

## 1.0 GENERAL SUBMISSION REQUIREMENTS - INSTITUTIONAL REVIEW BOARD

The Institutional Review Board (IRB), University of Pittsburgh (University), must review and approve all research activities involving human subjects which fall within its jurisdiction (see pages P1-P2).

### 1.1 Required Education Modules

In order to submit projects into the OSIRIS system, all investigators and staff of a research project involving human subjects are required to complete the following modules:

- Research Integrity; and either
- Human Subject Research in Biomedical Science; or
- Human Subject Research in Social and Behavior Sciences

In addition, all principal investigators, listed co-investigators and study coordinators will be required to complete the [Good Clinical Practice](#) module if the study being conducted is FDA-regulated. The IRB considers research to be FDA regulated if it falls under sections 505 (New Drug Application) or 520 (Devices intended for human use) of the Federal Food, Drug, and Cosmetic Act (the Act), as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

Research involving the "off-label" use of FDA-approved drugs is also considered FDA regulated if any of the following three conditions exists: (1) The research is intended to be reported to the FDA in support of a new labeling indication for the drug or to support any other significant change in the labeling of the drug, (2) or the research is intended to support a significant change in the advertising for the drug, or (3) the research involves a route of administration or dosage level, use in a subject population, or other factor that significantly increases (i.e., compared to the FDA-approved indication for use of the drug) the risks (or decreases the acceptability of the risks) associated with the use of the drug.

The modules can be accessed from the IRB web site ([www.irb.pitt.edu](http://www.irb.pitt.edu)) or at <http://cme.hs.pitt.edu>. Investigators who do not have faculty appointments (regular or adjunct) or other direct relationship with the University must demonstrate completion of an equivalent educational program on the protection of human research participants (i.e. they are not required to complete the University's computer based training but may do so if they do not have access to a similar program). In this scenario, the investigator of the study will have to contact the OSIRIS team in order to have the person's name added into the system before s/he can be selected as part of the research team.

### 1.2 Pre-IRB Reviews

The OSIRIS system is designed to forward all research studies to the appropriate groups noted below prior to submission to the IRB. This process is done in steps:

1. Review by a mentor (if required)
2. Scientific review (if required)
3. Ancillary reviews (if required)

### **1.2.1 Review by Mentor for Studies Conducted by Students at the University of Pittsburgh**

Research studies being conducted by students at the University of Pittsburgh require the oversight of a faculty mentor. The student investigator will identify the appropriate mentor within the OSIRIS application and the study will be sent to that individual for review prior to submission for the scientific review.

### **1.2.2 Scientific Review**

Unless the research study falls into one of the categories noted below, scientific review is required.

- 1) industry initiated and sponsored clinical trials of drugs or devices that are subject to prior FDA acceptance of an IND or IDE application
- 2) research reviewed by an external scientific committee as a condition of research funding (e.g., NIH sponsored research) or for inclusion in cooperative group trials.
- 3) studies which meet one of the exempt criteria defined by the federal regulations (See Chapter 2.0).

Substantial modifications to the specific aims and/or design of a research protocol (with the exception of the categories of research defined above) will also prompt the OSIRIS system to send a request to the appropriate scientific reviewer so that the study can undergo adequate scientific review prior to submission of the modifications for IRB approval.

#### **1.2.1.1 University of Pittsburgh Cancer Institute (UPCI) Protocol Review Committee**

As a condition of the NIH center grant awarded to UPCI, research protocols involving oncology patients or the use of UPCI resources must be reviewed and approved by the UPCI Protocol Review Committee. This requirement includes research sponsored by the pharmaceutical and device industry and research reviewed by an external scientific review committee as a condition of research funding or for inclusion in cooperative group trials. For protocols involving only behavioral medicine issues and endpoints, scientific review should be obtained from the WPIC Research Committee (see below for contact information)

#### **1.2.1.2 Research Committee, Western Psychiatric Institute and Clinic (WPIC)**

As a condition of the NIH center grant awarded to WPIC, all research protocols conducted by faculty or staff of the Department of Psychiatry and/or involving psychiatric patients or the use of WPIC resources must be reviewed and approved by the Research Committee, WPIC. This requirement includes research sponsored by the pharmaceutical and device industry and research

reviewed by an external scientific review committee as a condition of research funding or for inclusion in cooperative group trials.

### 1.2.1.3 Magee Women's Research Institute CRC Use Committee

All proposed human subject research funded by or through the Magee Women's Research Institute shall be prior reviewed and approved by the CRC Use Committee of the MWH CTRC.

## 1.3 Ancillary Review

The IRB requires certain ancillary reviews/notifications to occur prior to submission of a research project to the IRB. Most of the ancillary reviews/notifications are done through the OSIRIS system. However, there are still other reviews that have not yet been programmed into the system. For each ancillary review/notification listed below, the method of having the review completed is also included. These reviews may be done in parallel prior to submission to the IRB.

