University of Wisconsin-Madison Human Subjects Research Infrastructure

Presentation Goal

Provide study teams with an overview of:

- the human subjects research infrastructure at the University of Wisconsin-Madison
- resources, processes, and requirements for human subjects research

The slides at the front end of this document are applicable to all research. Latter slides are primarily aimed at clinical/biomedical research.

What is the 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 the UW.

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 used by the UW Institutional Review Boards (IRBs) and campus officials.

IRB Review Requirement

The UW requires all research involving human subjects, including exempt human subjects research, to be reviewed by an IRB

There are 3 campus IRBs, each with a different purview

Education and Social/Behavioral Science IRB (ED/SBS IRB)	Health Sciences Minimal Risk IRB (MR IRB)	Health Sciences IRB (HS IRB)

Researchers send their studies involving human subjects to the appropriate IRB based on the type of research project.

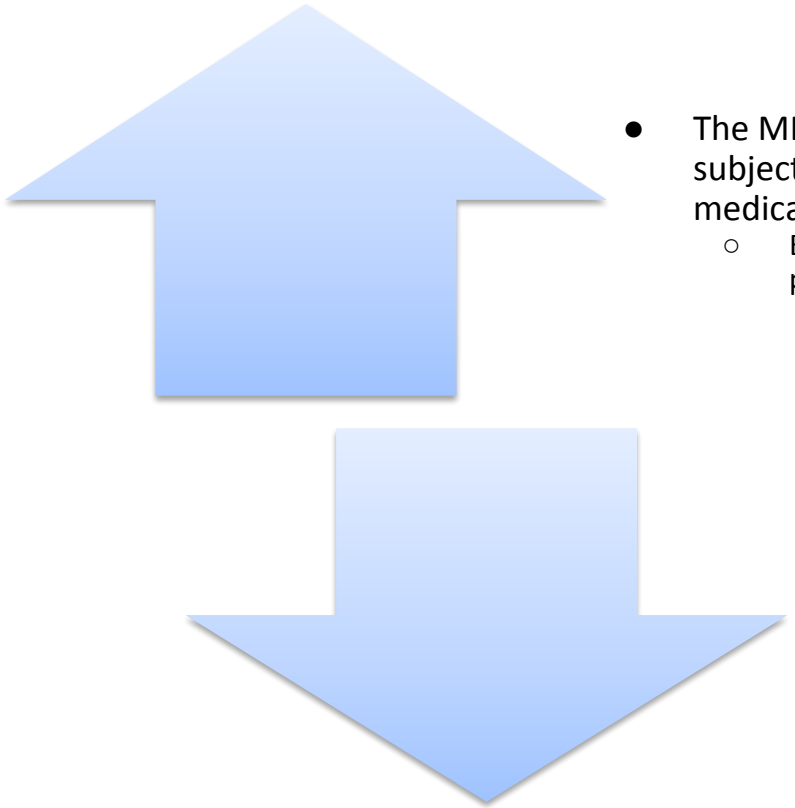
UW IRBs: ED/SBS IRB

The ED/SBS IRB reviews education, social, behavioral, and non-medical health research, including social and behavioral science genetic research and non-medical prisoner research.

- Examples: research about the education process/effectiveness of education programs, child development/decision processes and individual functioning in a social environment

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 (involving exercise, tape sensors, and single venipuncture)

UW IRBs: HS & MR IRBs



- 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
  - Examples: medical records research, research database and tissue banking projects, and survey and interview research)

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

Additional IRB Resources

- Training and outreach events
  - HS and MR IRB: https://kb.wisc.edu/hsirbs/18334
  - ED/SBS IRB: http://www.irb.wisc.edu/IRBtrainingseries.htm

- IRB Guidance pages
  - HS and MR IRBs: https://kb.wisc.edu/hsirbs/18837
  - ED/SBS IRB: https://kb.wisc.edu/sbsedirbs/search.php?q=&cat=4051

Office of Research Policy (ORP)

- 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:

    - Post-Approval Monitoring Program
    - Conflict of Interest Program & Committee
    - Outside Activity Reporting (OAR)
    - Stem Cell Research Oversight Committee

Post-Approval Monitoring (PAM) Program

- The PAM Program conducts routine and directed reviews of research studies approved by the campus Institutional Review Boards (IRB). Reviews are done to confirm that studies are being conducted in accordance with their IRB approval as well as applicable campus policies and federal regulations.
- With a few exceptions, all currently approved studies are eligible for routine review. Study selection is random.
- PAM Program is available to assist study teams through a self-requested review or consultation prior to study initiation.

