DCP Multicenter Guidelines

If an institution wishes to collaborate with other participating institutions in performing a DCP sponsored research protocol, then the following guidelines must be followed.

Responsibilities of the Awarded Contracting Center (ACC):

- The Awarded Contracting Center (ACC) will be the single liaison with the DCP Protocol and Information Office (PIO). The ACC is responsible for the coordination, development, submission, and approval of the protocol as well as its subsequent amendments. The protocol must not be rewritten or modified by anyone other than the ACC. There will be only one version of the protocol, and each participating institution will use that document. The ACC is responsible for assuring that all participating institutions are using the correct version of the protocol.
- The ACC is responsible for the overall conduct of the study at all participating institutions and for monitoring its progress, including accrual rates. All reporting requirements to DCP are the responsibility of the ACC.
- The ACC is responsible for the timely review of Adverse Events (AE) to assure safety of the study participants.
- The ACC will maintain documentation of AE reports. The participating institutions report to the ACC who in turn report to DCP.
- The ACC is responsible for reporting Serious Adverse Events (SAEs) to DCP.
- The ACC is responsible for the collection of laboratory certifications, laboratory normals, etc.
- The ACC is responsible for the preparation of all submitted data for review.
- The ACC will be responsible for the review of and timely submission of data for study analysis.
- Each participating institution will have an appropriate assurance on file with the Office for Human Research Protections (OHRP), HHS. The ACC is responsible for assuring that each participating institution has an OHRP assurance and must maintain copies of IRB approvals from each participating site.
- Prior to the activation of the protocol at a participating institution, an OHRP form 310 (documentation of IRB approval) must be submitted to DCP.
- The ACC is responsible for central patient registration as well as collection and transmittal of case report forms (CRFs).
- Audits may be accomplished in one of two ways (1) source documents and research records for selected patients are brought from participating sites to the ACC for audit; or, (2) selected patient records may be audited on-site at participating sites. If the NCI chooses to have an audit at the ACC, then the ACC is responsible for having all source documents, research records, all IRB approval documents, NCI Drug Accountability Record forms, patient registration lists, response assessments scans, x-rays, etc. available for the audit at the ACC site.

Inclusion of Multicenter Guidelines in the Protocol:
The protocol must include the following minimum information:

- The title page must include the name and address of each participating institution and the name, telephone number and e-mail address of the responsible investigator at each participating institution.
- The ACC must be designated on the title page.
- Central registration of study participants at the ACC is required. The procedures for registration must be stated in the protocol.
- The DCP Case Report Form (CRF) Template must be used for data collection and can be found at the URL: http://rcb.nci.nih.gov/appl/rfp/DCPPhase2/DCP.htm Completed forms should be submitted with the protocol. The frequency and timing of data submission forms to the ACC should be stated.
- Describe how AEs will be reported from the participating institutions through the ACC.

Drug Ordering:
Except in very unusual circumstances, each participating institution will order DCP-supplied investigational agents directly from DCP. Investigational agents may be ordered by a participating site only after the initial IRB approval for the site has been forwarded by the ACC to the DCP PIO. **The study coordinator will be responsible for the submission of drug order requests for the participating institution's sites**. Drug ordering procedures should be included in the protocol.