

Rapid Acceleration of Diagnostics – Underserved Populations (RADx-UP) Data Harmonization Guidance

National Institutes of Health Staff Recommendations

The Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) initiative is a cooperative agreement consortium of community-engaged research projects to address the urgent need to understand and address COVID-19 morbidity and mortality disparities among vulnerable and underserved populations across the United States. The goal of RADx-UP is to conduct community-engaged research to examine SARS-CoV-2 infection patterns, and to increase access, uptake, and effectiveness of diagnostic methods. The overarching goal is to understand factors that have led to disproportionate burden of the pandemic among underserved populations so that interventions can be implemented to decrease health disparities.

The consortium consists of four components:

1. Competitive revisions to existing community-engaged large-scale consortiums, consortia, or centers to examine SARS-CoV-2 infection patterns and efforts to increase access and effectiveness of diagnostic methods.
2. Competitive revisions to an existing pool of community-engaged individual research projects targeting specific underserved or vulnerable populations to examine SARS-CoV-2 infection patterns and efforts to increase access and effectiveness of diagnostic methods.
3. Social, Ethical, and Behavioral Implications (SEBI) projects to identify, analyze, and address the social, ethical, and behavioral factors likely to influence access to and uptake of COVID-19 testing in underserved and/or vulnerable populations.
4. Coordination and Data Collection Center (CDCC) which will serve as a national resource to coordinate and facilitate research activities within the RADx-UP consortium. It will also interface with the trans-NIH COVID data hub, providing deidentified individual data to this data resource.

Among the roles of the CDCC is to coordinate data collection, integration, and sharing across the RADx-UP consortium. Data harmonization across a complex consortium is challenging under usual circumstances; however, given the urgency to evaluate testing in underserved and vulnerable communities during the COVID-19 pandemic, rapid development of a data harmonization plan is critical. This guidance is provided to accelerate the process by which the RADx-UP CDCC and the consortium develop a data sharing and harmonization plan.

Harmonization Guidance

Working groups consisting of NIH staff with expertise in various aspects of data collection, measurement, and data elements and structures produced this guidance document and identified domains and constructs that the RADx-UP consortium might consider a priority for harmonization. This guidance considered potential harmonization with other RADx initiatives

and with the US Department of Health and Human Services (USDHHS) and the Centers for Disease Control and Prevention (CDC) testing reporting requirements that all RADx-UP projects or their healthcare collaborators will need to follow to report testing, both to the CDC and to Federal, national, state and local public health officials (see <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>). This guidance also is consistent with common data model (CDM) for the trans-COVID NIH data hub and the RADx Minimum data element requirements, thereby facilitating the process of the CDCC providing key de-identified data that will serve as a long-term data resource for future investigators.

The guidance is organized into three sections:

1. **Testing and Electronic Health Records (EHR):** Key testing data including procedures for obtaining the sample, analysis platform, analysis procedures, and test results will need to be collected and represented in a consistent manner for harmonization across the consortium, integrated with [test reporting requirements under the Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\)](#). To the degree that EHR data can be obtained, this section also describes common data elements and models for extracting and representing these data based on the [COVID-19 Real World Data \(RWD\) Data Elements Harmonization Project](#).
2. **Participant Provided Information (PPI):** Self-report is an essential component of RADx-UP and includes assessing experiences, knowledge, attitudes, and beliefs of the individual participants. This section covers a range of domains including sociodemographics, social determinants of health, medical status, mental health, substance use, adherence to various mitigation recommendations, knowledge and attitudes about testing and follow-up, and the impacts of COVID-19 on social, psychological, economic, and health outcomes.
3. **Community-level Characteristics:** The number and breadth of communities involved in the RADx-UP consortium require being able to characterize these various communities on dimensions relevant to testing in underserved and vulnerable populations. This section notes that much of this characterization can be produced by obtaining physical address (or minimally zip code and county) which can be linked to various geocoded administrative databases, but a number of relevant community characteristics will need to be determined from aggregating self-reports of community participants.

Tiers of Harmonization

Within each section, the recommended measures and data elements are divided into two tiers.

- **Tier 1** are data elements that the NIH recommends the consortium require all projects in the consortium to collect and report in the same format. These Tier 1 elements include those few elements required by the NIH across all RADx studies (see list below) as well as a number of key variables the specifically relevant to the RADx-UP initiative (e.g., prior testing experience and access to testing) that the consortium may want to agree all projects should collect and share.
- **Tier 2** are a longer list of variables or constructs that the NIH workgroups anticipate not all projects would collect, but if collected, should be considered for harmonization

across the consortium. The NIH wanted the guidance to be sufficiently broad to cover what might be considered by the RADx-UP consortium for Tier 2.

Harmonization Sources

RADx Minimum: NIH has developed a set of data elements that are considered minimum requirements for all RADx projects to collect and harmonize. Within the Tier 1 recommendations, these are the variables that the NIH requires all RADx projects to collect, harmonize, and include when providing data to the NIH COVID Data Hub:

- Race/ethnicity
- Age
- Sex (Biological)
- Education
- Domicile
- Employment
- Insurance Status
- Disability
- Medical History
- Medications
- Symptoms
- Health Status

Specifications for these constructs (e.g., specific measures, CDEs) are included in this guidance. These constructs are the only constructs that the NIH requires all of the RADx-UP projects to collect and share in a standard format.

Established Measures and Data Elements: For testing measures, the [test reporting requirements under the CARES Act](#) are recommended. EHR guidance is based on the [COVID-19 Real World Data \(RWD\) Data Elements Harmonization Project](#). For participant provided information, the recommended measures are drawn from the PhenX Toolkit (<https://www.phenxtoolkit.org/>) whenever possible. The PhenX Toolkit provides recommended standard data collection protocols selected by working groups of domain experts using a consensus process based on specified selection criteria (<https://www.phenxtoolkit.org/about/criteria>) and also provides data dictionaries and linkages (e.g., LOINC, RedCap) that will facilitate harmonization by the CDCC.

Survey and Clinical Assessment: For COVID-19 specific survey and clinical assessment tools, the recommendations are drawn from the COVID-19 Survey Repositories made available in [DR2](#) or [PhenX](#). These linked repositories contain over 100 COVID-specific surveys, but most have limited information available on their psychometric properties given the speed with which they were developed and fielded in response to the pandemic. Therefore, measures recommended from these repositories were based on being well-constructed, easily understood items fielded in large, diverse, and nationally representative samples, and with Spanish translations whenever possible.

New Survey Measures: In cases where no COVID-19 specific item or measure could be found (e.g., perceived benefits or barriers to SARS-CoV2 testing or vaccination), recommendations were based on measures adapted from related infectious disease research or suggestions made for new items that will need to be developed and tested using best practices in survey item development.

Harmonization Challenges

In addition to the urgency of harmonization development, harmonization across the RADx-UP consortium is further complicated by the fact this consortium is composed of ongoing community-engaged projects that already have measures in the field, some specifically vetted by and tailored to their communities. The RADx-UP consortium will need to reconcile this guidance with what is already being administered by these various projects. Alternative measures to those suggested in this guidance can and should be considered by the consortium, but the goal is to harmonize the data provided to the CDCC, regardless of which measure is selected.

The Social, Ethical, and Behavioral Implications (SEBI) projects pose a unique data harmonization challenge since the aims of these projects differ from the community-engaged projects evaluating testing in vulnerable and underserved communities. This data harmonization guidance has focused on the collection and data sharing and integration of the community-engaged testing projects, coordinated by the CDCC. Some of these data harmonization recommendations may be applicable to the SEBI projects as well, but the consortium will need to determine the measures all of the SEBI projects should collect and share with the CDCC, including some that may not have been considered in this harmonization guidance.

To harmonize key variables across the consortium, some projects will need to duplicate measures of a given construct, using their existing measure and adding the agreed harmonized measure, at least until there are sufficient data to co-calibrate similar measures of the same construct. In some cases, co-calibrated measures already exist, allowing projects to assess certain constructs differently as long as the data are provided on an agreed to reference metric (see <http://www.prosettastone.org/Pages/default.aspx> as an example). Some projects may need to generate a mirrored database from their existing project with a sharable database for the RADx-UP CDCC that converts some of the data elements to a common format and adds RADx-UP specific data harmonized elements.

It is urgently important that the consortium review existing IRB-approved protocols and consent forms and amend or submit new IRB protocols that will allow for broad consent and the sharing of deidentified data across the consortium and to the NIH COVID data hub. For some community-engaged projects, consultation and approval from community members also may be required. A smart IRB for the entire consortium to facilitate a single IRB approval and consent that includes data sharing language should be strongly considered.

Although only the CDCC is formally a cooperative agreement, the NIH expects for the entire consortium of awardees to function as a cooperative agreement consortium. As with all cooperative agreements, the NIH is a partner with the extramural investigators and is committed to working with the RADx-UP consortium to achieve its research goals, which include integration of key data from this project.

Section 1: Testing and Electronic Health Records (EHR)

The RADx-UP projects will use rapid scale-up of rigorous research strategies and integrate data collected across sites, and the Coordination and Data Collection Center (CDCC) will coordinate the data acquisition, collection, and curation strategies. This includes developing procedures for standardized collection of common data elements from a variety of sources including participant provided information, electronic health records (EHR), testing technology data, administrative data, and others. The purpose of this section is to provide guidance for the collection, sharing, and harmonization of EHR and testing-related data.

Testing

RADx-UP implementation will occur in two-phases and the testing guidance provided in this implementation section is specific for phase I research projects which are required to use [FDA-authorized/approved diagnostics](#).

Given the large NIH investment in developing and validating new testing technologies through RADx, the CDCC should anticipate significant changes in screening and diagnostic testing approaches over the next 3 to 6 months. Thus, it is recommended that the CDCC create a **testing advisory board** comprised of NIH staff or investigators involved in the other RADx projects as well as the FDA, CMS, private sector, and academia. The purpose of this advisory board will be to monitor the testing landscape, stay informed on emerging testing approaches, and develop and revise protocols for good testing practice. The testing advisory board should also stay informed of FDA consumer alerts and warning letters to companies regarding flagged COVID-19 test kits or devices. In addition, the testing advisory board should provide guidance on [CLIA certification](#), including recent guidance on [quick start CLIA certification for COVID testing](#), to facilitate return of results for all RADx-UP participants receiving testing.

