Human Subjects Research Guidance

UW requires all research involving human subjects, including exempt human subjects research, to be reviewed by an Institutional Review Board (IRB). This includes proposed research involving existing data and previously collected human fluid and tissue samples.

There are three campus IRBs, each with a different purview (Health Sciences IRB, Minimal Risk IRB, Social/Behavioral Sciences and Education IRB). The Health Sciences Institutional Review Boards Office is home to the Health Sciences IRB (HS IRB) and the Minimal Risk IRB (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, and survey and interview research). The HS IRB reviews research protocols involving medical interventions or procedures where medical expertise is required for evaluation.

IRB applications

Application Review for Research Oversight at Wisconsin (ARROW) is the system used to submit new applications, changes of protocol, reportable events and continuing reviews to the IRBs on campus. Due to the dynamic nature of IRB applications in ARROW (ARROW is a smartform and depending on how you answer certain questions, additional pages will populate), there are no templates available. However, we can provide examples and resources for specific application questions upon request. Please contact Amanda Espinosa, Pathology Dept. Research Administrator (briggs1@wisc.edu) for assistance.

Cancer-related clinical research:

Prior to submission to the HS IRB, all cancer-related human subjects research (whether or not a clinical trial) must be reviewed by the University of Wisconsin Carbone Cancer Center (UWCCC) Protocol Review and Monitoring Committee (PRMC). This process is outlined here: https://kb.wisc.edu/uwccc/internal/page.php?id=44463
Please contact prmc@carbone.wisc.edu for assistance with that process. The PRMC coordinator and staff help study teams that are not within an established UWCCC Disease Oriented Team (DOT) with the PRMC submission process. While they do not provide support for IRB submissions unless the project is being run by the UWCCC Clinical Research Central Office (CRCO), they do have staff who can give advice and an overview of the process.

Helpful Links

The Health Sciences Institutional Review Boards Office is available for consultations with investigators to talk through a project and answer questions prior to a submission. https://kb.wisc.edu/hsirbs/18204
HS IRB ARROW help (resources on how to complete the ARROW application): https://kb.wisc.edu/hsirbs/17466
Policy and guidance documents: https://kb.wisc.edu/hsirbs/18837
IRB for Beginners workshops (offered every six weeks): https://kb.wisc.edu/hsirbs/18334
HS IRB contact information for questions: https://kb.wisc.edu/hsirbs/17016
UW Institute for Clinical and Translational Research (ICTR) Clinical Research Toolkit: https://ictr.wisc.edu/clinical-research-toolkit/

UW Office of Clinical Trials (OCT)

OCT offers comprehensive support services to investigators conducting clinical trials (all areas of investigation except oncology). OCT provides services on a fee-for-service basis. In general, regulatory services are provided for a fixed fee ($1,562 for the initial preparation and submission to HS IRB; see pricing sheet for additional details), while financial and clinical coordination services are provided at hourly rates. OCT offers services to investigators regardless of funding source. While the majority of current studies are industry-sponsored, many federal grants, subcontracts, investigator-initiated studies, or foundation-sponsored trials are also supported.
For additional information on the regulatory, budgetary, and coordination services offered, please see: https://ictr.wisc.edu/groups/office-of-clinical-trials-oct/
To request a consultation: https://ictr.wisc.edu/consults/office-of-clinical-trials/