

Highlighted text indicates permissible changes to this master consent template.

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Research Subjects

Key Study Information & Informed Consent Form (Cycle 2)

Key Information	Details
Title of Study:	NIH RECOVER: A Multi-site Observational Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Pediatric Populations Study #: s21-01231
Study Site Leader:	Name Title Institution Address 1 Address 2 City, State, Zip Code Telephone
Study Leader:	Rachel Gross, MD, MS NYU Grossman School of Medicine 227 East 30 th Street New York, NY 10016 Tel (212) 263-8974
Research Information Leader:	Andrea Foulkes, Sc.D. Director Biostatistics, Massachusetts General Hospital Professor of Medicine, Harvard Medical School 50 Staniford Street, Suite 560 Boston, MA 02114 Tel (617) 724-8208
Additional Contact:	Institutional Review Board (212) 263-4110

Key Study Information Form (Cycle 2)

(If you are completing this form as a parent/caregiver, “you” means “your child.”)

Thank you for being in the RECOVER study. We are inviting you to be in the RECOVER study for up to 2 more years. We call these next 2 years “Cycle 2.” You may also see it called “second phase” and “next phase” in other study materials. These all mean the same thing: Cycle 2.

By staying in the study, you can help researchers understand how children’s health may change over time and whether symptoms get better, stay the same, or get worse. Your participation is voluntary, which means it is your choice if you would like to participate in Cycle 2 of the study.

Purpose of the Research Study

This study is part of a research project paid for by the National Institutes of Health (NIH) called RECOVER (Researching COVID to Enhance Recovery). RECOVER has moved into its second phase, Cycle 2. In Cycle 2, RECOVER researchers will study all children and young adults who have and have not had COVID-19, including participants with and without Long COVID, and those at risk of developing it. This includes children whose mothers joined the RECOVER pregnancy study.

Other Key Information

You may be asked to do Cycle 2 surveys and tests 2 times about 1 year apart. If you choose to be in Cycle 2, we will ask you to sign a consent form (a document that tells you information about the study) before you complete any of the Cycle 2 surveys or tests.

In Cycle 2, you will be asked to complete tests to see how your body works and how your brain thinks and learns. You will also be asked to give some samples from their body like blood, stool (poop), urine (pee), hair, and swabs from the nose, mouth, and skin. A full list of tests will be reviewed with you below in Section 3. RECOVER may also check your medical records to learn more about your health while you are in the study.

Foreseeable Risk and Benefits

A full list of all possible risks and discomforts related to being in Cycle 2 is included below in Section 4. The most common risks include possible loss of private information (which can happen in any study) or possible discomfort or feeling tired after doing some of the tests and giving samples (blood, stool [poop], urine [pee], hair, and cotton swabs from the nose, mouth, and skin).

We do not expect that your health will get better from being in Cycle 2, but continuing in the study could help children, young adults, families, and researchers understand how COVID-19 affects the body over time.

Alternatives to Participation

There are no other ways to be a part of the study if you do not want to participate in Cycle 2. For questions and concerns about any of this information, contact the study leader or study site leader, their information is found on page 1.

1. About volunteering for Cycle 2

You are being invited to take part in a research study. You can choose whether or not you want to take part in this study.

By staying in the study, you can help researchers understand how children's health may change over time and whether symptoms get better, stay the same, or get worse. The study will also look at whether children exposed to COVID-19 during pregnancy, or who had COVID-19 themselves, are linked to long-term health problems.

This consent form is about the study visits for Cycle 2. Before you decide if you want to stay in the study, you will need to know what Cycle 2 is about, what you will be asked to do, and the possible risks (or harms) from being in Cycle 2. You may also want to talk about this study and this form with your family, friends, or doctor. If you have any questions, please ask us. If you decide to take part in Cycle 2, you must sign this form. We will give you a copy of this form to keep once you have signed it.

An adult is someone who has reached the legal adult age in their state. Any person who becomes an adult while in the study will be asked to sign this consent form before doing any Cycle 2 surveys or tests.

The Informed Consent Form that you signed when you first joined RECOVER has information that is still true for Cycle 2. This includes an explanation of how your information is protected and stored. Since this information is still true, it is not included in the consent form for Cycle 2. Please review your original RECOVER consent form to read that information again. You can ask your study team if you need another copy.

Please let us know if you have any questions.

2. How long is Cycle 2? How many other people will be in Cycle 2?

Cycle 2 may take up to 2 years. There will be about 4,000 children and young adults in Cycle 2.

You may be asked to do Cycle 2 surveys and tests 2 times, about 1 year apart. The Cycle 2 study visits will be scheduled to happen at the place where the study is taking place (called the study site). This could be a hospital, doctor's office, or research center.

3. What will you be asked to do in Cycle 2?

If you choose to be in Cycle 2, we will ask you to sign this consent form before doing any of the Cycle 2 surveys and tests.

In the surveys, we will ask questions about you, your health, health habits, health problems, and any medicines you take. We will also ask questions about your home, and the neighborhood where you live. In addition, we will ask you about COVID-19, including any testing, if you have gotten the COVID-19 vaccine, and any health problems you had because of COVID-19 or the COVID-19 vaccine.

The table below shows the Cycle 2 study tests and information about each test. You will be asked to do some of the tests on the list below at each visit.

Name of test	Where survey or test will take place	Information about what will happen
Check-up or physical exam	Study site	Your study team will measure your height, weight, pulse, blood pressure, and oxygen level.
Tests to see how your brain thinks and learns	Study site	This testing uses special questions and games to measure how the brain works. We are interested in the way your brain thinks and learns. These tests are given by a specially trained person (a psychologist or a trained assistant). This may take about 1 hour.
Questions to see how you think and feel	Study site	These questions will ask about your feelings and thoughts about your life. Based on your age, you may answer these questions yourself and may have a caregiver answer as well. <i>Participants ages 11 and younger will only have their caregiver respond to these questions.</i> <i>Participants ages 12 to 17 will answer as well as have a caregiver respond.</i> <i>Participants ages 18 and older will only answer for themselves.</i> These will take about 30 minutes.
Standing test	Study site	You will be asked to lie down and rest for 5 minutes for this test. Then, you will be asked to stand for 10 minutes without moving. While standing, your heart rate and blood pressure will be measured. This will take about 20 minutes.
Walking test	Study site	This test will ask you to walk indoors for 6 minutes and will measure how far you can walk in that time. After walking, your heart rate and blood pressure will be measured. This will take about 15 minutes.

