

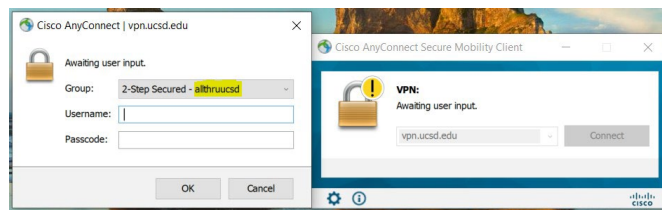
Study Activation Tracker Instructions

The Office of Clinical Research, led by Dr. Susan Little, has launched a new tool to simplify the tracking of research studies during the start-up process. The Study Activation Tracker provides a comprehensive view of the status of initial Institutional Review Board (IRB) submissions, budgets, coverage analyses, and contracts--all in one place! Accessible on the ACTRI website and updated daily, you can easily monitor your study's progress using your AD login information (after you have been added to the AD group). **Please see below steps for specific instructions for accessing the Study Activation Tracker as well as additional helpful information from colleagues in the central offices.**

With all this information in one place we hope that it will assist everyone during the start-up phase of studies. We hope to make improvements and add additional information, so we welcome feedback and suggestions here (select Tableau as request): <https://wkf.ms/3qggXMU>.

Step 1: Email 3help@health.ucsd.edu and ask to be added to the "ACTRI-Study Activation-BI-Consumer" AD group. Once added to this AD group, wait 24 hours, then continue with the steps below.

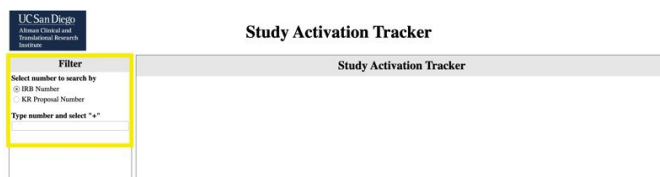
Step 2: If not onsite, log onto the VPN. Select "allthruucsd" for the group. Use your AD login information. Only use the first part of your email; don't enter @ucsd.edu or @health.ucsd.edu. For VPN assistance, please email 3help@health.ucsd.edu.



Step 3: Access the tracker through Tableau, using the following link: <https://ctri-tableau.ucsd.edu/#/site/CTPMO/projects/142>. Use your AD login information to log into Tableau. Only use the first part of your email; don't enter @ucsd.edu or @health.ucsd.edu (see below for example). For access issues, please submit a service request here (select Tableau as request topic): <https://wkf.ms/3qggXMU>.



Step 4: Enter IRB number or KR number and select '+' symbol to search for a study.



- You are able to search multiple IRB numbers or KR numbers at once. They must be in a list format to do so; they can't be in the same line or separated by a comma (see example below). Paste the list in the search box and hit enter to search.

80XXXX
80XXXX

Step 5: See all of the up-to-date statuses for a study in one place! The information includes IRB, KR number, PI first 3 letters, and the overall status for each office.

Study Activation Tracker								
IRB Number	KR Proposal #	PI	OIA IRB Status	OCAA Budget Status	OCAA CA Status	OCTA CTA Status	Velos Status	Additional Info.
80			Approved	In Negotiation With Sp..	Pending Approvals For ..	Negot. w-Sponsor	Not Active	Hover here
80			Approved	Not Found	CA Not Required	Not Found	Not Found	Hover here

Step 6: For additional information, hover your mouse over “Hover here” (make sure you click the view first then hover).

