



RADx-rad DCC

RADx-rad Discovery & Data Consortium Coordination Center (DCC)

Monthly All-Hands Meeting

12 July 2021

<https://www.radxrad.org/>

This meeting (video + chat) will be recorded.



Agenda

July 12, 2012

RADx-rad All-Hands	TIME	TOPIC
	10:00 - 10:05	Welcome – Lucila Ohno-Machado
	10:05 - 10:15	Admin Core - Lucila Ohno-Machado Awardee Anti-racism & Teamwork Interest poll and training schedule dbGaP reminders Q & A– Open discussion
	10:15 - 10:35	Data Core – Hua Xu Data Submission plan CDE Codebook update – <i>Kirk Roberts</i> Q & A– Open discussion
	10:35 – 10:50	Diagnostics Core Update – Eliah Aronoff-Spencer RADx Tech application submission Variant resources available FDA Update for questions & 1:1 meetings with awardees Q & A– Open discussion
	10:50 – 11:00	Closing Remarks – Lucila Ohno-Machado Questions & Open Discussion (*Next All-Hands Meeting August 9, 2021)

Awardee Anti-Racism Training

*10 second Poll (link in chats) for attendance count and time commitment

https://ucsd.co1.qualtrics.com/jfe/form/SV_3K7yqZoa7AKAnzM

- Anti-racism training will be offered during ELSI/IRB Office Hours starting the month of September

**ELSI/IRB support will continue through 1:1 meetings as needed; please email questions to: radx-rad-admin@ucsd.edu*

Please submit your dbGaP forms as soon as possible

dbGaP forms will need to be received before 1st data upload to DCC for all awardees

- **1/4 of awardees have submitted** their dbGaP forms for registration- ***Thank you*** to the awardees who have submitted or are in the process of submitting dbGaP forms!

dbGaP Registration

Questions or help with completing the forms?

- Email *Dr. Vivian Ota Wang* and *Erin Bailey* for assistance or to schedule a working meeting
 - Working meetings to complete dbGaP forms with Dr. Vivian Ota Wang take approximately 20-30 minutes; *Email Erin Bailey* (elbailey@health.ucsd.edu) to help coordinate a meeting

Please do not hesitate to reach out – we are here to help

dbGaP: Data Sharing form

Data will be submitted (choose one):

By date (MM/DD/YYYY)

Data will be submitted by batches over Study Timeline

(e.g. based on clinical trial enrollment benchmarks)

Specify:

Target data delivery date:	<input type="text"/>	(MM/DD/YYYY)	Target public release date:	<input type="text"/>	(MM/DD/YYYY)
Number of gigabytes of data to be deposited:	<input type="text"/>		Estimated number of study participants:	<input type="text"/>	

Please work with your NIH Project Officers on the Target data delivery date:

- Currently expected 6-months after enrollment begins
 - Submission to follow every 3-months (quarterly)

*Form is signed by your study Program Officer

dbGaP: Institutional Certificate form

Name of RADx Program Adm: **Dr. Vivian Ota Wang**

NIH, HHS 9000 Rockville Pike Bethesda, MD 20892-7395

Re: Institutional Certification of [NAME OF INSTITUTION] to Accompany
Submission of the Dataset from [ORIGINAL STUDY NAME¹] for
[PROJECT TITLE FOR DATA TO BE SUBMITTED]
to an NIH-designated data repository.

General Research will be selected for all studies (with exceptions)

*NIH general expectation of all RADx awardees

For all Studies:

- Program Admin: Dr. Vivian Ota Wang**
- Project Title: RADx-rad**

Leave blank

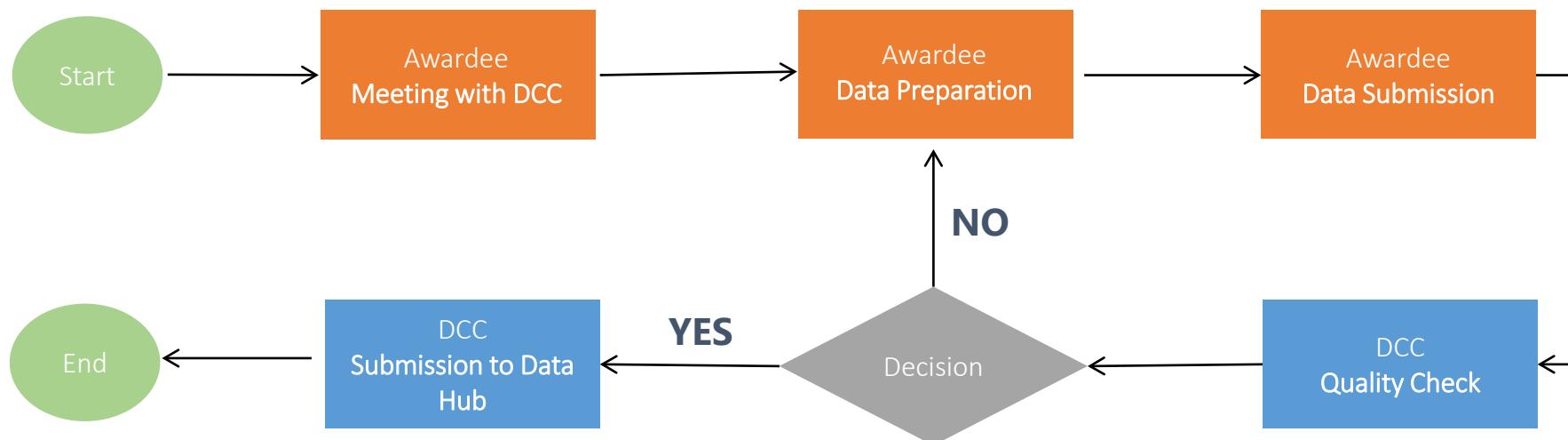
Unless special circumstance

Using the tables above, please indicate in the table below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	Data Use Limitation	Data Use Limitation Modifiers (optional)
Eg: Cold Cohort Study	Health/Medical/Biomedical	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
Eg: Cold Cohort Study	Disease Specific Research [Lung Cancer]	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input checked="" type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
	General Research Use	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
	Select consent group title	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
	Select consent group title	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>
	Select consent group title	IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>