Name of test	Where survey or test will take place	Information about what will happen
Joint flexibility test	Study site	This test will ask you to move your arms, legs, spine, elbows, knees, and fingers. This will take about 5 minutes.
Smell test	Study site	This test will ask you to smell scented cards and markers and tell us what you smell. This will take about 10 minutes.
Taste test	Study site	This test will ask you to taste pieces of paper. You will be asked to name what you tasted and how strong it tastes. This will take about 10 minutes.
Giving pee (urine) poop (stool), hair, and swab samples from the nose, mouth, and skin	Study site or home	We will ask you to give us urine (pee), stool (poop), and hair samples, and use cotton swabs in your nose, mouth, and on your skin. These will be stored for future testing. We will give you kits to help you collect the samples.
Giving a blood sample	Study site	We will use a thin needle to take blood from your arm. <i>Participants ages 9 years and younger will have less than 2 tablespoons of blood collected.</i> <i>Participants ages 10 years and older will have less than 3 tablespoons of blood collected.</i>

Future Use of Data from Surveys and Test Results

Information that identifies you, such as your name and address, will be removed from questionnaires and test results. After this happens, information may be used for future research studies or shared with other researchers without sharing your identity. We will not request another informed consent from you to use these results.

Future Use of Blood, Urine, Stool, Hair, and Other Things from Your Body (Called Biospecimens)

With your permission, biospecimens collected in Cycle 2 (blood, stool [poop], urine [pee], hair, and cotton swabs from the nose, mouth, and skin) will be sent to a storage place called the RECOVER Research Biorepository at Mayo Clinic, MN, to be stored for future research tests. These biospecimens are also called “study samples.”

Study samples in this storage place will be used mostly for research on COVID-19 and the long-term effects of COVID-19. They may also be used for research on other health problems.

Your study information and study samples may be shared with researchers around the world, including those working as part of businesses. However, the group in charge of this study (leaders of the RECOVER project at the NIH) controls who can get the information and study samples. To use your information and study samples, researchers must ask the leaders of the RECOVER study if they can be shared. Your name or other information that reveals your identity will not be given to other researchers. Samples that are stored will be given a code number. Only the researchers where you signed up to be part of this research and the researchers who are in charge of keeping study information will have the key that connects the code number with your personal information. Researchers must also agree to not try to figure out who you are. If you change your mind about sharing your samples, you can take back your study samples and study information by telling the study site leader listed at the beginning of this form.

At the end of the study, your personal information will be taken out of the RECOVER database, and there will no longer be a key to connect your information with the study samples. After taking away the key, the data and study samples we got from you for this study may be used for future research studies or shared with other researchers, but your identity will not be shared. We will not ask for consent from you to use these data and study samples. After the key is removed, you will no longer be able to request to take back your study samples.

Communicating with the Research Team

The research team will contact you by phone, email, or text message, depending on what you choose. When the research team sends email messages that include information about your health that is linked to who you are (identifiable), they will help keep your personal information safe by encrypting the message. Encrypted emails are locked so other people cannot see what they say. There is no way to encrypt the messages sent by text. This means that information you send or receive by text message could be looked at by someone who was not supposed to see it or by your mobile/cell phone provider or company. When text messages are sent or received on your phone, there may be risks related to your privacy. Please indicate below whether you agree to receive text messages from the research team:

☐	Yes, I agree to receive texts from the research team.
<i>Initial here</i>	
☐	No, I do not agree to receive texts from the research team.
<i>Initial here</i>	

Please make sure to keep the research team updated if your address, email, or cell phone number changes during the study.

4. What are the possible risks or discomforts?

Being in Cycle 2 may involve some added risks or discomforts from the surveys and tests being done. In addition to the risks listed below, there may be risks that we do not know about yet. You should contact the study site leader as soon as possible if you are concerned about anything while you are part of the study.

Risk of having blood taken

Blood will be drawn through a needle placed into a vein in your arm. Having blood taken may be uncomfortable or make you feel dizzy or faint (pass out). Tell your study team right away if you feel like you might pass out. Redness, pain, bruising, bleeding, or infection may also happen where the needle goes into the skin during blood collection.

Other testing risks

The collection of urine (pee), stool (poop), hair, and swabs from your nose, mouth, and skin may be unpleasant or embarrassing. If you are collecting these samples at the study site, the study team will make sure you are given a private space to do so.

In-person tests

Completing the in-person tests may take a long time. This may make you feel tired, uncomfortable, or frustrated. You can stop or take a break if you need to.

Risks of Future Gene Tests

It is possible that during the study, we may do tests on your biospecimens that find out things out about your genes. You can decide whether you want to be told about these things. There can be a risk in knowing these results. For example, researchers may look at the full set of genes in your body, including looking at the exact order of DNA, the building block of the genes. This is called whole genome sequencing. New information may be found that show that you have genes that make it more likely that you will have certain health problems. Knowing this information can be stressful, lead to worry and affect your relationship with your family. There may also be good things (benefits) about knowing about how genes might affect your health; sometimes you can change your habits or have screening tests that will help you from getting a disease or help you treat a disease earlier.

Group Risks of Gene Tests

Although we will not give researchers your name, we may give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes, stigmatize, or discriminate against members of a socially defined group such as race or ethnicity.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for certain employers and employer-based health insurance companies and group health plans to discriminate against you based on your genetic information. GINA also limits the organizations from sharing your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease. Health insurance companies and group health plans may not request your genetic information from this research and the Sponsor will not share this information with such companies, plans or employers.

5. What if a study test reveals new information related to my health?

During this study, we may find information that could be important to you. We will let you know as soon as possible if this kind of information is found.

In Cycle 2, some blood, heart, or lung test results may be shared with you. If we find something important for your health, a study doctor will explain the results to you. These results may also become part of your medical record, which means that anybody who is allowed to see your medical record, including your healthcare providers outside of the study, may be able to see the test results. Your healthcare providers may order more tests or treatments that are not part of the study based on certain test results. You will have to pay for any tests or treatments ordered by your healthcare provider that are not part of the study.

