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CTEP PIO Overview of ET-CTN Protocol Development Process

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The Project Team Application (PTA) Process

- IDB Project Team Leader forms NCI Project Team comprised of staff across NCI programs to identify appropriate subject matter experts in clinical, translational and basic biology
- IDB Project Team Leader drafts PTA announcement containing agent information and types of clinical trials being considered with input from Project Team
- PIO emails PTA announcement to NCI Clinical Network Investigators

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Writing and Submitting the PTA

PTA form will include areas for :

- Identifying particular trial of interest specific to disease/agent/biomarker area
- Strengths:
  - Special capabilities such as biomarker assay, imaging, labs, etc
  - SPORE, P01, R01 collaborators
  - Evidence of enrollment potential

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PTA Review and Selection by NCI

- PTAs are reviewed and prioritized at NCI meetings
- IDB Project Team Leader assembles Drug “X” Project Team including submitters of approved PTAs and SMEs identified by the NCI Project Team
- Drug “X” Project Team refines clinical and biomarker development plan and presents to the IDSC
- Following approval of the development plan by the NCI Senior Advisory Committee (SAC), CTEP requests full LOIs from Project Team members

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Project Team Collaboration

- Collaboration will take place via an NCI-supported SharePoint site
- SharePoint site will contain:
  - permission-based roles for each project area
  - repository of all documents needed for each project
  - reports on project progress

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Submission of Letter of Intent (LOI)

- Follows current LOI process:
  - OEWG clock starts with LOI receipt by PIO
  - Once LOI is approved, full protocol is drafted and submitted to PIO
  - Request for LOI submission does NOT guarantee approval of LOI

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Summary of Changes to LOI Process

Current PSL/MS Process	Future PTA Process
Pre-solicitation LOI (PSL) request sent to U01/N01 investigators	PTA request sent to NCI Clinical Trials Network investigators
PI submits completed PSL to PIO	PI submits PTA to PIO
PSL reviewed by CTEP	PTA reviewed by CTEP
Selected PSL invited to submit LOI	Selected PTAs invited to join Drug “X” Project Team
Mass Solicitation letter sent to all qualified investigators	Initial trials developed by Drug “X” Project Team
Responses to Mass Solicitation received by PIO	Project Team members submit LOIs to PIO

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Changes in Protocol Approval

Current Process	ET-CTN Process
Protocol reviewed at PRC	Protocol reviewed at PRC with biomarker review by BRC
Protocol cover page lists all participating PIs and sites (amendment needed when there are changes)	Protocol lists only lead ETCTN grant recipient (LAO)/PI and participating grant recipients. Individual treating sites/ investigators not listed; managed via network rosters
Protocol cannot be approved until 1st IRB approval is received at PIO	Protocol is reviewed at CIRB, once approved there, final CTEP approval is given

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Changes in Protocol Activation

Current Process	ET-CTN Process
Participating site IRB approvals collected by PIO before activating site	Participating sites utilize CIRB approval and submit “Study Specific Worksheet” to CIRB
Theradex is notified after CTEP approval to begin set up in ACES and Oracle	Theradex will be notified at time of CIRB receipt- triggers building of eCRFs for MediData Rave and Oracle
Lead site submits Protocol Status Update (PSU) form to PIO to activate protocol	LAO activates protocol through RSS
Protocol opens to accrual once site submits PSU to activate	Sites begin to accrue through OPEN once CTEP final approval is given and study status is updated to Active in RSS

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Questions?