The acquisition and administration of coronavirus tests is of critical importance for RADx-UP, and NIH is in discussions with test developers and suppliers to facilitate test access. For research project sites that need assistance obtaining tests, it is recommended the CDCC coordinate with NIH and RADx-Tech to determine if there is a vendor with an appropriate test and [Emergency Use Authorization \(EUA\)](#) with which sites can partner to obtain adequate testing capabilities.

The CARES Act requires reporting of results of COVID-19 tests to [HHS](#). In clinical trials, research clinicians who are responsible for clinical care of trial participants are responsible for linking de-identified specimen test results to participant demographic information and are required to report the positive results daily ([CDC Guidance](#)). In an effort to receive these data in the most efficient manner, HHS is requiring that all data be reported through existing public health data reporting methods and in an [electronic, standardized format](#). For sites without an EHR or Lab Reporting System, HHS will still require electronic reporting of required testing data. Those without electronic reporting capabilities should use the [flat file](#) format provided by the CDC to assist with electronic reporting.

To the degree that the RADx-UP projects are responsible for the testing conducted, these projects will be responsible for collecting and reporting coronavirus test result data as specified above. To reduce burden, however, we recommend that the CDCC use the same data specifications required by [HHS](#). All of the HHS required testing data is considered RADx-UP Tier 1 data. Table 1 provides a cross-reference of the patient variables required by CDC test reporting requirements that are also listed in the Participant Provided Information section that follows, along with the link to the recommended measure of each variable.

Table 1: RADx-UP Testing Variables also Listed in Participant Provided Information Tier 1 Elements

Testing Variables	PPI Source Recommendation Link
Age	https://www2.census.gov/programs-surveys/acs/methodology/questionnaires/2020/quest20.pdf
Race	https://www.phenxtoolkit.org/protocols/view/11901
Ethnicity	https://www.phenxtoolkit.org/protocols/view/11901
Sex	https://www.phenxtoolkit.org/protocols/view/11601
Residence Zip Code	https://www.phenxtoolkit.org/protocols/view/10801
Residence County	https://www.phenxtoolkit.org/protocols/view/10801
Employed in Healthcare (Requested)	https://loinc.org/sars-cov-2-and-covid-19/
Symptomatic (Requested)	https://www.phenxtoolkit.org/toolkit_content/PDF/CDC_PUI_v2.pdf
Resident in Congregate Care Setting (Requested)	https://loinc.org/sars-cov-2-and-covid-19/
Pregnant (Requested)	https://loinc.org/82810-3/

* Testing reporting to state and local public health departments also includes PII (Name, Street Address, Phone Number, Date of Birth) that could be used to generate GUIDs.

Testing reporting to state and local public health departments includes a number of Personally Identifiable Information (PII) fields that could be used for generating GUIDs. Appendix 1 summarizes NIH resources for generating GUIDs.

It is also recommended that adverse events occurring during testing (e.g., nasal swab breaking) be captured during the testing data collection process or via EHR extraction. The [COVID-19 Real World Data \(RWD\) Data Elements Harmonization Project](#) provides the Common Data Elements (CDEs) and Common Data Model (CDM) mappings for capturing adverse events.

Electronic Health Record (EHR)

Since RADx-UP is community-based, not health system based, access to EHR data may be challenging. Obtaining EHR data, when possible, is valuable and RADx-UP sites should include processes and consent procedures to identify, access, and extract relevant EHR data from participants.

The U.S. Food and Drug Administration (FDA) [COVID-19 Real World Data \(RWD\) Data Elements Harmonization Project](#) provides a harmonized list of COVID-19 common data elements (CDEs) across several Common Data Models (CDMs) and open standards that are particularly relevant to EHR data extraction and harmonization and also capture all CDEs required for reporting testing to the Department of Health and Human Services (HHS) under the [CARES Act](#).

Given the difficulties of obtaining complete and up-to-date EHR data on RADx-UP participants, redundancy with data provided by the participants (PPI) is recommended. Table 2 lists Tier 1 data elements that are anticipated to be available in EHRs but are also included in PPI to ensure that these data are collected in some form. The CDCC and the RADx-UP consortium will need to determine how to resolve any differences in data for the same variable obtained by both patient report and EHR.

Table 2
RADx-UP EHR variables also listed in Participant Provided Information Tier 1 Elements

EHR Variables	PPI Source Recommendation Link
Health Insurance Status	https://www.phenxtoolkit.org/protocols/view/11502
Current Medications	https://www.phenxtoolkit.org/protocols/view/140301
Current Conditions	https://www.phenxtoolkit.org/toolkit_content/PDF/JHU_C4WARD_Health.pdf
Height and Weight (BMI)	https://www.phenxtoolkit.org/protocols/view/20704 https://www.phenxtoolkit.org/protocols/view/21502
Pregnancy Status	https://loinc.org/82810-3/
Flu Vaccination	https://loinc.org/58131-4/
Previous Coronavirus Testing (method and results)	https://www.phenxtoolkit.org/protocols/view/570201
COVID-19 Symptoms (if presented to healthcare)	https://www.phenxtoolkit.org/toolkit_content/PDF/CDC_PUI_v2.pdf

COVID-19 Diagnosis and Hospitalization	https://www.phenxtoolkit.org/toolkit_content/PDF/MESA_COVID_19_Diagnosis.pdf https://www.phenxtoolkit.org/toolkit_content/PDF/MESA_COVID_19_Diagnosis.pdf
Tobacco Use	https://www.phenxtoolkit.org/protocols/view/30604
Alcohol Use	https://www.phenxtoolkit.org/protocols/view/30101

In addition to the items captured in the COVID-19 RWD spreadsheet, it is recommended that research projects include the CDEs listed below from the EHR whenever possible. These additions capture relevant information related to underserved populations (e.g., tribal affiliation and preferred language) or provide nuanced information to CDEs listed in the COVID-19 RWD spreadsheet (e.g., gender identity, second-hand smoke exposure). As stated in the [RFA-OD-20-013](#), the CDCC is encouraged to use the [United States Core Data for Interoperability](#) (USCDI). Thus, the following list references the USCDI when possible. When no CDE was available in USCDI, [LOINC](#) codes were referenced. It is also recommended that research sites carefully consider the appropriateness of CDEs for various patient populations, such as children or pregnant women.

Additional CDEs from EHRs for the RADx-UP Consortium to consider as possible Tier 1 data elements when available in the medical record.

Demographics

- [Gender Identity](#)
- [Preferred Language](#)
- [Tribal Affiliation](#)

Billing Information

- [Insurance Status](#)
- [Income](#)

Residential Characteristics

- [Overcrowded housing](#)
- [Housing Status](#)
- [Type of Resident without zip code \(e.g., migrant worker\)](#)

Social, Psychological, and Behavioral Data

- [All CDEs listed on the USCDI webpage should be extracted if available](#)

Health Status

- [BMI Percentile \(2 - 20 years\)](#)
- [Secondhand Tobacco Smoke Exposure](#)
- [Cognitive Status](#)
- [Physical Disability](#)

Common Data Models (CDMs)

A Common Data Model (CDM) provides a structure for sharing common data elements among RADx-UP supported applications and data sources in a consistent manner, and is particularly applicable to EHR, testing, and other clinical variables. As stated in [RFA-OD-20-013](#), the CDCC is

strongly encouraged to use OMOP models. It is expected the CDCC will facilitate collaboration across RADx-UP research project sites by coordinating common data sharing models, management and security, and data use and access agreements. The CDCC will also supervise and monitor these functions for fidelity and ensure data quality by using a CDM. The NIH expects that all research projects funded under the RADx-UP program will actively coordinate, collaborate, and share data with the CDCC, as allowed, and with considerations under tribal IRB processes, within the CDM framework required by CDCC. The CDCC data management model will serve as a repository for data obtained from research project sites and will link deidentified data for inclusion in a larger NIH data integration model under the NIH-wide CDM framework for RADx programs.

The NIH recommends the CDCC implement a CDM for pooling and sharing EHR data across the consortium. While NIH prefers OMOP, research project sites may have a CDM already implemented within their EHR system. Thus, it is recommended that the CDCC provides the infrastructure to allow sites to submit data using a variety of CDMs. For example, the [National COVID Cohort Collaborative \(N3C\)](#) allows investigators to [submit data using other CDMs](#) and provides all output for shared data analysis in OMOP ([N3C Demonstration Video](#)).

Another resource that the CDCC should utilize is the [COVID-19 Real World Data \(RWD\) Data Elements Harmonization Project](#) which provides CDE mappings across a variety of CDMs. The Excel spreadsheet provided on the website will be updated as more CDEs are mapped across CDMs.

The NIH recognizes that not all projects will have access to EHR data, and those who do may not have a CDM implemented. For research project sites without a CDM implemented, it is recommended that the CDCC works with these sites to assist with the mapping process. For all sites, regardless of EHR status, the CDEs from the testing section above should be mapped to a CDM and shared with the CDCC. For sites with EHR data but no CDM, the CDCC should work with the sites to map a core set of EHR CDEs to a CDM.

Section 2: Participant Provided Information (PPI)

This section provides recommendations on key constructs that can be self-reported by participants in four broad categories:

- 1) Sociodemographics, Household Characteristics and Social Determinants of Health;
- 2) Health Care, Medical History, and Mental Health/Substance Use;
- 3) Social, Behavioral, Economic, and Healthcare Impacts of COVID-19 (SBE); and
- 4) COVID-19-related Attitudes and Behaviors.

The first two categories represent primarily measures that are used across a range of health research (i.e., *not COVID-19-specific*) while the latter two categories represent primarily measures that are *COVID-19-specific*.