New findings from genetic research

Researchers may do research on the DNA in your genes while you are in the study, and also in the future after you have finished all of the study visits. In these tests, new information about your DNA may be discovered. DNA is the material that makes up your genes.

The genetic testing for the study is being done for research, but the study doctors might find a change in your gene DNA that may increase risk of certain diseases or health conditions for you and your family. You can choose whether or not you would like to know about the results of the genetic testing. If you choose to know about these genetic test results, it is important for you to know that results from a certified clinical laboratory may also be included in your medical record, which means that anybody who is allowed to see your medical record, including your health care providers outside of the study, will be able to see the test results. It is possible that you may have other changes in gene DNA that we do not come across as part of this research. Your health care providers may order more tests or treatments that are not part of the study, and may ask you to meet with a genetic counselor to help you understand the results of the genetic test. You will be financially responsible for any tests, treatments, and counseling ordered by your health care provider that are not part of the study.

Please initial one of the options below to confirm whether you would like to be told of findings from study gene testing:

_____ Yes, I would like to be told about gene test results that might affect my health.

Initials here

_____ No, I would not like to be told about gene test results that might affect my health.

Initials here

6. What are the possible benefits of being in Cycle 2?

Being in Cycle 2 may help you and your doctor better understand health problems that are related to COVID-19. The results of the study will be important in helping children, families, and doctors better understand how COVID-19 affects health over time. However, we do not expect that your health will get better from being in Cycle 2.

7. What else can I do if I decide not to be part of Cycle 2?

You do not have to be part of Cycle 2 of this research study. You do not have to take part in this research study to be treated for COVID-19. Not participating in Cycle 2 will not affect any future care you may receive at your study site, how your healthcare is paid for, or what kind of health insurance you can get.

8. Will you be paid for being in Cycle 2?

People who are in Cycle 2 will be paid for the time it takes to do study activities.

For completing Cycle 2, you will be offered the following payment:

SITES WILL INSERT PAYMENT AMOUNT(S) HERE. MAY BE PER TIMEPOINT, VISIT, OR TEST.

If you have to travel from outside the local area, the study team can tell you about additional reimbursements for travel (air, train, bus, gas) and hotels. We will pay you back for reasonable travel costs related to study visits, as long as receipts are provided.

Because you will be getting money to be part of this research study, you may need to give your study team either your Social Security number (SSN) or your Alien Registration number. You may also be asked to fill out a form called the Internal Revenue Service (IRS) W-9. This is because the team that leads the study at NYU Langone Health is required by laws of the United States to report to the IRS any amounts that are paid to research participants that are equal to or greater than \$2,000. You may need to pay taxes on payments for research that are greater than \$2,000. If you do not have an SSN or Alien Registration number or do not want to fill out the IRS W-9 form, you can be in the study but may not get any money.

Please track all payments made to you for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments from any research studies are \$2,000 or more (not including travel reimbursements) in one calendar year.

SITES MAY INCLUDE REQUIRED LOCAL INSTITUTIONAL LANGUAGE HERE. IF NO ADDITIONS, REMOVE THESE INSTRUCTIONS AND KEEP THE PARAGRAPHS ABOVE

9. Will I have to pay for anything?

There are no costs to you related to your being part of the study. Money from the National Institutes of Health (NIH) will cover the costs of your being part of the study. You or your insurance company will not be asked to pay for the costs of your visits related to the study. If you receive health care that would have taken place independent of your participation in RECOVER, you and/or your health insurance may be billed for the costs. If your insurance does not cover these costs or you do not have insurance, these costs will be up to you to take care of.

10. What happens if you are hurt from being in Cycle 2?

For emergencies, call 911. If you think you have been hurt because of being part of this research study, tell the study site leader as soon as you can. The study site leader's name and phone number are listed at the top of page 1 of this consent form.

If you get hurt from being part of this research, your study team can help you find a doctor to give you treatment if you want. You or your insurance company may need to pay for treatment.

There are no plans for your study site, NYU Grossman School of Medicine, or NYU Langone Health to pay you or give you anything else for getting hurt. You do not give up the rights you have under the law by signing this form.

11. When is Cycle 2 over? Can you leave the study before it ends?

Cycle 2 may take up to 2 years. Cycle 2 may be stopped early. It is also possible that you may be taken out of the study early for the following reasons:

- The researchers in charge of the study feel it is important to do this for your health or safety.
- You have not followed study instructions.
- The group funding the study, the main researchers in charge, or other groups in charge of looking at its safety decide to stop it.
- More information about Long COVID is learned, so the study is no longer needed.

You can leave the study at any time. Leaving Cycle 2 will not affect any future care you may receive at your study site, how your healthcare is paid for, or what kind of health insurance you can get.

12. Sharing your information and how will we protect your confidentiality (privacy)?

Information in your research record for this study may be used and shared with people involved in the study. These people are also allowed to look at information in your health record that the research team believes may be important to the study. This includes things like results from your study visits, laboratory tests, other tests, surveys, and diaries.

We will not talk about your participation in the research study with anyone else except the people who work on the study and your doctor. This means the samples and answers you give are private. If we need to talk to anyone else about you, we will ask you first if it is okay. We will not tell anyone that you are in the study or share any other information you give us. We will only share your information if we feel that your answers show that your health or safety, or someone else's health or safety, is at risk. If you tell us about something dangerous that has happened to you or other people, we may have to share the information with others to make sure you are safe.

Your medical information is also called protected health information, or "PHI", because it is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your health record at the place where you signed up to be part of the research study. In following the rules of your study site and with HIPAA, only those people who have a reason to look at your health information because of their job can look at this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to look at the information in your health record. In some cases, when it is needed to make sure the research is done in the best way possible so that results can be trusted, you may not be able to see or make a copy of certain information about the study while the study is going on, but you may have the right to see and copy the information once the study is over in line with your research center's policies and the law.

Certificate of Confidentiality

To help us further protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or diseases caused by germs that can be spread to others).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for the project.

By agreeing to be in this research and signing below, you are giving your consent (permission) to share research information with others at NYU Langone Health and other researchers who are working together with NYU Langone Health who are listed in the next section. This means that your research information, including lab results, may be included in your medical record.

