DCT GUIDELINES FOR MULTICENTER INVESTIGATIONAL AGENT STUDIES

1.0 PROTOCOL DEVELOPMENT

1.1 For each multicenter study, one institution shall be designated as the "Coordinating Center."

1.2 The Protocol Chairman at the Coordinating Center will be the single liaison with the CTEP Protocol and Information Office (PIO). The Protocol Chairman will coordinate the development, submission, and approval of the protocol as well as its subsequent amendments, results reports, and publications.

2.0 PROTOCOL DOCUMENT

There will be only one version of the protocol and each participating institution will use that document. It should not be rewritten or modified by any one other than the Protocol Chairman at the Coordinating Center who is solely responsible for obtaining CTEP approval and distributing the protocol to all participants, as well as formulating protocol amendments for CTEP approval and distributing protocol amendments to all participants.

2.1 Protocol Title Page

The protocol document developed for a multicenter study should contain the following information on the title page:

1) Date of Document
2) Title of Study
3) Protocol Chairman, including name, institution, address and phone number.
4) Name of each participating institution, and Responsible Investigator at each (with phone number)
5) NCI number, local protocol numbers
6) List of DCT-supplied investigational agent(s) and NSC number(s)

The multicenter protocol facesheet should be updated whenever new institutions are added.

2.2 Patient Entry Procedure: Patients should be centrally registered by telephone with the Coordinating Center. The protocol document should specify directions, including registrar's name and phone number. Registration procedures should include a check of eligibility and regulatory issues (see quality Assurance).

2.3 Records to be Kept: The Coordinating Center is responsible for developing common case report forms, and all data should be submitted to the Coordinating Center on these forms. The forms to be used should be submitted with the protocol. The protocol document should specify the for, submission schedule and where to send the data.

2.4 ADR Reporting: There are two options for the flow of Adverse Drug Reaction (ADR) Reporting: