Approved by the Nemours IRB
Valid From: January 26, 2023
to
[2002602]

# Nemours Parental Permission for Participation in a Research Study

*Nemours PP Template July 2021*

You have been asked to permit your child to be in a research study. If you are a parent or legally authorized representative of a child who may take part in this study, permission from you is required. This form explains the research, your child's rights as a research participant, and any responsibilities that you may have as a result of your child's participation. You should understand the research study before you agree to permit your child to be in it. ***You will receive a copy of this form***. ***Read this permission form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

1. **Title of the Study**: **Enhanced Community-Based Asthma Monitoring Through Remote Technology**

| Key Information for You to Consider |
|---|
| • **Voluntary Consent**. You are being asked **to volunteer your child** for a research study. It is up to you whether you choose to allow your child to participate or not. There will be no penalty or loss of benefits to which your child is otherwise entitled if you choose not to allow your child to participate or discontinue participation.<br>• **Purpose**. The purpose of this research is to test an at-home program for monitoring children's asthma using mobile spirometry (lung function testing) and video visits at home.<br>• **Duration.** It is expected that your child's participation will last approximately 6 months with one study visit per month.<br>• **Procedures and Activities.** You and your child will be asked to fill out several questionnaires about your child's health and asthma symptoms. Your child will be asked to complete lung function testing. The first visit will include training and will be about 2 hours in duration; other visits will take about 30 minutes.<br>• **Risks.** The main risk of this study is that some people may feel uncomfortable when answering questions about themselves or when completing the pulmonary function testing. You and your child may skip any question that makes you feel uncomfortable, may stop testing at any point, and may stop participating in the study at any time.<br>• **Benefits**. There may be no direct health benefits to you and your child. However, it is possible that the information learned from the study could lead to interventions that improve your child's asthma. Information learned from the study may help other people in the future.<br>• **Alternatives.** Participation is voluntary, and the only alternative is to not participate.<br><br>**If interested, please continue to the detailed consent.** |

**2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?**

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

| | **Nemours - WIL** |
|---|---|
| **Principal Investigator** | Dr. Abigail Strang |
| **Co-Investigator(s)** | Dr. Aaron Chidekel |
| **Study Coordinator(s)** | |
| **Address** | Division of Pulmonology<br>1600 Rockland Road<br>Wilmington, DE<br>19803 |
| **Daytime Phone**<br>**After Hours Phone** | 302-651-6400<br><br>302-651-4000 |

**3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?**

If you have questions about your child's rights as a research participant, what to do if your child is injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Chairperson, Nemours IRB 2 at 904-697-3806
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

**4. WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of the study is to test a program for remotely monitoring asthma at home using video visits and remote lung function testing.

**5. WHO IS SPONSORING OR PAYING FOR THE STUDY?**

The Centers of Biomedical Research Excellence (COBRE) award is the Sponsor of this study.

**6. WHO CAN BE IN THE STUDY?**

Children ages 12-17 with asthma who understand English and are able to complete lung function testing are able to participate in the study.

**7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?**

15 participants can be in the study.

**8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?**

Participation in the study will last approximately 6 months. There will be monthly study visits to answer questionnaires and complete lung function testing. Most visits will take about 20-30 minutes to complete. The first and last visit will include additional testing and will take approximately 2 hours to complete.

**9. WHAT ARE THE RESEARCH PROCEDURES?**

The research procedures will consist of study visits with both in-person and video visits. At the first visit, in the office, you and your child will complete questionnaires about your child's asthma and health history. Your child will complete pulmonary function testing. At the first visit, you and your child will be given a hand-hand mobile spirometry device to complete lung function testing at home at future visits. The research team will teach you and your child how to use the device for future visits from home. This visit will take about 2 hours. Subsequently, you and your child will complete visits from home (using a video visit format) on a monthly basis, which will take about 20-30 minutes. At these visits, you and your child will use the mobile spirometry device, which the assistance of a member of the research team, to measure your child's lung function at home. At these visits, you and your child will also complete questionnaires about your child's asthma and health as well as your satisfaction with the monitoring program. There will be one final study visit in-person to complete testing (lung function testing and questionnaires). The information collected will be analyzed to learn more about how doctors can monitor asthma in patients at home. As part of this study, the study team will also review your child's medical record to review information about your child's medical history, asthma, and other treatments and demographic information. In comparison to usual asthma care, there will be increased visits and increased measurements of lung function.

