Scientific Progress Reviews

Overview:

The Dana-Farber/Harvard Cancer Center (DF/HCC) is a NCI-Designated Comprehensive Cancer Center supported by a National Cancer Institute (NCI) Cancer Center Support Grant (CCSG). CCSG guidelines require DF/HCC to have a Protocol Review and Monitoring System (PRMS). **One of the responsibilities of the PRMS is to verify ongoing scientific merit, prioritization, and progress of the DF/HCC research portfolio.** Scientific Progress Review is the mechanism utilized to review active DF/HCC protocols to ensure that the scientific aims of each study can be completed. Scientific Progress Review is separate but complementary to the Institutional Review Board (IRB) Continuing Review of research requirement. Both Scientific Progress Review and IRB mandated Continuing Reviews are managed by the Office for Human Research Studies (OHRS).

Scientific Progress Review:

Scientific Progress Review is conducted by an individual member of the Scientific Review Committee (SRC). The assigned SRC reviewer will have the expertise (i.e., clinical versus non-clinical) required to review the protocol for scientific progress.

OHRS uses the following criteria to route Continuing Review submissions for Scientific Progress Review:

1) The protocol is reportable under the CCSG.
2) The protocol is new or active and could enroll participants in the future (e.g., temporarily closed studies or studies not yet activated will still need to be reviewed).

Scientific Progress reviewers are focused on the responses provided by the Principal Investigator to the asterisked questions in the Continuing Review submission form. Asterisked questions are designated primarily for Scientific Progress Review.

Scientific Progress Review Determinations:

- Approved to Continue. No Scientific Progress concerns and/or the plan for addressing any Scientific Progress concerns have been accepted.

- Request a Corrective Action Plan. The study team must provide a plan for addressing one or more of the following concerns:
    - Difficulties with enrollment and/or participant retention
    - Concerns with overall scientific progress
    - Concerns with scientific validity
    - Concerns with unanticipated problems and/or non-compliance
    - Other concerns affecting the ability for the research objectives to be met

  Note: If after 30 days the study team has not responded to any review requirements the continuing review submission will be automatically scheduled for full SRC review.

- Refer to Full Scientific Review Committee (SRC). Concerns, including those with respect to any proposed plans for addressing the studies Scientific Progress, have not been satisfied such that Full SRC review is required.

  The Full SRC can determine as a result of their review:
  - o Approved to Continue. No Scientific Progress concerns and/or the plan for addressing any Scientific Progress concerns have been accepted.
  - o Request a Corrective Action Plan from the study team that will be re-reviewed.
  - o Recommend Shortened IRB Continuing Review Period (e.g. 6 month approval)
  - o Require Accrual Benchmarks (e.g. 2 accruals by the time of the next Scientific Progress Review)
  - o Permanently Close the Research to New Accrual
  - o Permanently Close and Complete the Research
  - o Other recommendations as determined by the SRC

Exceptions

Slow accruing protocols may be granted an exception if the protocol is determined to target a rare disease. Rare disease is currently defined as occurring in "less than 6 per 100,000" individuals.

References

DF/HCC Standard Operating Procedures for Human Subject Research: Accrual and Scientific Progress by the Scientific Review Committee (COM-102)

NCI Cancer Center Support Guidelines (CCSG):
http://cancercenters.cancer.gov/ and http://grants.nih.gov/grants/guide/pa-files/PAR-13-386.html