Continuing Scientific Review of Established Protocols

Purpose

To maintain the high quality of the NICHD clinical research portfolio established protocols will undergo scientific review to ensure appropriateness for the intramural research program, productivity, competitiveness, and strong scientific quality.

Policy

1. Clinical protocols actively enrolling or following patients will undergo scientific review after ten years.

2. At the time of the ninth renewal, accountable/principal investigators will be notified that scientific review will be required prior to subsequent renewal. For protocols currently older than nine years, accountable/principal investigators will be notified, concurrent with approval of their next annual review, that scientific review will be required prior to subsequent renewal.

3. Accountable/Principal investigators will be responsible for requesting a scientific review six months prior to the protocol expiration date. Request will be made to the Office of the Clinical Director (OCD). At that time the investigators should provide the OCD with the following:
   a. A memorandum outlining the specific aims, progress, accomplishments, goals and expected future impact of this protocol.
   b. Complete protocol including consent documents.
   c. List of suggested reviewers. Reviewers may be intramural or extramural.
   d. Copies of relevant site review comments.
   e. Copies of DSMC review
   f. List of publications to which the clinical protocol contributed.
   g. Estimate of resources previously expended on this project and estimate of future resources required. This estimate should include staff time and direct section/unit expenditures per year.
   h. Projected per year outpatient visits and inpatient admission days.

4. Investigators with strong site visit reviews may request a waiver. This request must be made nine months prior to the protocol expiration date. Waiver requests will be evaluated by the Scientific Director, Clinical Director, and the Clinical Program Directors. Waiver requests will be acted on within two months. The waiver request should include:
   a. A memorandum outlining the specific aims, progress, accomplishments, publication list, goals and expected future impact of this protocol.
   b. Copies of relevant site review comments.
c. Estimate of resources previously expended on this project and estimate of future resources required. This estimate should include staff time and direct section/unit expenditures per year.

d. Projected per year outpatient visits and inpatient admission days.

5. Investigators will be requested to respond to reviewer critiques.

6. Reviews will be managed by the Office of the Scientific Director with the assistance of the Office of the Clinical Director in the same manner that is currently employed for new protocols.

7. The revised protocol, reviewer critiques and investigator responses will be evaluated by the Scientific Director, Clinical Director, and the Clinical Program Directors. This review should occur two months prior to expiration.

8. An approval memo from the Office of Scientific Director will be required prior to submission to the IRB. As with the current scientific review process, the Scientific Director may grant a waiver. A waiver may be time limited.

9. For purposes of protocol services, protocol tracking and FDA, protocols will retain their previous protocol numbers and not be considered new protocols. Annual/triennial reviews will be based on the renewal date which included scientific review.