Rowan University IRB Performance Site Guidance

**Performance Site: Thomas Jefferson University (TJU)**

Rowan University faculty, staff, and/or students should follow the guidance below when conducting human subjects research that involves:

* Thomas Jefferson University (TJU) hospital, clinic, or other facility
* Intervention and/or interaction with TJU patients;
* Access to TJU patient data, records, or specimens
* Collaborating with TJU physicians and/or staff in human subjects research

Rowan IRB Preliminary Review to Assist in Determining which IRB to Submit for Review and Approval

If your study requires consultation with the IRB, please complete a Rowan protocol template (Clinical, SBER, medical chart review, etc.). This initial protocol template can be abbreviated, including brief description/summary in the protocol sections to summarize important aspects of the research and their impacts to Jefferson Health/JUH IRB and Rowan are understood.

After developing your preliminary/consultation protocol and reading the guidance below, complete and submit an IRB Determination Form with the protocol. The protocol and IRB determination form should be separate documents. Click on the Jefferson/Rowan IRB Determination Form to download, complete and provide that form to the Rowan IRB.

Preliminary/consultation protocols and IRB Determination Forms can be submitted to the RowanSOM IRB contact and/or Director of Research Compliance. Rowan University IRB general emails will be routed to RowanSOM IRB administrative support. Click here to go to Rowan IRB Contact webpage.

Identifying Which IRB Should Review and Approve Human Subjects Research

Rowan University and Thomas Jefferson University will use a determination form to identify which IRB should review and approve the research.

Rowan University faculty, staff, and/or students should submit to the Rowan University IRB, when research includes Rowan University **and** TJU. **If** Rowan University faculty, staff, and/or students **will** conduct research at TJU **and** Rowan University **will not** be included, then TJU Health/IRB should be contacted first. Below is initial guidance to assist Rowan University faculty, staff, and students as to what type of Rowan Cayuse IRB submission should be submitted for review.

Research/Protocol - Initial Submission Type

* Retrospective chart reviews done at TJU and RowanSOM; Note TJU may perform HIPAA/PHI review
* Research involving interactions that only includes survey procedures, interview procedures, or observations of public behavior **or** secondary research using identifiable TJU and RowanSOM patient private information or identifiable specimens, **whereas** researchers record and collect information about the subject in a manner that the identity of the subject cannot be ascertained, either directly or through identifiers by the researchers; Note: TJU may perform HIPAA/PHI review
* Research on medical education, including research on regular medical educational strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods, being that the students’ ability to learn the educational content is not adversely impacted

Rely on Non-Rowan External IRB – Initial Submission Type

* Research involving interventions with **or** manipulations of external environments of TJU patients
* Research that will be conducted at TJU facilities and include the collection of blood samples by venipuncture, finger stick, heel stick, or ear stick **or** collection of biological specimens for research purposes by noninvasive means from TJU patients
* Research that will be conducted at TJU facilities and include the collection of TJU patient data through noninvasive procedures routinely employed in clinical practices
* Data or biospecimen repositories or registries
* Biospecimen research involving genomic material or DNA
* Research meeting all the description above, but publication/presentation of material will be done as/associated with a researchers faculty appointment, staff position and/or student

**Rowan University IRB Submission Process**

Researchers can submit to the Rowan University IRB based on the guidance above. If the research will require Jefferson IRB review, then Rowan University will conduct a local context review. In order for Rowan University IRB to complete a local context review, researchers will need to submit an abbreviated initial submission to the RowanSOM IRB. This can be done in tandem with the Jefferson IRB application submission.

Research that requires RowanSOM IRB review based on the guidance above must be submitted to the RowanSOM IRB as an initial submission in Cayuse IRB.

Residents or student researchers conducting and/or participating in research must identify a RowanSOM faculty as a PI on a RowanSOM IRB submission. The Rowan IRB highly encourages the resident or student researcher to identify the RowanSOM faculty as a researcher on both IRB submissions to the RowanSOM IRB and Jefferson IRB to ensure oversight and study management can be synchronized between the two institutions.

Thomas Jefferson University Important Information and Webpages

Thomas Jefferson University Office of Human Research Main Webpage - <https://www.jefferson.edu/university/human_research.html>

Thomas Jefferson University Office of Human Research Contact Webpage – <https://www.jefferson.edu/university/human_research/contact/dshp_contact.html>

For Rowan University faculty, staff, or students conducting research at Thomas Jefferson University, please reach out to Dawn Slowinski.