Website: https://kb.wisc.edu/gsadminkb/page.php?id=46261

Conflict of Interest & Outside Activities Reporting

- The UW-Madison encourages faculty, staff, and students to engage in outside activities and acknowledge that potential financial conflicts of interest may result. These conflicts can be common and unavoidable, but not necessarily problematic.
- To track outside activities, academic staff with greater than 50% appointment, key personnel on federal awards, and all study team members on human subject protocols must complete an Outside Activity Report (OAR) annually or shortly after joining UW-Madison.
- UW-Madison has a **Conflict of Interest Committee** comprised of faculty members from across campus that reviews the OARs and make determinations.

Website: COI Policy - https://kb.wisc.edu/gsadminkb/page.php?id=32993; OAR - https://research.wisc.edu/respolcomp/coioar/
Training: https://kb.wisc.edu/gsadminkb/page.php?id=32986

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.*

Website: https://kb.wisc.edu/gsadminkb/page.php?id=34484

Responsible Conduct of Research (RCR)

- Various government agencies require RCR ethic training.
- These requirements vary by source of funding. The website link below describes these varied requirements.

Website: https://kb.wisc.edu/gsadminkb/page.php?id=34483
Training: training information found at the link above

Research & Sponsored Programs

- All research proposals, contracts, grants and cooperative agreements with non-industrial extramural sponsors and all clinical trial agreements must be routed to UW-Madison Research and Sponsored Programs (RSP) through the Dean's office of the UW college or school you are affiliated with.
- This includes:
  - Clinical Trials Agreements
  - Confidential/Non-Disclosure Agreements associated with Clinical Trials
  - Non Industrial Research Agreements
  - Agreements for Licensing/Software/Equipment
  - Data Sharing Agreements
  - Interagency Personnel Assignment Agreements
- No contracts or agreements may be signed solely by the PI, but rather, must be signed by someone in RSP with the appropriate signature authority.

Website: https://www.rsp.wisc.edu/

Office of Industrial Partnerships

- The Office of Industrial Partnerships (OIP) facilitates the development and maintenance of relationships with for-profit organizations wishing to engage in research activities at UW. OIP works with entities whose interests range from accessing cutting-edge basic research to commercialization of existing technologies, and the office serves as the point of contact for both campus personnel and industry partners pursuing such activities. OIP's services include, but are not limited to, the provision of institutional review, negotiation, and signature for agreements supporting these relationships.
- The types of agreements handled by OIP include, but are not limited to, the following:
  - Industry sponsored research agreements
  - Data use agreements with industry
  - Facility use agreements for research related space
  - Non-clinical trial related confidentiality or non-disclosure agreements
  - All incoming and outgoing material transfer agreements
  - All fee for service agreements

Website: https://research.wisc.edu/projectagreementsip/oip/

ClinicalTrials.gov

- The Food and Drug Administration (FDA), and the International Committee of Medical Journal Editors (ICMJE) require that certain studies be registered at ClinicalTrials.gov.
- The two entities have different criteria for determining which studies must be registered as well as different requirements for what goes into that record:
    - Registration, annual updates, and results reporting when a study meet FDA criteria
    - Registration when a study meets ICMJE criteria
- Campus has staffing to support researchers who require assistance with determining whether or not their study meets registration criteria as well as those that have questions about the registration process in general.

Website: https://kb.wisc.edu/gsadminkb/page.php?id=34044

Clinical Research

The remaining slides are primarily aimed at investigators who conduct clinical or biomedical research.

Scientific Review

Many clinical and health sciences studies are required to undergo scientific review prior to IRB review. See https://kb.wisc.edu/hsirbs/page.php?id=18844 for a description of which studies require scientific review.