This distinction between *general* vs. *COVID-19-specific* measures is important. General measures are drawn primarily from the [PhenX toolkit consensus protocols](#), relying on the expert consensus in recommending the appropriate measure for a given construct. One reason for relying on PhenX consensus protocols is that PhenX allows for these protocols to be aggregated to create electronic data form systems compatible with RedCap as well as linkages to LOINC codes and CDEs, and common database structures such as dbGap. NLM also provides FHIR-compatible tools for electronic self-report form creation and electronic data transfer (see <https://lhcfirms.nlm.nih.gov/>).

In contrast, *COVID-19-specific* measures were developed only recently and rapidly with minimal data from which to identify consensus measures. Therefore, these measures are drawn primarily from the COVID-19 Survey Repositories available on the [PhenX](#) and [DR2](#) platforms.

There are over 100 surveys currently posted in the COVID-19 survey repository. In the absence of information for determining a “consensus” set of items or measures that RADx-UP should consider, the NIH PPI working groups drew primarily from well-respected survey sources fielding surveys in large, diverse, and often representative samples, and preferably with surveys also already translated in Spanish. As a result, many of the COVID-19 specific items are drawn from sources such as the [US Census Household Pulse Questionnaire](#), the [Center for Economic and Social Research Understanding America Survey](#) (CESR-UAS), and the [RAND American Life Panel](#). We also closely considered COVID items from the NIH *All of Us* [program COPE survey](#) which, although not nationally representative, is a large and diverse sample. Finally, the [Johns Hopkins University COVID-19 Community Response Survey](#) is a COVID-19 survey toolkit that, although not a single survey conducted in a large sample, is a reasonably comprehensive compendium of survey items. Linking to survey items from nationally representative samples allows the RADx-UP consortium to compare and weight data from their underserved and vulnerable communities to the general U.S. population; therefore, drawing items from surveys fielded in nationally representative samples should be preferred unless these surveys do not cover relevant constructs for the RADx-UP initiative.

The PPI working groups focused primarily on adult measures, but the COVID survey repository also has a number of surveys fielded in **child and adolescent samples** including the NIH

[Environmental Influences of Child Health Outcomes \(ECHO\) COVID-19 Questionnaires](#), the [Adolescent Brain and Cognitive Development \(ABCD\)](#), the [NIMH CRISIS Survey](#), and the [COVID-19 and Perinatal Experiences \(COPE\)](#). These child and adolescent measures are recommended as Tier 2 elements – not all projects will study children and adolescents, but those that do should harmonize these measures.

The RADx-UP consortium is encouraged to review the COVID-19 Survey Repository and consider additional measures that could be considered, particularly as Tier 2 measures or as measures unique to a specific project’s goals.

Each PPI subsection below briefly describes the key recommendations for harmonized data collection, and the details for each recommendation are found in the RADx-UP data harmonization Excel spreadsheet that accompanies this guidance report. Each spreadsheet tab represents a PPI subsection listing each construct recommended for consideration by the RADx-UP consortium, the name and linked source of 1 to 3 instruments or tools recommended to assess that construct, and if different from the source link, the CDEs for that variable. This spreadsheet is the primary document of the PPI and Community-level Characteristics working groups; the narrative descriptions below are to provide context when needed on the constructs considered.

The Tier 1 constructs are consistent with the RADx minimum dataset requirements. These required variables are augmented with a number of additional constructs that are considered central to the goals of RADx-UP and recommended for Tier 1 consideration by the consortium. All Tier 1 constructs are highlighted in green on the spreadsheet. Most PPI constructs, however, are listed as Tier 2. In weighing recommendations for Tier 1 versus Tier 2, relevance across all RADx-UP projects, respondent burden, and sensitivity of assessing some constructs (e.g., immigration status) were considered. All of the Tier 1 elements recommended in the PPI and self-reported Community-level Characteristics sections are listed in Appendix 2. Together, these Tier 1 elements consist of approximately 135 total items with an estimated respondent completion time of 23 minutes if the consortium adopts all of these Tier 1 recommendations as required for all projects to collect and share.

Sociodemographics, Household Characteristics, and Social Determinants of Health

Most of the sociodemographic, household characteristics, and social determinants of health constructs and measures are well-established. Therefore, the PhenX toolkit was the primary source for links to measures available. When measures do not exist in the PhenX Toolkit for a given domain, other sources are suggested in the accompanying spreadsheet.

Sociodemographic characteristics include the following **Tier 1** constructs:

- ***Race/ethnicity***
- ***Age/Date of Birth***
- ***Biological Sex***

- ***Gender Identity***
- ***Sexual Orientation***
- ***Physical Address***
- ***Reside in Congregate Care Setting***
- ***Education***
- ***Marital Status***
- ***English Proficiency***
- ***Disability Status***

Many of these Tier 1 recommendations are drawn from national standards for assessing these constructs and allow for linkages to nationally representative samples. Race and ethnicity are drawn from the [U.S. Census Bureau, Census 2020 Questionnaire](#). Those sites that wish to assess race and ethnicity in greater detail than the Census questions provide (e.g., country or regional origin of Hispanic ethnicity, specific tribal affiliation within American Indian or Alaska Native) are encouraged to consider some of these additional racial or ethnic breakdowns as Tier 2 data, especially since data integration may provide sufficient sample sizes across those projects interested in more detailed race and ethnicity data.

Age/date of birth are also required for testing reporting although the assessment method is not specified; therefore, the workgroup recommends the formats for reporting age and date of birth in the [National Health and Nutrition Examination Survey \(NHANES\), 2005-2006](#) or the 2020 [U.S. Census American Community Survey](#). DOB is strongly encouraged over reported age alone so that age can be computed from various events (e.g., date of enrollment, date of testing, date diagnosed, etc.), but if there are concerns about potential re-identification from storing DOB at the CDCC, computed age can be shared with the CDCC instead provided that all projects follow a standard protocol for computing and sharing age. Also, DOB or age of family members is recommended as a Tier 2 variable. Not all projects will obtain family member ages, but if the number of family members in the household is collected by the project, then a standard procedure for collecting age of family members also should be specified.

Biological sex, gender identity, and sexual orientation are drawn from the PhenX Toolkit. These items have been selected in consultation with the NIH Sexual and Gender Minority Office as well (see [Sexual and Gender Minority Research Office measurement-related website](#)). The CDC testing reporting requirements list patient sex and require a truncated indication of male/female/other. However, given that sexual and gender minorities are among the vulnerable populations of interest in RADx-UP, the consortium should require these variables be collected and shared across all projects.

Physical address is a key variable for characterizing communities of the participants. Zip code is among the variables in this protocol for obtaining current address and is the variable within physical address, along with county, that must be reported with testing to HHS/CDC. Zip code is also a critical variable in the community level characteristics section (see section 3) since it provides geo-linkages to various administrative databases to characterize the communities of

the participants. The entire physical address is recommended as a Tier 1 variable because census tract geo-linkages may be needed for some geo-linked databases. Given the potential for re-identification via physical address, the consortium has the option of either converting physical address to a census tract prior to sharing with the CDCC or have the CDCC produce this conversion, store census tract and zip code information only, and remove the physical address from the CDCC databases after this conversion. However, if the consortium concludes that obtaining the entire physical address is not feasible for some projects and their participants, then zip code and county should be collected at a minimum. Note that years living at address is considered a Tier 2 construct.

In addition to physical address, the CDC requests that test reporting include if the patient resides in a congregate care setting. This is recommended as a Tier 1 variable since risk of infection is higher in these facilities.

Disability status is included as a Tier 1 construct and the CDC six-item Disability item set is recommended. There are many potential measures of disabilities that could provide more in-depth assessments if some projects desire to do so, and the CDC measure is more accurately a measure of functional limitations, not disability status, but the CDC measure is short, well-accepted, and used in multiple large probabilistic health surveys.

Education, marital status, and English proficiency also are considered Tier 1. There are a number of valuable constructs considered Tier 2 including immigration status and broadband access. Given sensitivities to immigration questions, it seemed appropriate to make this construct optional for projects to measure. Broadband access may be particularly important for some projects to measure, but perhaps not applicable to all projects.

Among **household characteristics**, only the number in the household and number of child/adult dependents is recommended as a **Tier 1** data to be shared by all projects. The PhenX toolkit lists the GSS version of assessing household number, but the Census ACS is included in the spreadsheet as an alternative. We were unable to identify a well-established measure of housing density or house square footage; it may be possible to derive housing density using property tax or real estate records linked to physical address and compute a household number per square foot. A self-report alternative to consider is developing items asking about having sufficient space in the household for someone to self-quarantine if they test positive.

There are many characteristics of these household members, including age, health status, educational status, and caregiver status that are important variables that many of the projects may choose to collect, but these are recommended for the consortium to consider as Tier 2, not Tier 1 constructs.

It may be helpful in some projects to ascertain the **number of people the participant typically comes into contact with daily**. The U.S. Centers for Disease Control has several helpful resources related to contact tracing that investigators may find helpful in assessing the contact domain. Contact tracing [interview protocols](#) and [training](#) are suggested resources. Additionally,

a 2017 article in the journal [Scientific Reports](#) has a potential measure examining social contact between individuals in the context of respiratory disease for the consortium to consider (see page 19 of the Scientific Reports article).

Social Determinants of Health (SDOH) include the following **Tier 1** Elements:

- ***Employment Status***
- ***Employed in healthcare with direct patient contact***
- ***Job Security***
- ***Housing Stability and Security (and homelessness)***
- ***Food Insecurity***
- ***Perceived Discrimination***

Some of these assessments are sensitive in nature, and these measures should be administered with appropriate expertise. The [Panel Study of Income Dynamics \(PSID\), 2007](#) in the PhenX Toolkit evaluates **employment status**, which can include currently working, retired, being a student and keeping a home. **Employed in healthcare** is a requested variable for CDC testing reporting and clearly relevant to motivations to be tested and, therefore, is recommended as a Tier 1 element. General assessment of **job security** can be measured using [General Social Survey \(GSS\), 2018](#) available in PhenX. To examine the impact of the pandemic on job security, the [2020 Census Pulse Survey](#) and [Environmental influences on Child Health Outcomes \(ECHO\) survey](#) are additional COVID-19 attributed measures of job security that may be considered. To examine the impact of the pandemic on job security, the [2020 Census Pulse Survey](#) and [Environmental influences on Child Health Outcomes \(ECHO\) survey](#) are additional COVID-19 attributed measures of job security that may be considered.

