

<b>Primary/Secondary Reviewer System</b>	Effective Date	
	Revision Date	11.1.19

**1.0 Purpose:**

The purpose of this Standard Operating Practice (SOP) is to establish guidelines for the ECU University & Medical Center Institutional Review Board (UMCIRB) when utilizing a primary and secondary reviewer system in proposed and ongoing human research activities.

**2.0 Reviews Affected:**

All human research submissions for consideration by the convened UMCIRB committee or the IRB Chairperson (or designee).

**3.0 SOP:**

All proposed or on-going human research activities requiring review by the convened UMCIRB will receive preliminary review by an IRB member(s) with the appropriate experience and/or expertise who serves as a Primary or Secondary Reviewer during the IRB deliberations. The IRB Chairperson (or designee) will serve as the Primary Reviewer for all proposed research submitted for exempt certification and all proposed or on-going human research activities that qualify for expedited review, including Continuing Review Reports, Amendment Requests, Reportable Events, and Final Reports.

**4.0 Definitions:**

4.1 **Initial Review:** The first IRB review of human research activities by the convened full board or expedited review procedures.

4.2 **Continuation Review:** Review of on-going, previously approved human research activities; conducted by a primary reviewer.

4.3 **Amendment Request:** Request to revise on-going, currently approved human research activities; conducted by a primary reviewer.

4.4 **Deviation Reports:** Reports that describe how IRB approved processes, procedures, interventions, interactions, data collection methods or actual data collected have been changed without prior IRB review and approval; conducted by a primary reviewer.

4.5 **Unanticipated problems involving risks to participants or others:** Reported events for currently or previously approved research that are unexpected, related or possibly related to the research and suggest that the research places participants or others at greater risk of harm than previously known or recognized; requires convened IRB review with presentation by a primary reviewer.

4.6 **Final Report:** activity within the electronic IRB Submission system that creates an application to close a study; conducted by a primary reviewer.

4.7 **Primary / Secondary Reviewers:** IRB members assigned to review research materials for which they have specialized knowledge and/or are within their areas of expertise, and if requires full review, leads IRB deliberations.

**5.0 Responsibilities**

5.1 **Authority of the IRB Chairperson (or designee) when serving as primary reviewer:** The IRB Chairperson (or designee) when serving as primary reviewer for expedited or exempt submissions has the authority to approve, require clarifications/modifications to expedited submissions, or request additional information to clarify whether an exempt proposal meets the federal criteria for exemption certification. The Chairperson does not have the authority to disapprove proposed or expedited submissions but must refer these for consideration by the convened UMCIRB committee.

5.2 **Authority of Primary and Secondary Reviewers at convened UMCIRB committee meetings:**

- 5.2.1 Have the authority to make recommendations to the full convened UMCIRB.
  - 5.2.1.1 These recommendations can be accepted as presented, modified, or rejected by a motion and passed by a majority.
- 5.2.2 Have the authority to vote on the final determinations of those recommendations.

5.3 **Ad Hoc and Continuing Consultants:** Ad Hoc and Continuing Consultants' roles are similar to Primary Reviewers with the same authority to make recommendations. However, consultants do not have the authority to vote on the final determinations of those recommendations.

**Revision History:**

Date	Change	Reference Section(s)
10.2.2014	Reformatted from manual	All
11.1.19	Added reference to review of Final Reports; clarification of IRB name	3.0; 4.6; throughout