Frequently Asked Questions – RADx Exec Common Data Elements (CDEs)
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Introduction:

All projects funded under the RADx program are required to collect data on 12 variables
known as the RADx Exec CDEs according to specified instructions. A list of the RADx Exec
CDEs is appended to this document. Program Officers (sometimes called Project Officers or
PO) make the final determination regarding CDEs application, use and reporting. There is
an expectation CDE adherence and that exception requests will be rare.

As of June 3, 2021, several modifications to RADx CDEs already have been approved and
remain in force. These do not need to be changed. The proposed guidance here is as a living
document and will be updated as needed.

The following are several frequently asked questions designed to assist NIH staff in making
CDE exception decisions.

1. What is the process for requesting exceptions to the RADx Exec CDEs?

    A exception request can be initiated in several ways, including by authorized
    personnel (e.g. PI) from a specific award, by the data coordinating center staff for
    the Specific RADx program, or by NIH staff. Requests should be submitted by the
    project to their respective data coordinating center. The data coordinating center
    staff will determine whether the exception represents a major or a minor change.
    Minor changes can be made at the data coordinating center and reported to the
    program officer, who notifies the RADx Data Hub and the appropriate Grants
    Management Officer. Major changes are to be reviewed and made by the Program
    Officer who notifies the project staff, the RADx Data Hub and the appropriate Grants
    Management Officer.

2. What kind of a request is considered *minor* exception*?* What constitutes a *major*
    exception?

    A minor exception is a request for a change in wording that result in a semantically
    equivalent expression of the same concept (e.g. "When were you born" vs "What is
    your birthdate"). A major exception is a request to eliminate one of the RADx Exec
    CDEs, or to substantially change the query stem and/or the response options (e.g.
    substituting "Do you have a disability" for the six-item disability variable).

3. We are engaging human participants as key informants. We do not need to know anything about their health status. Why do we need to gather all of the RADx Exec CDEs?

   NIH accountability requires balancing the NIH's accountability to society to ensure that we have broad input into our efforts and the burden and intrusion experienced by the individual participant. For a specific project, on rare occasions, it might acceptable for the PO to approve a MAJOR CHANGE eliminating one or more health status and medical history items. However, it would NOT be acceptable to waive demographics, domicile, education, employment or disability status. The project is still required to submit data on the required CDEs to the data coordination center for ultimate deposit to the RADx Data Hub with an indication that the item was not collected on any participants in the particular study.

4. Why do we need to collect information about disabilities? Our community partners don't want us to collect this information?

   NIH has a responsibility to society to demonstrate that we are engaging with the full range of society. Collecting information about disabilities is like collecting information about gender, ethnicity and race. There are no exceptions for collecting information about disability using the six-item disability questionnaire.

5. My study only includes women participants. How do I handle reporting on the CDE related to biological sex?

   In the RADx Exec CDEs there is an item related to biological sex. When information about a specific CDE is inherent in the inclusion criteria there is no need to include a question about that specific CDE in the interview or data collection form. When depositing data into the RADx Hub, it is necessary to include every variable and option and substituting information indicating that either the item was eliminated or the response option was never included (e.g. in this particular case, indicating that the study enrolled only women).

6. Our population is NOT disabled, and disability status is not relevant to our study. We do not want to include the 6-item disability assessment.

   An important component of the RADx program is demonstrating that we have reached a broad distribution of the US population. Collecting information about the demographics, including disabilities of the people participating in a study is very important. There are no exceptions for collecting information about disability

7. Our target population includes School Children. Why do we have to collect information about employment?

The PO must make a reasoned judgment here. For example, high school and college students may be employed and it would be relevant to know employment status. If the PO makes a decision to eliminate this item, this constitutes a MAJOR CHANGE. The project is required to submit data on the required CDE to the data coordination center with an indication that the item was not collected on any participants in the particular study.

8. Our project wants to eliminate the response "temporary" from the employment item.

    The PO must make a reasoned judgment here. If the PO waives the need to include this specific ITEM *response* for a specific project, it is equivalent to deleting the question. The project is still required to submit data on the required CDEs to the data coordination center for ultimate deposit to the RADx Data Hub with an indication that the item was not collected on any participants in the particular study.

It is expected that all research involving human subjects funded in the RADx program will collect information on these 12 concepts using these questions and specified response options.

Concept	Stimulus	Response
Identity	None	Project-specific identifier
Ethnicity [1]	What ethnicity do you identify with?	Hispanic or Latino; not Hispanic or Latino
Race [1]	What race do you identify with?	AI/AN; Asian; Black or African American; Native Hawaiian or other Pacific Islander; White
Sex	What was your assigned sex at birth?	Male, Female
Age	When were you born?	Date of Birth
Education	How many years of education have you completed?	0 - +20
Domicile	Where do you live?	Zip Code
Employment	Are you employed?	Yes, no, temporary
Insurance Status	What kind of insurance do you have?	Private, Public, none
Disability status [2]	Are you deaf or do you have serious difficulty hearing?	Yes, no
	Are you blind or do you have serious difficulty seeing, even when wearing glasses?	Yes, no
	Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions?	Yes, no
	Do you have serious difficulty walking or climbing stairs?	Yes, no
	Do you have difficulty dressing or bathing ?	Yes, no
	Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?	Yes, no
Medical History	Vaping use	Yes, no
	Nicotine use	Yes, no
	Alcohol use	Yes, no

[1] https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm
[2] Reported as disabled if the response to any one of the six items is yes.
https://www.cdc.gov/brfss/data_documentation/pdf/BRFSS_Data_Users_Guide_on_Disability_Questions_2018-508.pdf

	Asthma	Yes, no
	Cancer	Yes, no
	Cardiovascular disease	Yes, no
	Chronic kidney disease	Yes, no
	Chronic lung disease	Yes, no
	Diabetes	Yes, no
	Hypertension	Yes, no
	Immunosuppressive condition	Yes, no
	Serious mental illness	Yes, no
	Sickle cell disease	Yes, no
	Pregnancy status	Yes, no
Symptoms	Cough[3]	Yes, no
	Fever[3]	Yes, no
	SoB or Difficulty breathing[3]	Yes, no
	Headache[3]	Yes, no
	Muscle ache[3]	Yes, no
	New Loss of taste or smell[3]	Yes, no
	Chills[3]	Yes, no
	Excessive fatigue[3]	Yes, no
	Nausea/vomiting[3]	Yes, no
	Diarrhea[3]	Yes, no
	Abdominal pain[4]	Yes, no
	Skin rash[4]	Yes, no
	conjunctivitis[4]	Yes, no
Health Status	BMI	Weight & height
	Would you say that (your) health in general is excellent, very good, good, fair or poor? [5]	Excellent, very good, good, fair, poor

For all items:
1. Participants have the right to refuse to respond to any item
2. Various RADx programs or groups of projects may add required items specific to their project (e.g., wastewater assessment, greater specification of education or gender)
3. Researchers are encouraged to consult the Phenx Tool Kit, the NIH Public Health Emergency and Disaster Research Response (DR2) resource or the CDC to identify valid and reliable items and instruments
4. Program officer approval required for modifications that make significant changes in response.

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[3] https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
[4] Added by RADx Executive Committee
[5] https://www.phenxtoolkit.org/protocols/view/770101?origin=search