INSTITUTIONAL REVIEW BOARD – SCIENTIFIC REVIEW
FREQUENTLY ASKED QUESTIONS

Q1. Why is this change being implemented?

A. To reduce the number of review committees, and to facilitate the review of human subjects research.

Q2. Why is Scientific Review required?

A. To approve human subjects research, the IRB must determine that research subjects are treated ethically and equitably and that research design minimizes risks to subjects. However, it is not the primary charge of the IRB to assess the scientific merit of proposals submitted for review, except for those instances when merit cannot be established by another entity. Scientific review assures that the research has scientific validity, feasibility, statistical relevance and potential benefit to participants and/or to society. The IRB will utilize the expertise of the biostatisticians in the Biostatistics, Epidemiology, & Research Design (BERD) unit of the ICTS to review the methodological and statistical information prior to IRB review.

Q3. What type of Scientific Review is required for research conducted at UCI?

A. **Scientific Review of Human Subjects Research at UCI falls into one of five categories:**

1. **For research previously subjected to full peer review** (e.g., review by a study section, grant committee or grant agency), no additional internal scientific review is required. The actual protocol (which describes in detail the involvement of human subjects) submitted to the IRB must have been reviewed in its current form. The IRB may request copies of peer review comments. Peer review of a grant describing a clinical trial in general terms does not satisfy this criterion. In addition, an industry-sponsored, clinical trial authored by a UCI investigator does not satisfy this criterion for independent peer-review.

2. **For research involving cancer**, patients with cancer, individuals at risk for cancer, or individuals in a study involving a specific cancer focus (e.g., program evaluations, quality of life, and health education), scientific review is conducted by the Chao Family Comprehensive Clinical Trials Protocol Review and Monitoring Committee (CTPRMC). No additional scientific review is required. Go to the CTPRMC web page for more information.

3. **For non-cancer research that is UCI investigator-authored and has not been subject to full peer review:**

   A. **For biomedical/clinical research involving greater than minimal risk (full board review),** the Lead Researcher must complete and submit the most recent version of the Protocol Narrative for Expedited and Full Committee Review *(available for download on the **Applications and***

Forms *web page under the "IRB Forms" heading)* with the IRB application. The UCI Human Research Protections (HRP) staff will coordinate with the BERD unit to facilitate the scientific review. If the methodological or statistical information provided in the narrative is incomplete or unclear, the researcher will be required to revise the narrative. IRB review may be delayed. Lead Researchers proposing investigator-authored studies are strongly encouraged to seek the consultation of a biostatistician prior to submission of an IRB application. This review will help assure the quality of the IRB submission and reduce the turnaround time for IRB review and approval.

B. **For biomedical/clinical research involving minimal risk (Exempt and Expedited level of review),** scientific review remains the responsibility of the school or department. The Department Chair or Institute Director signature on the IRB application serves as the verification that the research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known). However, the IRB reserves the right to require scientific review on a study-by study basis.

C. **For social, behavioral and educational research (all levels of review),** scientific review also remains the responsibility of the school or department. The Department Chair or Institute Director signature on the IRB application serves as the verification that the research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known). However, the IRB reserves the right to require scientific review on a study-by study basis.