13. HIPAA authorization

As noted in the Confidentiality part of this consent form above, federal laws in the U.S. have been made so that we, and the researchers working with us, health care providers, and the people who care for you protect the privacy of information that identifies you (used to know who you are) and relates to your past, present, and future physical and mental health problems. We are asking for your permission to use and share your health information with others related to this study in order for this research to happen, including doing and watching over the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not give permission the use and sharing of your information for this study.

What information may be used or shared with others related to this study?

All information in your research record for this study may be used and shared with those people who are in the list at the end of this part of the consent form. Also, information in your health record that the research team believes may be important to the study may be looked at by those in the list. This includes, for example, results from your study visits, laboratory tests, body pictures, scans, other tests, surveys, and diaries.

Who can use and share information in connection with this study?

The following individuals may use, share, or get your information for this research study:

- The research team, including the Study Site Leader and other people helping with the study or who are in charge of watching over the study at the place where you signed up to be part of the research study
- The researchers at NYU Grossman School of Medicine, who are in charge of helping with and watching over the study at all the places across the country where the study is happening
- Non-research staff who need this information to do their jobs (such as for treatment, payment, or health care operations)

- Researchers within the RECOVER network: The researchers at Massachusetts General Hospital, who are in charge of storing the information for this study, the researchers at Mayo Clinic who are in charge of the research biorepository, and other RECOVER study centers or national centers in charge of storing research information
- RECOVER Data Gateway (RDG)
- People working with NIH-designated data repositories such as the National Center for Biotechnology Information, the database of Genotypes and Phenotypes (dbGAP), NHLBI BioData Catalyst (BDC), and BDC-PIC-SURE
- The group that funded the study: National Institutes of Health (National Heart Lung and Blood Institute)
- The ethical review board (also called institutional review board or IRB) that oversees the research and the research quality improvement programs
- The group that is watching over the safety of patients and families in the study (called the Observational Study Monitoring Board). The National Institutes of Health decides who will be in this expert group
- A company hired to oversee the quality of the RECOVER research information (Biomedical Research Alliance of New York)
- People or groups that we hire to do work for the study, such as data storage companies, insurers, and lawyers
- Governmental agencies in charge of watching over the research (for example, the US Department of Health and Human Services)
- Health care providers, including your doctors and others who care for you related to this study, and laboratories or other people who are looking at your health information as part of this study
- Other places that are involved in this research; and
- Researchers not affiliated with RECOVER, only upon request and approval following established policies and procedures

Your information may be re-disclosed (shared) or used for other reasons if the person who gets your information is not required by law to protect the privacy of the information.

What if you do not want to give permission to use and share your information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to be part of this study.

Can you change your mind and withdraw (take back) permission to use or share your information?

Yes, you may take back your permission to use and share your health information at any time for this research study. If you choose to take back permission, you can choose to stop the collection of new information, or request that previously collected information, including biological samples, be removed from the study. If you take back your permission, we will not be able to take back information that has already been used or shared with others. To take back your permission, send a written notice by mail or email to the Study Site Leader noted at the top of page 1 of this form. If you take back your permission, you will no longer be able to stay in this study.

How long can my information be used or shared?

Your permission to use or share your personal health information for this study will never end unless you take it back.

SITES MAY INCLUDE REQUIRED LOCAL INSTITUTIONAL HIPAA LANGUAGE HERE OR HAVE A PARTICIPANT COMPLETE A SEPARATE HIPAA FORM IN ADDITION TO THIS CONSENT. IF NO ADDITIONS, REMOVE THESE INSTRUCTIONS AND KEEP THE PARAGRAPHS ABOVE

14. Caregiver participation

Parents or caregivers of a child in the RECOVER study are also invited to take part in Cycle 2. We ask caregivers to take part in this research study to understand how the impact of COVID-19 on a caregiver may affect how the child gets better after COVID-19. A child can be in the study even if the caregiver decides that they do not want to be in the study.

In Cycle 2, a caregiver will complete survey questions about their child and household. These questions will ask about the child's health, health history, and how the child is doing at home and in the neighborhood where they live. There will also be some brief questions about the caregiver and the household where their child lives. These surveys may be done by telephone, computer, tablet or smartphone, or by written on paper. The surveys will take about 1 hour. They can be done together or separately, such as on different days or over 1–2 weeks.

Caregivers will also be given the option to sign up to answer more questions about themselves. We are asking the child's caregiver to take part in this research study to understand how the impact of COVID-19 on a caregiver may affect how the child gets better after COVID-19. In the caregiver surveys, we will ask questions about caregivers' health, health history and daily habits, any medicines they may be taking, and about how they think and feel. We will also ask questions about their home and the neighborhood they live in. Other questions will be about COVID-19 testing, vaccines, and issues related to COVID-19, such as whether caregivers have had any health problems because of COVID-19 or the COVID-19 vaccine. If a caregiver chooses to answer their own surveys, we will have them complete a separate consent form as well.

Please initial one of the options below to confirm whether you would like to complete surveys for yourself and your child or complete surveys only for your child:

Initials here

Caregiver and Participant Surveys. I would like to participate in answering survey questions about myself and my child. The study team will have me complete a separate Caregiver Consent Form.

Initials here

Participant Only Surveys. I would like to participate in answering survey questions about only my child and their household.

Initials here

Not Applicable, I am not a caregiver to a RECOVER participant

15. The Institutional Review Board (IRB) and how it protects you

The Institutional Review Board (IRB) reviews all research involving people before it can be started and then as long as the study continues. The main concern of the IRB is to protect the people who are part of the study. For questions about your rights while you are part of the study, contact the NYU IRB Office number on (212) 263-4110. The NYU School of Medicine's IRB and other IRBs that may be part of this study are made up of doctors, nurses, scientists, and people from the community.

SITES MAY INCLUDE LOCAL IRB CONTACT INFORMATION HERE IF REQUIRED. IF NO ADDITIONS, REMOVE THESE INSTRUCTIONS AND KEEP THE PARAGRAPH ABOVE

16. Who can you call with questions, or if you are worried about your rights as a research subject?

You can call the study team with your questions or concerns. Our telephone numbers are listed on page 1. If you want to speak with someone not directly involved in this research study, you can contact the Institutional Review Board (IRB) at 212-263-4110. You can talk to them about:

- Your rights as a research participant.
- Your concerns about the research.
- A complaint about the research.

