



UC San Diego
MOORES CANCER CENTER

UCSD Moores Cancer Center Clinical Trials Office

Investigator-Initiated Trials

Operational Guidance Document

Version 2.1

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List of Abbreviations

CA	Coverage Analysis
CCSG	Cancer Center Support Grant
CDA	Confidentially Disclosure Agreement
COI	Conflict of Interest
CRC	Clinical Research Coordinator
CRF/eCRF	Case Report Form/electronic Case Report Form
CRO	Clinical Research Organization
CTA	Clinical Trial Agreement
CTO	Clinical Trials Office
DCF	Data Clarification Form
DMP	Data Monitoring Plan
DSMP	Data and Safety Monitoring Plan
DSMC	Data and Safety Monitoring Committee
DT	Disease Team
DTAF	Disease Team Approval Form
DTCA	Disease Team Committee Analyst
DT PM	Disease Team Project Manager
DTAF	Disease Team Approval Form
FDA	Food and Drug Administration
FSE	First Subject Enrolled
GCP	Good Clinical Practices
HERC	Human Exposure Review Committee
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
IDS	Investigational Drug Services
IIT	Investigator Initiated Trials (or Studies)
IND	Investigational New Drug
IRB	Institutional Review Board
KIRB	Kuali IRB Portal
LOI	Letter of Intent
LTFU	Long Term Follow Up
MCC	Moore's Cancer Center
MSML	Multi-Site Management Lead
NCI	National Cancer Institute
OCAA	Office of Coverage Analysis Administration
OCGA	Office of Contract and Grants Administration

OIA	Office of IRB Administration
PDO	Protocol Development Officer
PI	Principal Investigator, also called Sponsor/Investigator
PM	Project Manager
PRF	Protocol Registration Form
PRMC	Protocol Review and Monitoring Committee
PRMS	Protocol Review and Monitoring System
QA	Quality Assurance
RA	Regulatory Associate
SAP	Statistical Analysis Plan
SOW	Scope/Statement of Work
SPF	Sponsored Projects Finance
SIV	Site Initiation Visit
SU PM	Start Up Project Manager

This guide outlines the procedures for initiating, maintaining and closing interventional institutional (UCSD-sponsored) investigator-initiated trials (IITs). For multi-center IITs, utilize this guideline to commence the study at UCSD, and consult the multi-center IIT operations guide for activating external subsites. It is important to note that this guide exclusively pertains to interventional UCSD-sponsored IITs and should not be applied to externally sponsored IITs.

The Moores Cancer Center (MCC) is a recipient of the Cancer Center Support Grant (CCSG) and is obligated to report to the National Cancer Institute (NCI). The NCI mandates that Comprehensive Cancer Centers must actively participate in clinical research by initiating internally sponsored IITs.

MCC-CTO IIT Unit Composition:

The MCC Clinical Trials Office (MCC-CTO) will provide centralized resources for institutional cancer related interventional (therapeutic and non-therapeutic) clinical trials. This will be provided through the IIT Unit. The IIT Unit will be overseen by the Assistant Director of Clinical Trial Activation and IIT Support. UCSD serves as the sponsor for all institutional investigator-initiated trials (IITs). As the sponsor, UCSD is tasked with initiating, overseeing, and monitoring the study, as well as owning all study data.

The IIT Unit is composed of:

- The Principal Investigator (PI): Responsible for ensuring compliance with UCSD-sponsored IITs.
- Assistant Director, Clinical Trial Activation and IIT Support.
- The Protocol Development Officer (PDO): Supports development and revisions of protocol and informed consent forms (ICFs); helps with creating other study documents (laboratory manual, pill diary, and relevant protocol appendices). The PDO will also assist with protocol amendments and ICFs updates as needed.
- Regulatory Associate (RA): Ensures all relevant regulatory standards and compliance requirements are met. Responsible for regulatory study maintenance, annual reviews, new safety updates and regulatory submissions of assigned studies. Responsible for regulatory submissions and document execution during clinical trial activation. Responsible for handling initial submissions to both the Food and Drug Administration (FDA) and internal bodies, such as the Institutional Review Board (IRB), Protocol Review and Monitoring Committee (PRMC), Human Exposure Review Committee (HERC), etc. Reviews the ICFs and other required regulatory documents.
- Multi-Site Management Lead (MSML): Oversees external sites of UCSD multi-site IITs. The MSML will support the external sites throughout the lifetime of the study. The MSML is responsible for initiating, maintaining and scheduling sub-site close outs.

