Scientific Review Committee Guidance

What types of applications to the HSIRB are generally excluded from ICTR SRC review?

- Oncology studies: All oncology-related IRB applications (including exemptions) are assessed by the UW Carbone Cancer Center Protocol Review and Monitoring Committee (PRMC) to determine whether PRMC scientific review is required.
- Multi-site Industry sponsored studies
- Studies that **have** received a highly meritorious peer review (funding approved or pending). Examples of adequate peer review organizations:
    - NIH, DOD, NSF and other PHS funding agencies
    - UW Internal granting mechanisms, including OVCRGE competitions, ICTR pilot studies, UWCCC core grant sub-award projects
    - VA merit grant
    - Foundations with adequate peer review (for example American Heart Association, American Kidney Foundation, Wisconsin Partnership Program, etc.)
- Extended/Emergency use applications, Humanitarian Use Device Applications, or training/umbrella grant applications.
- Studies that solely include the following procedures:
    - Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
    - Prospective collection of biological specimens for research purposes by noninvasive means
    - Use of materials (data, documents, records, images, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)
    - Collection of data from voice, video, digital, or image recordings made for research purposes
    - Surveys
    - Interviews, including focus groups
    - Wearable devices, such as accelerometers and fitbits, or tests that use external sensors that do not otherwise result in physical stimulation (e.g. EEGs)
    - Walking tests
    - Imaging (MRIs, ultrasounds) with FDA-approved devices (hardware and software) when the imaging is performed within the FDA indications and evaluation of the device is not the focus of the research
        - NOTE: PET-MRI does not fall under this category.

Scientific Review Committee Guidance

What is reviewed during ICTR SRC?

The SRC reviews the formal study protocol uploaded into the ARROW application for the following:

- Adequate rationale and justification for the study based on a literature review or other data
- Adequate study objectives and clearly defined primary and secondary outcomes
- Valid, reliable and rational proposed measures
- When applicable, planned treatments commensurate with standard of care or a reasonable experimental alternative
- Subject population that is appropriate to answer the scientific question, including whether inclusion/exclusion criteria will allow the study team to enroll the intended population
- Adequate statistical considerations (e.g., sample size/justification, estimated accrual and duration) to meet study objectives
- Data monitoring procedures to ensure the collection of high-quality data

How are studies routed to SRC?

The Scientific Review: Other page appears in ARROW for HSIRB initial review applications that do not have federal funding.

- If your study has received non-federal peer review (see examples above), please select "funding proposal has already undergone peer review."
- If your study only involves the minimal risk procedures listed above, select "protocol solely involves any or a combination of the minimal risk procedures outlined in the SRC guidance document."

Do changes of protocol require ICTR SRC Review

If a study underwent ICTR SRC review during the initial review process, subsequent changes of protocol may require ICTR SRC review if the study changes affect the study design or methodology.