

FLIGHT™ Study Consent to be Screened

TITLE: Facilitated Longitudinal Intensive Investigation of Genuine Health Transformation (FLIGHT)

PROTOCOL NO.: None
WIRB® Protocol #20200327

SPONSOR: Epidemic Answers

PRINCIPAL INVESTIGATOR: Martha Herbert, PhD, MD
777 Concord Avenue
Suite 301
Cambridge, Massachusetts 02138-1053
United States

STUDY-RELATED PHONE NUMBER(S): The Documenting Hope Project
(833) 935-5543
research @documentinghope.com

The FLIGHT™ Study team has determined that your child is eligible to participate in the next phases of screening for the FLIGHT™ Study. The purpose of this consent form is to help you decide if you want to proceed toward enrollment. Children whose parents/guardians wish them to be screened for this study are considered “candidates.”

Before signing this document, please read it carefully to ensure you fully understand the eligibility screening process and procedures. It is necessary for you to provide informed consent prior to any additional screening activities.

Before your child can participate in the FLIGHT™ study, we will need to determine whether he/she is eligible. Eligibility screening involves multiple steps. You may be excluded, or you may elect not to continue at any point. You will be informed at each step of screening whether your child’s candidacy has advanced to the next step. You may cancel your permission to participate in the screening process at any time by contacting the researchers listed below.

Screening Procedures

The screening process involves:

- Step 1: Brief private, online screening survey (about 15 minutes)
- Step 2: Second private, online screening survey (about 30 minutes)

- Step 3: An online video conference interview (about 60 minutes)
- Step 4: Review of personal health records including documentation of your child's chronic condition diagnos(es)

Candidates who successfully advance through all stages of above screening may be asked to take part in the final phase of screening, a physical exam with a local licensed medical doctor. Information from the exam will contribute to determining the child's fitness to participate in the study. Due to the small subject pool for the FLIGHT™ Study, only a very small number of candidates will be asked to undergo a physical exam.

If your child qualifies to be included in the FLIGHT™ study and you wish your child to participate, you will be given another consent form prior to enrollment that will explain the FLIGHT™ Study in detail.

Participating in any part of the eligibility screening process for the FLIGHT™ Study is voluntary. Even if you do qualify for the study and decide to join, you can change your mind later and leave the study.

Costs to be screened

There are no costs to be screened for this study.

Benefits to be screened

The benefit of being screened for this study is the potential opportunity to participate in the FLIGHT™ Study if you are deemed eligible.

Who is eligible to be screened for the FLIGHT™ Study?

- Candidates who are family members or close associates of any members of the FLIGHT™ Study Team are not eligible to be screened.
- Parents/guardians must have completed the CHIRP™ Survey on behalf of the candidate, and have indicated their willingness to be contacted for additional research opportunities.
- Candidates must meet preliminary screening criteria for FLIGHT™.
- Candidates must be between the ages of 2 and 15.
- Candidate's diagnosis(es) must fall into one or more of the following categories:
 - **Immune/Autoimmune Conditions** (for example: Juvenile Idiopathic Arthritis, Juvenile Rheumatoid Arthritis, asthma, eczema, atopic illness, allergies, Crohn's disease, ulcerative colitis, other gastrointestinal disorders, Lupus, other autoimmune conditions)
 - **Conditions of Metabolic Dysregulation** (for example: Obesity/Type II diabetes)
 - **Mood/Behavioral/Developmental Conditions** (for example: autism spectrum disorders, ADHD/ADD, depression, OCD, anxiety)
- Candidates must live within one of the following zip codes in Northern Virginia:

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Non-discrimination of Candidates

The FLIGHT™ study welcomes candidates of any gender, race, ethnicity, and socio-economic origin to be screened.

Your Child's Health Information

Signing this form gives the FLIGHT™ Study Team your permission to obtain, use, and evaluate information about your child for purposes of determining eligibility for the FLIGHT™ Study.

Any private health information you provide as part of the screening process will be kept private and confidential throughout the screening process.

Who will have access to my child's information?

Researchers and administrators of the FLIGHT™ Team or other authorized personnel of Epidemic Answers will have access to your contact information. This information will be used to keep you informed of study-related activities.

Your child's health information collected through the screening process may be viewed by:

- Researchers and administrators of the FLIGHT™ Study Team.
- Other authorized personnel of Epidemic Answers, the study Sponsor.
- Vetted advisors to the FLIGHT™ Study.
- The Institutional Review Board (IRB) for this study. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects. These people may look at your child's health information to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way.
- Authorized technical support staff from LivingMatrix, the online questionnaire software platform used to administer screeners.

