DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

REVIEW AND APPROVAL BY OTHER (SPECIALTY) COMMITTEES

7/13/2021

The Duke University Health System Institutional Review Board (DUHS IRB) works in coordination with other University Committees and external review resources to protect the safety and welfare of research participants as part of the Human Research Protection Program (HRPP). The DUHS IRB functions independently, but in concert with these other University Committees and external resources.

Investigator Responsibilities

Depending upon how the Investigator and study team answer the questions in the New Study application in iRIS, a study will be automatically routed to Specialty Committees for review and approval. Specialty Committee reviews occur before the study reaches the IRB. Most of these reviews occur within iRIS, but some are conducted outside of the iRIS system, in which case the study team will usually upload documentation of the review, along with their other study documents in iRIS.

The investigator is responsible for obtaining the required approval(s). If the IRB reviews the protocol and determines that a Specialty Committee approval is needed, the protocol can be routed to that Specialty Committee within iRIS.

Institutional approval to conduct human subjects research is contingent upon the review and approval of all required Specialty Committee(s), in addition to IRB approval.

In the event of an amendment to a previously approved protocol, the IRB may request review by the appropriate Specialty Committee(s) before the IRB approves the amendment.

Specialty Committee Descriptions

- **Duke Cancer Institute Protocol Review & Monitoring Committee (PRMC) – (FORMERLY CPC)** The Duke Cancer Institute PRMC is a multidisciplinary standing committee of the Duke Comprehensive Cancer Center. It is a requirement of the National Cancer Institute that all research protocols involving cancer patients undergo scientific peer review by this committee prior to submission of the protocol to the Institutional Review Board. Therefore Duke Comprehensive Cancer Center policy requires that any protocol that proposes to use a cancer patient population that is not merely incidental to the research (e.g., a study on chronic diseases wherein cancer is merely included as one of those diseases) must be reviewed by Duke Cancer Institute PRMC. The proposed study may be therapeutic or non-therapeutic.

The PRMC judges the acceptability of the proposed research according to scientific design, feasibility, risks and benefits, background data justifying the proposed research, and biostatistics. The primary review emphasis is on the scientific aspects of the proposed research.

- **Duke Early Phase Research Unit (DEPRU)** All investigators proposing to use the DEPRU and its resources must complete a Redcap request form (outside of iRIS) for use of DEPRU services, and must obtain approval from the DEPRU prior to initiation of the study. The Redcap request form does not need to be uploaded into iRIS.

- **Duke Health Brand Center** Research advertisements and other marketing materials containing the Duke logo must receive review and approval by the Duke Health Brand Center.

- **Duke Office of Clinical Research (DOCR)** Studies that involve billing risk (procedures will be billed to the funding source/sponsor and separately to the subject/insurer for clinical care) require review by DOCR to make sure study procedure costs are properly allocated.

- **Duke Raleigh Hospital Committee** Protocols that will utilize the resources of Duke Health Raleigh Hospital and/or recruit its patients require approval from its Clinical Trials Specialist and Chief Medical Officer or designee(s) prior to initiation of the protocol.

- **Duke Regional Hospital Committee** Protocols which will utilize the resources of Duke Regional Hospital and/or recruit its patients require approval from its Director of Pharmacy and Chief Medical Officer or designee(s) prior to initiation of the protocol.

- **Duke Stem Cell Research Oversight Committee (SCRO)** All investigators planning to conduct research with human embryonic stem cells, and other human stem cells, must seek review by the Duke Stem Cell Research Oversight Committee to ensure compliance with the federal regulations and DUHS policies and priorities.

- **Hyperbaric Committee** Protocols which will utilize the resources of the Duke Hyperbaric Chamber require approval from this committee or its designee prior to initiation of the protocol.

- **Institutional Biosafety Committee (IBC)** This committee works to: 1) ensure that all recombinant DNA (rDNA) research conducted at the institution or sponsored by the institution complies with the National Institutes of Health Recombinant DNA Guidelines, and 2) ensure that research protocols involving Select Agents (defined by the Centers for Disease Control and Prevention), including but not limited to recombinant DNA, are reviewed and found to comply with all national, state, and local requirements.

  Investigators are advised to consult with the Institutional Biosafety Office to learn what types of rDNA experiments must be reviewed and approved by the IBC. All Human Gene Transfer or Therapy and all Select Agent protocols will be referred to the full IBC for review. **All** studies involving the manipulation of recombinant

DNA molecules must be registered with the Institutional Biosafety Committee prior to initiation of the study.
All viral vectors must be registered with the IBC. Any research activity utilizing a "Select Agent" as defined by the CDC in 42 CFR 72 Appendix A must be approved by the IBC before final DUHS IRB approval may be granted.

All studies involving the use of botulinum toxin, including the FDA-approved clinical product (Botox), must receive IBC review.

- **IT Security Office (ISO)** This office reviews the following:
  - Studies using mobile apps developed by Duke employees or students
  - Studies requiring that external technology or hardware (e.g., cameras/recorders) be installed in Duke clinical patient areas (e.g., Operating Rooms)
  - Studies involving integrations with Duke MyChart, Epic, or clinical applications.

- **Office of Regulatory Affairs and Quality (ORAQ)** Investigator-initiated new protocols involving drugs or devices route to ORAQ for a regulatory review. Duke Investigators who hold an IND or IDE must complete training from ORAQ and give the IRB evidence that the training has been satisfied.

- **Office of Research Administration (ORA)** Protocols that are funded by an external entity, such as a federal agency or foundation, may require review by ORA to confirm that all requirements under the grant, contract, or research agreement have been met.

