POLICY

1. Purpose
Describe the institutional committees that review research activities, in addition to RSRB review, including those who must approve the research prior to RSRB approval.

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.

3. Description of Institutional Ancillary Committees

3.1. Cancer Center Clinical Trials Office (CTO): The CTO reviews and approves hematology/oncology related studies proposed at UR and its affiliates and those studies that plan to enroll individuals with cancer. Documentation of CTO approval is required before RSRB review begins. CTO review is obtained for each amendment and annually. Contact the Clinical Trials Office at (585) 275-5345 for further information regarding the protocol review process.

3.2. Clinical Research Center (CRC): The CRC reviews and approves research that is conducted at or uses any resources of the CRC. The CRC reviews the research after RSRB (or central IRB) approval has been obtained. Refer to the CRC website for more information regarding the protocol approval process.

3.3. Perinatal Research Committee (PRC): The PRC reviews research involving pregnant to post-partum women, neonates, or infants. RSRB review and PRC review occur simultaneously; however, PRC approval is required before RSRB review will begin. Refer to the PCRO website for more information regarding the protocol approval process.

3.4. Emergency Medicine Research Committee (EMRC): Research that involves recruitment activities in the emergency department or includes emergency department patients must be approved by the EMRC. RSRB review and EMRC review may occur simultaneously; however, EMRC approval is required before RSRB approval will be granted. EMRC review is obtained annually. 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 recombinant DNA or gene transfer vectors (including viral vectors) into human subjects; introduction of genetically engineered micro-organisms or...
infectious agents into human subjects (including live vaccines if they are experimental in nature or not FDA approved for use in the specific human study population); or involving, at minimum, agents of moderate potential hazard to personnel and the environment (Biosafety level 2 agents) which includes the analysis of, or experimentation with, sera, blood products, or other specimens derived from humans 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: Research using fresh tissue, banked tissue, or archived tissue blocks and slides must submit a request for human tissue through the clinical laboratory services. Surgical Pathology will review the research once RSRB approval has been obtained. Refer to the Clinical Laboratory Services “For Researchers” website for more information and forms.

3.7. Human Use of Radiation Committee (HURC): 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.

3.9. 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. Contact the Research Coordinator (char_smith@urmc.rochester.edu) for further information regarding the protocol review process.

4. Responsibilities

4.1. The Investigator is responsible for determining which ancillary committee approvals must be obtained to conduct the research activities submitted to the RSRB.
4.2. The RSRB is responsible for ensuring any ancillary committee approvals required prior to RSRB approval have been obtained.

5. Requirements

5.1. Investigators will indicate in the RSRB Online Submission System (ROSS) application whether the research requires review by any of the institutional review committees, and, if applicable, will indicate which ancillary committee review(s) are necessary.

5.1.1. The RSRB will review the ancillary committees selected by the Investigator and will either concur with the selections or require changes based upon the research and the research procedures.

5.2. Research that requires ancillary committee approval must include documentation in the ROSS application prior to RSRB approval being granted, as applicable.

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. For ancillary committee approvals that may occur after RSRB approval has been granted, the Investigator must ensure that all applicable ancillary committee approvals are in place prior to starting any research activities.
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None

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Not Applicable

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