Introduction to the Common Data Elements (CDE) Optional Survey:

**Main Issue: This survey will collect a LIMITED data set, with no direct identifiers, but dates and zip codes may be retained.**

Thank you for your continued interest in our wastewater surveillance research study, which we will refer to as the main study in which you have given verbal consent to participate.

You have indicated an interest in taking an additional, optional survey, the Common Data Elements (CDE) Optional Survey. We would like to tell you what you need to think about before you choose whether or not to take this optional survey. It is your choice. If you choose to participate, you can change your mind later on and stop the survey.

You have an option to fill out this 105-question survey (CDE Tier 1, version 1.5, date 4/1/22) common to a group of COVID- 19 studies funded by the NIH. The survey data collected will be a limited data set with no direct identifiers, but dates and zip codes may be retained. The limited data will be collected using Colectiv. Colectiv is a web-based data collection system hosted and managed by the Coordination and Data Collection Center (CDCC) at Duke University. The CDCC may share deidentified data with the National Institutes of Health (NIH) or other researchers.

**Additional Details:**

This survey is an activity that will be offered alongside study headed by Dr. Spaulding at Emory University. Dr. Spaulding’s main project is to learn about implementation of wastewater surveillance strategies in jail settings.

For the main study, for which you already gave verbal consent: We want to gain more knowledge about the benefits, limitations, and practicality of using wastewater to monitor and detect SARS-CoV-2. We want to solicit ideas about how the project could be improved. The study is funded by the National Institutes of Health (NIH). This study will take about two years to complete. You were asked to participate in implementation team meetings, interviews, surveys and/or focus groups.

*What are the possible risks and discomforts of the additional CDE survey?*

There is a very small risk of loss of confidentiality. We will discuss your experience in the COVID-19 pandemic and you may not want that information to be shared with others. However, several measures will be taken to prevent this. Your privacy is very important to us. All members of the study team are carefully trained to maintain the confidentiality of study participants. Any publications that may result from this study will refrain from mentioning participants by name. Unless an individual is in a unique role held by no one else, the study will not report any information about participants that someone could recognize and trace back to them.

*Will you benefit from the optional CDE survey?*

No. This study is not designed to benefit the participant directly; however, it is designed to learn more about best practices for COVID-19 surveillance.

*Will you be paid for your time and effort?*

 No. You will not be compensated for the additional time to take the optional CDE survey.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this survey, just as there was one for the main study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

* Giving state public health officials information about certain infectious diseases,
* Giving law officials information about abuse of a child, elderly person or disabled person.
* Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Storing and Sharing your Information**

As with the main study, Duke University’s Coordination and Data Collection Center will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or a medical record number. They will keep a file that links this code to your limited identifiers in a secure location separate from the data. Data will be stored on protected, secure computer systems. They will limit and keep track of who can see these data. Anyone who can see these data will have to use a password and multi-factor authentication. We will take steps to protect your information from others that should not be able to see it.

Neither Emory nor Duke researchers will allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

**Confidentiality**

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

**People Who will Use/Disclose Your Information:**

The following people and groups will use and disclose your information in connection with the research study:

* The Principal Investigator and the research staff will use and disclose your information to conduct the study.
* Emory may use and disclose your information to get payment for study related activities and to run normal business operations.
* The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
* The National Institute of Health is the Sponsor of the study. The Sponsor may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
* The **Coordination and Data Collection Center at Duke University, which coordinates data collection for NIH sponsored studies on COVID-19** will have access to your limited data set as it relates to data items collected during this additional survey.
* The following people and groups will use your information to make sure the research is done correctly and safely:
	+ Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
	+ Coordination and Data Collection Center at Duke University
	+ Government agencies that regulate the research including: Office for Human Research Protections
	+ Public health agencies.
	+ Research monitors and reviewer.
	+ Accreditation agencies.
* Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.