CHAPTER #4

Additional Reviews and Approvals

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CHAPTER #4: Additional Reviews and Approvals

4.1 IT Evaluation – Submission and Review process for Research

To ensure that all software and hardware technology is secure, complies with UC policies, State and federal regulations, and leverages existing UCDHS technology investments, thoughtful assessments must be completed prior to investment in the new technology or bringing the technology to UCDHS as a part of a clinical trial. The Information Technology (IT) Evaluation Process was created to fill this need. IT Evaluation is required for any UCDHS department in need of purchasing new technology or using the technology provided by the industry sponsor.

Examples of technology subject to review include:

- Laptops and tablets with EDC or other survey instruments that transmit data wirelessly to a central database.
- Medical devices that store and transmit de-identified or identified patient data.

Many research studies, however, may qualify for an exception from the full IT evaluation process. To determine if the technology is exempt, the study team must provide a brief description of the technology and answer the questions on the Request for Exception from Technology Evaluation.

Users can submit the exception requests through the IT Service Catalog. Once you have completed the request, a Research IT analyst will be in touch with you to help guide you through the rest of the process.

The results of the exception request could be:

- Approved
- Further review required from IT evaluation
- Full IT evaluation required

If the Exception request is approved, the Principal Investigator will be asked to fill out the Attestation for Exception to Technology Review.

If the full IT Evaluation is required, the technology manufacturer will be asked to complete additional security questionnaires.

For any questions, please feel free to contact IT at: ResearchIT@ucdmc.ucdavis.edu

4.2 Clinical Engineering Review

The Clinical Engineering (CE) Department provides a wide scope of medical equipment planning, installation, repair and maintenance services to the UC Davis Health System (UCDHS). Specialty areas include: medical imaging, respiratory therapy, dialysis, radiation therapy systems, anesthesiology, operating room, ICU equipment, and medical device integration with IT systems.

For licensed facilities, various regulations and policies require that ALL medical devices be tested before clinical use and those tests must be documented. Clinical Engineering assures compliance
with these relevant medical device service regulations including: the Joint Commission, CMS, State of California Department of Public Health, NFPA 99 and others.

The FDA-approved equipment used on human patients at UCDHS also requires evaluation and testing by Clinical Engineering. For example, blood pressure monitors and EKG machines sent by an industry sponsor to support multicenter drug trials also need to be reviewed.

Or if a researcher is studying a new, not-yet-approved, ultrasound contrast material provided by a pharmaceutical company, and is using the pharmaceutical company owned, commercially available, ultrasound machine, the ultrasound machine still needs to be evaluated by Clinical Engineering. The ultrasound machine should be listed in the protocol for the IRB review and approval. If the equipment used in research is already installed in the hospital, it would have been already checked and tested, and therefore does not need another test/inspection.

Studies with medical equipment that have not yet been FDA-approved require that the evidence of the IRB approval is provided to Clinical Engineering.

For each device that is not FDA-approved, the following information needs to be provided to the Clinical Engineering Department by the Principal Investigator:

1. List of equipment that is not FDA-approved.
2. A short description of the research equipment including its FDA Risk Class or proposed FDA risk class. This may be provided via a copy of the IRB proposal.
3. A block diagram of the system if there are multiple components, including all power supplies.
4. An operations manual with service information and/or service manual for each component/subsystem.
5. For those devices where there are no formal manuals (e.g., prototypes), provide a short description of each device’s function and the technology used.

CE services are available on a recharge basis via DaFIS at a current rate of $140/hr. Upon the completion of the evaluation, Clinical Engineering will enter the equipment into the CE Database, tag the piece of equipment and provide a report summary, including billing information (monthly). CE will also determine frequency of calibration, electrical leakage testing, performance testing and preventative maintenance. Equipment maintenance schedules vary based on manufacturer’s published requirements and intervals (ranging from monthly to every 3 years), although annual is most common.

For more information, see the CE website or call at 916-734-2846 (http://intranet.ucdmc.ucdavis.edu/cehelp/)

### 4.3 Radiation Use Committee

Health Physics (http://intranet.ucdmc.ucdavis.edu/safety/hp/) is responsible for overseeing the safe and effective use of ionizing radiation within the Health System, X-Ray machines and radioactive materials used at the University of California, Davis Medical Center and the Primary Care Network for diagnostic and therapeutic purposes, as well as in research and development. When an investigative procedure involves exposure of human subjects to ionizing radiation, including radiation from machines, or radioactive materials, Federal, State, and University regulations require
an additional approval by the UCDMC Radiation Use Committee (RUC). This committee verifies the radiation exposure calculations, which, together with other information, determine the potential risks. The committee meets at least quarterly and consists of at least nine members, including five of the medical staff, the Medical Center Radiation Safety Office, and a representative from Administration. At least one medical staff member of the committee is recognized as a specialist in each of the following areas: Nuclear Medicine, Diagnostic Radiology, and Therapeutic Radiology.

Human Radiation Use Research Application (Form 5) ([http://intranet.ucdmc.ucdavis.edu/safety/hp/radprotocol.shtml](http://intranet.ucdmc.ucdavis.edu/safety/hp/radprotocol.shtml)) should be completed and submitted when requesting authorization to:

- Use radioactive materials/radiopharmaceuticals in human research
- Use diagnostic x-ray, fluoroscopy, or any other external radiation source in human research.