**10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?**

Any research has some risks (things that could make your child sick, make your child feel uncomfortable, or hurt your child). The risks with the most chance of happening to someone in this study are listed below. Also, there is a chance of other risks that almost never happen, or unknown risks. The risks involved in this study are the same as the risks that your child would ordinarily encounter in daily life or during a routine physical exam. The research is observational which means there is no change to any treatment your child is receiving. When filling out the questionnaires or when completing the lung function testing, your child may feel uncomfortable. Your child does not need to answer any questions that they do not wish to answer and may stop testing at any point. Your child's information will be protected and used only for research purposes. To ensure the confidentiality each participant will be assigned an ID number. Electronic data will be saved only on Nemours secure computer network computers. The questionnaires will be deidentified (your child's name and other identifying information will be removed). Paper documents that contain patient information will be stored and locked in the office of the principal investigator or study coordinator.

**11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

You and your child will probably not directly benefit from participation in the study. While participants are unlikely to benefit directly from participation, the knowledge gained from this research may help to provide better care and support other families in the future.

**12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?**

Nemours will assure that your child receives treatment, if needed, for study-related injuries. Neither Nemours nor the study doctor has a program to pay for medical care provided to treat the injury. If you have health insurance, it may, or may not, pay for the cost of treatment resulting from a study-related injury. If your insurance does not pay, or if you do not have insurance, you understand that you may be responsible for paying for the cost of treatment. If you think that your child has been injured while in this study or has a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor(s)' names and phone numbers are on the first page of this form.

The study staff is available Monday - Friday from 8:00am to 5:00pm. During these hours, you should call 302-651-6400 for medical advice.

During evenings, weekends, and holidays, you should call 302-651-4000. You will reach the Nemours operator. Ask to page the pulmonologist on call.

**13. IS BEING IN THE STUDY VOLUNTARY?**

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your child's usual medical care if you decide not to permit your child to be in the study or decide to stop your child's participation in the study. No one will be angry with you or your child, or
treat your child any differently than before your child was asked to be in the study. If you withdraw your child from this study, your child may continue treatment with his / her doctor, or you may seek treatment for your child from another doctor of your choice. You may ask the researcher to destroy your child's information.

**14. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?**

You can refuse to permit your child to participate in this study.

**15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?**

No, the researcher will not remove anyone from the study.

**16. WHAT ARE THE COSTS OF BEING IN THIS STUDY?**

There are no costs to be in the study.

**17. WILL MY CHILD BE PAID FOR BEING IN THIS STUDY?**

Your child will receive direct payments from being in the study for completion of different parts of the study. No arrangements exist that would allow participants to share in any profit generated from this study or future research. After completing the study visit for enrollment and questionnaires, you will receive $25. You will receive $10 for each monthly study visit, and you will receive an additional $25 for completing the final visit (total of $100 for completing all study visits).

**18. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO PERMIT MY CHILD TO STAY IN THE STUDY?**

Any new information that may change your mind about your child being in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while your child is taking part in this study, it will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

**19. WHAT INFORMATION ABOUT MY CHILD WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION)**

Identifiable health information about your child will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for research use and disclosure of health information that includes "identifiers" that can connect the health information to your child. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This Identifiable health information is called Protected Health Information (PHI).

**Use of Health Information by Nemours Staff**

The health information that will be used within Nemours includes all data collected for this study, as described in this form. Your child's identity will be protected as much as possible. Nemours protects your child's health information by storing records in files or computers that can only be used by authorized Nemours staff.

The people within Nemours that may use this health information include:

- The investigators listed on the first page of this permission form and their staff;
- The Nemours Institutional Review Board (IRB). (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;
- Nemours internal audit staff.

**Disclosure of Health Information to Others**

Information from this research study will also be contained in your child's Nemours' medical record along with the information about your child's regular office visits. This will help other doctors to know about the research study your child is in and give them extra information from the research that might help them take better care of your child. The same information might also be seen by anyone who can look at your child's medical records, such as your insurance company.

