NCI Formulary Process Overview: Clinical

- **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**

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

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

- **PIO forwards eligible LOI Proposal to Collaborator**

- **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**

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

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

- **Submit protocol information to clinicaltrials.gov**

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

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

- **Submit protocol information to clinicaltrials.gov**