Confidentiality of information collected for screening purposes

We will take necessary steps to keep your personal information private. All screening information and records will be stored electronically on a secure database with encryption and password protection to help prevent unauthorized access to your personal information. We will not release information about you/your child to others not listed above. Our contracted third party online survey and database service providers and consultants have agreements with us that they will keep all information confidential. We will not use your/your child's name or your identity for publication purposes, unless we have your written permission.

Who Can Answer My Questions?

FLIGHT™ Study Team

If you have any questions, concerns, or complaints about this screening process, contact Epidemic Answers at research@documentinghope.com or call (833) 935-5543.

Research Coordinators: Beth Lambert, MA, Josie Nelson, MA

Institutional Review Board (IRB):

The IRB is a group of people who independently review research. The IRB may not be able to answer some study-specific questions. Please contact the Institutional Review Board at (800) 562-4789 if:

- You want to talk to someone other than the study staff about research-related questions, concerns or complaints
- You have a hard time reaching the study staff
- You have questions about your rights as a research subject

Consent and Assent: Understanding the Difference

As a legal adult, you have the right to consent for yourself to be screened to participate in this study.

Individuals under the age of 18 do not have the legal right to consent for themselves. However, children who have the capacity to understand the study parameters must give their assent to be screened for participation in the study.

Both consent and assent assume a level of mental capacity necessary to understand informed consent. Some children who may be screened for this study may not have that capacity at the time of consent or assent. The study relies on your parental consent to make decisions on behalf of your child if your child is not able to assent.

Consent and Assent Procedures

This entire document is a consent document intended for you as an adult and parent or guardian to review and sign on behalf of both yourself and your child. Now that you have read most of this document, please make sure to ask any questions you may have before you sign it. For legal reasons, you will be asked to formally sign the signature fields at the end of this form to document your consent to your and your child's willingness to be screened for participation in the FLIGHT™ Study.

Assent

The FLIGHT™ Study Team has prepared separate age-appropriate assent language for you to share with your child. This language effectively restates the main points of this consent form, but in more child-friendly language.

Children who can understand the Assent to Participate form, and who wish to be screened for participation in the study, are required to sign below to acknowledge their assent; at least one of their parents or caregivers will also need to sign the form.

Assent to be Screened for Participation (for children who are able to do so)

Please have your child read the following information and give their assent by signing below. If your child is unable to read and understand the information, please read it to him/her.

Scientists are looking for children who want to be part of a research study. The name of the research study is FLIGHT. They are studying how children can get healthier over time.

The scientists would like to ask you some questions to find out if you want to participate, and if you might fit well into their study.

Your parents will be asked to complete several online surveys. Then you might be asked to participate in an online video conference call with your parent(s) and the researchers (that will last about 60 minutes). Your parents might also be asked to share your health records with the research team.

A few families who complete these first steps will be asked to do one more activity. If you and your family are chosen, and you would still like to be considered for participation in the study, you will then be asked to go to a doctor's appointment. This would be a check up with a local doctor who will make sure that it is safe for you to participate in the study.

If you want to be in the study, you will need to go through all the steps. But, you do not have to be in the study. If you do not want to be in the study, you can tell your parents that you do not want to be in the study.

Before you decide, you can ask your parents or the scientists any questions you like.

Statement of Parent/Guardian:

Consent for Myself and My Child

I have read this consent form (or it has been read to me). All my questions about the screening process and my part in it have been answered. I freely consent to take part in the screening process.

I understand that I may be asked to participate in multiple steps in the screening process and I can withdraw my consent at any time.

By signing this consent form, I have not given up any of my legal rights.

I agree to participate in the FLIGHT™ Study Screening Process.

I agree for my child to be considered as a candidate in the FLIGHT™ Screening Process. I authorize the use and disclosure of my child's health information to the parties listed above for the purposes described.

What Your Signature on this Document Means

By applying your electronic signature to this document using DocuSign, you indicate that you have reviewed it, understand the content, and agree to be screened for the FLIGHT™ Study.

By signing this document, you certify that you are the parent/legal guardian of the child listed above.

You will be able to print a final copy of this signed consent form.

- I consent to take part in the screening process.
- I agree to be contacted about future research opportunities.

Consent/Assent Instructions:

- One parent is required to consent. It is optional for both parents to provide consent.
- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the child sign an assent form, unless the investigator determines that the child is not capable of signing.

Print Name of the Child Participant

Date of Birth

Child Signature (if able) for Assent

Date

Signature of Parent/Authorized Guardian 1

Time

Print Name of Parent/Authorized Guardian 1

Date

Signature of Parent/Authorized Guardian 2 (optional)

Time

Print Name of Parent/Authorized Guardian 2(optional)

Date