Income, while valuable, is recommended as a Tier 2 variable. An in-depth assessment of income is available through the [National Health Interview Survey \(NHIS\) Family Questionnaire, 2020](#), but the interviewer needs to be knowledgeable of current poverty levels to properly administer this measure. Therefore, a simpler but less detailed income survey item from the Census Household Pulse survey is included as an option, especially if the RADx-UP consortium decides this variable should be a Tier 1 variable.

The workgroup identified two measures assessing **housing status/housing security/homelessness** that exist outside of the PhenX Toolkit. The VA Homeless Screening Clinical Reminder is brief measure of housing security that is recommended as Tier1. Investigators can refer to the [Enhancing Family Stability: A Guide for Assessing Housing Status and Coordinating with Local Homeless Programs for TANF \(Temporary Assistance for Needy Families\) Agencies](#) that includes questions assessing where individuals slept the previous night and evaluating violence, health, and safety factors associated with this location if a more in-depth assessment of housing security is desired.

Food security is also another important SDOH. The [U.S. Household Food Security Survey Module: Six-Item Short Form, Economic Research Service, USDA, 2012](#) provides a reliable measure considered as Tier 1. As an alternative, the [Perceived Availability of Healthy Foods](#)

[Scale from the Multi-Ethnic Study of Atherosclerosis \(MESA\)](#) is an additional scale that is adaptable for both interviewer-administered and self-administered formats.

Perceived discrimination can be evaluated through the [Major Experiences and Everyday Discrimination Scales](#) available in PhenX. This comprehensive survey measures discrimination on multiple levels, including in the workplace (e.g., denial of promotion) and in everyday life (e.g., treatment in restaurants and stores). This questionnaire is extensive with each question about a discriminatory experience followed up with additional questions. The consortium will need to review which items it considers Tier 1 versus Tier 2, but it is included as a Tier 1 recommendation to assess this construct in some form given its importance to the RADx-UP goals.

Health Care Access, Medical History - General and COVID-19, Mental Health/Substance Abuse

Health Care Access: Given the importance of health care access to the goals of RADx-UP, all of health care access data elements and measures are considered **Tier 1**.

- **Healthcare access and utilization** is drawn from the NHIS health utilization section that assesses where the person receives healthcare and how long it has been since they last received care.
- **Health insurance status** is based on the Health Reform Monitoring Survey
- **Disparate healthcare quality** is from a single item of the California Health Interview Survey
- **Transportation barriers** are important to access, and a measure assessing these barriers is available from the scale described in a [Journal of Applied Measurement](#) article. The workgroup also considers proximity to the nearest testing site and transportation barriers to obtaining testing as a potential Tier 1 variable but was unable to identify a well-established measure of this. Therefore, the consortium is encouraged to adapt a selected subset of items from the transportation barrier scale above and apply it specifically to testing access.

General Medical History: Some of the domains and constructs listed in this subsection may be ascertained from EHRs, but are included in the PPI section as well since access to EHRs may be limited and the information in them dated if the participant has not had a healthcare encounter for a number of years or has received fragmented care from multiple facilities. Obtaining consent to access medical history documented in medical records is a priority, but there is valuable redundancy in obtaining key medical history by self-report as well.

The **Tier 1** PPI constructs recommended for assessing the General Medical History domain are:

- **Current Medications:** Two options for assessing current medications are provided. The MESA assessment protocol requires participants to have their medications with them to facilitate recording each medication and dosage. A less burdensome alternative is from the U Penn COVID-19 survey that asks about taking medications for various types of conditions. It is not as specific as the MESA protocol but is included as an option should

the RADx-UP consortium conclude that a more detailed medication list cannot be obtained from most participants.

- **Current Conditions:** A number of options for documenting current conditions is included in the spreadsheet, but the workgroup recommends the C3PNO approach that is included in the JHU COVID-19 Survey toolbox.
- **Height and weight:** These variables for computing BMI can be obtained via self-report or via stadiometer and weight scale. The method of assessment is captured in the CDE and LOINC codes for these variables.
- **Pregnancy status:** CDC testing reporting includes pregnancy (yes/no/unknown) as a requested variable; therefore, it is recommended as a Tier 1 element for RADx-UP. Two more in-depth assessments are included in the spreadsheet as Tier 2 elements for those projects with prenatal and perinatal research goals.
- **Flu Vaccination:** Given the relevance to testing and vaccine uptake, history of vaccination behavior is recommended as a Tier 1 construct.

Tier 2 constructs under General Medical History include:

- Allergies: Two options are provided for assessing current allergies
- Physical activity via the Stanford Brief Activity Screener
- Sleep disorders or insomnia severity
- Cognitive or functional impairments
- Cognitive function

COVID-19 Medical History: In contrast to therapeutic studies of COVID-19, many RADx-UP participants will not have experienced any COVID-19 symptoms or care, but for those who have, these variables appear essential for all to assess and warrant consideration by the consortium as Tier 1.

- **Tested for coronavirus and how tested:** There is limited prior research on testing uptake. One source for the assessment of prior testing is the *All of Us* COVID-19 items that ask if the person has been tested and how.
- **COVID-19 symptoms.** There are many variations of COVID-19 symptom checklists in the COVID-19 survey item repository. The workgroup recommends the CDC symptom checklist, but there are many options available and the consortium should select a single checklist that includes all of the symptoms in the CDC list of symptoms that are required for CDC testing reporting and assesses any other related symptoms that the consortium wants all projects to assess.
- **COVID-19 diagnosis and hospitalization**
- **Exposure to others who have tested positive with COVID,** assessed from section 2 of the COVID-19 Experiences instrument.

Mental health and Substance Abuse: There are a number of well-established measures for assessing mental health and substance abuse. Assessment of similar constructs are also included in the Social, Behavioral, and Economic Impacts (SBE) subsection. To reduce respondent burden and facilitate linkage to a nationally representative sample, the **Tier 1**

recommendation is to use the 2-item GAD and PHQ items used by the Census Household Pulse survey on the SBE COVID tab of the spreadsheet. It is important to note that the recommended Tier 1 measure of current conditions (C3NPO) includes mental health and substance abuse conditions. The healthcare and medical history tab lists the longer version of the GAD and PHQ that can be administered as a Tier 2 element for those projects who desire to have a more detailed assessment of anxiety and depression. It is also important to note that co-calibration of various anxiety and depression measures as well as other self-report questionnaires is available (see <http://www.prosettastone.org/measures/Pages/default.aspx>) which would allow projects to use different instruments to assess these constructs but share the data on a common metric.

From the Healthcare and Medical History spreadsheet tab, the following are considered **Tier 1** elements that the consortium should consider all projects assess and share.

- **Stress:** A number of stress scales are available (see <https://www.stressmeasurement.org/measurement-toolbox>). The RADx-UP consortium also may wish to consider the Responses to Stress Questionnaire adapted for COVID-19 (<https://my.vanderbilt.edu/stressandcoping/rsq/>), but given its length (57 items), it is recommended as a Tier 2 element for those projects that wish to assess stress responses in more detail.
- **Tobacco use:** Use of tobacco products assessed via the PATH protocol is recommended as Tier 1. E-cigarette use also is recommended as Tier 1 given the role of vaping as a risk factor for COVID-19. Ever use, current use, and everyday use for cigarettes and e-cigarettes are considered Tier 1 recommended elements. Additional patterns of use (experimental, some day use) and additional forms of tobacco and nicotine use (e.g., cigars, pipes, hookahs, etc.), are recommended as Tier 2 elements. Additional options that assess other aspects of tobacco use such as nicotine dependence are included in the spreadsheet as Tier 2 element recommendations.
- **Alcohol use:** Lifetime use is recommended as a Tier 1 element assessed via the AUDIT-2. Additional instruments assessing alcohol use in greater depth are included as Tier 2 elements.
- **Self-reported health** – single item assessing health as excellent, very good, good, fair, or poor.

Tier 2 constructs in the mental health/substance abuse domain include:

- Other drug use
- Coping strategies
- Health-related Quality of Life or Well-being
- Emotional support
- Instrumental support
- School and social support for children and adolescents
- Loneliness or social isolation – a single item assessment of loneliness on the SBE Impacts tab is recommended as Tier 1 but the UCLA Loneliness Scale listed on the Healthcare and Medical History tab should be strongly considered as a Tier 1 element instead if the

RADx-UP consortium believes it is an essential construct relevant to all projects and will not add substantial respondent burden across all projects.

Social, Behavioral, Economic, and Healthcare Impacts of COVID-19

The prior two PPI sections focused predominately on common domains and constructs frequently assessed in a wide range of clinical and population health research. As noted earlier, however, the *COVID-19-specific* survey items and measures were rapidly developed and fielded with varying and often unknown levels of evaluation prior to fielding. Therefore, for the SBE Impacts and Attitudes and Behaviors subsections, the recommended measures are drawn primarily from the COVID-19 survey repository. In the absence of other criteria, the workgroups selected items that were from well-respected sources and are fielding these items in large, diverse, and in most cases also nationally representative samples, providing the ability of the RADx-UP investigators to link these measures to the existing samples and increase generalizability.

Social Impacts: The pandemic and associated public health mitigation strategies have disrupted social functions in a number of ways. For the **Tier 1** elements, ***social support stability*** as assessed by two items from ABCD, and a single item assessing ***loneliness*** from the JHU Community Survey are recommended. As noted in the prior subsection, more in-depth assessment of loneliness and social isolation (UCLA Loneliness Scale) should be strongly considered instead of this single item measure if the consortium considers the respondent burden reasonable. A number of alternative items assessing social isolation or connectedness also are included as options to consider. Social impacts on families, children, childcare, eldercare, and of homeschooling on work are recommended as **Tier 2** elements.

