NATIONAL CANCER INSTITUTE

NCI Formulary Process Overview: Clinical

= Investigator Responsibility = NCI Responsibility = Collaborator Responsibility

Review list of available agents and the Collaborator's studies of interest, if available, on the NCI Formulary website

Investigator submits Letter of Intent (LOI) Proposal to NCI PIO mailbox: pio@ctep.nci.nih.gov and copies the NCI Formulary mailbox: NCIFormulary@mail.nih.gov

NCI reviews investigator eligibility to participate in the NCI Formulary

PIO forwards eligible LOI Proposal to Collaborator

Collaborator has sixty (60) days to review the LOI Proposal and render decision

Collaborator approves/disapproves LOI Proposal, response is sent to PIO and NCI Formulary mailboxes

NCI informs investigator of approval/disapproval status

Collaborator and Investigator can now discuss details of proposed research plan and Investigator can begin drafting the Protocol

Investigator submits the initial draft protocol to NCI PIO and NCI Formulary mailboxes

NCI sends Investigator a non-negotiable NCI Formulary Material Transfer Agreement (MTA). Investigator returns partially-executed MTA to NCI.

NCI fully-executes the MTA and returns a copy to the Collaborator and Investigator

Once the protocol is final, submit protocol and Collaborator approval notice to NCI PIO and NCI Formulary mailboxes, and submit IND Application to FDA

Obtain IRB Approval and develop clinical data reporting set-up for protocol with NCI

Submit all regulatory documentation (e.g., IND safe to proceed, IRB approval) to NCI PIO and NCI Formulary mailboxes and Collaborator

NCI PIO notifies investigator that protocol is ready for activation and that agent supplies may be requested

Submit protocol information to clinicaltrials.gov

Conduct protocol in accordance with FDA IND regulations as IND sponsor of the protocol

Submit required trial data and regulatory documentation to NCI and Collaborator in accordance with MTA throughout conduct of the protocol