

2021 RADx-rad Discoveries and Data Coordinating Center (DCC) All Hands Monthly Meeting: July 12, 2021 Minutes

Admin Core

1. Anti-racism training will be offered to awardees and teams during ELSI/IRB Office Hours starting in September
 - Please complete the Anti-racism attendance survey if you have not already in the All-Hands meeting: https://ucsd.co1.qualtrics.com/jfe/form/SV_3K7yqZoa7AKAnzM
 - ELSI/IRB support will continue through 1:1 meetings as needed
 - Email radx-rad-admin@ucsd.edu with any questions
2. dbGaP forms need to be received from all awardees before 1st data upload to DCC
 - Email Dr. Vivian Ota Wang (otawangv@mail.nih.gov) and Erin Bailey (elbailey@health.ucsd.edu) to schedule a working meeting
3. Awardees to work with their NIH Program Officer to determine "Target data delivery date" on dbGaP Data Sharing Plan & Submission form
 - NIH expectation that data will be submitted to DCC 6-months from enrollment and every 3-months following

Data Core

1. Overview of Data Submission Workflow
 - Awardee meeting with DCC for CDEs and codebook review > Awardee Data Preparation > Awardee Data Submission > DCC Quality Check (returned to PI with revisions as needed) > DCC Submission to Data Hub
2. Data Preparation Requirements
 - Submission of dbGaP forms (Institutional Certification and Data Sharing Plan & Submission) need to occur prior to 1st data upload to the DCC
 - Every data submission needs: Metadata; Data dictionary; Data files
 - Waivers for minimum CDEs will be uploaded with Data Dictionary (work with your Program Officer and Kirk E. Roberts)
 - Data Preparation tools from DCC will be sent to awardees including: DCC Unique Study Participant ID, Zip code de-identification
3. Data Submission Workflow
 - PIs to assign 2 users per award for data submission; DCC will provide training
 - Obtain Secure Tokens from DCC to access UCSD SFTP site to download and install
 - Upload required data files via SFTP
4. Upcoming Timeline:
 - Training and documentation for uploads complete last week of July
 - SFTP ready to accept data August 2021
5. CDE Codebook review
 - Harmonizing data amongst all RADx initiatives; Employment variables remains unique to RADx-rad

Diagnostics Core

1. Strains available: WA1; B1.351; B.1.1.7; P.1;
 - Delta variant available early August
2. To procure VQA samples

- Request Material Transfer Agreement (MTA); materials usually ship within 3-days of executed MTA.
- 3. RAD2 Tech Pathway released July 6th. Awardees interested in submitting a proposal:
 - Complete Readiness Self-Assessment Checklist
 - Submit Proposal via the Submission Form: <https://airtable.com/shreoBUu0jhrZmHC2>
 - Awardees will receive a confirmation receipt of submission within 24 hours
 - Proposals will be reviewed within 14 business days by the DCC
 - Selected proposals will be returned to PIs and their PO with instructions for submitting the full proposal
 - Eli Aronoff-Spencer (earonoffspencer@health.ucsd.edu) and Alexandra Hubenko (ahubenko@ucsd.edu) and your Program Officer are available for any questions

FDA Update

1. FDA is opening Friday morning meetings to RADx-rad awardees;
 - Two 15 minute slots per week are available (*5-min presentation* and 10-min Q&A)
 - Contact Alexandra Hubenko (ahubenko@ucsd.edu) with any questions or to get on the FDA schedule
2. Next FDA Q&A Session Wednesday July 28th; Questions due Thursday July 22nd.
 - Following FDA meetings:
 - August 19th & September 23rd

Announcements

1. Please submit your dbGaP forms
Updates can be found at www.radxrad.org, including FAQs from this meeting
2. Next All-Hands meeting: August 9, 2021

FAQs from Meeting – added to www.radxrad.org website

Data Sharing FAQ

Q: If we miss August 1st data submission deadline, does that mean we have to wait to submit until November 1st?

A: No, data can be submitted anytime.

Q: Can you please clarify how data could be protected for studies with Intellectual Property (IP) legal protections?

A: Please work with your Program Officer to request a waiver as needed for IP related data (common for FDA approval), Awardee requests will be submitted to NIH Leadership for review. Decisions will be communicated to Program Officers, Awardees, and RADx-rad DCC.

dbGaP FAQ

Q: When should we expect an official dbGaP PHS ID after submitting the forms?

A: Awardees will be aware their studies have begun the dbGaP registration process through automated emails. PHS IDs will be sent to Awardees, Program Officers, and the RADx-rad DCC for tracking.