Healthcare Impacts: Access to non-COVID healthcare has been disrupted during the pandemic. The **Tier 1** elements recommended to assess this impact include two items regarding ***missed or canceled appointments***, either on the part of the provider or on the part of the patient, one item on ***access to prescription medications***, and one item on ***postponement of medical procedures***. Although these are from a survey of cancer treatment impacts, they are generic items that cover any type of treatment for any type of condition. A number of other constructs are included as Tier 2 elements including some specific to those evaluating children and use of telehealth as an option for receiving care.

Economic Impacts: For the communities involved in RADx-UP, economic impacts are widespread and serious. A number of constructs are recommended as **Tier 1** elements. These include:

- ***Job loss***
- ***Job security***
- ***Education disruption***

In contrast to similar measures recommended in the social determinants subsection, these measures of job loss, job security and education disruption are pandemic attributable items

(e.g., I lost my job vs. I lost my job due to COVID). A number of other economic impacts such as reduction in hours, financial strain, and ability to pay rent/mortgage are recommended as **Tier 2** elements. The workgroup also recommends that eviction, ability to obtain stimulus funds or collect unemployment, and ability to pay for coronavirus testing be considered Tier 2 elements as well but was unable to identify existing items assessing these constructs. Therefore, the consortium may need to develop specific items assessing these constructs if the consortium wishes to consider these as Tier 2 elements that those projects choosing to assess may want to harmonize.

In most cases, the Tier 1 and Tier 2 element recommendations for economic impacts can be linked to large nationally representative surveys such as Census Household Pulse, GSS, and RAND American Life Panel, allowing the RADx-UP consortium to compare and/or weight responses from their respective communities to the general population.

Psychological Impact: As noted previously, the consortium may determine it would prefer longer and more reliable measures of anxiety and depression than the two-item GAD and PHQ items recommended as Tier 1. One benefit of all projects assessing via these two-item scales is the ability to link to Census surveys that used these items. The JHU Mental Health Impact Module (items 1 and 2) which assesses aspects of ***anxiety, depression, worry, and loneliness since the pandemic began*** are recommended as **Tier 1** given that many projects may not have sufficient pre-pandemic assessments of depression and anxiety to assess changes pre to post pandemic. In addition, there are a number of other possibilities listed for assessing anxiety, depression, and general mental health that the consortium can consider as options for Tier 2 elements.

COVID-19 and Testing Attitudes and Behaviors

This subsection includes a key set of constructs for RADx-UP – knowledge, attitudes, and behaviors regarding coronavirus testing. This subsection also includes relevant constructs such as knowledge and attitudes regarding the coronavirus and COVID-19, adherence to various mitigation strategies, and trust in scientific advice. It also includes attitudes regarding intentions to get vaccinated if and when a vaccine is approved and becomes available.

For attitudes regarding mitigation and adherence, selected items from the CESR are recommended as **Tier 1**. These include ***knowledge regarding and adherence to handwashing, physical distancing, face coverings, and covering coughs***. For some projects, assessing the infrastructure available to perform these mitigation behaviors (e.g., indoor plumbing) may need to be considered. The workgroup also considered the assessment of knowledge regarding what to do if COVID-19 symptoms are experienced but was unable to identify self-report items for this; therefore, if the consortium wishes to include it as a Tier 2 element, assessment of knowledge regarding what to do if symptomatic will need to be developed.

Attitudes and behaviors regarding testing are a critical aspect of RADx-UP, but there is surprisingly little item development regarding testing uptake and the factors that contribute to it. Constructs the workgroup considered that would need to be addressed include perceived

testing accessibility, perceived accuracy of testing, perceived benefits and risks of testing, intention to be tested, perceived peer norms regarding testing, and the interpretation or implication of negative and positive test results. In the absence of any prior work, the RADx-UP consortium will need to rapidly develop and evaluate key testing uptake survey items and propose them to the consortium as **Tier 1** required elements. RADx-Tech does include a couple of items on knowledge of what to do if tested positive or negative that should be consulted. Given the paucity of such items in the COVID-19 survey item repository, the consortium is encouraged to make this item set, after evaluation, available for others to use. On the spreadsheet, some examples of potential items assessing each of these constructs is included, but these are only for illustrative purposes.

In contrast to the paucity of coronavirus testing survey items, the CESR does include ***vaccination risk, benefits, and intention to be vaccinated***. These items are considered **Tier 1** elements since vaccine uptake is an increasing concern, particularly in underserved and vulnerable communities. These vaccine items also could be used as a template from which testing uptake items are developed. If additional vaccine items need to be developed as Tier 2 elements, then the spreadsheet includes the Sage/WHO vaccine hesitancy report and measure. Although this report focused on childhood vaccination hesitancy, these items could be adapted for coronavirus testing.

Finally, included as Tier 2 element recommendations are the assessment of attitudes and behaviors about trust in various institutions including government, media, the scientific community, and healthcare or medicine. The RAND American Life Panel, the GSS, and a recent PsyArXiv article provide options for assessing trust. These variables are important to RADx-UP and the communities evaluated by this initiative but are recommended as Tier 2 elements – all do not need to assess but those who do assess should do so consistently.

Section 3: Community Level Characteristics

RADx-UP is a community-engaged initiative. Assessing and comparing community level characteristics is essential to the project. Community-level characteristics can provide insight about populations in specific geographic regions that are particularly vulnerable to COVID-19 infection (e.g. concentration of essential workers) and have resource constraints that might limit access to care for testing/treatment of COVID-19 or other health effects. Community-level comparisons also help identify characteristics of communities that facilitate or inhibit testing and follow-up from testing. We recommend that RADx-UP sites carefully consider the definition of community in their measurement decisions. Communities can be defined by different geographic boundaries and scale (e.g. zip code, census tract) or by cultural or common affinities and backgrounds that do not have boundaries of space and place (e.g., social media consortiums).

Linkages of Physical Address to Administrative Data Sets

Physical address will provide the greatest benefit in linking communities to administrative datasets at national, state, county, or local level. Specifics of collecting and sharing physical address are described in the previous PPI section. Current physical address information that is collected from the study participant can be geocoded to link the address to their neighborhood in a Census-defined area such as Census tracts of blocks, or by ZIP code area. Obtaining a physical address and linking to geocoded datasets is not without challenges; in rural areas there may not be street names, or the street names may not be recognized by Census; or physical address may be intentionally misreported by respondents to avoid legal issues (i.e. immigration status/citizenship). In cases where a physical address cannot be obtained, minimally a zip code and county should be obtained since these are required field in testing reporting. Census tract location can be extrapolated from participants who are able to report where they live based on proximity to an intersection, major highway, or distance from a well-known commercial or government building. Self-report of physical location of residence also may be aided by online mapping services (e.g., Google Maps), especially those living in rural and remote locations, and/or by cellular or smartphone location mapping to a stable location (especially a stable location during the night).

Regardless of how obtained, obtaining a **current physical residential address** for participants in the RADx-UP is a high priority, **Tier 1** variable. As noted previously, to allay re-identification concerns, the projects or the CDCC can convert these physical addresses to zip codes and census tracts and not retain the physical address. Alternatively, physical address can be recoded as latitude and longitude with fuzzy logic to change these geolocations sufficiently to prevent reidentification but still retain the same census tract and zip code and compute distances within an acceptable error range (e.g., miles to the nearest testing facility) if desired.

If the participant has been living at the current physical address for less than one year, the RADx-UP consortium is encouraged to consider including the previous physical address as a **Tier 1** required variable as well. Some community influences take time to occur and the previous

physical address may be necessary to characterize adequately the influence of community on the participant, especially if they have lived in their current location after the pandemic began.

The Community-Level Characteristics Administrative tab of the RADx-UP Data Harmonization spreadsheet lists a number of administrative data sets that can be linked to physical address to characterize the communities of the RADx-UP participants. From these administrative datasets, it is possible to characterize communities on the following variables:

- Demographics including race/ethnicity, age, marital status, educational level, number of persons in a family, number who are children, and number over 60.
- Income including household incomes, poverty level, and public program assistance use.
- Employment including unemployment rates, labor force participation rates, mix of occupations, and wages.
- Housing including homeownership, high housing cost burden, evictions, percentage with basic housing problems, and physical condition of homes and neighborhoods.
- Neighborhood experiences such as concentrated disadvantage and residential racial segregation.
- Transportation characteristics including walking as transportation, modality of work commuting, and availability and use of mass transit.
- Physical environmental factors such as ambient air pollution, EPA Air Quality Index, safe drinking water, water access and quality, and environmental justice.
- Violence and safety including violent crime rate, injury deaths, and child maltreatment.
- Disadvantaged community indices such as the Area Deprivation Index, Social Vulnerability Index, and Social Deprivation Index.
- State social distancing actions including stay-at-home orders, mandatory quarantine for travelers, non-essential business closures, and face covering mandates. See (<https://www.bu.edu/sph/2020/04/01/tracking-covid-19-policies/>) and (<https://coronavirus.jhu.edu/data>).
- State COVID health policy actions such as free vaccine when available, waiver of prior authorization requirements, premium payment grace periods, paid sick leave, and expanded access to telehealth services.
- Long-term care facility information such as state reports on COVID cases and deaths in these facilities.
- Coronavirus hotspots including rates of infections, hospitalizations, and deaths over time.
- Health and Health care access including cases, access to care, testing, and health care utilization.

It is strongly recommended that the CDCC serve as the hub for all administrative data linkages since this is clearly more efficient than each project performing linkages on their own data and then providing it to the CDCC. In addition to efficiency, this is a clear value of the CDCC to the projects sharing their data since the CDCC can share these community characteristics back to the projects for their own further analyses. The CDCC also should evaluate these various administrative database linkages, ensure that the most current (or most aligned to when the participant participated in the study) administrative data are used, and work with the

consortium to prioritize the linkages with physical address to be conducted to characterize the RADx-UP communities.