The IIT unit will integrate with key individuals within the clinical trials office including:

- Associate Director(s) of Clinical Operations: Responsible for overseeing clinical operations of Disease Teams (DTs).
- Disease Team Project Manager (DT PM): Responsible for supervising day to day activities for assigned clinical trials and staff. Responsible for Project Management activities of IITs.
- Disease Team Committee Analyst (DTCA): Responsible for supporting the coordination and administration of protocols in the feasibility process, completing first stage PRMS review and study prioritization.
- Start Up Project Manager (SU PM): Responsible for coordinating and managing clinical trial start up activities.
- Regulatory Manager: Responsible for supervising day-to-day regulatory activities for MCC-CTO clinical trials and staff.
- Budget Manager: Responsible for overseeing the budget development team.
- Budget Analyst: Responsible for budget development and negotiations of MCC-CTO clinical trials including institutional IITs. Budget Analyst will also be responsible for budget amendments.
- Data and Safety Monitoring Committee (DSMC).
- Quality Assurance (QA): Responsible for ensuring data quality and adherence to Good Clinical Practices (GCP) by auditing and monitoring IITs. Queries will be provided by the QA team to the PI in data clarification form(s) (DCF).
- Statistician/statistical team: Although not part of CTO, the statistical team is responsible for the development of the statistical analysis plan (SAP) within a protocol, for providing overall feedback during protocol development (e.g. study timelines, endpoints, etc.), and for analyzing the data, including for DSMC review, throughout and at the end of the study.

This integrated IIT Unit, along with the DTs and PIs, will be tasked with developing, activating, maintaining, and finalizing UCSD interventional IIT.

Concept Development:

The PI is responsible for developing the full research concept, including the background, rationale, hypothesis, objectives, eligibility criteria, study design, feasibility, and anticipated impact. The PI must complete the concept form (or indicate where information is found if not on concept form) and budget form.

The fully vetted concept form/ information should be reviewed by the DT, who assess the scientific merit and clinical relevance, providing preliminary approval to proceed with securing funding and providing DT support for the study.

Once approved, the study enters the IIT Unit's queue for protocol development. It's important to note that protocol development for grant applications can begin before funding is fully secured. This allows investigators to prepare strong grant submissions with well-developed protocols. The IIT Unit supports investigators throughout the process, offering guidance on methodology, regulatory requirements, and protocol development to ensure the research is viable and compliant.

Protocol Development and Activation:

Once the Protocol, ICF(s), and other study documents are considered FINAL and all other required steps are completed as outlined in section 1.0 IIT Unit, the study will be moved into the Activation Unit (section 2.0) for study activation support. Requests for study to enter the Activation Unit will be sent by the DT PM or DT CA.

Study Maintenance:

The DT is responsible for lead site study maintenance:

- DT PM to assign CRC (to lead site, if multi-center study)
- RA or designee provides quarterly checks for updated IBs/package insert
- PDO supports protocol, ICF, and study documents amendments
- RA processes amendments
 - MSML will be included in amendments during which study is updated from a Single Site IIT to a Multi-Site IIT. MSML will follow the same sub-site management process as for studies that start as multi-site IITs
- Budget amendments are requested by the DT PM with support of the CTO budgeting team.
- Clinical Research Organization (CRO) support:
 - Refer to the study-specific CRO responsibilities

1.0 IIT UNIT

Appendix 1 provides a visual workflow of the UCSD IIT study start-up.