- **Office of Research Contracts (ORC)** Protocols that are funded under a sponsored research agreement require review by ORC to ensure the consent form (in particular, the research-related injury language) and any other key protocol documents are consistent with the fully executed agreement.

- **Pathology Review** Whenever a patient has a biopsy for diagnostic purposes, Duke University Health System policy requires that the tissue be reviewed by a representative of the Department of Pathology prior to its being used for any other purpose, including research. Studies proposing to use tissue samples from Duke patients will require review and approval by Department of Pathology.

- **Radiation Safety Committee** Any IRB protocol that employs ionizing radiation (x-ray, nuclear medicine, radiation therapy) in any amount for research purposes (not standard of care) must be reviewed by a designee of the Radiation Safety Committee.

  The purpose of the review is to ensure that research subjects are informed of the amount of radiation exposure they will receive as a consequence of their participation and the risks of that exposure.

  "Ionizing radiation" includes diagnostic x-rays, cardiac catheterization and electrophysiology studies, nuclear medicine procedures, and bone mineral densitometry (DEXA). Magnetic resonance imaging (MRI), ultrasound, ultraviolet light and lasers are *not* considered to be ionizing radiation. Radiation Safety Committee review is not required for protocols involving **only** these modalities

that are not considered to be ionizing radiation.

Investigators are advised to prepare their consent forms according to IRB guidelines, making sure to (a) list any additional radiation procedures the subjects will undergo as a consequence of their participation in the study, beyond standard of care, and (b) include an appropriate Radiation Risk Statement in the "Risks and Discomforts" section of the consent document.

Investigators are advised to consult the Radiation Safety Committee web site, which has ready-made risk information that can be used in consent forms: https://lsw.duhs.duke.edu/radsafety/consents/

- **Radioactive Drug Research Committee (RDRC)** meets separately from the Radiation Safety Committee. The RDRC reviews those research protocols that involve the use of novel radioactive drugs that are developed or synthesized at Duke, as required by FDA under 21 CFR 361. Such protocols must be separately reviewed by both the RDRC and the IRB. Protocols performed under RDRC are usually limited in scope, and are designed primarily to provide basic information on the metabolism of novel radioactive drugs in healthy subjects and subjects with disease. The RDRC determines: (a) whether or not the radiation dosimetry conforms to limits specified in 21 CFR 361, and (b) whether or not radiochemical purity, sterility and pyrogenicity of the product have been adequately documented.

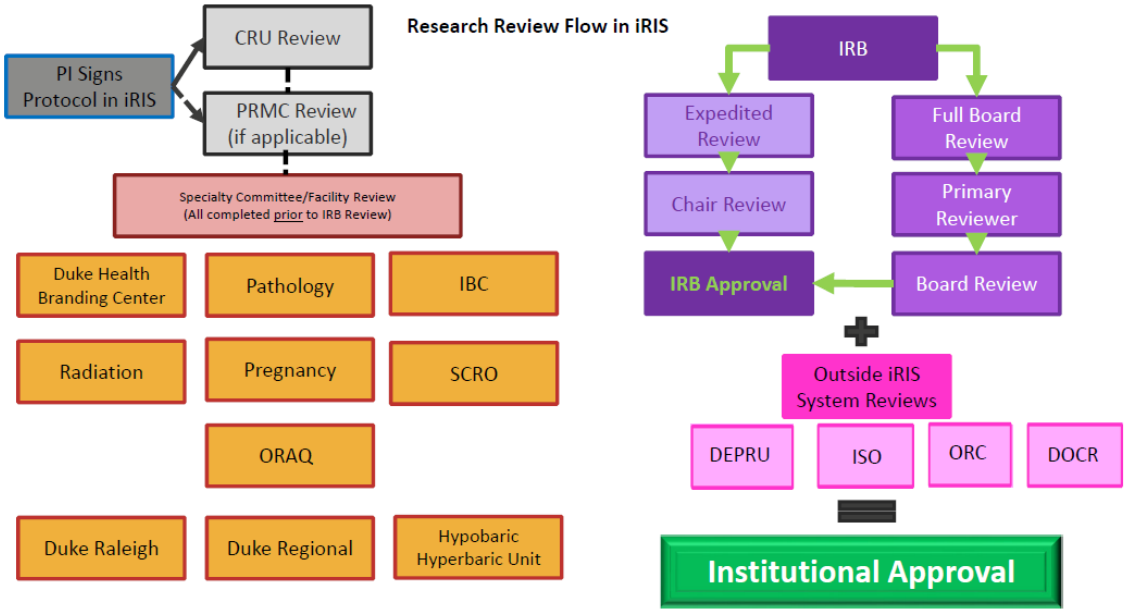
- **Reproductive Risk (Pregnancy) Review** New protocols are reviewed by Department of OB/GYN reviewer to assess adequacy and appropriateness of pregnancy testing plans and contraceptive use language in consent documents.

- **Research Integrity Office (RIO)** Research involving an entity from whom any of the key personnel on the research study receives personal compensation may indicate a potential conflict of interest (COI) requiring management. RIO notifies the IRB of all COI management plans issued to individual researchers.

- **VA Hospital – VA IRB** Protocols that will utilize the resources of the Durham VA Hospital and/or recruit its patients require approval from the VA IRB prior to initiation of the protocol. Investigators must upload the VA IRB approval document into iRIS.

The graphic below reflects the fact that Specialty Committee reviews are conducted prior to IRB review:

DUHS HRPP Review Process



*Institutional Approval is issued through OnCore

Previous Version Date(s): 10/1/2008, 6/6/2011, 2/29/2016, 1/8/2020