Ancillary Committee Review

The University of Rochester's Human Research Protection Program (UR-HRPP) is comprised of several integrated offices and committees aimed at ensuring individuals involved in conducing human subject research understand and apply their obligations to project the rights, dignity, welfare and privacy of research subjects. An essential component of the UR-HRPP is the collaboration between the Research Subjects Review Board (RSRB) and the UR-HRPP Ancillary Committees. The purpose of these ancillary committees is to provide expertise in a given field and ensure applicable regulatory and institutional requirements are met and adequate resources are available.

A summary of ancillary review requirements is provided in Appendix 1 below; a full description is provided in Office for Human Subject Protection (OHSP) Policy 503 Ancillary Committee Review. Note: This policy applies to *all* human subject research conducted or supported by the University of Rochester, inclusive of research reviewed and approved locally, by the RSRB, as well as research reviewed by an external Institutional Review Board (IRB).

Critical to this process is planning, well in advance, and 'doing your homework' to understand:

a) Whether ancillary review is required, based on the nature of the study and the procedures involved in the research; and
b) If ancillary review is required, what the review process is for each required review committee.

While ancillary committee review is facilitated by the Click® IRB system, **each ancillary committee has their own review process.** Some committees complete their reviews based upon the contents of the Click® IRB submission, whereas others require a separate application and/or review processes that take place outside of the Click® IRB system. For example, initial review by the Emergency Medicine Research Committee (EMRC) requires the submission of an EMRC cover sheet and study-related documents, as well as the presentation of the research at an EMRC meeting. **Some committees further require additional reporting and/or review of modifications and at the time of continuing review**.

The timing of ancillary committee review is also committee-dependent. Review may be required:

- Before RSRB Review – RSRB review is not initiated until after the applicable ancillary committee approval is provided;
- Simultaneously with RSRB Review – RSRB review is conducted concurrently with ancillary review, though final RSRB approval is held until the applicable ancillary committee approval is provided; or
- After RSRB Review – RSRB review and approval is conducted prior to ancillary committee review.

For studies reviewed and approved by an external IRB, in accordance with OHSP Policy 504 IRB Reliance and Collaborative Research, ancillary review is conducted as part of the institutional review process that occurs *prior to* submission to the Reviewing (external) IRB.

Knowing exactly what each committee's requirements are, what their review process is, and when their review occurs relative to RSRB review will help study teams plan sufficient time for review and avoid unnecessary frustration.

To reiterate, in regards to ancillary review, it is the Principal Investigator's (PI) responsibility to:

- Ensure all applicable Ancillary Committee approvals are in place prior to enrolling subjects;
- Adhere to applicable Ancillary Committee reporting requirements; and
- Maintain documentation of all Ancillary Committee approvals/acknowledgements (these should be maintained in the site file).

Questions concerning ancillary review can be directed to the relevant ancillary committee or your IRB Coordinator.

APPENDIX 1: SUMMARY OF ANCILLARY COMMITTEE REVIEW REQUIREMENTS

Ancillary review is required by…	**At this point…**	**When the research involves…**
Wilmot Cancer Institute (WCI) Protocol Review and Monitoring Committee (PRMC) WCI_PRMS@urmc.rochester.edu	Before RSRB Review	Cancer related research at UR and its affiliates, including studies that plan to enroll individuals with cancer or plan to review WCI patient health information. *When the PI's primary appointment is with the Department of Hematology/Oncology, Department approval will serve as PRMC approval.
Department of Radiation Oncology Protocol Review Committee (DROIPR) DROIPR@urmc.rochester.edu	Before RSRB Review	Radiation therapy treatment at UR and its affiliates *When the PI's primary appointment is with the Department of Radiation Oncology, Department approval will serve as DROIPR review.
Obstetrical Research Committee (ORC) Eva Pressman or Kathryn Drennan	Before RSRB Review	Pregnant to post-partum women
Neonatal Clinical Trials Group (NCTG) (585) 275-1521	Before RSRB Review	Study procedures on newborns hospitalized in the Birth Center, Newborn Nursery, or Neonatal Intensive Care Unit (including research for which pregnant women have given consent prenatally)
Emergency Medicine Research Committee (EMRC) (585) 275-1198 EMResearch@urmc.rochester.edu	Simultaneously with RSRB Review	Enrolling patients in the Emergency Department *When the PI's primary appointment is with the Department of Emergency Medicine, Department approval will serve as EMRC review.

Institutional Biosafety Committee (IBC) (585) 275-2402	Simultaneously with RSRB Review	1. Introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.) into human subjects; 2. Cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects; 3. Introduction of genetically engineered micro-organisms into human subjects; 4. Biohazardous organisms or materials handled at Biosafety Level 2 or higher (including the shipping of, analysis or, or experimentation with human specimens in any UR lab that is not accredited); or 5. Procedures that ***could*** result in droplet or aerosol COVID-19 exposure (e.g., spirometry and respiratory function testing)[#]
Surgical Pathology LabSRSS@urmc.rochester.edu	Simultaneously with RSRB Review	Receiving or obtaining fresh, banked or archived human tissue from Surgical Pathology
Human Use of Radiation Committee (HURC) (585) 275-3781 rsu@urmc.rochester.edu	Simultaneously with RSRB Review	Radioisotopes or radiation-generating devices used for research purposes
UR Center for Advanced Brain Imaging & Neurophysiology (UR CABIN) (585) 275-4540	Simultaneously with RSRB Review	Activities that require access to the UR CABIN
Data Security InfosecRiskandCompliance@ur.rochester.edu	Simultaneously with RSRB Review	Collection, transmission, or storage of electronic data (e.g., software, mobile applications, wearable devices, digital/video recording, text messaging) *Review is required per RSRB discretion, in accordance with the Guideline for Human Subject Research Data Security Requirements.
Clinical Research Center (CRC) (585) 275-0653	After RSRB Review	Procedures taking place in the CRC or use of CRC resources

Highland Hospital Administrative Research Review Committee (AARC)	After RSRB Review	Subject recruitment, enrollment or the conduct of study procedures at Highland Hospital *Note: Although AARC review is conducted after RSRB, AARC approval must be obtained prior to initiating any recruitment, enrollment or any other study procedure at Highland Hospital.

ADDITIONAL RESOURCES:

- OHSP Policy 503 Ancillary Committee Review
- OHSP Guideline for Ancillary Committee Contacts
- OHSP Policy 504 IRB Reliance and Collaborative Research
- Click® IRB: Study Staff Manual
- Click® IRB: Department & Ancillary Reviewer Manual