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New Greater-than-minimal-risk Studies Require a Scientific Protocol Starting 5/1/15

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Change Affecting New Greater-than-Minimal-Risk [1] Studies

Effective May 1, 2015, investigators will be required to submit a scientific protocol for new greater-than-minimal-risk [1] studies. New study applications requiring a scientific protocol will be sent back to the investigator without Committee on Human Research (CHR) review if one is not attached. FAQ?s and resources for developing a scientific protocol can be found below.

FAQs

1. Why is the CHR asking for this?
Most of the greater-than-minimal-risk applications that are submitted to the CHR already have a scientific protocol, but some do not. While the CHR application focuses on human subject issues, the scientific protocol includes a comprehensive description of the study and operational details of how it will be conducted. It serves as a reference document for the CHR reviewers.

2. Does this affect me?
This does affect you if you meet all three of the following criteria:

- You have a new study (biomedical or behavioral) which presents greater than minimal risk to study participants, **AND**
- You do not already have a study-specific scientific protocol from your study sponsor or cooperative group (e.g. Industry-sponsored protocols, RO1 grants, investigator-initiated

cooperative group protocols, and some funding grants which describe the scope of human subjects work), **AND**
- You submit the study to the CHR on or after May 1, 2015

This does not affect you if you are submitting the following types of study application:

- Compassionate Use (Single-patient Treatment IND or IDE) [2]
- Humanitarian Device Exemption (HDE) [3]
- Minimal risk (expedited and exempt applications) [1]

3. What is a scientific protocol?
A scientific protocol:

- Describes how the investigators will conduct the research,
- Serves as a procedural guide for the study team to help ensure that research procedures are performed in a standardized way by different people over time, and
- Facilitates high quality science as it requires the investigators to plan all aspects of the study in detail, including study objectives, selection of subjects, assessments of efficacy and safety, statistical analysis, quality control, data handling, recordkeeping, and study discontinuation

4. What is the difference between a scientific protocol and the CHR application?
While there is some overlap in the content of a scientific protocol and the CHR application, the two documents differ in their focus and scope. The scientific protocol provides greater detail about the science and design of the study (preliminary data, methodology, statistics, study-specific data management, details of interim data safety analysis plans, quality control procedures and operational instructions), while the CHR application focuses on human subjects issues (risks and benefits, local recruitment plans, consent process, differences between standard of care and study treatment, and special measures that will be taken to ensure subject safety).

Resources for Developing a Scientific Protocol

- For an outline of what belongs in a scientific protocol, download a **protocol template** from the UCSF Clinical Research Resource HUB [4].
- For help with **non-cancer** study design and protocol development, consultation services are available through CTSI Consultation Services [5]. The first hour of consultation is free, but for protocols that require more than 1 hour of consultation, there will be an hourly recharge fee. Please plan accordingly, as it may take up to 2 weeks to schedule a consultation appointment.
- For help with **Cancer Center** study design and protocol development, you can receive assistance from the Cancer Center Clinical Research Support Office [6]

Please contact the Committee on Human Research at (415) 476-1814 or IRB@ucsf.edu [7] with questions.

Links
[1] http://irb.ucsf.edu/levels-review
[2] http://irb.ucsf.edu/emergency-use-and-compassionate-use-experimental-drugs-and-devices
[3] http://irb.ucsf.edu/investigational-devices
[4] https://hub.ucsf.edu/protocol-development
[5] http://accelerate.ucsf.edu/research/protocol-consult
[6] http://cancer.ucsf.edu/research/cores/crso
[7] mailto:IRB@ucsf.edu