Protocol Exemption from Radiation Use Committee Review form (Form 35) should be submitted if the study meets specific exemption criteria, such as if the study has been already reviewed by any of the national cooperative groups. It must be signed by the principal investigator of the study, and submitted to Health Physics (Radiology) for review. It will then be signed by a representative from Health Physics and faxed back to the research team to be included in the New Submission packet.

### 4.4 Biological Use Authorization

The Institutional Biosafety Committee (IBC) at UC Davis reviews research activities involving biological materials that may pose a risk to human, animal, or environmental health. IBC review and approval is required for research activities involving use of recombinant or synthetic nucleic acids, potential employee exposure to infectious agents, and generation of medical waste outside of clinical (patient care) environments.

Examples of research activities which may require IBC review and approval are:

- downstream uses of human blood and tissues for research purposes,
- processing of patient samples for downstream research uses,
- work with primary or established human cell lines,
- isolation and culture of infectious disease agents,
- research involving recombinant or synthetic nucleic acid molecules,
- experimental uses of nucleic acids or infectious agents in human subjects, and
- employee exposure to any of the aforementioned activities or materials.

With the exception of human gene transfer research, activities conducted in clinical environments by employees covered under established health surveillance and infection control plans do not generally require IBC review. Researchers who plan on conducting research involving use of experimental recombinant or synthetic nucleic acid technologies in human subjects are encouraged to contact the Biosafety Office at the earliest stages of their research plan for advising. If uncertain whether IBC review is required, it is always best to contact the Biosafety Office ([biosafety@ucdavis.edu](mailto:biosafety@ucdavis.edu)).

The **Biological Use Authorization (BUA)** is the vehicle for IBC review and authorization of research. Information required for BUAs is entered and submitted through the Biosafety Information Online (BIO) web application ([https://ehs.ucop.edu/bio/](https://ehs.ucop.edu/bio/)). Principal investigator may delegate data entry tasks to other staff, but only the Principal Investigator can submit the BUA. BUAs must be
The IBC reviews BUAs according to:
- CalOSHA standards 5193 ([http://www.dir.ca.gov/title8/5193.html](http://www.dir.ca.gov/title8/5193.html)), [Bloodborne Pathogens], and 5199 ([http://www.dir.ca.gov/title8/5199.html](http://www.dir.ca.gov/title8/5199.html)) ([Aerosol Transmissible Diseases] for occupational exposure to biological agents;
- and other guidance on best practices in biological research.

Prior to forwarding the BUA for IBC review, members of the Biosafety Office work with Principal Investigators and their representatives to complete the BUA form and application process. As part of the BUA application process, Biosafety Office staff performs audits of research locations to verify information provided in the BUA, review training records, and assess site-specific practices. Once IBC approval is granted, the BUA is active for three years with annual site audits and project reviews conducted by the Biosafety Office.

The **Principal investigator** is responsible for completing all required training and for ensuring their employees complete required training commensurate with tasks performed. Annual biosafety and laboratory safety training is offered through the School of Medicine and through Safety Services ([http://safetyservices.ucdavis.edu/tr/biologicalSafety](http://safetyservices.ucdavis.edu/tr/biologicalSafety)). Questions regarding the IBC review process or biosafety training should be directed to the Biosafety Office via email (biosafety@ucdavis.edu) or by calling the main Safety Services phone number (530-752-1493).

### 4.5 Stem Cell Research Oversight Committee

The Research Compliance & Integrity unit of the UC Davis Office of Research provides administrative support on issues pertaining to stem cell research and supports the Stem Cell Research Oversight committee (SCRO, [http://research.ucdavis.edu/policiescompliance/stem-cell-research/](http://research.ucdavis.edu/policiescompliance/stem-cell-research/)). SCRO approves, requires modification, or disapproves human adult and embryonic stem cell research at UC Davis and the UC Davis Health System. It also reviews all research involving human stem cells at least once each year. Committee members are comprised of individuals with expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical issues in stem cell research. It includes at least one non-scientist member of the public who is not employed or remunerated by UC Davis and who is not part of the immediate family of a person who is affiliated with the institution (for details, see SCRO SOPs).
The Application to conduct Human Stem Cell Research can be found at: http://research.ucdavis.edu/policiescompliance/stem-cell-research/

### 4.6 Scientific Review Committee (SRC) (Cancer Center Only)

The Scientific Review Committee oversees the oncology clinical trials program by reviewing all cancer-related clinical protocols to assure feasibility, research quality, and statistical validity prior to submission to the IRB. The SRC thus provides a centralized mechanism for prospective evaluation of scientific merit and prioritization of clinical trials, resource allocation and accrual monitoring. SRC meetings are held on the first Thursday of each month. Scientific Review Committee members are nominated by the Associate Director of Clinical Research and approved by the Cancer Center Director, based on the following criteria:

- Experience with clinical research trials
- Expertise in medical, pediatric, surgical, and radiation oncology, cancer drug development, nursing, molecular biology, or data management
- Expertise in clinical pharmacology and in investigational drug requirements
- Expertise in biostatistics
- Familiarity with the UC Davis Cancer Center research base

Prior to SRC review, proposed clinical research protocols are vetted through disease site groups. National Cooperative Group trials and trials conducted under the NCI-supported California Cancer Consortium can be submitted without disease site group review. Next, the principal investigator submits a full protocol to the SRC Administrative staff electronically, along with a completed SRC Protocol Submission Form. The application must be received 15 working days prior to the next meeting. To obtain the form contact SRC Coordinator at 916-734-2596.