first check with IRB Admin. whether another IRB member possesses the needed expertise. If available, that additional IRB member may be assigned to provide secondary expedited review. If there is not another IRB member available to provide the needed expertise, the primary expedited reviewer will work with the IRB Chair and IRB Admin. to identify an ancillary reviewer, as outlined in this SOP.

2. Provision of Materials

- 2.1** Ancillary reviewers are provided with relevant printed materials (either hard copy or electronic format) from the UMBC Kuali system, submitted by the Investigator and any other materials requested by the IRB (see IRB SOP 301: Research Submission Requirements). If the ancillary reviewer is not affiliated with UMBC, they will be issued a sponsored account and designated as an ancillary reviewer in Kuali. Ancillary reviewers must review the materials and provide the IRB with a written assessment and evaluation of a risk-benefit ratio, any ethical concerns, identify any additional safety concerns or procedures which may pose serious harm to subjects, and respond to other specific requests made by the IRB. This written assessment is made available to IRB members via Kuali and becomes part of the permanent electronic record. The IRB Admin. attaches the written assessment to the appropriate study for accessibility and may summarize the ancillary reviewer's report in the minutes at a convened board meeting.



- 2.2** In the case of Expedited review, IRB Admin. will attach the ancillary reviewer's written assessment as one or more action items within the Kuali protocol application. IRB Admin. will activate these additional, anonymous-appearing action items so that they are visible to the Investigator when the protocol is returned with Revisions Required via Kuali.