Data Core Update

Data Submission Workflow Overview



Data Preparation



Institutional
Certification

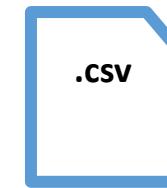


Data Sharing
&
Submission



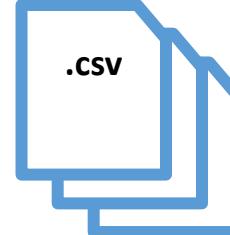
Metadata

**Waivers for
Minimum CDEs**



Data Dictionary

Tools from DCC:
• Study ID
• Zipcode



Data Files



Once; prior to first data submission



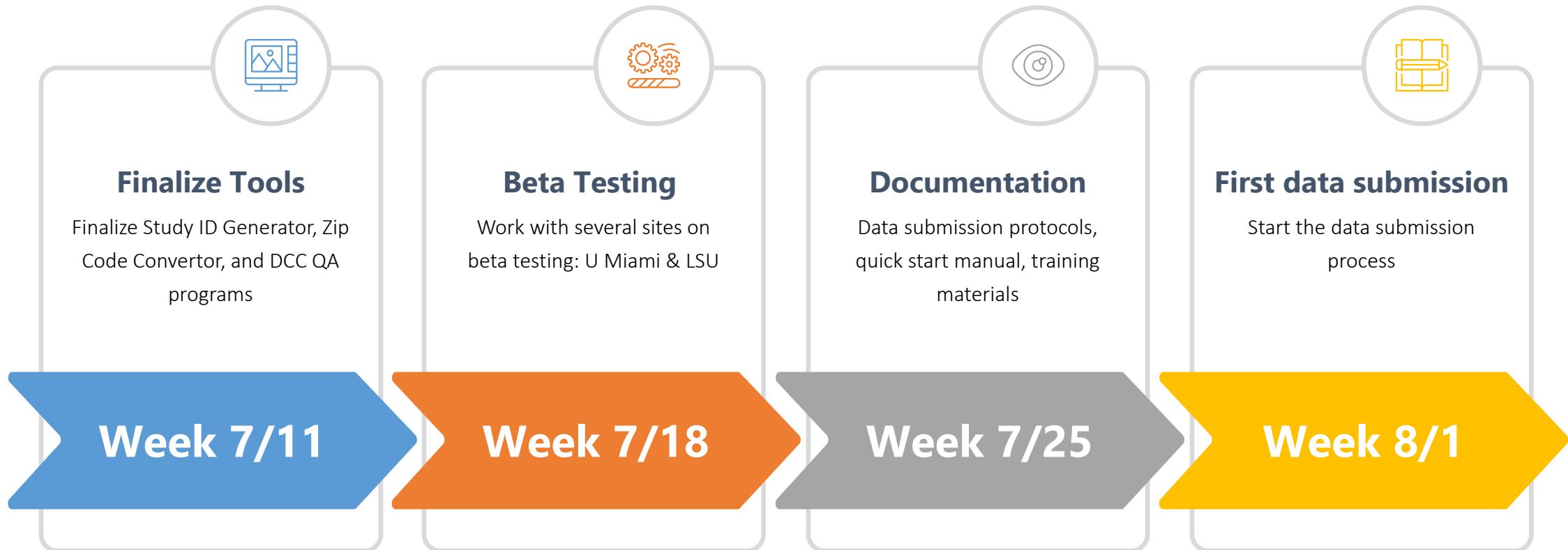
With every data submission

Data Submission

- Assign two users per award by PIs, for data submission
- User training by DCC
- Obtain Secure Tokens to access UCSD Secure File Transfer Protocol
- Download /Install SFTP tools
- Upload required data files through SFTP
- Revise the data files if DCC QA finds issues

Timeline

- Goal – ready to accept data submission in August 2021



CDE Codebook Update

Example 1: Race

Variable & Response Option Mapping					
Program	RADx Global Codebook	RADx-UP	RADx-rad	RADx-TECH	RADx-TECI
Variable	nih_race	race_ethn_race	race	race_black	race_white
All Response Options	0, American Indian or Alaskan Native	1, American Indian or Alaskan Native	1, American Indian or Alaskan Native	,Unchecked;0,Uncheck	,Uncheck
	1, Black or African American	2, Black or African American	3, Black or African American	1,Checked	,Uncheck
	2, Asian	3, Asian	2, Asian	,Unchecked;0,Uncheck	,Uncheck
	3, Native Hawaiian or Other Pacific Islander	4, Native Hawaiian or Other Pacific Islander	4, Native Hawaiian or Other Pacific Islander	,Unchecked;0,Uncheck	,Uncheck
	4, White	5, White	5, White	,Unchecked;0,Uncheck	1,Checked
	5, Middle Eastern or North African			,Unchecked;0,Uncheck	,Uncheck
	6, Two or more races			,Unchecked;0,Uncheck	,Uncheck
	97, Some other race	15, Some other race	6, Some other race	,Unchecked;0,Uncheck	,Uncheck
	98, Do not know			,Unchecked;0,Uncheck	,Uncheck
	99, Prefer not to answer	99, Prefer not to answer		,Unchecked;0,Uncheck	,Uncheck

Example 2: Employment

Diagnostic & Discovery Core

Diagnostic & Discovery Update

Strains available:

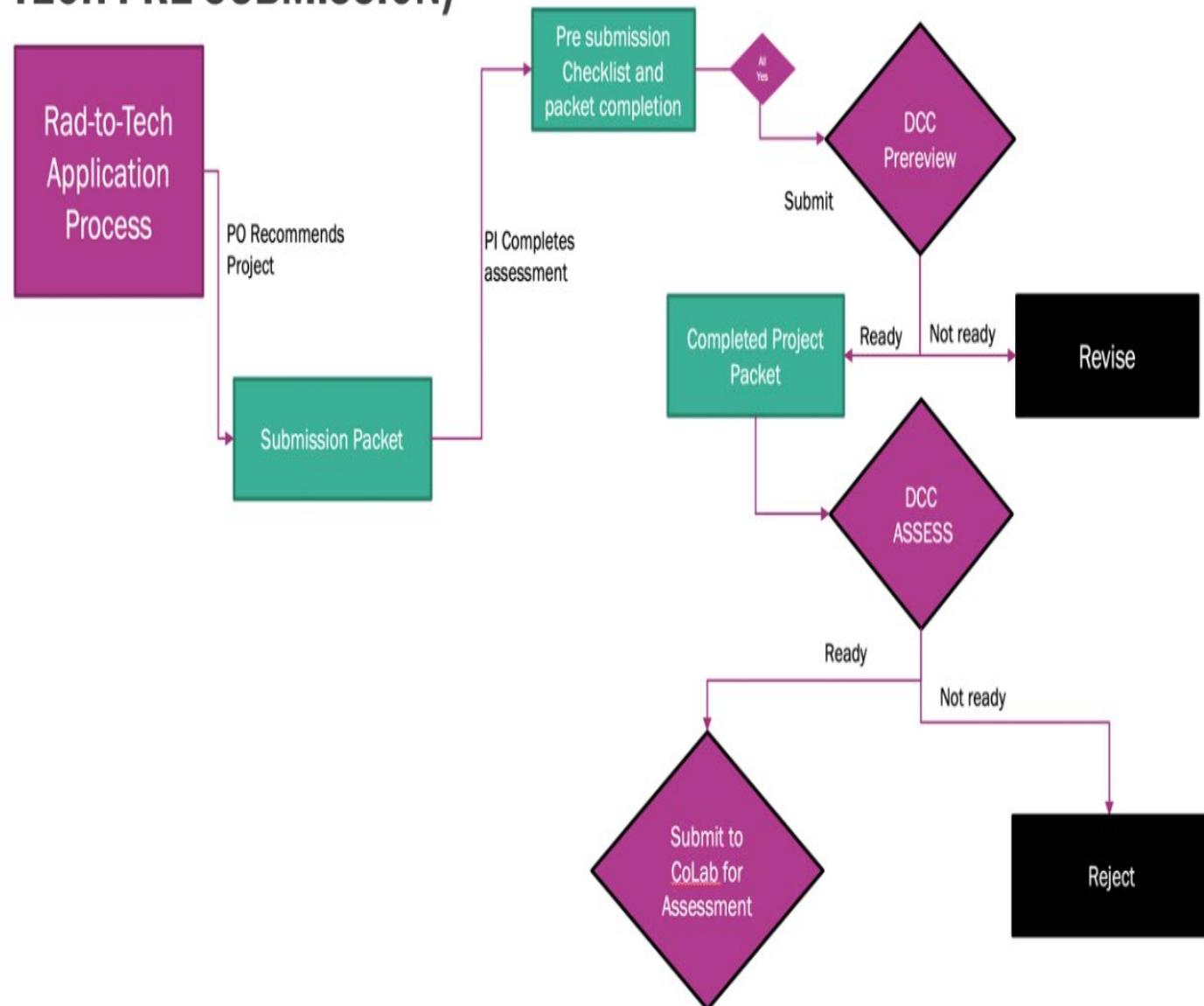
- WA1
- B.1.351
- B.1.1.7
- P.1
- **Delta variant available in early August**

To Procure VQA samples:

- Request an MTA
- Virus should ship within 3 days of MTA's execution

RAD2Tech Pathway released *July 6, 2021*

RADX TO TECH PATHWAY (DCC TO TECH PRE-SUBMISSION)



RAD2Tech: Application Submission Process

- Complete Readiness Self-Assessment Checklist
- Submit your proposal by completing the form at
<https://airtable.com/shreoBUu0jhrZmHC2>
- You will receive confirmation of proposal receipt within 24 hours of submission
- DCC will be check proposals for completeness and review within 14 business days.
- Selected proposals will be returned to PIs and their PO with instructions to submit full proposals to the POCTRN/RADx Tech CoLab grants portal
- Still have questions? Contact:
 - Eli Aronoff-Spencer earonoffspencer@health.ucsd.edu
 - Alexandra Hubenko ahubenko@ucsd.edu
 - Your RADx-rad program officer

FDA Update

- FDA is opening Friday morning meetings to RADx-rad awardees
 - Bi-weekly 15 minute blocks
 - Present technology (CLIA waiver)
 - Contact Alexandra Hubenko (ahubenko@ucsd.edu) to get on the schedule.
- Next FDA Q&A session ***Wednesday July 28th***
 - Questions for FDA Q&A are due to Alexandra Hubenko (ahubenko@ucsd.edu) by the end of the day on **Thursday, July 22**.
- Next deadlines for question submittal:
 - Thursday, August 19
 - Thursday, September 23

THANK YOU!

To the NIH and RADx-rad Awardees

Announcements

- Don't forget to submit your dbGaP forms for registrations (Contact Dr. Vivian Ota Wang or Erin Bailey with any questions)
- Continue to find updates on the RADx-rad website
<https://www.radxrad.org/>
- Next All-Hands Meeting August 9, 2021