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 RSRB 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

(For current contact information, see the Guideline for Ancillary Committee Contacts.)

Ancillary Review and Approval Required Before RSRB Review

3.1. *Wilmot Cancer Institute Protocol Review and Monitoring Committee (WCI PRMC):* The PRMC reviews and approves all cancer related research at UR and its affiliates. This includes studies that plan to enroll individuals with cancer or plan to review WCI patient health information. These types of studies include, but are not limited to, the following: drug, biologic, device, interventions, epidemiologic, behavioral, other observations, ancillary, preventive, surveillance or correlative. Cancer related also includes retrospective, prospective, treatment and non-treatment studies irrespective of the department from which the study originates or will be conducted. Specifically, the PRMC should review a study when the objectives/endpoints are cancer-related or have implications for cancer prevention or control. When the Principal Investigator's home department is the Department of Hematology/Oncology, the department approval is the PRMC approval. When the PI is from another department, the PRMC review will occur in addition to department approval.

3.1.1. PRMC review and acknowledgement is obtained for each modification prior to RSRB review, as appropriate per the WCI PRMS Charter.

3.2. *Department of Radiation Oncology Protocol Review Committee (DROIPR):* The DROIPR reviews and approves studies with a radiation therapy treatment component proposed at UR and its affiliates. When the Principal Investigator's home department is the Department of Radiation Oncology, the department approval is the DROIPR approval for all studies, with or without the radiation component. When the PI is from another department, DROIPR review will occur after department approval, but before RSRB review.

3.2.1. DROIPR review and acknowledgement is obtained for each modification prior to RSRB review, as appropriate.

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

3.4. *Neonatal Clinical Trials Group (NCTG):* The NCTG reviews research involving any planned study procedures on newborns hospitalized in the Birth Center, Newborn Nursery, or Neonatal Intensive Care Units. 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. Include the completed materials with the RSRB application at the time of initial submission.

Ancillary Review Occurs <u>Simultaneously</u> with RSRB Review

3.5. *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. When the Principal Investigator's home department is the Department of Emergency Medicine, the department approval is the EMRC approval. When the PI is from another department, the EMRC review will occur after department approval. RSRB review and EMRC review may occur simultaneously for initial submissions; however, EMRC approval is required before RSRB approval will be granted.

3.5.1. EMRC review and acknowledgement is obtained for each modification prior to RSRB review. If the research continues beyond a year, the PI must submit a request to EMRC for re-approval; this will occur annually. EMRC re-approval is required in order for the RSRB to grant re-approval.

3.6. *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.

3.7. *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 review system application before RSRB approval will be granted.

3.8. *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 also obtained annually.

3.9. *UR Center for Advanced Brain Imaging & Neurophysiology (UR CABIN):* For any research involving activities that require access to UR CABIN, refer to the UR CABIN Research website for more information regarding the protocol approval process. RSRB review and UR CABIN review may occur simultaneously; however, UR CABIN approval is required before RSRB approval will be granted. This ancillary committee was formerly known as the Rochester Center for Brain Imaging.

3.10. *Data Security:* For research involving the collection, transmission, or storage of electronic data (e.g. software, mobile applications, wearable devices, digital/video recording, text messaging). For additional information, see the *Guideline for Human Subject Research Data Security.* When required, RSRB staff will assign this review, and approval is required before RSRB approval.

3.10.1. Data Security review and acknowledgement may be required for a modification prior to RSRB review, if the modification modifies or adds the collection, transmission, or storage of electronic data. If required, Data Security approval is required before RSRB approval.

Ancillary Review Not Required Before RSRB Review or Approval

3.11. *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 review and approval of the research can occur at any time and it is not related to the timing of RSRB or Reviewing IRB approval.

3.12. *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 at Highland Hospital. ARRC will review the research once RSRB or Reviewing IRB approval is 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. References

4.1. Guideline for Ancillary Committee Contacts
4.2. Guideline for Human Subject Research Data Security Requirements

5. Responsibilities

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

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

6. Requirements

6.1. Investigators will indicate in the IRB Review System whether the research requires review by any of the institutional ancillary review committees.
6.1.1. The RSRB will review the ancillary committees selected by the Investigator and may require changes based upon the research.

6.2. Ancillary Committees will include documentation of their committee review in the IRB review system before RSRB approval is granted or Institutional review is provided, as applicable.
6.2.1. The Investigator must ensure that all applicable ancillary committee approvals are in place prior to enrolling subjects.

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Appendices:

None

Revision History:

04/2017: Sect 3 updates to reflect current practice; editorial and administrative changes
03/2019: Sect 3.2 added Radiation Oncology committee; Sect 3.9 updated ancillary committee name; edits throughout to reflect current practice and new online review system; remove T. Gommel as signatory; editorial and administrative changes
08/2021: Sect 3.1 Update the name and description of the Cancer Center Peer Review Committee to the Wilmot Cancer Institute Protocol Review and Monitoring Committee; Add Data Security Ancillary Committee; Remove contact information and created guideline; administrative and editorial revisions

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Approved By:

Kelley A. O'Donoghue — 09/08/2021

Kelley A. O'Donoghue
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Date