The PHI that will be disclosed (given) to people or groups outside of Nemours for research purposes are listed in the table below (mark an 'X' for each one that applies):

- Greenphire

| **Type of Identifiable Health Information:** | **Disclosed:** |
|---|---|
| History and Physical | ☐ |
| Results of Procedures | ☐ |
| X-Ray Reports | ☐ |
| Surgery Reports | ☐ |
| Genetics Studies | ☐ |
| Demographics (information about race, ethnicity, gender, age) | ☐ |
| Questionnaires | ☐ |
| Other: Lung function testing results | ☐ |
| Greenphire Gift Card data: Name, contact number, email, address | ☒ |

**Limits on Protection of Privacy and Confidentiality**

Only health care organizations have to follow laws and rules about protecting the privacy of health information. If health information containing peoples' identities is given to other kinds of companies or organizations, they are not required by law to safeguard the privacy and confidentiality of that information. Nemours expects these companies and organization to protect the privacy and confidentiality of research participants, but it is not possible for Nemours researchers to assure that this happens.

Government agencies that may look at records for this research study, including the above health information, include:

- The U.S. Food and Drug Administration
- The U.S. Department of Health and Human Services
- Other agencies of State and local government as required by law

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This means that the researchers may not disclose any research information that may identify you or

your child in any kind of lawsuit, court action, hearing or other proceeding unless you agree beforehand. You and your child's research information cannot be disclosed to anyone else who is not connected with the research except if:

- There is a federal, state or local law that requires disclosure (such as to report child abuse or communicable diseases)
- You agree to the disclosure; or
- It is used for other scientific research, as allowed by federal regulations.

However, the researchers cannot refuse a request for information from federal or state government agencies that need it to complete legally required monitoring of this research study. A Certificate of Confidentiality does allow you to willingly release information about yourself or your involvement (or your child's) in this research. If you want your or your child's research information released to any person or organization not connected with the research, you must consent in writing to allow the researchers to release it.

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

**20. SIGNATURES:**

I am making a decision whether or not to permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before she / he will be allowed to be in this study. I have read this form, or have had it read to me in a language that I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which my child is entitled under law.

I understand that:

- I can withdraw permission for my child's participation in this study and for the use and / or disclosure of my child's PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and/or disclosure of my child's PHI will stop after Nemours receives the withdrawal notice.
  Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw permission, the use and / or disclosure of my child's PHI described in this form will expire when the research study is complete and analysis and publication have ended.
- My child's PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this permission form.
- If I refuse to sign this permission form, my child will not be allowed to participate in this research study.
- I have the right to ask Nemours to tell me who has received my child's protected health information.
- I have the right to revoke my permission_for the use and disclosure of my child's health information at any time, which would end his/her participation in this study.
- I will receive a signed and dated copy of this form.

**<u>Parent / Legal Guardian Signature Section</u>**

My signature indicates that:

- As his or her parent(s) or legally authorized representative(s), I(we) give my(our) permission for the minor child named below to participate in the research study described in this Parental Permission Form.
- I(We) give the researchers and Nemours permission to use and / or disclose my(our) child's individually identifiable health information for this research study as described in this form.

| | |
|---|---|
| Name of Participant (**Print**) | Participant Date of Birth |
| Name of Parent / Legally Authorized Representative (**Print)** | |
| **Signature** of Parent / Legally Authorized Representative (#1) | Date |

**Check Relation to Participant**: ☐ Parent ☐ Legally Authorized Representative
(Legally Authorized Representatives must have documented authority to give permission for a child's participation in a research study according to the laws of the State in which the treatment occurs.)

**Second parent signature ☐ N/A**
***Do NOT check this box if the IRB determined that two (2) parent signatures are required as noted in the IRB final approval correspondence.***

| | |
|---|---|
| Name of Parent / Legally Authorized Representative (**Print)** | |
| **Signature** of Parent / Legally Authorized Representative (#2) | Date |

**Check Relation to Participant**: ☐ Parent ☐ Legally Authorized Representative
(Legally Authorized Representatives must have documented authority to give permission for participation in a research study according to the laws of the State in which the treatment occurs.)

**Study Team Member Signature Section**

I, the undersigned, certify that to the best of my knowledge the parent(s) / legally authorized representative(s) signing this permission had the study fully and carefully explained and that she / he (they) understand(s) the nature, risks and benefits of their child's participation in this research study.

I, the undersigned, certify that the participant completed no research procedures for this study prior to signing this permission.

Name of Person Obtaining Permission (**Print**)
(Investigator or Designee)

Approved by the Nemours IRB
Valid From: January 26, 2023
to
[2002602]

**Signature** of Person Obtaining Permission
(Investigator or Designee)

Date

A copy of the signed form was provided to Parent(s) / Legally Authorized Representative(s) ☐