### 1.3.1 UPMC Fiscal Review

The OSIRIS system will send to the UPMC fiscal review office, all proposed human subject research involving the performance within a UPMC facility of procedures or tests, the provision within a UPMC facility of services or hands-on care; or the collection from UPMC patients of biological specimens. For more information on this process, please see the IRB website ([www.irb.pitt.edu](http://www.irb.pitt.edu)).

### 1.3.2 Research Protocols Involving Human Subject or Patient Exposure to Ionizing Radiation ([see Appendix D](#))

The OSIRIS system will forward to the Human Use Subcommittee (HUSC), Radiation Safety Committee (RSC), and, if applicable, the Radioactive Drug Research Committee (RDRC) any research protocols involving the exposure of human subjects or patients to experimental sources of ionizing radiation (e.g., from investigational or experimental radiopharmaceuticals, diagnostic x-ray procedures, or radiation therapy procedures). The OSIRIS system will forward modifications which affect the radiation exposure aspects of the research study or modifications to increase the number of subjects to the RDRC for review prior to submission to the IRB.

Exceptions to the above requirement are limited to research protocols wherein human subject or patient exposure to ionizing radiation involves the use of (1) a standard diagnostic procedure (e.g., nuclear medicine procedure, chest X-ray, computerized tomography, angiography) in a routine clinical manner and frequency for research subject screening and/or to evaluate a therapeutic response; or (2) a standard radiation therapy procedure indicated for medical management of the patient.

### **1.3.2.1 Radioactive Drug Research Committee ([see Appendix D](#))**

Food and Drug Administration (FDA) regulations (21 CFR 361.1) permit the research use, in human subjects, of radioactive drugs that are not currently the subject of an approved Investigational New Drug (IND) exemption or New Drug Application (NDA), provided that certain specified conditions are met. The Radioactive Drug Research Committee (RDRC), an institutional committee established under the authority and in accordance with these regulations, serves to initially approve and continually review such research studies to insure their compliance with the provisions of 21 CFR 361.1. As noted above, the OSIRIS system will automatically forward to the RDRC studies which meet these criteria.

### **1.3.3 Gene Transfer Research University of Pittsburgh Institutional Biosafety (rDNA) Committee (IBC-rDNA)**

The OSIRIS system will forward all research studies that involve the deliberate transfers of recombinant DNA (rDNA) or DNA or RNA derived from rDNA into human subjects to the University of Pittsburgh Institutional Biosafety (rDNA) Committee (IBC-rDNA) at the time of initial submission as well as at the time of renewal or if modifications are made that involve the gene transfer intervention.

### **1.3.4 Conflict of Interest**

The OSIRIS system will forward all research studies where the investigator has identified a conflict of interest to the Conflict of Interest Office for review and approval prior to submission to the IRB. Investigators may be requested to complete a Standard Conflict of Interest Management Plan.

### **1.3.5 Investigational Drug Service**

The OSIRIS system will provide notification to the Investigational Drug Service, UPMC Department of Pharmacy, of all research protocols wherein the research involves the administration of an investigational new drug or an approved drug.

The Investigational Drug Service will evaluate planned procedures for the ordering, receipt, storage, preparation (if applicable), dispensing (including randomization), and billing (if applicable) of drugs used in research studies. The Investigational Drug Service will also evaluate procedures to ensure the accountability of investigational new drugs, compliance with informed consent documentation, and the provision of critical information on investigational new drugs to the caregivers of involved research subjects. Information about the IDS can be located at <http://druginfo.infonet.upmc.com/ids.htm>.

### **1.3.6 Embryonic Stem Cell Research Oversight Committee (ESCRO)**

Approval of the ESCRO Office is required for any proposed human subject research involving stem cell research is submitted into OSIRIS. There are two

categories of ESCRO Committee review, i.e. an administrative review and a review by the convened ESCRO Committee. Protocols qualifying for an administrative review are to be submitted to ESCRO after review and approval by other relevant committees, i.e. the IRB, IACUC or rDNA. Protocols not meeting one of the administrative review categories must be submitted for review and approval by the convened ESCRO Committee prior to submission to the IRB. Investigators conducting this type of research should contact the ESCRO Office for the appropriate forms and procedures to follow in order to have the study reviewed.

#### **1.3.7 Office for Investigator Sponsored IND and IDE Support (O3IS)**

Investigators are responsible for notifying the Office for Investigator-Sponsored IND and IDE Support (O3IS) when the proposed application indicates that there is an investigator-sponsored Investigational New Drug (IND) application or Investigational Device (IDE) application associated with the research. This office was established for the purpose of providing assistance to University researchers involved in the development and submission of investigator-sponsored Investigational New Drug (IND) applications and Investigational Device Exemptions (IDEs) for acceptance by the U.S. Food and Drug Administration (FDA) and the conduct of clinical research studies under such FDA-accepted applications and exemptions.

### **1.4 Exceptions to Pre-Clearance Approvals/Notifications**

Exceptions to the requirement for Pre-Clearance Approval/Notifications may be granted by the IRB Chair or his/her designee. In the event of an exception, final IRB approval will not be granted until approvals/notifications are submitted for all applicable committees.