



RADX-UP INFORMED CONSENT DATA SHARING TEMPLATE LANGUAGE

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How to use this informed consent form template language:

- Text in **blue** indicates example text to include in your informed consent form.
- Text in *italicized black* are instructions and suggestions on what to include in certain sections or scenarios.

WHAT IS THE NIH AND RADX-UP?

The NIH stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. The NIH funded (provided support) for the RADx-UP program.

RADX-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP, we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

WHAT WILL YOU ASK OF ME?

If you decide to join this study, we will gather data (information) about you. We will gather some of the data from you directly. We will gather some of the data from other places.

Examples of the information that we may collect from you or other places include, but not limited to: *[Tip: being inclusive of all the information that will be collected will help avoid future IRB amendments as common data elements continue to be developed]:*

- We will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history.
- We will ask you for your Social Security number (SSN), if you agree. We will use your SSN to help us link your data with other data, such as your electronic health record and Centers for Medicare and Medicaid Services, among others. We will not share your SSN with anyone or use it for any other purpose. You may choose not to provide your SSN and still be able to take part in this study.
- We will ask you information about COVID-19, including information about any symptoms (a change in your health) and test results. If you had a positive COVID-19 test, we will ask information about contact tracing (people who may have come in contact with you while you had COVID-19). We will ask about your medical history and if you have or have not had vaccines and why.
- We will ask you information about your health, education, family, home, relationships, and social life, among others.



- We may ask you to fill out questionnaires, surveys and other forms in order to collect the information above.

WHAT WILL YOU DO WITH MY DATA?

*Because the RADx-UP program will collect data for future research, you **must** include the following language:*

We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies.

The DCRI will build two RADx-UP databases (systems that hold electronic information).

The first database will only hold information that can identify you (called identifiable information). Examples are your name, address, email, and gender.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.

The second database will not hold information to identify you. It will hold all the non-identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

Optional:

I agree to let the DCRI collect the following **identifiable** information: name, address, contact information, and date of birth, as stated above.



Yes No
Initials Initials

I agree to let the DCRI collect **my Social Security number** as stated above.

Yes No
Initials Initials

I agree to let the DCRI collect **only** my zip code and no other **identifiable** information as stated above.

Yes No
Initials Initials

I agree to be contacted for future research as stated above.

Yes No
Initials Initials

HOW WILL YOU PROTECT MY PRIVACY?

Your privacy is **very** important to us. We will take great care to protect your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- When your data are shared with other researchers, they will not have information that can identify you.
- This project has a Certificate of Confidentiality from the United States government. Certificates of Confidentiality protect your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree, or in a few other specific situations.