1.1 IIT Concept Development and Approval:

- PI in collaboration with the DT PM completes the Concept Form (**Appendix 2**)
- PI in collaboration with the DT PM completes budget form located at [Clinical Trials Budgeting One Note \(sharepoint.com\)](#) and collaborates with MCC-Business office and/or MCC-CTO Budgeting Team
 - Budget form should be used when potential funder/industry partner requires a preliminary budget estimate with concept/letter of intent (LOI) submission
 - Return completed form to CTOBudgeting@health.ucsd.edu

- PI in collaboration with DT PM completes internal statistical request form to schedule protocol review. Initial request is on a no fee basis:
<https://moorecancercenter.ucsd.edu/research/shared-resources/biostatistics/index.html>
- Disease Team Concept Review:
 - PI presents concept to the DT
 - PI is encouraged to use template slide:



- DT recommendations:
 - 1) Support the study
 - 2) Further concept development or refinement and represent to disease team
 - 3) Reject further concept development
- DT PM and/or DTCA document the decision on the concept form. *Only studies supported by the DT* can enter the IIT Unit
- Study funding needs to be secured prior to sending study to IIT Unit
 - Exception: IITs for grant submissions can be submitted to IIT Unit prior to secured funding

1.2 IIT Protocol Development:

- DT PM submits New IIT Request (**Appendix 3**): Concept form (with documented DT support), presentation slides, and budget/secured funding information to IIT Unit for PDO Assignment: CTOIIT@health.ucsd.edu
 - SU PM is assigned at the time of the New IIT request
 - RA is assigned at the time of the New IIT Request. IRB # is generated by RA as soon as possible, and provided to all email recipients
 - RA action is requested when study is ready for FDA submission. The PDO will notify via email the RA and study team when protocol is submission ready (see below)
- Upon study assignment, PDO schedules a launch call with PI, RA (optional), SU PM (optional) and any other relevant team member

Potential stakeholders during protocol development:

- PI
- PDO
- RA or designee
- SU PM or designee
- Statistician (internal or external)

- Pharmacy (if needed)
- Nursing (if needed)
- Funder and/Industry Partner (if applicable) will want to sign off on protocol. Typically, sign-off of ICF is not required
- Biosafety (if needed)

PDO responsibilities:

- Protocol development with PI. Most up to date OIA IIT Protocol Template should be used, but this is not mandatory
 - Data and Safety Monitoring will be performed by the DSMC based on risk assessment, and according to the DSMP. Final risk assessment is done by PRMC. Standard protocol language concerning DSMC and clinical monitoring can be used in the body of the protocol if PI and other sites, if applicable, agree to comply with current version of DSMP. Otherwise, the PI needs to provide a different data monitoring plan to be added as an appendix to the protocol
- Manual generation (laboratory, pharmacy, imaging, pathology and other as necessary)
- Informed Consent Form(s) (MCC-CTO ICF template should be used)
- Statistical plan development with either internal or external statistical support (requires funding).
- Blank (not signed) protocol signature page
- Supplemental materials, such as pill diary, study-specific questionnaires, and recruitment materials. Note that license for use of validated questionnaires (FACT, EPIC, EQ, etc.) should be requested by SU PM during study activation (see below under SU PM responsibilities)
- Protocol revisions (usually following IRB and PRMC review) and amendments

FDA submission:

- RA reviews protocol and ICF to ensure regulatory compliance
- RA prepares FDA application. A formal IND Exemption and/or IDE is required
- Protocol should be considered submission ready at the time of FDA application
- PI should review FDA provided guidance materials: <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application>
- RA, SU PM and PDO work with PI to respond to FDA concerns and questions
- PI to interact early with the FDA during conceptualization and planning strategies of study before submitting an IND application
 - Optional: Pre-IND meeting can be beneficial for complex IND applications, and can occur:
 - When an IND application has never been filed

- When no existing IND is available to cross-reference pharmacology/toxicology and manufacturing information for the product
- Pre-IND meetings can occur before involvement from the protocol development team, prompting the PI or study team to request and conduct these meetings independently. However, assistance from the PDO and RA can be requested

SU PM responsibilities:

- Supports any project management activities that occur during protocol development, examples include:
 - Support with contract/agreement submissions
 - Obtaining questionnaires with licenses (if applicable)
 - Logistical support for sample collection (i.e. supplies, methods, BTTSR requests etc)
 - Work with industry partner to obtain drug or device
 - Coordinate protocol review with industry partners
 - Submits to MCC DSMC (once protocol is submission ready and when IRB approved)

Final Protocol and Study Documents:

- Protocol and ICF(s) are considered final once the PI provides final approval
- The Protocol, and ICF(s) along with any other study documents are sent by the PDO to the RA, SU PM, PI with cc: DT PM, DTCA, Assoc Dir, Clin Ops; Asst Dir, IIT by the PDO:
- Subject Line should include at minimum: **FINAL _Study Name_PI Name**
- Note that the PDO does not send final study documents to the statistician/statistical team. Rather, the RA sends the protocol to the statistician/statistical team at the time of IRB submission
- SU PM should acknowledge receipt of study documents within **2 business days** of email and communicate to the DT PM that voting can occur
- Study is ready for DT voting: DT PM and/or DTCA prepares study for DT presentation and voting
- Upon favorable DT Vote, study is ready to be sent to Activation Unit
- Official Activation Unit entry is the date the Disease Team Approval Form (DTAF) and Protocol Registration Form (PRF) is provided to the SU PM and CTO Data Management Team by DT PM or DTCA

2.0 IIT Activation Unit:

For detailed MCC-CTO activation steps, refer to the MCC-CTO “New Study Activation Guide”.

IITs are a high priority for our institution, and the time to activation target is **120 days or less** from PRMC submission to activation

Documents required for Activation Unit entry: Protocol, ICF, manuals (pharmacy, lab, etc.), funding information, IND determination, CTA template (if applicable), DTAF

- Prior to study proceeding in Activation Unit, **DT PM must provide the DTAF and PRF to the SU PM and CTO Data Management Team (Official Activation Unit date entry)**
- SU PM can schedule a launch call with PI, RA, PDO, and any other relevant team members.
- SU PM follows the MCC-CTO Activation Guideline to activate the assigned study

Coverage Analysis:

- Created by OCAA
- Principal Investigator, SU PM work together to finalize the CA. PDO should be involved in CA discussions to help ensure alignment with protocol
- It is recommended that the PI, SU PM, PDO, and OCAA Analyst schedule a meeting to review any questions
- It is recommended that the CA is finalized prior to the initial IRB submission

Contract(s):

- Contract/agreements can be submitted during the protocol development stage. An OCGA Analyst will not be assigned until the study is awarded (E.g. NOA received for NIH trials)
- SU PM should follow up with the DT PM or designee to inquire if any negotiations started or were finalized during the protocol development phase
- Contracts/agreements submitted and negotiated with support of OCGA. PI is encouraged to have a brief call with OCGA to discuss the project and contractual requirements. Assigned SU PM will facilitate scheduling and should be attending the call
- SU PM should check with all funding partners, drug manufacturers providing study drug, external vendors or labs for correlative studies, and any other partners supporting study on any agreements needed
 - As IITs can have multiple agreements, it's important to check and communicate this to the assigned OCGA analyst

Pharmacy:

- SU PM discusses drug management and shipment with IDS
- PDO (SU PM as back-up) creates pill diary, if needed
- If study enrolls in any of the Network sites, drug shipping to the network site should be discussed both with drug manufacturer and the pharmacy

EDC:

- eCRF creation can begin after the protocol is finalized
- SU PM to notify the team responsible for eCRF development at the time of IRB Submission
 - If using internal MCC biostats with Karen Messer, RA will notify the biostats team and cc DT PM
 - CTO Data Core can create eCRF if the MCC biostats team of Karen Messer is not involved in the study
- eCRF templates are developed in partnership with PI. Team developing eCRF needs to obtain sign-off from PI. Designed according to the data required for data analysis according with endpoints
- Database systems can vary: Velos, Redcap or other system if used by CRO
- eCRFs needs to be developed and signed off by PI prior to study activation
- Upon enrollment, all patients who signed the ICF need to be registered in Velos, regardless of database used

Site Initiation Visit(SIV)/In-service:

- SIV/In-service is scheduled by the SU PM and will be led by the study PI (DT PM can request that they schedule the SIV/In-service)
- SU PM notifies DT PM when SIV/in service scheduling should start

Clinicaltrials.gov:

- Registration of the study to clinicaltrials.gov will be facilitated by the PDO and Data Analytics Team
- Registration is usually performed by the PDO (with Data Analytics Team as backup) soon after IRB approval and before activation. To this end, RA should notify PDO and Data Analytics Team of IRB approval
- SU PM or DT PM should notify PDO and Data Analytics Team in a timely fashion when study is activated and of other relevant information (sites, completion dates, etc.) so that study status can be updated

Safety Information:

- SU PM will ensure method of safety information receipt is obtained (via email or pulled from central location). This will include IBs, package inserts and any other new safety information. This information will be conveyed to the clinical operations team (DT RA and DT PM) and access will be granted as necessary

Award Creation:

- Finalization of award is conducted by Sponsored Project Finance (SPF), with help of OCGA
- Once award is done, chart string can be obtained
- There might be more than one award/chart string. SU PM should enter award associated with patient procedure funding to Velos Research form

Activation:

- Study activation approved and study team notified of activation status via email notification from RA. Study status updated in Velos and clinicaltrials.gov:
 - Activated/Open to Accrual – study can immediately start enrolling
 - Activated/Enrollment hold – study needs final steps to open to accrual, example study drug is not yet received on site

3.0 IIT Maintenance - Clinical Operations

DT PM Responsibilities:

- DT PM to assign CRC, Data CRC and/or LTFU CRC
- Treatment plan build
 - Should be drafted at the time of SIV/In-Service, prior to the first patient enrolled by the assigned CRC or DT PM
 - Accrual monitoring/enrollment DT meetings
 - Requesting Protocol Amendment support from the PDO

Protocol Amendment Support for Active Trials: Requests should be sent to the MCCCTOAmendments (MCCCTOAmendment@health.ucsd.edu) via email request. Refer to the “Amendment Guide”

- **Protocol Amendment Workflow:**
 - Protocol amendments should be limited to up to 2 per year, unless there are significant safety concerns that need to be incorporated sooner
 - PI requests protocol changes by notifying DT RA
 - DT RA prepares Protocol Amendment submission to IIT Unit for PDO assistance and PM assignment (if applicable). Refer to the “Amendment Guide” for detailed instructions.
 - Most up to date/current protocol (word and pdf) and ICF(s) word versions should be sent to the PDO by the RA or DT RA
 - If changes to any manuals are needed, final word version should be included as well

- PDO updates protocol and determines ICF and other documents impact (no changes OR updating with relevant changes)
- All Protocol/consent/manual changes require PI approval. Small administrative edits (for example, misspelling or changes to header/footer, list of abbreviation, table of content, etc.) do not require PI approval
- PI and RA assess for possible FDA submission. If needed, RA submits to FDA
- Final Protocol Amendment packet is sent by the PDO to RA, DT PM, PI
- The RA sends amended protocol to the statistician/statistical team
- RA is responsible for submitting the amendment to IRB and other regulatory bodies, as applicable, within 30 days from receiving the amended documents
- The RA should notify the DT PM and PDO when study is submitted and subsequently approved by IRB and PRMC

New Safety Information:

Safety updates received by PI and/or site staff will be sent to the RA, DT PM and any other relevant staff for processing as described below:

- When new safety information, either in the form of a safety report or updated investigator brochure (IB), is received, the RA saves the documentation in the study files.
 - New Safety Information/IB(s) need to be submitted to the IRB of record within 10 days of receipt
- RA should ensure that at minimum, the PI and DT PM are included on the new safety receipt email
- The QA team, through the routine monitoring visits, will review the IBs filed in the regulatory folders and source verify that a new ICF was amended within 30 days delineating the new risks, as applicable. QA will verify if new enrolled subjects are consented under the new amended ICF and will verify if active patients were re-consented under the new ICF to ensure new risks were disclosed to subjects enrolled in the study, to ensure patient's rights

PI Risk Determination:

- RA notifies PI and Study Team (DT PM, CRC)
- The RA will email the safety information (for example, investigator's brochure [IB]) to the PI.
- The email will include the safety documents received from the manufacturer and the cover letter, incorporating any relevant summaries or risk impacts into the email text
- The PI has 2 business days to respond with any additional input, request revisions, or a decision to perform verbal notification based on the safety documents
- The PI will determine if the safety updates warrant a protocol or ICF update

- The email correspondence will be saved as a PDF in the study's safety folder for the drug/safety document(s)
- If the new safety information indicates a change in risk, the RA requests support of PDO to revise the ICF(s) and/or Protocol
 - Follow above steps as requesting Protocol Amendment support
- PDO along with PI updates the ICF(s) and/or protocol
 - In case of a tight deadline that the PDO cannot meet, the RA will serve as the back-up
- PDO sends final and tracked changes documents to the RA, PI, and DT PM
- RA submits to relevant regulatory bodies within the required timelines