There are an extensive number of administrative databases that can be accessed to characterize the communities of the RADx-UP participants. The consortium will need to prioritize the databases for linkages based on their value to the RADx-UP research goals. The following are some key data linkages that the workgroup recommends the RADx-UP consortium consider as priorities in addition to those specifically listed in the spreadsheet.

- **American Community Survey (ACS)** The ACS helps local officials, community leaders, and businesses understand the changes taking place in their communities. It is the main source for detailed population and housing information about our nation. <https://www.census.gov/programs-surveys/acs>
- **Census Bureau Small Area Income and Poverty Estimates** Using data from several sources to create area measures of income and program use, the SAIPE data provide annual estimates of local-area poverty, household income and SNAP use. <https://www.census.gov/programs-surveys/saipe.html>
- **County Health Rankings & Roadmaps** Ranking the health of nearly every county in the nation, the County Health Rankings help us see how where we live, learn, work, and play influence how healthy we are and how long we live. The Rankings & Roadmaps show us what is making residents sick, where we need to improve, and what steps communities are taking to solve their problems. The health of a community depends on many different factors – ranging from individual health behaviors, to education and jobs, to quality of health care, to the environment, therefore we all have a stake in creating a healthier community. Using the County Health Rankings & Roadmaps, leaders and advocates from public health and health care, business, education, government, and the community can work together to create programs and policies to improve people's health, reduce health care costs, and increase productivity. <https://www.countyhealthrankings.org/explore-health-rankings/measures-data-sources/county-health-rankings-model/health-factors/social-and-economic-factors/employment>
- **The Distressed Communities Index (DCI)** is a customized dataset created by EIG examining economic distress throughout the country and composed of interactive maps, infographics, and a report. It captures data from more than 25,000 zip codes (those with populations over 500 people). In all, it covers 99 percent — 312 million — of Americans. <https://eig.org/dci>

Health and Health Care Community Measures

Community-level measures of health and health care will assess the community level constructs relevant to RADx-UP initiative testing uptake goals. The measures of health that are recommended here are specific to COVID-19 epidemiology and disease, but certainly other measures of health and well-being could be considered and included (e.g., health indicators such as infant mortality rate as a proxy for overall health or life expectancy).

A challenge with health measures on COVID-19 is that the data will be changing over time and continuously updated. For some data sources, the data are updated on a daily basis versus others are updated on a monthly or weekly basis. It will be critically important to determine the time frame for sampling the data as some sources provide daily data whereas others are cumulative or averaged over variable time periods.

Community-level test access and testing rates have underlying assumptions that will be important to reconcile and consider in defining the common measure. There are multiple testing modalities available with different approvals, supply chains, and protocols. Currently available datasets and measures do not take this into account. While the rates are reported per 100,000 population, in many states, the data do not reflect the number of people tested but rather the number of tests performed, with some individuals having serial tests. Moreover, the frequency and quality of data are variable based on the source of data (even for reporting to federal agencies, like the CDC).

For health care access, there are multiple ways to examine access by age, race/ethnicity. Because of the vulnerability and variability in exposure across the life course, considering variability in health care access across age groups could be important. While several health care/public health infrastructure constructs could be valuable to consider for COVID-19 testing such as the number of sites providing free FDA approved testing, or the availability of contact tracing programs/trained personnel, or the test required for test results to become available, no single source of information is available. As referenced on the CDC website, local (<https://www.naccho.org/membership/lhd-directory>) or state (<https://www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html>) health departments may provide valuable data on the status of testing in a given region.

Another consideration for these measures and data sources is that many of the “non-COVID-19” data sources have significant lag times before reliable data is publicly reported and the local context may have changed considerably during 2020, including employment and insurance status.

Community Characteristics Obtained from Individual Self-Report

Some community-level characteristics may only be obtainable via self-report. These may be due to limitations in administrative dataset or because some community characteristics such as social cohesion can be assessed only via aggregate self-report of those in the community. In other cases, perception is as or more important than the statistical data from administrative datasets. For instance, although community level data on crime and injury rates are clearly relevant for health outcomes, research indicates that an individual’s perception of their community/neighborhood also plays a critical role in health-related outcomes. Administrative data also can be dated. For example, child maltreatment data from the Administration of Children and Families (ACF) is typically two years old and, given recent reports of concerns about increasing rates of child maltreatment since March 2020 when children were no longer as visible to teachers and other professionals who typically report (see [Washington Post article about decline in children reported to advocacy centers](#) and [reports of emergency rooms seeing](#)

[more severe injuries](#)), efforts should be made to obtain self-report data on child maltreatment if possible. Similarly, obtaining actual rates of IPV during a pandemic is challenging. However, [historical information on other crises points to the potential impact](#). Indeed, [a recent report by the National Domestic Violence hotline](#) indicates an increase since March compared to the same time period last year.

The Community-Level Characteristics self-report tab of the RADx-UP Data Harmonization spreadsheet includes some participant provided information (PPI) highly relevant to characterizing communities. These PPI variables include:

- Individual perception of community/neighborhood cohesion
- Individual perception of community/neighborhood safety
- Individual experiences of community resilience

These three measures are considered **Tier 1**. To reduce respondent burden across all projects, the Perception of School Social Environment is recommended as a Tier 2 element. There may be additional community level self-report measures that the RADx-UP consortium wishes to consider as Tier 2 elements.

Assessing Unique Community Characteristics

As community-engaged projects, the RADx-UP projects will generate various datapoints unique to their communities. For example, the *Alaska Native Community Resilience Study* (ANCRS U19 MH113138) identified vital community assets associated with a reduction of youth suicide risk on a community level via an intensive, iterative, and qualitative process involving community members of 64 Alaska Native villages. This effort identified important and relevant community domains to assess such as cultural continuity, self-determination, culturally responsive services, community relations, community support, and spirituality and religion. Measures of unique community domains such as these are not readily harmonized across studies, at least not a priori, but the RADx-UP consortium is encouraged to create a trans-consortium group that shares their processes and procedures for the qualitative assessment of the unique needs and characteristics of the communities involved, and considers ways to share and harmonize measures that assess these unique domains relevant to large number of communities involved in the consortium.

Appendix 1: GUID resources

[Global Unique Identifier Overview](#) (September 30, 2019)

Global Unique Identifiers (GUIDs) are alpha-numeric codes randomly generated by a computer algorithm and assigned to individuals enrolled in research studies to avoid exposing personally identifiable information (PII) and match participants across multiple projects, databases, biobanks, and repositories. The GUIDs available through the National Institutes of Health (NIH) report that they meet Federal data privacy standards.

National Institute of Mental Health (NIMH)

The National Institute of Mental Health Data Archives (NDA) offers researchers a GUID Tool that accepts personal information from an individual and converts the information to a unique GUID, without the information leaving the local computer drive

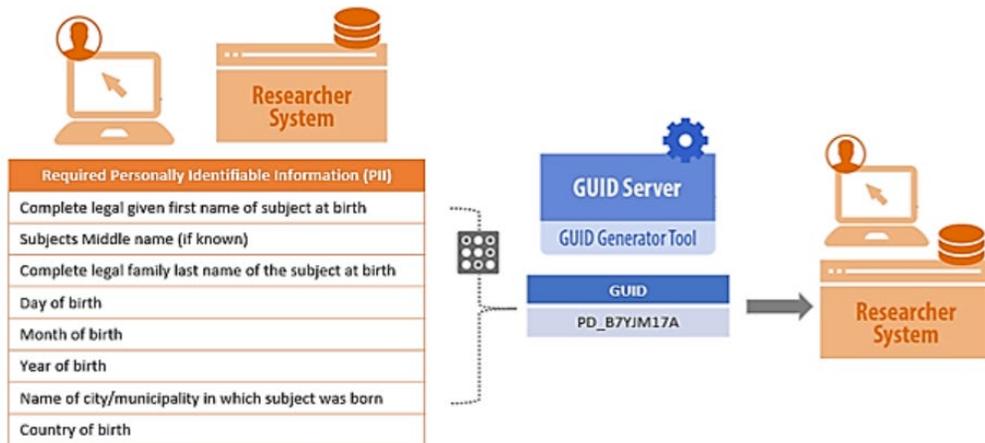
(<https://nda.nih.gov/s/guid/nda-guid.html>).¹ The GUID is then checked against the GUID database and if the code has been found, the individual already has a GUID. If the individual is not found, a new GUID is generated. GUID generation requires the following information: sex, first name, last name, middle name, DOB, and city/municipality of birth. PseudoGUID, another tool provided by the NDA, creates GUID-like codes if the required information is not available. The NDA also suggests entering data directly from the individual's birth certificate to ensure integrity of information.

National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Aging (NIA)

The National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Aging NIA, and the Parkinson's Disease Biomarkers Program (PDBP) have collaborated to produce the NINDS Centralized GUID solution, a multitenant GUID program

(<https://pdbp.ninds.nih.gov/ninds-centralized-guid-server>).² The tool generates a 10-digit alpha-numeric code. This tool introduces new capabilities, such as: 1) management of study participants using generated GUIDs, 2) mapping of participants for more efficient and comprehensive analysis, 3) access for institutes to see patient matching, 4) enhance collaboration between researchers. The NINDS Centralized GUID server uses the same information to generate a GUID and checks if the patient is already in the system. If the individual is in the system, the user is provided with metadata, such as the first and last name of the individual who originally registered the GUID, the institute that generated the GUID, and the date. No study data or information pertaining to a study is ever accessible through the NINDS Centralized GUID solution.