By signing this form, you agree to participate in Cycle 2 as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer to participate in Cycle 2.

Name of Participant (Print)

Signature of Participant

Date

Name of Caregiver/Parent (Print)

Signature of Caregiver/Parent

Date

Name of Person Obtaining Consent (Print)

Signature of Person Obtaining Consent

Date

Witness to Consent Process for Non-English-Speaking Subjects (Using a Translated Consent Form OR “Short Form” in Subject’s Spoken Language)

Statement of Witness

As someone who understands both English and the language spoken by the subject, I listened to and heard the research team member talk about the information in the English version of the consent form with the subject in the subject’s own language. The subject was also given the chance to ask questions.

Name of Witness (Print)

Signature of Witness

Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has shown their consent and authorization for being part of the study by (check box that applies).

- ☐ Subject making his/her own “X” above in the subject signature line
- ☐ Subject showed approval for being part of the study in another way; describe:

Name of Witness (Print)

Signature of Witness

Date

Highlighted text indicates permissible changes to this master consent template.

Insert site logo here

Caregiver Cycle 2

Key Study Information and Informed Consent Form

Key Information	Details
Title of Study:	NIH RECOVER: A Multi-site Observational Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Pediatric Populations Study #: s21-01231
Study Site Leader:	Name Title Institution Address 1 Address 2 City, State, Zip Code Telephone
Study Leader:	Rachel Gross, MD NYU Grossman School of Medicine 227 East 30 th Street New York, NY 10016 Tel (212) 263-8974
Research Information Leader:	Andrea Foulkes, Sc.D. Director Biostatistics, Massachusetts General Hospital Professor of Medicine, Harvard Medical School 50 Staniford Street, Suite 560 Boston, MA 02114 Tel (617) 724-8208
Additional Contact:	Institutional Review Board (212) 263-4110

Key Study Information Form (Cycle 2)

Thank you for being in the RECOVER study. We are inviting you to be in the RECOVER study for up to 2 more years. We call these next 2 years “Cycle 2.” You may also see it called “second phase” and “next phase” in other study materials. These all mean the same thing: Cycle 2.

By continuing in the study, you can help researchers understand how children’s health may change over time and whether symptoms get better, stay the same, or get worse. Your participation is voluntary, which means it is your choice if you would like to participate in Cycle 2 of the study.

Purpose of the Research Study

This study is part of a research project paid for by the National Institutes of Health (NIH) called RECOVER (Researching COVID to Enhance Recovery). RECOVER has moved into its second phase, Cycle 2. In Cycle 2, RECOVER researchers will study all children and young adults who have and have not had COVID-19, including participants with and without Long COVID, and those at risk of developing it. This includes children whose mothers joined the RECOVER pregnancy study. RECOVER will continue to follow children and young adults for up to 2 more years in Cycle 2.

Other Key Information

Cycle 2 will last for about 2 years, and your child will have 2 more visits. If you choose to be in Cycle 2, we will ask you to sign a consent form (a document that tells you information about the study) before you or your child completes any of the Cycle 2 surveys or tests.

In Cycle 2, you will be asked to do surveys about yourself, your household, and your child. Your child will be asked to complete tests to check how their heart works, a test to see how they think and learn, and to give some samples from their body, like blood, stool (poop), pee (urine), hair, and swabs from the nose, mouth, and skin. A full list of tests will be reviewed with you in the full consent form. We may also check your or your child’s medical records to learn more about your health while you are in the study.

Foreseeable Risk and Benefits

A list of all possible risks and discomforts related to being in Cycle 2 is included in the full consent form. The most common risks include possible loss of private information (which can happen in any study) or feeling uncomfortable or very tired from answering some of the surveys.

We do not expect that your health will get better from being in Cycle 2, but being part of the study may help you and your doctor better understand problems related to COVID-19. The results of the study will be important in helping children, young adults, caregivers, and parents understand how COVID-19 affects the body over time.

Alternatives to Participation

There are no other ways to be a part of the study if you do not want to be in Cycle 2. For more details about Cycle 2, please read the full informed consent document attached. For questions and concerns about any of this information, contact the study leader or study site leader, their information is found on page 1.

1. About volunteering for Cycle 2

You are being invited to take part in a research study. You can choose whether or not you want to take part in this study.

Before you decide if you want to continue in the study, you will need to know what Cycle 2 is about, what you will be asked to do, the good things that may come from being part of it, and the possible risks (or harms) of being in this study. You may also want to talk about the study and this form with your family, friends, or doctor. Please ask us if you have any questions about the study or about this form. If you decide to take part in Cycle 2, you must sign this form. We will give you a copy of this form to keep once you have signed it.

2. Why are we doing Cycle 2?

This study is part of a research project paid for by the National Institutes of Health (NIH), called RECOVER (Researching COVID to Enhance Recovery). We are doing this study to understand how COVID-19, the sickness caused by a virus called SARS-CoV-2, affects children's health, and why some children who get COVID-19 stay sick many months or even years. Taking a long time to recover from COVID is called "Long COVID" or "PASC", which stands for Post-Acute Sequelae of SARS-CoV-2.

Children who have and have not had COVID-19 will be part of the study. The main person who takes care of these children (the caregiver) is also invited to take part in this study. We are asking you, your child's caregiver, to take part in this research study to understand how the impact of COVID-19 on a caregiver may affect how the child gets better after COVID-19. Your child can be in the study even if you decide that you do not want to be in the study.

3. Who is the main caregiver that can be in Cycle 2?

The main caregiver is a person, such as a family member (related by blood, or biological)) or non-biological (not related by blood) or guardian, who is in charge of caring for the child who is part of the study. The main caregiver:

- Is the person who spends the most time with the child.
- Is the person most responsible for taking care of the child every day.
- Lives in the same home as the child.
- Knows the most about the child.
- Must be older than 18 years of age if non-biological

Some caregivers who are able to take part in this study may not be able to give consent (permission) because they are not yet legal adults (a minor as defined by the local/state regulations). In this case, the parent(s) or guardian of the caregiver will be asked to give consent. We will also ask the minor caregiver to agree (give their assent) to take part in the study. The minor caregiver will be given an assent form to sign. Throughout the consent form, "I", "you" and "your" always refers to the child's caregiver (the person who is taking part in the study).

