

Scientific Review Process Town Hall Meeting September 27, 2016

- The Office of the Vice Chancellor for Research
- The Office of Clinical Trials
- The Office of Human Research Ethics



Introductions

- John B. Buse, MD, PhD
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Chief, Division of Endocrinology
Director, NC Translational and Clinical Sciences Institute
Executive Associate Dean, Clinical Research
- Elizabeth Kipp Campbell, Ph.D., CIP
Director, Office of Human Research Ethics
- Christine Nelson, RN, BSN, MBA, CCRC
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Scientific Review

Scientific review of human subjects protocols is required as there is no acceptable risk to human subjects in the absence of valid scientific benefit. The regulatory rationale for requiring science merit reviews emanates from 45 CFR 46.111(a)(1) as follows:

- Risks to participants are minimized by using procedures consistent with sound research design and which do not unnecessarily expose participants to risk.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.



Overview

During the review of research protocols, the Institutional Review Board (IRB) is responsible for ensuring that

- (i) risks to participants are minimized by using procedures consistent with sound research design and that do not unnecessarily expose participants to risk
- (ii) risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.



Overview

In order to fulfill these two criteria, a level of scientific or scholarly review is required before the IRB can approve a research protocol.

The IRB may draw on its own knowledge and expertise, or the knowledge and expertise of others, to provide this review.

Background

- Scientific Review has been conducted by the Scientific Review Subcommittee within the IRB review for approximately 4 years.
- This review was not perceived as a distinct review but instead part of the IRB review which resulted in IRB stipulations which had the potential to significantly delay the approval and start of a clinical trial.



Scientific Review

By conducting the scientific review prior to submission of the research protocol to the IRB will increase efficiencies while allowing UNC to remain compliant with all applicable regulations.

Science merit reviews help assure the quality of the IRB submission and processes (including IRB members' decisions about "risk versus benefit"), and reduce turnaround time for review and approval.

Scientific Review Process

UNC SRC review is required:

- If a study has not been reviewed externally (e.g., external IRB for multicenter industry-sponsored research –or- protocol review committee or the equivalent for multicenter federally or foundation funded research),
 - Study section or FDA IND/IDE review is not adequate for this purpose.
 - A single site RO-1 funded by NIH will generally require review by the UNC SRC.

Scientific Review Process

UNC SRC review is not required if:

- Research conducted under the oversight of an external IRB (e.g., institution, NCI CIRB or Independent/Commercial IRB) does **not** require scientific review by the UNC SRC.
- Research that recruits cancer patients or has a focus on cancer or risk factors for cancer does not require SRC review as it will undergo scientific review by the Oncology Protocol Review Committee (PRC).
- Multi-center, industry-sponsored research with an available external IRB does not require scientific review by the UNC SRC. However, if the UNC researcher is the regulatory Sponsor (i.e., holds the IND or IDE), UNC SRC is required.
- Research that involves the collection of blood specimens or the use of investigational devices to perform research measurement should be reviewed by the IRB to determine if the research requires SRC review

Scientific Review Process

- If your study meets the criteria for UNC SRC review, investigators are now required to submit the complete protocol document or master protocol document for review.
- In line with new
- For information on how to develop a complete protocol document please refer to the OCT website.
- Submission of a full protocol and statistical analysis plan will be required by as part of the new rules for Clinicaltrials.gov



Scientific Review Process

- To submit your study for Scientific Review, please complete the SRC Review Request form found on the Office of Clinical Trials website. Send the completed form along with your complete protocol document or master protocol document (not grant proposal) to OCT@unc.edu

Scientific Review Process

- For resources and templates for writing study protocols please refer to the OCT website or NC TraCS website.
- For further assistance in developing your protocol, including biostatistics, please contact NCTraCS.
<http://tracs.unc.edu/>

Scientific Review Process

- UNC SRC meets weekly
- Protocol modifications should not result in a delay of 1 month that the IRB review currently requires if a study must be deferred due to scientific review stipulations
- This new process will significantly accelerate the approval of investigator initiated studies.

Scientific Review Process

- The IRB application has been modified to assist you in determining if your protocol requires SRC review
- Additional information is available on the Office of Clinical Trials (OCT) website <http://research.unc.edu/offices/clinical-trials/scientific-review-committee/>

Scientific Review Process

The protocol will be evaluated on the following:

- Objectives are clearly stated
- Background and rationale provides justification for conducting the study
- Design is adequate to determine stated objectives
- Specific inclusion/exclusion requirements
- Outcome characteristics and endpoint definitions are clear
- Statistical analysis and sample size
- Data management
- Data and safety management plan

Scientific Review Process

How long can a protocol be with the UNC SRC?

- The SRC will limit its review of a protocol to two times
- At that time it will be forwarded to the IRB with comments
- The UNC SRC cannot “approve or disapprove” a protocol, only the IRB can do this
- The longest a protocol will be with the SRC is 3 weeks

FAQ's

The hope is scientific review will be complete required prior to IRB review for studies posing greater than minimal risk.

If the scientific review is meant to precede the IRB review, how is the determination of risk supposed to be made?

- Additional questions have been added to the IRBIS application to help the researcher in making this determination
- The IRB can always refer any study to the UNC SRC based on their determination

FAQ's

- If you have questions, submit the protocol for SRC review.
- The coordinator may bounce it back to you and say it does not need review because it is minimal risk in a day or two.
- If not, it will take us about a week to get back to you.



Questions

