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UW-MADISON HUMAN SUBJECTS RESEARCH INFRASTRUCTURE

This module provides a brief overview of the entities involved in the oversight of research involving human subjects at the University of Wisconsin-Madison (UW-Madison). Not all researchers come in contact with all of the offices or committees described below, but all involved in human subjects research should be aware of the role that each plays.

ALL INVOLVED IN HUMAN SUBJECTS RESEARCH SHOULD BE AWARE OF THE FOLLOWING ENTITIES.

HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

The Human Research Protection Program (HRPP) provides oversight of all research activities involving human subjects at the UW-Madison. The HRPP is not an **office**, but rather a **collective effort of all who participate** in the Conduct, Review, Approval and Facilitation of Human Subjects Research at UW-Madison. All UW-Madison faculty, students, and staff who are involved in research involving human participants are required to comply with federal, state and university policies for the protection of human research participants. The HRPP maintains the human subjects research protections policies utilized by the UW-Madison Institutional Review Boards (IRBs) and campus officials.

All research involving human subjects must be reviewed by an IRB. Under the Common Rule, a "human subject" is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

- **"Intervention"** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **"Interaction"** includes communication or interpersonal contact between investigator and subject.
- **"Private information"** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). "Private information" must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for

obtaining the information to constitute research involving human subjects.

UW-Madison has three IRBs: the Health Sciences IRB, the Health Sciences Minimal Risk IRB, and the Education and Social/Behavioral Science IRB. Researchers can send their protocols involving human subjects to the appropriate IRB based on the type of research project.

HEALTH SCIENCES (HS) IRB

The HS IRB reviews research protocols involving medical interventions or procedures where medical expertise is required for evaluation.

HEALTH SCIENCES MINIMAL RISK (MR) IRB

The MR IRB reviews research protocols that present minimal risk to subjects and that involve medical interventions or procedures requiring medical expertise or that require knowledge of the health care setting (e.g., medical records research, research database and tissue banking projects, survey and interview research, and exemption applications).

EDUCATION AND SOCIAL/BEHAVIORAL SCIENCE (ED/SBS) IRB



The ED/SBS IRB reviews education, social, behavioral, and non-medical health research. Protocols include human subjects research about the education process, effectiveness of education programs and child development as well as studies that focus on the decision processes and individual functioning in a social environment. The ED/SBS IRB also reviews human subjects research involving prisoners, certain types of social and behavioral science genetic research, and all non-medical prisoner research. The ED/SBS IRB does not have appropriate expertise for review of medical research, but may review research protocols involving minimal risk health-related studies, such as those involving exercise, tape sensors, and single venipuncture, where medical training is not necessary for the evaluation of risk to research participants.

SCIENTIFIC REVIEW COMMITTEE (SRC)

Many studies submitted for review by the Health Sciences IRBs are required to undergo scientific review prior to IRB review.

ICTR SRC

The requirement for review by a UW Scientific Review Committee (SRC) is aimed at enhancing the quality of health sciences protocols conducted at the UW. Non-cancer research studies that require scientific review are sent to one of two Institute for Clinical and Translational Research (ICTR) SRCs. Most interventional studies that have not undergone scientific review by an external body, such as a federal funding agency, will be reviewed by one of the ICTR SRCs.

UW Carbone Cancer Center (UWCCC) Protocol Review Monitoring Committee (PRMC)

The University of Wisconsin Carbone Cancer Center Protocol Review and Monitoring Committee (PRMC) functions as the Scientific Review Committee, as mandated by the NCI, for all cancer-related research protocols. The PRMC is charged with the scientific and resource review of all new and ongoing clinical and translational research protocols. In addition, the PRMC reviews all cancer-related clinical and translational research for compliance with the UW-Madison Conflict of Interest policies and assures an appropriate Data and Safety Monitoring Plan is included in each proposal. The UWCCC PRMC works in concert with the UW HS-IRB, in that all cancer-related protocols must first receive PRMC approval before they can be submitted to the UW HS-IRB.

The Office of Research Compliance (ORC) coordinates and facilitates research policy, ethics, and compliance activities for research conducted across the UW-Madison campus.

Major responsibilities include staff support for the following committees and activities:

- Human Research Protection Program (HRPP)
- Responsible Conduct of Research (RCR)
- Research Misconduct
- Outside Activities Report (OAR) and Conflict of Interest (COI) Committee
- Stem Cell Research Oversight (SCRO) Committee
- Export Control

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

The federal Office of Research Integrity (ORI) defines Responsible Conduct of Research as nine elements:

- Acquisition, management, sharing and ownership of data
- Conflict of interest and commitment
- Human subjects
- Animal welfare
- Research misconduct
- Publication practices and responsible authorship
- Mentor/trainee responsibilities

- Peer review
- Collaborative science

Additional training focusing on responsible conduct of research (RCR) is **required** for any undergraduate student, graduate student or postdoctoral researcher supported by NSF research funding or trainees included on an NIH T32 grant.

RESEARCH MISCONDUCT

The federal Office of Research Integrity defines Research Misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

The UW-Madison strives to foster the highest scholarly and ethical standards among its students, faculty, and staff. Though extremely rare, we realize there are times when misconduct may occur in our midst and that it is our responsibility as an academic community to take steps to rectify it. There are mechanisms and processes for researchers to follow if they suspect research misconduct.