4. How long will you be in Cycle 2? How many other people will be in the study?

Cycle 2 may take up to 2 years. There will be about 4,000 children and young adults in Cycle 2. You may be asked to do Cycle 2 survey questions 2 times, about 1 year apart.

5. What will you be asked to do in Cycle 2?

As your child's caregiver, you will answer survey questions about their health and their household. You can also answer survey questions about your own health. In Cycle 2, we will ask questions about your health, your health history and daily habits, any medicines you may be taking, and about how you think and feel. We will ask questions about your home and the neighborhood you live in. Other questions will be about COVID-19 testing, vaccines, and issues related to COVID-19, such as whether you have had any health problems because of COVID-19 or the COVID-19 vaccine.

While you are in the study, we may check national registries (places where information about people across the country is kept) and your medical records to learn more about your health and any tests you may have had outside of the research study. Information from your health records may be included in the study to help researchers understand how you or your child was affected by COVID-19 or the COVID-19 vaccine.

We may let your main doctor know that you are part of this study. Being part of the study does not change the healthcare you get from your doctor.

Communicating with the Research Team

The research team will contact you by phone, email, or text message, depending on what you choose. When the research team sends email messages that include information about your health that is linked to who you are (identifiable), they will help keep your personal information safe by encrypting the message. Encrypted emails are locked so other people cannot see what they say. There is no way to encrypt the messages sent by text. This means that information you send or receive by text message could be looked at by someone who was not supposed to see it or by your mobile/cell phone provider or company. When text messages are sent or received on your phone, there may be risks related to your privacy. Please indicate below whether you agree to receive text messages from the research team:

_____ Yes, I agree to receive texts from the research team.

Initial here

_____ No, I do not agree to receive texts from the research team.

Initial here

Please make sure to keep the research team updated if your address, email, or cell phone number changes during the study.

Future Use of Survey and Test Results Data

Information that identifies you, such as your name and address, will be removed from the questionnaires. After this happens, information may be used for future research studies or shared with other researchers

without risk of your identity being revealed. We will not request another informed consent from you to use these results.

6. What are the possible risks or discomforts?

Being in this study may involve some risks or discomforts from study activities. There may be risks that we do not know about yet in addition to the ones listed below. You should contact the study site leader as soon as possible if you are concerned about anything while you are part of the study.

Possible loss of privacy (confidentiality)

When we share your information and study samples, there is a small risk that people may see them who are not supposed to. Researchers will do their best to protect you by keeping your study information and study samples in safe places and separate from your name and contact information. Other researchers who use your study samples must agree to not try to find out who you are. But there is still a small chance that they may be able to find out who you are.

The research team may communicate with you over email or text message. Even though the researchers will take steps to protect your privacy and confidentiality, there is still a risk that people who are not supposed to may see the messages. The researchers will only send limited information in these messages.

When you use apps or software made by companies, such as wearable fitness trackers, wearable sleep monitors, or other mobile or web apps, there is a small risk that people outside the study may get to see your information.

Risk of doing survey questions

Answering the survey questions can take a long time. This may make you tired, uncomfortable, or frustrated. You can stop or take a break if you need to.

7. What if new information becomes available?

During this study we may find information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will let you know as soon as possible if this kind of information is found.

8. What are the possible good things (benefits) from being part of Cycle 2?

We do not expect that your health will get better from taking part in this study. The results of the study will be important in helping children, families, and doctors better understand how COVID-19 affects children over time.

9. What else can I do if I decide not to be part of Cycle 2?

You do not have to be part of Cycle 2 of this research study. You do not have to take part in this research study to be treated for COVID-19. Not participating in Cycle 2 will not affect any future care you may receive at your study site, how your healthcare is paid for, or what kind of health insurance you can get.

10. Will I be paid?

Caregivers who take part in the RECOVER study will be paid for the time it takes children to do study activities. There is no separate payment for the primary caregiver.

11. Will I have to pay for anything?

There are no costs to you related to your being part of the study. Money from the National Institutes of Health (NIH) will cover the costs of your being part of the study. You or your insurance company will not be asked to pay for the costs of your visits related to the study. If you receive health care that would have taken place independent of your participation in RECOVER, you and/or your health insurance may be billed for the costs. If your insurance does not cover these costs or you do not have insurance, these costs will be up to you to take care of.

12. What happens if you are hurt from being in Cycle 2?

For emergencies, call 911. If you think you have been hurt because of being part of this research study, tell the study site leader as soon as you can. The study site leader's name and phone number are listed at the top of page 1 of this consent form.

If you get hurt from being part of this research, your study team can help you find a doctor to give you treatment if you want. You or your insurance company may need to pay for treatment.

There are no plans for the study site, NYU Grossman School of Medicine, or NYU Langone Health to pay you or give you anything else for getting hurt. You do not give up the rights you have under the law by signing this form.

13. When is Cycle 2 over? Can I leave the study before it ends?

Cycle 2 may take up to 2 years for each participant. Cycle 2 may be stopped early. It is also possible that you may be taken out of the study early for the following reasons:

- The researchers in charge of the study feel it is important to do this for your health or safety.
- You have not followed study instructions.
- The group funding the study, the main researchers in charge, or other groups in charge of looking at its safety decide to stop it.
- More information about Long COVID is learned so that the study is no longer needed.

You can leave the study at any time. Leaving Cycle 2 will not affect any future care you may receive at your study site, how your healthcare is paid for, or what kind of health insurance you can get.

14. Sharing your information and how will we protect your confidentiality (privacy)?

Information in your research record for this study may be used and shared with people involved in the study. These people are also allowed to look at information in your health record that the research team

believes may be important to the study. This includes things like results from your study visits, surveys, and diaries.

We will not talk about your participation in the research study with anyone else except the people who work on the study and your doctor. This means the samples and answers you give are private. If we need to talk to anyone else about you, we will ask you first if it is okay. We will not tell anyone that you are in the study or share any other information you give us. We will only share your information if we feel that your answers show that your health or safety, or someone else's health or safety, is at risk. If you tell us about something dangerous that has happened to you or other people, we may have to share the information with others to make sure you are safe.