Study Identifiers:

IRB Number: [REDACTED]
KR Proposal #: [REDACTED]
PI: [REDACTED]

OIA:
 Initial Review Type: **External Reliance**
 Funding Source: **Industry (Sponsor-Initiated)**
 Initial IRB Submission Status: **Approved**
 IRB Status Date: **9/21/2023**
 Analyst: **Lopez, Mary Jo**
 Expiration Date:

OCAA Budget:
 Budget Status: **In Negotiation With Sponsor**
 Budget Status Date: **12/12/2023**
 Analyst:

OCAA CA:
 CA Status: **Pending Approvals For CA Harmonization**
 CA Status Date: **12/21/2023**
 Analyst: **Tara Krieg**

OCTA:
 CTA Status: **Negot. w-Sponsor**
 CTA Status Date: **4/2/2024**
 Analyst: **Alistair Khalessi**

VELOS:
 Current Status: **Not Active**
 Current Status Date: **7/17/2024**
 Last Status: **Study - Study Created in EMR**
 Last Status Date: **7/17/2024**

Additional Info.
 Hover here
 Hover here

Some important things to remember and to be aware of:

- This tracker is for activation only, NOT for amendments or renewals.
- Acronyms and definitions for the central offices are noted below.
- If the tracker says “Null” for KR number and “Not found” for Office of Clinical Trials Administration (OCTA), it is because it is most likely with the Office of Contract and Grant Administration (OCGA), please refer to OCGA’s dashboards or contact researchadmin@ucsd.edu for additional information.
- Budget information is only available if using Office of Coverage Analysis Administration (OCAA) for budget services.
- Each study is listed once (if in the Office of IRB Administration (OIA) Quali Protocols database).
- This tracker displays the most recent status update and associated date (for each study in the activation process). You will be able to see the last time an update was made on the study and whether to follow-up or not with your assigned analyst.

OCTA Status Definitions:

Step	Status	Definition
1	Assigned	Received in OCTA's contract queue and assigned to a contract officer.
2	Contract Template Pending	Sponsor is considering OCTA request to work from a specific contract template to expedite negotiations.
3	Under Review	Internal review of submitted documents and redlining of the initial contract draft (as applicable) in progress by OCTA.
4	Negot. w-Sponsor	Action/Redline required by Sponsor to move contract negotiation forward.
4	Negot. w-OCTA	Action/Redline required by OCTA to move contract negotiation forward.
4	Negot. w-PI/Dept	Action/Redline required by PI/Dept to move contract negotiation forward.
4	Negot. w-Other	Action/Redline required by Other (e.g. Risk, Legal) to move contract negotiation forward.
5	Final Pending	Contract terms within contracting office purview are confirmed mutually agreeable. (Signature ready version of the contract may or may not be ready depending on outstanding items). Outstanding items or approvals relate to payment terms, budget, IRB, COI, or Export Control status and require action from PI/Dept/Sponsor/Compliance Office in order for contract to be finalized and signed.
6	Out for PI Sig.	Contract is with PI for signature.
6	Out for Sponsor Sig.	Contract is with Sponsor for signature.
7	Fully Executed	Contract is signed by all required parties.
8	Start-up Fees Pending	PI/Dept has confirmed contract negotiating is no longer moving forward. OCTA is waiting for PI/Dept to confirm applicable study start-up fees and if such will be invoiced to sponsor.
8	Award Set-Up Requested	The signed contract is in the process of being Awarded in Quali Research.
9	Final Info Requested to Complete Award/Fund Setup	OCTA is waiting on PI/Dept to provide requested information that is required in order for OCTA to complete the Award and/or request Financial Set-up for the study.
9	Fund Set-Up Requested	The financial team is generating the financial chart string for the study.
10	Complete	All activity pertaining to a contract transaction is complete. (This status is only used by OCTA Admin as it relates to CTAs and Amendments). This is the final status.
	On Hold	All contract activity is on hold at the directions of PI/Dept or Sponsor (with confirmed approval of PI).
	Withdrawn	Contract is not moving forward at the direction of PI or Department.
	Not Funded	Contract is not moving forward at the direction of Sponsor.
	Void	Contract submission made in error and removed from contract queue.
	Transferred	Contract outside of OCTA's delegated scope or authority, transferred to the appropriate contracting office.