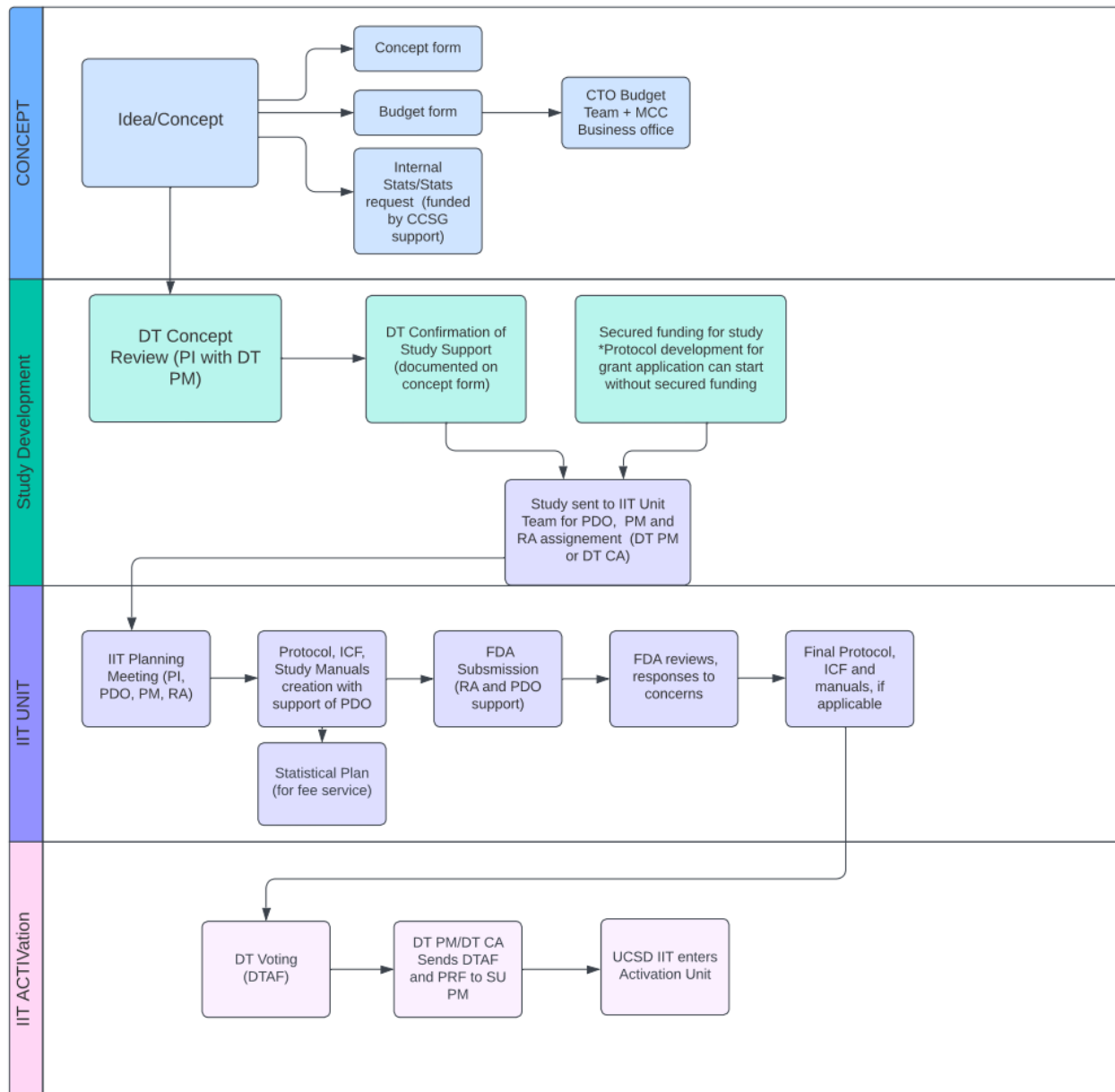
IB Submission Process:

- All IBs, whether they contain administrative updates or corresponding risk updates, will be submitted to the IRB within 10 days of receipt
- If no ICF edits are required and there are no changes to the risk or risk/benefit ratio as per the PI's risk determination, the OIA submission will be processed in a timely manner