Your medical information is also called protected health information, or "PHI", because it is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your health record at the place where you signed up to be part of your research (your study site). In following the rules of your study site and with HIPAA, only those people who have a reason to look at your health information because of their job can look at this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to look at the information in your health record. In some cases, when it is needed to make sure the research is done in the best way possible so that results can be trusted, you may not be able to see or make a copy of certain information about the study while the study is going on, but you may have the right to see and copy the information once the study is over in line with your research center's policies and the law.

Certificate of Confidentiality

To help us further protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or diseases caused by germs that can be spread to others).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for the project.

By agreeing to be in this research and signing below, you are giving your consent (permission) to share research information with others at NYU Langone Health and other researchers who are working

together with NYU Langone Health who are listed in the next section. This means that your research information, including lab results, may be included in your medical record.

15. HIPAA authorization

As noted in the Confidentiality part of this consent form above, federal laws in the U.S. have been made so that we, and the researchers working with us, health care providers, and the people who care for you protect the privacy of information that identifies you (used to know who you are) and relates to your past, present, and future physical and mental health problems. We are asking for your permission to use and share your health information with others related to this study in order for this research to happen, including doing and watching over the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not give permission the use and sharing of your information for this study.

What information may be used or shared with others related to this study?

All information in your research record for this study may be used and shared with those people who are in the list at the end of this part of the consent form. Also, information in your health record that the research team believes may be important to the study may be looked at by those in the list. This includes, for example, results from your study visits, laboratory tests, body pictures, scans, other tests, surveys, and diaries.

Who can use and share information in connection with this study?

The following individuals may use, share, or get your information for this research study:

- The research team, including the Study Site Leader and other people helping with the study or who are in charge of watching over the study at the place where you signed up to be part of the research study
- The researchers at NYU Grossman School of Medicine, who are in charge of helping with and watching over the study at all the places across the country where the study is happening
- Non-research staff who need this information to do their jobs (such as for treatment, payment, or health care operations)
- Researchers within the RECOVER network: The researchers at Massachusetts General Hospital, who are in charge of storing the information for this study, the researchers at Mayo Clinic who are in charge of the research biorepository, and other RECOVER study centers or national centers in charge of storing research information
- RECOVER Data Gateway (RDG)
- People working with NIH-designated data repositories such as the National Center for Biotechnology Information, the database of Genotypes and Phenotypes (dbGAP), NHLBI BioData Catalyst (BDC), and BDC-PIC-SURE
- The group that funded the study: National Institutes of Health (National Heart Lung and Blood Institute)
- The ethical review board (also called institutional review board or IRB) that oversees the research and the research quality improvement programs
- The group that is watching over the safety of patients and families in the study (called the Observational Study Monitoring Board). The National Institutes of Health decides who will be in this expert group

- A company hired to oversee the quality of the RECOVER research information (Biomedical Research Alliance of New York)
- People or groups that we hire to do work for the study, such as data storage companies, insurers, and lawyers
- Governmental agencies in charge of watching over the research (for example, the US Department of Health and Human Services)
- Health care providers, including your doctors and others who care for you related to this study, and laboratories or other people who are looking at your health information as part of this study
- Other places that are involved in this research; and
- Researchers not affiliated with RECOVER, only upon request and approval following established policies and procedures

Your information may be re-disclosed (shared) or used for other reasons if the person who gets your information is not required by law to protect the privacy of the information.

What if you do not want to give permission to use and share your information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to be part of this study.

Can you change your mind and withdraw (take back) permission to use or share your information?

Yes, you may take back your permission to use and share your health information at any time for this research study. If you choose to take back permission, you can choose to stop the collection of new information, or request that previously collected information, including biological samples, be removed from the study. If you take back your permission, we will not be able to take back information that has already been used or shared with others. To take back your permission, send a written notice by mail or email to the Study Site Leader noted at the top of page 1 of this form. If you take back your permission, you will no longer be able to stay in this study.

How long can my information be used or shared?

Your permission to use or share your personal health information for this study will never end unless you take it back.

SITES MAY INCLUDE REQUIRED LOCAL INSTITUTIONAL HIPAA LANGUAGE HERE OR HAVE A PARTICIPANT COMPLETE A SEPARATE HIPAA FORM IN ADDITION TO THIS CONSENT. IF NO ADDITIONS, REMOVE THESE INSTRUCTIONS AND KEEP THE PARAGRAPHS ABOVE

16. The Institutional Review Board (IRB) and how it protects you

The Institutional Review Board (IRB) reviews all research involving people before it can be started and then as long as the study continues. The main concern of the IRB is to protect the people who are part of the study. For questions about your rights while you are part of the study, contact the NYU IRB Office number on (212) 263-4110. The NYU School of Medicine's IRB and other IRBs that may be part of this study are made up of doctors, nurses, scientists, and people from the community.

SITES MAY INCLUDE LOCAL IRB CONTACT INFORMATION HERE IF REQUIRED. IF NO ADDITIONS, REMOVE THESE INSTRUCTIONS AND KEEP THE PARAGRAPH ABOVE

17. Who can I call with questions or if I am worried about my rights as a research subject?

You can call the study team with your questions or concerns. Our telephone numbers are listed on page 1. If you want to speak with someone not directly involved in this research study, you can contact the Institutional Review Board (IRB) at 212-263-4110. You can talk to them about:

Your rights as a research participant

- Your concerns about the research
- A complaint about the research

By signing this form, you agree to participate in Cycle 2 as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer to participate in Cycle 2.

_____	_____	_____
Name of Participant (Print)	Signature of Participant	Date

_____	_____	_____
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Signature of Parent(s)/Guardian for subject who has not yet reached the age of majority in their state. I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____	_____	_____
Name of Parent/Guardian (Print)	Signature of Parent/Guardian	Date

**Witness to Consent Process for Non-English-Speaking Subjects (using a translated consent form
OR “Short Form” in Subject’s Spoken Language)**

Statement of Witness

As someone who understands both English and the language spoken by the subject, I listened to and heard the research team member talk about the information in the English version of the consent form with the subject in the subject’s own language, and that the subject was given the chance to ask questions.

Name of Witness (Print)

Signature of Witness

Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has shown their consent and authorization for being part of the study by (check box that applies).

