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Early Phase Trial Oversight Committee Charter for NCI-Sponsored Trials
Version 1: June 18, 2019

I. Purpose

To describe the procedures to be used by the Early Phase Trial Oversight Committee for oversight of protocol monitoring for Phase I and non-randomized Phase II trials, and safety lead-in components of protocols.

II. Scope

This Charter applies to NCI-sponsored NRG Oncology trials.

III. Procedures

A. Responsibilities

The Early Phase Trial Oversight Committee reviews protocol safety and toxicity meeting minutes for Phase I trials and safety lead-in components, and reviews the study team statistician's report and study monitoring meeting minutes, or overview memo in the event of no change in trial status, of non-randomized Phase II trials. The Early Phase Trial Oversight Committee may request additional information either in-person or in writing from the Protocol PI/Chair of a protocol under review about the protocol team monitoring activities.

B. Membership

The Early Phase Trial Oversight Committee includes at least seven members with at least one member from each of the disciplines of medical oncology, radiation oncology, surgical oncology and biostatistics, one of whom, at the discretion of the Group Chairs, will serve as the committee chair.

C. Meetings

Meetings/conference calls of the Early Phase Trial Oversight Committee occur at least quarterly. Face-to-face meetings are held at the semiannual NRG Oncology group meetings and intervening quarterly meetings are held by conference call. The committee also meets as called upon by any Protocol PI/Chair who requests review and recommendation regarding any particular aspect of the trial for which the Protocol PI/Chair desires an opinion outside of the protocol team.

D. Recommendations

The Early Phase Trial Oversight committee reaches consensus on whether the trials under review are being monitored in accordance with the relevant procedures and whether the decisions reached by the monitoring teams are consistent with patient safety and ethical research practices.

The Chair of the Early Phase Trial Oversight Committee meeting submits meeting minutes to document the reviewed protocols, the outcome of the committee's evaluation of the protocol team's monitoring, and to describe recommendations for or inadequacies in the protocol team's monitoring or decision making, if any exist. Should any inadequacies be noted, the Protocol

PI/Chair and Protocol Statistician will be notified by the Chair of the oversight committee and, if warranted, asked to respond in writing with a corrective action plan. The committee will follow up on compliance with the corrective action plan at the next committee meeting. If warranted the committee will recommend audit or other remediation in conjunction with the Group Chairs. Electronic copies of these minutes and any corrective action plans will be forwarded by the Chair of the oversight committee to the NRG Oncology Group Chairs and also to the staff of the NRG Oncology Operations Office to archive the minutes.

E. Confidentiality

Members must submit confidentiality agreements.

F. Conflict of interest

Members must submit yearly conflict of interest information; refer to the NRG Oncology Conflict of Interest program and procedures.

IV. Reference

SDMC STAT SOP Protocol Monitoring for Phase I NRG Oncology Trials
SDMC STAT SOP Protocol Monitoring for Non-randomized Phase II NRG Oncology Trials
NRG Oncology Conflict of Interest Program (TBD)
NRG Operations SOP Early Phase Trial Oversight Committee Administration

V. Appendices

NRG Oncology Early Phase Trial Oversight Committee Statement on Confidentiality

VI. Regulations and Guidelines

CTEP Early Phase Trial Slow Accrual Guidelines

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NRG ONCOLOGY EARLY PHASE TRIAL OVERSIGHT COMMITTEE STATEMENT ON CONFIDENTIALITY

The NRG Oncology conducts clinical studies carefully designed and managed to eliminate any biases that might jeopardize the objective oversight of clinical trials. The purpose of this document is to ensure that Early Phase Trial Oversight Committee members understand and accept their obligation to maintain complete confidentiality with respect to all information, or the deliberations of the committee, with individuals who are not members of the Early Phase Trial Oversight Committee. Such confidentiality is essential to protect NRG Oncology clinical studies from the introduction of biases that could threaten their scientific integrity, and compromise the ability of the medical community to unambiguously interpret the results of these studies. Statement of the Early Phase Trial Oversight Committee MEMBER: I, the undersigned member of the Early Phase Trial Oversight Committee of the NRG Oncology, have reviewed the above statement. I understand and accept my responsibility to refrain from discussing or divulging the deliberations of the Committee, or information provided to the Committee, to any individuals who are not members of the Early Phase Trial Oversight Committee.

Please Print Name _____ Please Sign Name _____
Date _____