POLICY

1. Purpose
Describe the institutional committees that review research activities, in addition to RSRB review.

2. Scope
This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester (UR) that requires additional review by institutional ancillary committees.

“RSRB approval” in this policy refers to RSB approval as the Reviewing IRB or the RSRB completing institutional review when the RSRB is the Relying IRB, as applicable.

3. Description of Institutional Ancillary Committees

Ancillary Review and Approval Required Before RSRB Review

3.1. Cancer Center Peer Review Committee (PRC): The PRC reviews and approves hematology/oncology related studies proposed at UR and its affiliates, including studies that plan to enroll individuals with cancer or studies that plan to review Cancer Center patient health information. Documentation of PRC approval is required for initial submissions before RSRB review begins. PRC review and acknowledgement is also obtained for each amendment prior to RSRB review. Contact the Clinical Trials Office at (585) 275-5345 for further information regarding the protocol review process.

3.2. Obstetrical Research Committee (ORC): The ORC reviews research involving pregnant to post-partum women. ORC approval is required before RSRB review will begin.

3.3. Neonatal Clinical Trials Group (NCTG): The NCTG reviews research involving any planned study procedures on hospitalized newborns. This includes research for which pregnant women have given consent prenatally for research involving their newborn. NCTG approval is required before RSRB review will begin. Contact the NCTG coordinator (585-275-1521) to obtain the necessary submission documents. Include the completed materials with the RSRB application at the time of initial submission.

Ancillary Review Occurs Simultaneously with RSRB Review

3.4. Emergency Medicine Research Committee (EMRC): Research that involves Emergency Medicine faculty, residents, fellows, or staff, or research that involves enrollment of emergency department patients, must be reviewed for initial approval by the EMRC.
RSRB review and EMRC review may occur simultaneously for initial submissions; however, EMRC approval is required before RSRB approval will be granted. EMRC review and acknowledgement is also obtained for each amendment prior to RSRB review. If the research continues beyond a year, the PI is responsible for submitting a request for EMRC re-approval annually. EMRC re-approval is required in order for the RSRB to grant re-approval. Refer to the Emergency Medicine Research website for more information regarding the protocol approval process.

3.5. Institutional Biosafety Committee (IBC): The IBC is required to review and approve research involving the introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.) into human subjects, cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects, and/or the introduction of genetically engineered micro-organisms into human subjects (including live vaccines if they are experimental in nature and/or not FDA approved for use in the specific human study population). Additionally, the IBC reviews and approves all research involving biohazardous organisms or materials handled at Biosafety Level 2 or higher, which includes the shipping of, analysis of, or experimentation with human specimens in any UR lab that is not accredited within the College of American Pathologists (CAP) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). RSRB review and IBC review may occur simultaneously; however, IBC approval is required before RSRB approval will be granted. Refer to the IBC website for more information regarding types of research that must be registered with IBC and the protocol approval process.

3.6. Surgical Pathology: Receiving or obtaining fresh tissue, banked tissue, or archived tissue blocks and slides for research purposes from Surgical Pathology requires a request for human tissue. Surgical Pathology will review and approve the request included in the RSRB Online Submission System (ROSS) application before RSRB approval will be granted.

3.7. Human Use of Radiation Committee (HURC), which includes the Radioactive Drug Research Committee (RDRC): Radioisotopes or radiation-generating devices used for research purposes require review and approval by HURC. RSRB review and HURC review may occur simultaneously; however, HURC approval is required before RSRB approval will be granted. HURC review is obtained annually. Refer to the HURC website for more information regarding the protocol approval process.

3.8. Rochester Center for Brain Imaging (RCBI): For any research involving activities that require access to the RCBI, refer to the RCBI Research website for more information regarding the protocol approval process. RSRB review and RCBI review may occur...
simultaneously; however, RCBI approval is required before RSRB approval will be granted.

**Ancillary Review and Approval Required After RSRB Review**

3.9. Clinical Research Center (CRC): The CRC reviews and approves research procedures taking place on the CRC or using any resources of the CRC. The CRC reviews the research after RSRB or Relying IRB approval has been obtained. Refer to the CRC website for more information regarding the protocol approval process.

3.10. Highland Hospital Administrative Research Review Committee (ARRC): For all research conducted at Highland Hospital, the ARRC must review and approve the study before enrolling subjects. ARRC will review the research once RSRB approval has been obtained. Refer to the Highland Hospital Policy 4.20 Participation of Human Subjects in Research for further information about the research process and requirements.

**4. Responsibilities**

4.1. The Investigator is responsible for determining which ancillary committee(s) are relevant to the research submitted to the RSRB.

4.2. The RSRB is responsible for ensuring any required ancillary committee approval(s) are obtained prior to granting RSRB approval.

**5. Requirements**

5.1. Investigators will indicate in the ROSS application whether the research requires review by any of the institutional ancillary review committees.

5.1.1. The RSRB will review the ancillary committees selected by the Investigator and may require changes based upon the research.

5.2. Ancillary Committees will include documentation of their committee approvals in the ROSS application before RSRB approval is granted.

5.2.1. When applicable, ROSS will automatically block RSRB approval of studies lacking documentation of review and approval by a required ancillary committee.

5.2.2. The Investigator must ensure that all applicable ancillary committee approvals are in place prior to enrolling subjects.
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Appendices:
None

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04/2017: Sect 3 updates to reflect current practice; editorial and administrative changes

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Approved By:

[Signatures]

[Signature]
Director, OHSP

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Director, RSRB

4/27/2017  Date

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