- ☐ Subject making his/her own “X” above in the subject signature line
- ☐ Subject showed approval for being part of the study in another way; describe:

Name of Witness (Print)

Signature of Witness

Date

Insert site logo here

ASSENT FORM (ages 7–17 years) Cycle 2

Short Title of the Research Study: Understanding the Long-Term Impact of COVID on Children and Families

Why we would like to speak with you

Thank you for being in the RECOVER study. So far in the study, you have answered questions, played games, gave some spit and blood, and came to the study site to do some activities. We would like to invite you to stay in the study for up to 2 more years. We call the next 2 years of the study “Cycle 2.” You may also see it called “second phase” and “next phase” in other study materials. These all mean the same thing: Cycle 2.

By staying in the study, you can help researchers understand how children's health may change over time and whether symptoms get better, stay the same, or get worse. After we tell you more about Cycle 2, we will ask you if you would like to be in it. If you decide to take part in Cycle 2, you will be asked to agree to the activities we talked about in this form, and you will be able to take a copy of this form home with you.

If you have any questions while we talk about Cycle 2 of the study, you can ask them right away. It's okay to say “no” if you do not want to be in Cycle 2. It's also okay to say yes now and change your mind later or stop at any time. You should talk to your parent or the person who takes care of you (guardian) about what you decide. We'll also talk to them about everything in this form so they also know about Cycle 2.

Why are we doing this research study?

The reason we are doing this study is to understand why some children who get COVID-19 feel better quickly and other children who get COVID-19 feel sick for a long time. Feeling sick for a long time after having COVID-19 is sometimes called Long COVID. Cycle 2 of the study will help us understand what's going on with parts of the body and how Long COVID affects children as they grow.

In Cycle 2 of the research study, we will get information from about 4,000 children and young adults who have and have not had COVID-19 symptoms.

What will happen if you are in Cycle 2 of the research study?

In Cycle 2, we will ask you to do activities that help us learn how your heart, lungs, and brain are working. We will also ask you to give some samples such as blood, stool (poop), pee (urine), hair, and swabs from the nose, mouth, and skin. You will be asked to do some of the activities listed below at each visit and might be asked to do them 2 times, about 1 year apart. The researchers will tell you which activities you will be asked to do.

If you agree to be in Cycle 2, you may be asked to:

- **Stand for a short time:** You will lie down for a few minutes then stand for 10 minutes. We will see how your body responds while you are standing.
- **Walk for 6 minutes:** You will walk indoors as far as you can for 6 minutes. At the end of 6 minutes, we will measure how fast your heart is beating.
- **Do a movement activity:** You will bend your fingers, arms, legs, and back to see how they move.
- **Do a smell activity:** You will be asked to smell a card or marker with different scents and name what you smell.
- **Do a taste activity:** You will be asked to taste pieces of paper and name what you taste.
- **Wipe a cotton tip in your mouth, in your nose, and on your skin to get bacteria samples:** Bacteria are tiny germs that live on your skin, in your nose, and in your mouth. We will use a new, soft cotton tip for each area to collect samples of the bacteria from your skin, inside of your nose, and inside of your mouth.
- **Give a pee (urine) and poop (stool) sample:** You will pee in a cup and put a little bit of poop on a cotton swab to put in the mail for testing.
- **Give a hair sample:** The researchers will use scissors to cut some of your hair.
- **Give a blood sample:** The researchers will use a needle to collect blood from your arm.
- **Play learning games:** You will play some games to see how you think about and learn things.
- **Answer questions:** We will ask you questions to learn how you feel and think about different things. Children ages 12–17 years old will answer a short questionnaire for themselves. These questions ask about your thoughts and feelings, including questions about being sad, feeling tired or angry, or thinking about hurting yourself.

What else do I need to know about these activities?

Some of the activities for Cycle 2 might make you feel tired or uncomfortable because of how long they take. If you ever need a break during the activities, just let us know, and we can take a break.

- The exercise activities can make you work hard. For a small number of people, it can make their heart beat too fast or change the way it beats for a few minutes. These activities may also make you feel out of breath or dizzy. If they do, let us know, and we will stop the activity. We will watch you very closely and look for these changes the whole time to make sure you stay safe. The day after the exercise activity, you may feel very tired.
- Giving your pee or poop may be embarrassing, but it should not hurt.
- Giving a blood sample may feel like a quick pinch on your skin and can hurt for a little while, just like getting a blood test or a shot at the doctor.

During or after any of the activities, if you feel sick or hurt, it is very important that you tell your parents and the researchers. You can stop doing an activity at any time.

Do you have to be in Cycle 2 of the study?

No, you do not have to participate in Cycle 2 of the study if you do not want to. If you do not want to be in Cycle 2, let us know. Nobody will be upset with you if you say no. If you do want to be in Cycle 2, let us know. And remember, you can say yes to being in the study now and change your mind at any time. It's up to you.

Please talk this over with your parent or guardian before you decide whether or not to be in Cycle 2. Your parent or guardian has said that it is okay with them if you want to be in Cycle 2. Even though your parent or guardian has said it is okay with them, you can still say “no.”

What will this cost?

It will not cost you or your parent or guardian anything to be in Cycle 2. Your parent or guardian will get money for the time you spend doing Cycle 2 activities.

What if you have questions?

You can ask us questions at any time, now or later. Your parent or guardian knows how to reach us even after you go back home.

What about your privacy?

We may talk about you and the research study with your parent or guardian but will not talk about it with anyone else except the people who work on the study and your doctor. This means the samples and answers you give are private. If we need to talk to anyone else about you, we will ask you and your parent or guardian first if it is okay. We will not tell anyone that you are in the study or share any other information you give us. We will only share your information if we feel that your answers show that your health or safety, or someone else’s health or safety, is at risk. If you tell us about something dangerous that has happened to you or other people, we may have to share the information with others to make sure you are safe.

Saying “Yes” or “No” to being in Cycle 2 of the research study

If you sign this form, it means that:

- You have read this form
- You have talked with the researchers and your parent or guardian about it
- You have had all your questions answered, and
- You want to be in Cycle 2 of the research study

By signing below, you agree to participate in Cycle 2 of this research study. You will receive a signed copy of this form.

_____ Name of Child (Print)	_____ Signature of Child	_____ Date
_____ Name of Person Obtaining Consent (Print)	_____ Signature of Person Obtaining Consent	_____ Date