Regulatory Manager will hold quarterly meeting to check of IB/Package Insert Status:

- The RA will check the status of the IB/package insert quarterly, either by emailing for updates or logging into the appropriate system
- The RA should maintain the sponsor portal and login information

Appendix 1: Start Up Overview:



Appendix 2: IIT Concept Form

UNIVERSITY OF CALIFORNIA SAN DIEGO INVESTIGATOR INITIATED CLINICAL TRIAL CONCEPT FORM	
Study Title	
Study Phase	
LOI submission Date	

SPONSOR INVESTIGATOR	
Name	
Lead Institution	
Address	
Phone	
Fax	
Email	
SENIOR MENTOR, if applicable	
Name	
Phone	
Email	
COLLABORATING INVESTIGATOR(S)	
Name	
Phone	
Email	

STUDY DRUG (S)/ INTERVENTIONS AND FUNDING SOURCE	
Name of Study Drug(s)/Interventions	
Study Drug Supplier, if applicable	
Placebo?	☐ Yes ☐ No
Name of Commercial Drug(s)	
Trial Funding Source(s)	
MSL Contact	

STUDY DESIGN INFORMATION	
Background and Rationale	
Hypothesis	
Objectives	
Primary	
Secondary	
Endpoints	
Primary	
Secondary	
Indication	
Study Population	
Diversity and Inclusion <i>How will your proposal support diversity in enrollment access and inclusion of people of</i>	

<i>varying age, race, ethnicity, and gender?</i>	
Key inclusion/exclusion criteria	
Treatment Plan <i>State the dose, method of administration, and schedule of each drug, and, if phase 1, provide the dose escalation scheme, and definitions of DLTs.</i>	
Study Assessments <i>Specify all non-routine care assessments and their specific time points using objective practice guidelines (e.g., NCCN). Study calendar template recommended.</i>	
Follow-up Durations	
Estimated Accrual (per month)	
Estimated Number of Sites	
Estimated Total Study Duration	
Statistical Methods <i>Include sample size justification and stopping rules.</i>	Sample size justification: Stopping rules:
Publication Plan	

<i>List specific journals, scientific meetings, and target dates for publication and presentation.</i>	
Does this proposal involve an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application? (Please choose one) Formal IND Exemption is required	☐ IND ☐ IDE ☐ N/A
Additional Comments (e.g., rare population, significant challenges, contingencies)	

CORRELATIVE STUDIES (PHARMCOKINETICS / PHARMACOGENOMICS)	
Describe proposed correlative studies. Please specify which sample collections are optional vs. mandatory for study participation.	
Funding source for correlative studies	

FUNDING	
Funding	☐ Funding secured

Filled out by DT PM:

Disease Team Acknowledgement	
Disease Team: Date study presented:	DT Determination: ☐ DT Agreement to support study ☐ Further concept development or refinement and represent to disease team ☐ Reject further concept development
Supported by: - list DT members (MDs) that support study - email response/confirmation is sufficient	

Appendix 3- New IIT Request Email:

To: CTOIIT@health.ucsd.edu; cto-dmt@health.ucsd.edu, Asst. Dir, IIT Support [Julia Appelt](#)

CC: RA (Regulatory Lead, Michaela Doering), PDO (Roberta Alexander)

Subject: New IIT Request; | PI Last, First Name | Study Name |

Hello,

We are writing to request study Title: “...” to be added to the CTO IIT Unit. Please let us know the assigned Protocol Development Officer, SU PM, and RA.

Attached are the following documents:

- Concept Form, with DT support acknowledgment *
- Funding Source/budget* (exception: studies seeking grant support)

If available:

- Presentation slides
- CTA
- Protocol
- ICF and/or IB
- Manuals Regulatory, Pharmacy, Lab, Imaging, Pathology and other manuals, as applicable
- Other, please list _____

*Required Documents

Study Identifier	
Principal Investigator (Last, First Name)	
Disease Team	
Disease Team PM	
Any other study contacts:	

- DT PM to indicate where the study will take place, apart from MCC.
 - DT PM to consolidate with Network/Affiliate Guide. For questions about network sites, please reach out to the Network Sites Project Manager.