

Scientific Pre-Review

The University of Cincinnati strives to ensure that our research meets the highest level of scientific integrity and to ensure that human study participants are enrolled in high-quality research projects.

As described in [Human Research Protection Policy III.01 REVIEW BY THE INSTITUTIONAL REVIEW BOARD OF HUMAN SUBJECTS RESEARCH](#), in order to approve human subjects's research, the IRB shall determine that "Scientific or Scholarly Review by qualified individuals(s) has demonstrated that (a) the research uses procedures which are consistent with sound research design; (b) the research design is likely to answer the proposed scientific questions, and (3) the importance of the knowledge expected to result justifies approval of the research. Such review shall be certified by the academic department chair or responsible administrator."

In keeping with these standards and the recommendations of the Institute of Medicine, **scientific review prior to submission to the IRB for all non-exempt medical human research protocols, except those solely involving pre-existing records and/or specimens** is required prior to submission to the IRB. This scientific pre-review does not replace IRB review, but the results help the IRB complete their deliberations with a more complete understanding of the importance of the scientific question being addressed, as judged by the experts in the field.

The process for scientific pre-review is established by the academic unit (Department, division, center etc.). **Each Academic unit (division, departments, etc) engaged in non-exempt medical human subjects research must have a scientific pre-review process.** We have created a template checklist to use as a starting point. Each academic unit should customize their process to fit their individual needs. Academic Units may choose to accept the review of protocols that have already been reviewed and approved (Center, NIH, multi-center industry sponsored, etc.); however, they are advised that external reviewers may not always have their depth of scientific knowledge and the application submitted and reviewed by NIH may not have sufficient details to ensure a comprehensive scientific review. Upon completion of review by the academic unit, the following should be included along with protocol to IRB: all pertinent correspondence between reviewers and investigators clearly communicating to IRB all concern regarding science and their resolution, and documentation that concerns were addressed.

Please note that the [Center for Clinical and Translational Science and Training \(CCTST\)](#) can provide support for pre-review of study design and implementation.