



REVIEW AND APPROVAL BY OTHER (SPECIALTY) COMMITTEES

10/1/2008

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. The DUHS IRB functions independently, but in concert with these other University Committees and external resources.

Investigator Responsibilities

When preparing a **New Protocol Submission** for the DUHS IRB, the investigator must complete the section of the submission form titled "Specialty Committee Reviews" by checking all the required committee reviews needed for the protocol, and by obtaining approval from these specialty committees.

To gain protocol approval from one of the committees listed below, investigators are advised to consult with the committee about the specific requirements for submission of materials.

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, or if the IRB is waiting for a specialty committee review before the IRB's final approval letter can be issued, the investigator may be prompted by a modification request for the specialty committee approval documentation. The letter of final approval from the IRB and thus the investigator's ability to initiate the protocol are contingent upon the prior receipt of any required specialty committee approvals.

In the event of an amendment to a previously approved protocol, if the amendment introduces an increased risk to participants, the IRB may request review by the appropriate specialty committee(s) before the IRB grants final approval.

Specialty Committee Descriptions

- **Cancer Protocol Review Committee (CPRC)** The Cancer Protocol Review Committee 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 CPRC. The proposed study may be therapeutic or non-therapeutic. For all retrospective studies in which cancer patients are included as an integral part, including retrospective chart reviews, CPRC review is required.

The CPRC 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.

- **Center for Living** The Duke Center for Living is home to several nutrition and wellness, cardiac rehabilitation, and lifestyle management programs. Protocols that propose to use the resources of the Center for Living, including its campus facilities, or recruit patients at the Center for Living, must be approved by the Center for Living Director of Clinical Research or designee before the initiation of the protocol.
- **Davis Ambulatory Surgery Center** This facility located near Durham Regional Hospital serves as a DUHS site for outpatient surgery. Duke investigators whose protocols involve the use of the resources or patients at the Ambulatory Surgery Center must seek protocol approval from the Director of the Center or designee before initiation of the study.
- **Duke Health 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.
- **Durham Regional Hospital Committee** Protocols which will utilize the resources of Durham 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 Clinical Research Unit (DCRU)** All investigators proposing to use the DCRU and its resources must obtain protocol approval from the DCRU Scientific Advisory Committee prior to study initiation. Some studies performed there will be reviewed by an independent review board, with the DUHS IRB performing an administrative review only.
- **Hypo/Hyperbaric Unit Safety Committee** This committee reviews for safety and merit of proposed research projects involving use of the Duke hypo/hyperbaric chamber.
- **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.

Experiments involving deliberate transfer of rDNA into human subjects must also be reviewed by the NIH OBA (Office of Biotechnology Activities) and the DUHS IRB. The P.I. must also notify the Duke Clinical Research Pharmacy for approval of a process for handling the material for patient delivery and Duke Hospital Infection Control for proper patient care precautions when a viral vector is used in a clinical trial.

- **Operating Room/Anesthesia Time** Some protocols require the use of the Operating Room if, for example, they involve the surgical placement of a device in research subjects, or the evaluation of a new surgical procedure. For studies that cause an extension in anesthesia time needed (beyond the normal "standard of care"), the investigator will indicate this in the **New Protocol Submission** form.
- **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. The Department has established a procedure whereby one of its representatives may be available to examine the specimen in the Surgical Pathology Accessioning Laboratory or visit the Operating Room (OR) to confirm that after a portion of the tissue is acquired for diagnostic purposes, some excess tissue may be released for an IRB-approved research project. In the absence of this review in the Surgical Pathology Accessioning Laboratory or the OR, the entire biopsy specimen must be submitted for Pathology examination. Subsequent release of tissue for research purposes will not occur without documentation of IRB approval for this use of the tissue.

Ordinarily the Department of Pathology as the agent for Duke University Hospital will not release a tissue block containing human diagnostic tissue because the tissue block may be needed for future diagnostic purposes or for medical-legal considerations. Therefore, when a research protocol includes a requirement that a tissue block be used for the research, the investigator should endeavor to have a tissue block prepared for this research purpose. If a tissue block cannot be prepared for the research protocol, then usually only recut histological sections will be available for the investigator. The investigator should confer with a representative of Surgical Pathology before agreeing to implement the research protocol to ensure its feasibility. The investigator must provide documentation to the IRB of Pathology approval of the protocol.

- **Radiation Safety Committee** Any IRB protocol that employs ionizing radiation (x-ray, nuclear medicine, radiation therapy) in any amount that is in addition to "standard of care" must be reviewed and cosigned by a designee of the Radiation Safety Committee, formally known as the "Duke University Medical Center Radiological Control and Radioactive Drug Research 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. For diagnostic studies, the "risk language" that must be included in the consent form is standardized and compares the radiation exposure to familiar "benchmarks". The review ensures that the consent language conforms to the standard and is quantitatively correct. For radiation therapy, the review ensures that the subject is made aware of the known adverse effects associated with a particular therapeutic regimen.

"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 have (a) listed any additional radiation procedures the subjects will undergo as a consequence of their participation in the study, beyond "standard of care", and (b) included an appropriate Radiation Risk Statement in the "Risks and Discomforts" section of the consent document.

Investigators are advised to consult with the Medical Center Radiation Safety Committee for "Ready-Made" Radiation Risk Statements which can be used in consent forms; for a Risk Statement Computer to help determine radiation risk; and for specific instructions on submitting research protocols to the Committee for its review. Investigators must secure approval from the Radiation Safety Committee before seeking IRB approval.

The **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.

- **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.
- **Other Hospital, University or External Committees** At times, research may be subject to review and approval of other University Committees or Offices (e.g., Conflict of Interest Committee, Office of Grants and Contracts, etc.) or an External Review Committee. The need for these required approvals will be

documented by the IRB as a “Modification Required” issued to the P.I. prior to receiving final IRB approval.