CONFLICT OF INTEREST AND OUTSIDE ACTIVITIES

REPORTS

The UW-Madison encourages faculty, staff, and students to engage in outside activities and to share their knowledge and expertise. It acknowledges that potential financial conflicts of interest may result and are common, often unavoidable, and not necessarily problematic. UW-Madison has a **Conflict of Interest Committee** comprised of faculty members from across campus to review Outside Activity Reports submitted by all faculty and academic staff for potential financial conflicts of interest. *All new faculty members should complete an Outside Activity Report (OAR) shortly after starting employment at the UW-Madison.* This will help expedite any protocol submissions or grant proposals made before the next annual reporting period.

THE FOLLOWING INFORMATION DESCRIBES COMMITTEES OR OFFICES THAT YOU MAY COME IN CONTACT WITH DURING THE CONDUCT OF HUMAN SUBJECTS RESEARCH.

OFFICE OF RESEARCH AND SPONSORED PROGRAMS (RSP)



All research proposals, contracts, grants and cooperative agreements with extramural sponsors must be routed to UW-Madison Research and Sponsored Programs (RSP) through the Dean's office of the UW-Madison college or school you are affiliated with. This includes:

- Clinical Trials Agreements
- Confidential/Non-Disclosure Agreements
- Research Agreements
- Incoming and Outgoing Material Transfer Agreements
- Licensing/Software/Equipment Agreements
- Data Sharing/Use Agreements

- Interagency Personnel Assignment Agreements
- Memoranda of understanding
- All amendments, modifications and extensions to the above.

Depending on the agreement type, the document will be reviewed by RSP.

Agreements cannot be finalized until reviewed and negotiated by the appropriate office, and signed by an authorized signatory of the University.

No contracts or agreements may be signed solely by the PI, but rather, signed by someone in RSP with the appropriate signature authority.

RSP performs the final review of federal, state, and non-profit project proposals for UW-Madison and transmits the proposals to those sponsors of extramural support. They are also an authorized signature authority, accepting awards on behalf of The Board of Regents. They are the entity responsible for negotiating language in the funded research agreement/contract with federal, state, and non-profit sponsors, interpreting sponsor policy, and negotiating our indirect cost rate. RSP also provides financial assistance (i.e. preparing financial reports, submitting invoices, and processing payments), and other administrative services addressing other primary functions (audit, administrative policy, etc.)

STEM CELL RESEARCH OVERSIGHT:

The Stem Cell Research Oversight (SCRO) committee *provides* oversight for all research on campus involving:

- the use of human embryonic stem cells (hESCs) or their derivatives; or
- the introduction of human pluripotent stem cells (hPSCs), or their derivatives,

obtained from a non-embryonic source, into non-human animals at any embryonic, fetal, or postnatal stage, if an expected effect is that human cells will be integrated into the central nervous system, testes, or ovaries of the animal.

There are separate training requirements for researchers involved in the types of stem cell research described above.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The IBC is managed through the UW-Madison Office of Biological Safety (OBS). The IBC reviews and approves all UW-Madison research involving the use of *recombinant DNA and infectious agents* (plant, animal and human).

RADIOACTIVE DRUG RESEARCH COMMITTEE



Primary purpose is to review and oversee any clinical research study involving radioactive drugs where no Investigational New Drug (IND) application is required. The FDA classifies radioactive drugs into two groups: (1) as a new drug requiring an IND (21CFR312) for investigational use, and (2) as generally safe and effective when administered under the conditions specified in RDRC regulations (21CFR 361.1). In addition to the initial protocol review and approval, the RDRC must review and approve all protocol amendments. Adverse events related to the radioactive drug must be reported to the RDRC. When RDRC review is required, RDRC approval must be obtained before the Health Sciences IRB will review and approve the protocol.

RADIATION SAFETY

The Office of Radiation Safety provides information and training for use of radiation emitting materials, devices, or instruments, and waste handling. This includes both ionizing radiation and non-ionizing (electromagnetic) radiation. This office is responsible for radiation safety training, provision of radioactive materials, dosimetry, radioactive waste handling, etc.

The University Radiation Safety Committee (URSC) administers UW-Madison's radioactive license. All radioactive material use and research must be approved by the URSC prior to using such material. All individuals authorized to use radionuclides must be licensed and meet certain qualifications.

RESEARCH SAFETY COMMITTEE

The University of Wisconsin Hospital and Clinics (UWHC) Research Safety Committee (RSC) is a multidisciplinary committee whose purpose is to review research protocols that could pose potential safety concerns to employees are not adequately covered by existing policies; this includes protocols involving gene therapy, infectious agents and other novel therapies.

Any clinical research protocol that requires Institutional Biosafety Committee approval will require submission and approval by the RSC. RSC approval is required before IRB Approval may be issued. RSC approval is granted on a per protocol basis and NOT on a per agent basis.

LABORATORY SAFETY:

Many activities involving research with human subjects include activities conducted in a laboratory setting or require staff to handle, process, and/or package and ship infectious substances and other biological materials. In this case there are additional

training requirements to be met.

- Bloodborne Pathogens (BBP) (renamed Occupational Health 102) training is available online through Learn@UW. This training is made available by the Environment, Health & Safety Department, Occupational Health Office.
- Safety and Infection Control online training is also available for UWHC employees or SMPH staff/students that work in the UWHC facilities (UWHC, AFCH and/or UWHC Clinics) to complete annually.
- Training and certification on how to package, ship or otherwise transport biohazardous materials (HazMat) is provided online through Learn@UW. This training is made available through the Environment, Health & Safety Department, Office of Biological Safety (OBS).

Depending on the scope of your research, laboratory safety resources and requirements vary. The Department of Environment, Health and Safety (EHS) has several units providing consultation services, training opportunities and compliance resources.



There is no quiz for UW-Madison Human Subjects Research Infrastructure

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