

Process for NIH Supervision of Collection of NIH RADx-rad Minimum Common Data Elements (CDEs)

The process is:

The role of the RADx-rad Discoveries and Data Coordinating Center (DCC) is to track changes in and use of the NIH RADx-rad Minimum CDEs.

The role of the awarding IC Grants Management Officer (GMO) is to monitor the business management aspects of the award and, if NIH approval is required, provide NIH written approval or disapproval of requested changes on behalf of NIH, such as changes to the Terms and Conditions of Award, working closely with the assigned Program Official (PO).

The role of the awarding IC PO is to monitor the programmatic, scientific, and/or technical aspects of the award, including review of CDEs and progress reports, and to provide programmatic recommendations to the IC GMO regarding its post-award administration, such as prior approval requests.

Therefore,

- If a RADx-rad recipient institution proposes an insignificant change in wording or expansion of wording choice to better fit the needs of the community in which the project is being implemented, the recipient institution and project PI should work with the DCC Data Core to ensure that the item(s) retain fidelity to the initial item.
- If NIH approval is required, it must be requested of, and obtained in writing from, the awarding IC GMO in advance of the change as specified in the *NIH Grants Policy Statement (8.1.2)*. For example, if a RADx-rad recipient institution proposes to omit collection of an NIH RADx-rad Minimum CDE, a prior approval request with documentation of the justification should be submitted through the recipient institution's Authorized Organization Official (AOR) to the GMO at the awarding IC.
- If the change is approved, approval should be communicated by the recipient institution to the project PI. The project PI should send a record of the disposition with accompanying documentation to the DCC Data Core for tracking purposes with a copy to the DCC PO (Dr. Yanli Wang) as a record to be archived.

The project POs and DCC PO will track changes, such as changes of the Terms and Conditions of Award and approval not to collect specific NIH RADx-rad Minimum CDEs, for future reference and reporting purposes for the NIH. The DCC will follow the same process for the integrity of the data collection process.