Institute for Clinical & Translational Research Scientific Review Committee (ICTR SRC)	• Reviews non-cancer research studies. • 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)	• Functions as the SRC for all cancer-related research protocols • Conducts a resource review of all new and ongoing clinical and translational research protocols

ICTR IND/IDE Support Services

- ICTR IND/IDE Consultation Service offers expertise, resources, and consultation for investigators that interact with the U.S. Food and Drug Administration (FDA) regarding the use of investigational drugs, biologics or devices.
  - The ICTR IND/IDE Consultation Service focuses on providing assistance to researchers during the early stages of research development as well as maintenance of their INDs and IDEs.
  - Our experts are well versed in regulatory strategy to include the planning, generation, and submission of various types of materials to the FDA (meeting requests, pre-meeting materials, pre-IND materials, IND/IDE applications, Annual Reports, SAE Reports, etc.).

Website: https://ictr.wisc.edu/groups/ictr-indide-consultation-service/

Institutional Biological Safety Committee

- The Institutional Biosafety Committee (IBC) reviews and provides approval for research activities involving biologically hazardous materials and/or recombinant DNA molecules/organisms.
- Clinical researchers must submit a Biosafety protocol within the ARROW system prior to Initial IRB review.
- Personnel listed on Biosafety protocols are required to complete training - consult training link below

Website: http://www.ehs.wisc.edu/ibc.htm
Training: http://www.ehs.wisc.edu/biosafetytraining.htm

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.

Website: https://research.wisc.edu/respolcomp/scro/

Radioactive Drug Research Committee

- The UW RDRC evaluates research applications involving the use of radioactive drugs intended to obtain basic information regarding the metabolism of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry, but not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes as defined by the FDA.

- RDRC research applications can involve human research protocols involving radioactive drugs without either: (1) a New Drug Application (NDA), (2) an approved Investigational New Drug (IND) application, or (3) an IND Exemption.

- Any human research subject protocol submitted to the RDRC is also required to receive Institutional Review Board (IRB) approval. IRB approval is contingent upon RDRC review and approval. Any revisions or modifications required by the RDRC must be incorporated into the protocol before final, full approval by the IRB will be granted.

Website: https://kb.wisc.edu/uwrdrc/

Office of Radiation Safety

- 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 radionucleotides must be licensed and meet certain qualifications.

Website: http://www.ehs.wisc.edu/radsafety.htm

UWHC Research Safety Committee

- The University of Wisconsin Hospital and Clinics (UWHC) Research Safety Committee (RSC) reviews research protocols that could pose potential safety concerns that are not adequately covered by existing biohazardous or cytoxic policies. Protocols requiring this review may include:
  - Protocols involving gene therapy, infectious agents and other novel therapies
  - Protocols involving agents with a novel location, route of administration or concerns for employee exposure
- Any clinical drug research protocol that requires Institutional Biological Safety Committee approval will require submission and approval by the RSC
  - IRB approval will not be granted until approval from the Research Safety Committee has been obtained for protocols requiring this oversight.

Website: https://uconnect.wisc.edu/policies/administrative/uwhc/uwhc-wide/environmental-safety/resources/name-67213-en.file

VA Research & Development Committee (R&DC)

- The VA R&DC, part of the Research Service, reviews and monitors all Madison VA human subjects research.
- R&DC review focuses on the scientific merit of research protocols, whether all VA-specific regulations are met, and whether the research is aligned with the VA's needs and mission.
- R&DC review is required IN ADDITION to IRB review for human subjects research.
- For more details regarding the VA R&DC application process call 608-280-7007.

Research Billing Compliance Program

- The Research Billing Compliance Program facilitates billing compliance, acting as a liaison between the research/study team and the UW Health Patient Billing representatives, to ensure that procedures performed for research purposes are billed appropriately.

- Additional attention is given to those studies that could enroll Medicare patients as research subjects in their studies.

Website: https://uconnect.wisc.edu/depts/programs/research-billing-compliance-program/

Questions or Comments?