From the website:



National Center for Advancing Translational Sciences (NCATS)

The National Center for Advancing Translational Sciences (NCATS) hosts the Rare Diseases Registry (RaDaR) program that offers researchers a GUID generation tool (<https://rarediseases.info.nih.gov/radar/global-unique-identifier-generator>).³ If an existing GUID is located it will be returned to the researcher. If an existing GUID is not found a new GUID is generated. The required information Name, Middle Name at Birth, Family Last Name, Day of Birth, Month of Birth, Year of Birth, City of Birth, Country of Birth. The tool has two methods: (1) Online GUID tool one at a time and generates online in real time; and (2) CSV upload – multiple GUIDs and runs offline. This tool utilizes many of the same methods mentioned above, however, it also assigns a new GUID for individuals participating in a different BRICS disease instance.

National Institutes of Health, Center for Information Technology, National Institute of Neurological Disorders & Stroke, U.S. Army Medical Research and Development Command, and The Federal Interagency Traumatic Brain Injury Research (FITBIR) also offers tools for GUID generation and follows the NIMH NDA model closely (<https://fitbir.nih.gov/content/global-unique-identifier>). The GUID is made up of random alpha-numeric characters and is not generated from PII/PHI. It has been approved by the NIH Office of General Counsel. A user executes the GUID tool client locally and no data is sent to the GUID server. If an existing GUID is found the tool returns that GUID.

Other GUIDs

Cual-id, a new global unique identifier solution, hopes to make a global unique identifier for “omics” samples due to the large number of samples currently being analyzed (<https://omictools.com/cual-id-tool>). The number of samples in high-throughput comparative “omics” studies is increasing rapidly due to declining experimental costs. To keep sample data and metadata manageable and to ensure the integrity of scientific results as the scale of these projects continues to increase, this group proposed a transition to better-designed sample identifiers. Key components included: identifiers should be globally unique across projects,

project teams, and institutions; short (to facilitate manual transcription); correctable with respect to common types of transcription errors; opaque, meaning that they do not contain information about the samples; and compatible with existing standards. The GUID tool is a lightweight command line tool that creates, or mints, sample identifiers that meet these criteria without reliance on centralized infrastructure. Qual-id codes are too long to be written or comprehended so researchers are provided with 4-12 character codes that can be used for local records.

Standardization

In 2014, a workgroup focusing on global implementation of unique identifiers convened in Stockholm to draft a best practices guideline for using GUIDs.⁶ The group's main points focused on the difference between legacy and new biocollections, need for metadata collections to respond to persistence missions, and unambiguous identity of the object that is being identified. Wimalaratne et. al. also describe a novel method of compacting unique identifiers across biomedical data.⁷ The group has successfully resolved over 600 source databases to the original source. The group has named this source identifiers.org.

Privacy

Key word search of PubMed and Google did not find any studies or articles addressing privacy concerns related to re-identification of patients by their GUID. There is an open community for bioinformaticians and developers called stackoverflow.com and they operate a forum describing the ease of identifying previous GUIDs due to incorporating consortium ID codes.⁸ While current versions of GUIDS may not be easily identifiable, one day they may be with the invention of new deciphering algorithms.

Summary Table of GUID Resources

Institute	Link	PII Required for GUID
National Institute of Mental Health Data Archives (NDA)	https://nda.nih.gov/s/guid/nda-guid.html	<ol style="list-style-type: none"> Sex First Name Last Name Middle Name DOB City/municipality of birth
National Institute of Neurological Disorders and Strokes (NINDS)	https://pdbp.ninds.nih.gov/ninds-centralized-guid-server	<ol style="list-style-type: none"> Sex First Name Last Name Middle Name DOB City/municipality of birth
Rare Disease Registry (RaDaR) from NCATS	https://rarediseases.info.nih.gov/radar/global-unique-identifier-generator	<ol style="list-style-type: none"> First Name Last Name Middle Name DOB City/municipality Country
FITBIR	https://fitbir.nih.gov/content/global-unique-identifier	<ol style="list-style-type: none"> Complete legal given (first) name of subject at birth Complete legal additional name of subject at birth (If the subject has a middle name) Complete legal family (last) name of subject at birth Day of birth Month of birth Year of birth Name of city/municipality in which subject was born Country of birth
Cual-id	https://omictools.com/cual-id-tool	None- Opaque numbers that do not reveal information about the sample – Identifier sequences contain some sample information if needed

References

- <https://nda.nih.gov/s/guid/nda-guid.html>
- <https://pdbp.ninds.nih.gov/ninds-centralized-guid-server>
- <https://rarediseases.info.nih.gov/radar/global-unique-identifier-generator>
- <https://fitbir.nih.gov/content/global-unique-identifier>
- Chase JH, Bolyen E, Rideout JR, Caporaso JG. cual-id: Globally Unique, Correctable, and Human-Friendly Sample Identifiers for Comparative Omics Studies. *mSystems*. 2015;1(1):e00010-15. Published 2015 Dec 22. doi:10.1128/mSystems.00010-15
- Guralnick RP, Cellinese N, Deck J, et al. Community next steps for making globally unique identifiers work for biocollections data. *Zookeys*. 2015;(494):133–154. Published 2015 Apr 6. doi:10.3897/zookeys.494.9352
- Wimalaratne SM, Juty N, Kunze J, et al. Uniform resolution of compact identifiers for biomedical data. *Sci Data*. 2018;5:180029. Published 2018 May 8. doi:10.1038/sdata.2018.29
- <https://stackoverflow.com/questions/3652944/how-securely-unguessable-are-guids>

Appendix 2: Tier 1 Recommendations

Construct	Measure	CDE link
Social Determinants of Health and Sociodemographics		
Race	Is Person 1 of Hispanic, Latino, or Spanish origin? What is person 1's race?	https://www.phenxtoolkit.org/protocols/view/11901
Ethnicity	Is Person 1 of Hispanic, Latino, or Spanish origin? What is person 1's race?	https://www.phenxtoolkit.org/protocols/view/11901
Age (or Date of Contact - DOB)	What is Person 1's age and what is Person 1's date of birth?	https://www2.census.gov/programs-surveys/acs/methodology/questionnaires/2020/quest20.pdf
Biological Sex	What was your biological sex assigned at birth?	https://www.phenxtoolkit.org/protocols/view/11601
Gender Identity	What terms best express how you describe your gender identity?	https://www.phenxtoolkit.org/protocols/view/11801
Sexual Orientation	Which of the following best represents how you think of yourself?	https://www.phenxtoolkit.org/protocols/view/11701
Physical Address	I would like to verify your address. Please give me your complete current residential address (where you spend most of your time).	https://www.phenxtoolkit.org/protocols/view/10801
Resides in Group Home or Congregate Care Setting	Does you reside in a group care setting, such as a nursing home, residential care facility for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care, or other setting.	https://loinc.org/sars-cov-2-and-covid-19/
Education	What is the highest grade or level of school you have completed or the highest degree you have received?	https://www.phenxtoolkit.org/protocols/view/11002
Marital Status	Are you...Married, Divorced, Widowed, Separated, Never Married or a member of an unmarried couple?	https://www.phenxtoolkit.org/protocols/view/10903
English Proficiency	Does this person speak a language other than English at home? What is this language? How well does this person speak English?	https://www2.census.gov/programs-surveys/acs/methodology/questionnaires/2020/quest20.pdf?#
Disability Status	CDC six-item Standard Disability Questions	https://www.cdc.gov/ncbddd/disabilityandhealth/datasets.html
Number of dependents: Child and Adult	Please tell me the names of the people who usually live in this household. Let's start with the person or one of the persons who owns or rents this home.	https://www.phenxtoolkit.org/protocols/view/11402
Employment Status	We would like to know about what you do-are you working now, looking for work, retired, keeping house, a student, or what?	https://www.phenxtoolkit.org/protocols/view/11301
Employed in Healthcare (with direct patient contact)	Are you employed in healthcare and have direct patient contact?	https://loinc.org/sars-cov-2-and-covid-19/
Job Security	Thinking about the next 12 months, how likely do you think it is that you will lose your job or be laid off—very likely, fairly likely, not too likely, or not at all likely? About how easy would it be for you to find a job with another employer with approximately the same income and fringe	item 50 of https://www.phenxtoolkit.org/toolkit_content/PDF/Census_HPS.pdf

	benefits you now have? Would you say very easy, somewhat easy, or not easy at all?	
Housing Status/Housing Security/Homelessness	In the past two months, have you been living in stable housing that you own, rent, or stay in as part of a household? (Negative response indicates homelessness). Are you worried or concerned that in the next two months you may NOT have stable housing that you own, rent, or stay in as part of a household? (Positive response indicates risk of homelessness).	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4612177/
Food Security	The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more. Was that often, sometimes, or never true for (you/your household) in the last 12 months?	https://www.phenxtoolkit.org/protocols/view/270301
Perceived Discrimination	At any time in your life, have you ever been unfairly fired? Unfairly denied a promotion? You receive poorer service than other people at restaurants or stores. You are treated with less respect than other people.	https://www.phenxtoolkit.org/protocols/view/210302
Health Care, Medical History - General and COVID-19, Mental Health/Substance Abuse		
Health Insurance Status	Source of Health Insurance	https://www.phenxtoolkit.org/protocols/view/11502
Healthcare access	This protocol includes 10 interviewer-administered questions from the National Health Interview Survey (NHIS) Adult Access to Health Care & Utilization Module. Questions capture when medical care was last sought, usual place of care, frequency of getting medical care and reasons for not getting medical care.	https://www.phenxtoolkit.org/protocols/view/270101
Disparate Health Care Quality	A protocol to examine the perception of prejudice, stereotyping, and discrimination in clinical encounters and experience.	https://www.phenxtoolkit.org/protocols/view/280101
Transportation Barriers (Healthcare)	When you visit your primary care doctor, how do you usually get there?	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704937/#APP1
Self-reported health	NHIS Self-reported general health	https://www.phenxtoolkit.org/protocols/view/770101
Pregnancy	Standard LOINC code for pregnancy	https://loinc.org/82810-3/
Current Medications	PhenX	https://www.phenxtoolkit.org/protocols/view/140301
Current Conditions (including other mental health diagnoses and substance use disorders)	C3PNO from JHU Community Survey	https://www.phenxtoolkit.org/toolkit/content/PDF/JHU_C4WARD_Health.pdf
Flu Vaccination	LOINC	https://loinc.org/58131-4/
Height	Self-reported height	https://cdebrowser.nci.nih.gov/cdebrowserClient/cdeBrowser.html#/dataElement
	Self-reported height	https://www.phenxtoolkit.org/protocols/view/20704?origin=search

