**National Institute of Mental Health (NIMH) Clinical Trials Operations Branch (CTOB) Project Management of Studies Reviewed by a NIMH Data and Safety Monitoring Board**

The NIMH Clinical Trials Operations Branch (CTOB) will serve as your study team’s liaison to the NIMH Data and Safety Monitoring Board (DSMB), and will work in conjunction with your Program Officer to support the operational aspects of this research study. CTOB will work with your team to establish strong monitoring and oversight practices for human subject protections, good clinical practice (GCP), protocol compliance, and data integrity.

After an initial call to provide an orientation to CTOB’s role as the NIMH operational lead, CTOB will work collaboratively with the study team throughout the project to review and develop, among other activities, the items listed below. Also, the NIMH has a web-based [toolbox](https://www.nimh.nih.gov/funding/clinical-research/clinical-research-toolbox/nimh-clinical-research-toolbox.shtml) that will be of use to the study team; the toolbox provides information and templates relevant to studies being reviewed by the NIMH DSMB, as well as general information related to the conduct of clinical research and clinical trials.

1. **Orientation to CTOB**
	1. CTOB’s function and role
	2. [NIMH policy and guidance on data and safety monitoring](https://www.nimh.nih.gov/funding/clinical-research/clinical-research-toolbox/nimh-clinical-research-toolbox.shtml#data-safety-monitoring)
	3. NIMH DSMB Charter
	4. Timeline for study initiation activities
	5. Recommended staffing for clinical research study
2. **Study Initiation**
	1. Initial DSMB review
		1. [Protocol](https://www.nimh.nih.gov/funding/clinical-research/clinical-research-toolbox/nimh-clinical-research-toolbox.shtml#protocol-templates)
		2. Informed consent forms (ICFs)
			1. [Data sharing ICF template language](https://data-archive.nimh.nih.gov/ndct/s/sharedcontent/plan/project-startup.html)
		3. DSMB data report template
	2. [Certificate of Confidentiality](http://grants.nih.gov/grants/policy/coc/index.htm)
	3. Regulatory approval status and plans (e.g., Institutional Review Boards (IRBs), DSMB, Food and Drug Administration (FDA))
		1. Order of approvals
		2. Documentation of approvals
		3. Synchrony between protocols submitted to each regulatory body
	4. Additional documents and activities needed prior to study initiation
		1. [Manual of Operating Procedures (MOP)](https://www.nimh.nih.gov/funding/clinical-research/clinical-research-toolbox/nimh-clinical-research-toolbox.shtml#protocol-associated-documents)
		2. [ClinicalTrials.gov Registration](https://clinicaltrials.gov/)
		3. Data Submission Agreement
		4. Study Kick-off Meeting
3. **Study Implementation and Enrollment**
	1. Scheduled study operations calls (e.g., PI and study coordinator calls)
	2. When to contact your CTOB liaison
		* 1. Event that triggers contact with regulatory body
			2. Serious Adverse Event (SAE) reporting, as indicated by protocol
			3. Unanticipated problems
	3. DSMB report submission process
	4. Proposed changes to study documents (e.g., protocol, ICF, etc.)
	5. Monitoring visits
	6. [Data submissions to NIMH Data Archive (NDA)](https://nda.nih.gov/)
4. **Study close out**
	1. Close out monitoring visit
	2. Final DSMB data report
	3. Data sharing
	4. Publications