GUIDANCE: SETTING UP A DEPARTMENTAL RESEARCH REVIEW PROCESS

Background: The Institute of Medicine and the Association for Accreditation of Human Research Protection Programs (AAHRPP) recommend that all protocols involving human participants undergo an independent and rigorous scientific review to assess scientific quality, the importance to increase knowledge, and the appropriateness of the study methodology to answer a precisely articulated scientific or clinical question. Study design of clinical trials should be based on sound statistical principles and methodologies, including sample size, use of controls, randomization, population stratification, stopping rules, and the feasibility of relating endpoints to objectives.

Objectives: The objective of initial departmental review is to assess scientific validity and feasibility of successful completion of the study. The department review mechanism will achieve its objectives by:

- Facilitating conduct of research protocols which meet department research goals.
- Advising on the scientific validity of proposed protocols.
- Assessing the feasibility of proposed protocol:
    - Whether the protocol would answer the research question,
    - Whether investigators are qualified by experience, education and training to conduct the research,
    - Whether the investigator has access to adequate resources including facilities and research staff,
    - Whether the recruitment plan will be able to meet target accrual.
- Establishing prioritization for recruitment when there are multiple open protocols with similar eligibility criteria.
- Assist researchers to conduct research according to the good clinical practice guidelines.
- Oversee the progress of various projects in the department's research program.

Membership: Depending on the size and breadth of the clinical research program, departments may choose committees on either a department-wide or divisional basis. Departments with smaller or more diverse research programs may elect to join forces with other departments to share expertise and resources. Senior colleagues with extensive clinical trial and peer review experience, acquainted with the qualifications of the investigators, their resources and subject populations are good members, in addition to individuals with expertise in epidemiology, study design and statistics. Participation by an experienced study coordinator may be useful in assessing logistical feasibility. Graduates of the Clinical Research Curriculum within the department are generally well equipped to provide scientific pre-review of protocols. Membership may be supplemented through other institutional resources with specific expertise in study design and statistics, such as CCTS BERD and SPARK programs and the Center for Clinical Research and Evidence-Based Medicine.

Review Criteria: A frank and objective analysis should be provided on the topics listed below. It is understood that not all reviews will be positive. In some cases, sponsored multi-center protocols may not be easily modified to an ideal state at one site. Furthermore, legitimate differences of opinion may occur. Investigators are encouraged to respond to departmental concerns and suggestions; however an unfavorable departmental review will not preclude

submission to CPHS. Nonetheless, the comments of the departmental committee will be viewed by CPHS with due respect.

1. Background and significance:
    a. Has an adequate review of relevant literature and prior studies been performed? Is it accurately reflected in the submitted materials?
    b. When appropriate, is there a sufficient body of pre-human data to justify a human trial?
2. Hypothesis:
    a. Does the study address a meaningful scientific question?
    b. Is it clearly stated?
3. Methodology:
    a. Is the methodology appropriate to address the hypothesis?
    b. Are subject and control/ comparator populations constituted appropriately to address the stated hypothesis?
    c. Are the subject inclusion and exclusion criteria appropriate to optimize benefit and risk?
    d. Is the study powered sufficiently to provide a meaningful outcome?
    e. Is the statistical analysis plan appropriate?
4. Feasibility:
    a. Is the research feasible as designed at this site?
    b. Is the PI likely to meet enrollment goals?
    c. Are stated recruitment methods appropriate for this population?
    d. Has appropriate permission to recruit patients been secured?
    e. Have appropriate permissions and letters of support been secured from involved hospital units and clinics?
    f. Will other clinical studies compete for the same subject population at this site? If so, how will triage of recruitment be handled?
5. Comparison to routine clinical care:
    a. Describe routine clinical care for the condition being studied?
    b. If local standards of care deviate from regional standards or from clinical guidelines, please justify.
    c. Are any subjects denied access to routine care at any time in the course of the study? If so, please justify.
    d. How does the risk of the study intervention compare to that of the routine care?
6. Risk to participants:
    a. Are study risks accurately described?
    b. Could reasonable modifications to the protocol improve the benefit to participants or reduce risks?
    c. Is the data safety monitoring plan appropriate for the study?
7. Resources:
    a. Do the investigators have the qualifications (education, experience, expertise, hospital privileges) to carry out the protocol?
    b. Does the study site have the necessary resources to carry out the protocol?

Reporting: Effective January 1, 2013, CPHS will require completion of the Departmental Research Review form for all new protocols meeting criteria for full-board IRB review and approval. It must be digitally signed by delegates of the department chair. This document is to

be attached to the submission by the investigator. Protocols qualifying for exempt or expedited IRB review are not required to undergo this step. The iRis application process will guide the investigator to determine review status.

Support: The department review program should have administrative support to help coordinate submissions from investigators, arrange committee meetings (or meetings between reviewer and investigator), issue outcome letters and facilitate communication and timely reviews.

Attachments:

- Protocol development & templates
- Departmental Research Review form