	Standing height	https://www.phenxtoolkit.org/protocols/view/20703?origin=search
Weight	Self-reported weight	https://www.phenxtoolkit.org/protocols/view/21502?origin=search
	Measured weight	https://www.phenxtoolkit.org/protocols/view/21501?origin=search
	Growth charts (for pediatric samples to calculate BMI)	https://www.phenxtoolkit.org/protocols/view/221201
COVID-19 Symptoms	CDC CRP	https://www.phenxtoolkit.org/toolkit_content/PDF/CDC_PUI_v2.pdf
Tested previously for coronavirus	Self-report of COVID Testing	https://www.phenxtoolkit.org/protocols/view/570201
Diagnosed with COVID-19	Self-report of being previously diagnosed with COVID-19	https://www.phenxtoolkit.org/toolkit_content/PDF/MESA_COVID_19_Diagnosis.pdf
Hospitalized for COVID-19	Self-report of being hospitalized for COVID	https://www.phenxtoolkit.org/toolkit_content/PDF/MESA_COVID_19_Diagnosis.pdf
Exposure to others who tested positive or were dx with COVID-19	COVID-19 Experiences (COVEX) questionnaire: Section 2: Vulnerability to COVID and Direct Exposure	https://www.phenxtoolkit.org/toolkit_content/PDF/CDC_PUI_v2.pdf
Stress	Perceived stress scale	https://das.nh.gov/wellness/docs/percieved%20stress%20scale.pdf
Alcohol Use	Alcohol - Lifetime Use	https://www.phenxtoolkit.org/protocols/view/30101
Tobacco/Nicotine Use	Use of Tobacco Products	https://www.phenxtoolkit.org/protocols/view/30604
Social-Psychological-Economic-Healthcare impacts of COVID		
Social support system stability	I have noticed increased conflict in our family since our area started worrying about coronavirus	https://www.nlm.nih.gov/dr2/ABCD_COVID-19_Impact_Measure-Parent.pdf
Social support system stability	I think it is likely that someone very close to me will be hospitalized or die from the coronavirus	
Loneliness	Is your life more lonely because of the COVID-19 pandemic?	https://www.phenxtoolkit.org/toolkit_content/PDF/JHU_C4WARD_Social_Distancing.pdf
Adult Missed/cancelled appointment	Has your clinic, doctor's office or dental practice closed or cancelled an appointment because of COVID-19	https://www.phenxtoolkit.org/toolkit_content/PDF/OSUMC_Impact-COVID19_Health.pdf
Adult Missed/cancelled appointment	Have you cancelled a clinic, doctor or dental appointment to avoid being around others?	https://www.phenxtoolkit.org/toolkit_content/PDF/OSUMC_Impact-COVID19_Health.pdf
Access to Medication	Have you been unable to obtain one or more prescription medications because of the COVID-19 pandemic	https://www.phenxtoolkit.org/toolkit_content/PDF/OSUMC_Impact-COVID19_Health.pdf
Missed Medical Procedure	Since the COVID-19 pandemic (March 1, 2020), have you needed to postpone any medical procedures?	https://www.phenxtoolkit.org/toolkit_content/PDF/JHU_C4WARD_Health.pdf
Job loss	Q9 Have you, or has anyone in your household experienced a loss of employment income since March 13, 2020?	https://www.phenxtoolkit.org/toolkit_content/PDF/Census_HPS.pdf

Job security	1. Thinking about the next 12 months, how likely do you think it is that you will lose your job or be laid off—very likely, fairly likely, not too likely, or not at all likely?	https://www.phenxtoolkit.org/protocols/view/280301?origin=tree
Job security	2. About how easy would it be for you to find a job with another employer with approximately the same income and fringe benefits you now have? Would you say very easy, somewhat easy, or not easy at all?	https://www.phenxtoolkit.org/protocols/view/280301?origin=tree
Education disruption	Q43 How has the coronavirus pandemic affected how the children in this household received education?	https://www.phenxtoolkit.org/toolkit_content/PDF/Census_HPS.pdf
Anxiety	Q32 Over the last 7 days, how often have you been bothered by the following problems ... Feeling nervous, anxious, on edge	https://www.phenxtoolkit.org/toolkit_content/PDF/Census_HPS.pdf
Anxiety	Q33 Over the last 7 days, how often have you been bothered by the following problems ... Not being able to stop or control worrying?	
Depression	Q34 Over the last 7 days, how often have you been bothered by ... having little interest or pleasure in doing things?	
Depression	Q35 Over the last 7 days, how often have you been bothered by ... feeling down, depressed, or hopeless?	
Mental Health Impacts	Module 6, items 1-2 of JHU Community Survey	https://www.phenxtoolkit.org/toolkit_content/PDF/JHU_C4WARD.pdf
Attitudes and Behaviors		
Accuracy of Knowledge about/Adherence to Handwashing (Adherence to CDC guidelines)	COVID-19 Knowledge, Attitudes, and Avoidant Behaviors (Knowledge)	https://www.phenxtoolkit.org/toolkit_content/PDF/CESR_UAS_Knowledge.pdf
Adherence to Physical Distancing/Accuracy of information for all questions.	COVID-19 Knowledge, Attitudes, and Avoidant Behaviors (Behavior)	https://www.phenxtoolkit.org/toolkit_content/PDF/CESR_UAS_Knowledge.pdf
Adherence to Face Coverings	COVID-19 Knowledge, Attitudes, and Avoidant Behaviors (Behavior)	https://www.phenxtoolkit.org/toolkit_content/PDF/CESR_UAS_Knowledge.pdf
Adherence to cover cough/sneeze	COVID-19 Knowledge, Attitudes, and Avoidant Behaviors (Behavior)	https://www.phenxtoolkit.org/toolkit_content/PDF/CESR_UAS_Knowledge.pdf
Accessibility to testing	(Illustrative example of possible item in next column)	I know where I can get coronavirus testing in my community (strongly agree to strongly disagree). It is easy to get tested for coronavirus (strongly agree to strongly disagree).
Perceived accuracy of testing	(Illustrative example of possible item in next column)	How confident are you that a negative test result means that you do not have coronavirus? (Very confident to not at all confident). How confident are you that a positive test results means that you

		have coronavirus? (very confident to not at all confident).
Perceived benefits of testing	(Illustrative example of possible item in next column)	How much do the following encourage you to get tested? (very much to not at all). (Reduce worry that I might have coronavirus; Believe that I was exposed to someone who has coronavirus; to know if I am safe not to give the coronavirus to family and friends; to know if I am safe not to give the coronavirus to anyone I am around; to let my employer know that I am safe to work; to get treated early if I am positive)
Perceived risks of testing	(Illustrative example of possible item in next column)	How much do the following discourage you to get tested? (very much to not at all). (May experience discomfort from being tested; even if I don't have it when tested, I can still get the coronavirus later; I don't have COVID-19 symptoms so I don't need to be tested; if I'm positive, officials will need to contact the people I've been in contact with; I don't want to know if I have it; not much they can do for me if I have it; difficult to get needed healthcare if I have it).
Intention to be tested	(Illustrative example of possible item in next column)	I plan to get tested as often as needed (strongly agree to strongly disagree)
Interpretation of negative or positive test results	(Illustrative example of possible item in next column)	If I get a negative test result, it means (check all that apply) (I don't have to worry about getting COVID-19; I don't have COVID-19 now; I can be around others without giving the virus to them; I can be around others without getting the virus from them). If I get a positive result, I will need to be admitted to the hospital; I will need to isolate myself from others; I will need to take off work)
Perceived peer norms regarding testing.	(Illustrative example of possible item in next column)	Which statement below best describes the desire of people in your community to get coronavirus testing as it is available? (Very few plan to get tested; Some plan to get tested; Many plan to get tested; Most or all plan to get tested)
Vaccination risks, benefits, and	General: UAS Cr025 and cr30	https://www.phenxtoolkit.org/toolkit_content/PDF/CESR_UAS.pdf

intention to be vaccinated		
Community-level-characteristics collected from an individual		
Individual's perception of community/neighborhood cohesion	Multiple measures: community cohesion; Informal Social Control	https://www.phenxtoolkit.org/protocols/view/210801
Individual's perception of community/neighborhood safety	Safety	https://www.phenxtoolkit.org/protocols/view/210901?origin=domain
Community Resilience		https://www.nlm.nih.gov/dr2/COVID_Impact_on_Health_Wellbeing_Eng.pdf

NOTE:

- Estimated Total Tier 1 items: 135
- Estimated time to completion: ~ 23 minutes (assuming 10 seconds per item)

Appendix 3: List of NIH staff contributing to the RADx-UP guidance document (Name, IC affiliation) by Team Section

Staff Name	ICO Affiliation
Community-Level Characteristics	
Alice Kau	NICHD
April Oh	NCI
Aubrey Miller	NIEHS
Dara Blachman-Demner	OBSSR
Dorothy Castille	NIMHD
Doug Joubert	NLM
John Phillips	NIA
Juliana Blome	THRO
Katia Howlett	NIDA
Laura Bartlett*	NLM
Michael Schoenbaum	NIMH
Michelle Freemer	NHLBI
Mike Spittel	OBSSR
Monica Hooper	NIMHD
Rebecca Goodwin	NLM
Rebecca Roper	NHLBI
Stephanie Holmgren	NIEHS
Participant Provided Information	
Alla Keselman	NLM
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Anna Napoles	NIMHD
Bill Riley*	OD
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Tracy King	NICHD
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*- Served as co-chair for the respective sub-groups