OCAA Coverage Analysis Status Definitions:

Step	Status	Definition
1	Triaging in Process	Received in OCAA's Coverage Analysis (CA) queue and collecting all study documents needed.
2	CA not required	CA review was performed by analyst and it was deemed that a CA is not required at this time.
2	CA in process	CA assigned to Analyst, draft in process.
3	First Draft Sent To PI/Study Team	Draft in review with Study Team and/or PI.
4	PI Approved CA	CA was approved by PI and is considered final.
5	Pending Approvals For CA Harmonization	CA is finalized. Analyst is waiting on final ICF, Budget and CTA to be able to perform harmonization.
6	CA Sent For Calendar Build	CA Harmonization was completed and documents were sent to Velos team for study calendar creation.
7	CA Activated	CA is finalized and active.
	Study Withdrawn Not Required	Study was withdrawn during activation process, CA no longer required.
	Study Closure Not Required	Study was closed during activation process, CA is no longer required.
	Study Withdrawn Completed	Study has been withdrawn with OCAA office.
	Study Closure Completed	Study has been closed with OCAA office.
	On Hold	All contract activity is on hold at the direction of PI/Dept or Sponsor (with confirmed approval of PI).

OCAA Budget Status Definitions:

Step	Status	Definition
1	Added to OCAA Work Queue	Received in OCAA's budget queue.
2	Budget Development In Process	Budget assigned to analyst, working on the gridding of the budget.
3	First Draft Sent To PI/Study Team	Budget draft in review with Study Team and/or PI.
4	PI Approved Budget	Budget was approved by PI.
5	In Negotiation With Sponsor	OCAA analyst is negotiating PI approved budget with Sponsor.
6	Budget Finalized With Sponsor	Negotiations are complete and Sponsor agreed to budget. Budget considered final.
7	Award Created Recharged Study Account	Budget was added to CTA and CTA was executed, award was created. This is the final status.
	Withdrawn (billable)	Study was withdrawn, Sponsor will be charged for start-up cost.
	Withdrawn (non-bill)	Study was withdrawn, Sponsor will not be charged for start-up cost.
	On Hold	All budget activity is on hold at the direction of PI/Dept or Sponsor (with confirmed approval of PI).

OIA Status Definitions:

Step	Status	Definition
1	In Progress	A study has been started in the Quali IRB system by the PI and/or study team and is not yet submitted to the UCSD IRB/OIA for review.
2	Submitted for Review	The study has been submitted to the UCSD IRB/OIA for review and has not yet been reviewed by triage and/or an analyst.
3	Returned to PI	The study has been screened by OIA triage and changes are needed from the PI and/or study team to complete the submission before it can move on to review.
3	Revisions In Progress	The study has been reviewed by an OIA analyst or UCSD IRB and either 1) needs revisions from the PI/study team to meet criteria for approval or 2) has received clearance for submission to an External IRB and the PI and/or study team should now submit the study to the External IRB for review and approval of the UCSD site.
3	In Progress (Withdrawn)	The study has been temporarily withdrawn from the review process. The PI and/or study team should resubmit to OIA when ready for further review.
4	Resubmitted	The study has been resubmitted to the UCSD IRB/OIA for review following a "Returned to PI" or "Revisions In Progress" status.
5	Approved	The study has been initially approved by the UCSD IRB.
5	Not Human Subjects Research	The study has been determined by OIA to not meet the definition of Human Subjects Research.
5	Exempt	The study has been determined to meet regulatory criteria for being Exempt from regulatory requirements for human subjects research by OIA and/or the UCSD IRB.
5	External Reliance	The study has been accepted for reliance on an External IRB.
5	Disapproved	The UCSD IRB has determined that the study does not meet the criteria for approval and cannot suggest changes to allow the study to meet these criteria.
6	Abandoned	The study has been permanently withdrawn from the review process.
6	Closed	The study has been closed by the UCSD IRB.

For study specific questions, please contact the appropriate office:

OIA - Office of Institutional Review Board Administration (irb@ucsd.edu)

OCAA - Office of Coverage Analysis Administration (ocaa@ucsd.edu)

OCTA - Office of Clinical Trial Administration (octa@ucsd.edu)

Additional questions, please submit a service request here (select Tableau as request topic):

<https://wkf.ms/3qggXMU>.