**Who is eligible? / Who can participate in the NCI Formulary?**

NCI registered investigators from NCI-Designated Cancer Center sites in good standing.

**What is the process to apply for access to available agents?**

Eligible investigators may submit LOI proposals to CTEP, using the NCI Formulary Letter of Intent Submission Form, to conduct protocols with agents available from the NCI Formulary (alone or in combination with other NCI Formulary agents) or agents available from the NCI Formulary in combination with other marketed agents.

**Is it possible to combine NCI Formulary Agents with other investigational agent that are being developed by CTEP or by industry?**

No. NCI Formulary agents may only be used in combination with other NCI Formulary agents or with marketed agents.

**Is funding available?**

Investigators must provide evidence of funding to support trial at the time of LOI proposal submission. Investigators may request funding; however, Pharmaceutical Collaborators are not required to provide funding. If funding is requested, complete the Formulary CRADA: Cost Estimate Worksheet attached to the NCI Formulary LOI form.

**Will CTEP perform a scientific review of the LOI proposals and protocols?**

CTEP will not perform scientific reviews on the incoming LOI proposals and protocols. The Pharmaceutical Collaborator(s) providing the agent(s) will assess the scientific validity of the proposed studies.

**Will Investigators be able to communicate with Pharmaceutical Collaborators directly?**

Yes, direct discussions between the Investigator and Pharmaceutical Collaborator(s) are required.

**Who will prioritize access to the NCI Formulary agents?**

As the supply of agents may be limited, the Pharmaceutical Collaborator(s) providing the agent(s) will prioritize access to agents based on the submitted proposals and ongoing protocols.

**What reporting responsibility does the investigator have once they start their study?**

Investigators are required to conduct the trial in accordance with IND regulations and the responsibilities of sponsor and report all required information to the FDA. Investigators are required to submit all clinical trial data to the NCI and Pharmaceutical Collaborator in accordance with the specified clinical data reporting system. Investigators are required to provide all other information to NCI and Pharmaceutical Collaborator in accordance with the NCI Formulary Material Transfer Agreement.

**Can an Investigator make changes to a Final Protocol?**

Yes, but only with the Pharmaceutical Collaborator’s prior approval.

**Who will hold the IND and be responsible for regulatory submissions relating to an approved study?**

The Investigator or Cancer Center will be the IND sponsor and responsible for all regulatory submissions to the FDA.

**Who will have rights to the data generated under the approved protocol?**

Data rights are described in the NCI Formulary Material Transfer Agreement.

**Are agents available for pre-clinical studies?**

NCI Formulary agents will be available to investigators from NCI-Designated Cancer Center sites for pre-clinical use in support of NCI Formulary protocols. A NCI Formulary Non-Clinical Study Proposal form is to be completed and submitted to the NCI to make the request for consideration.