

Form Approved
OMB No.
Expiration Date:

Attachment 21

Adult Consent, Parental Permission, and Adolescent Assent Forms

<<Permission and Consent Form for Parents or Guardians of Adolescent Participants>>

(Reading level: 7.9)

Centers For Disease Control And Prevention
The Registry Of Unexplained Fatiguing Illnesses And Chronic Fatigue Syndrome
Permission and Consent Form for Parents or Guardians of Adolescent Participants

INTRODUCTION

Your child is being asked to take part in a study of unexplained fatiguing illnesses and chronic fatigue syndrome (CFS). This research study is sponsored by the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. Abt Associates Inc. in Cambridge, Massachusetts has been hired by CDC to conduct this study. Around 240 persons will be studied.

In this study, CDC is developing a registry of unexplained fatiguing illnesses, including CFS. By unexplained fatiguing illness, we mean severe tiredness that is not due to illness, disease, or a condition. This registry will collect information on patients to study the history of their illness and track changes in their illness over time. Studying persons with CFS will help us understand how CFS changes over time and what makes it get better or worse. The best way to study CFS is to study people who recently developed CFS. We will also study people with unexplained fatiguing illness that is not CFS.

Earlier, a health care provider in Bibb County, Georgia referred your child to this study. Recently, you completed a telephone interview about your child. Your child is now eligible to take part in a clinical evaluation to see if he/she qualifies for the registry. Your child may have CFS, or he/she may have another fatiguing illness that is not CFS.

PURPOSE OF THE RESEARCH

CDC would like to find out:

1. How different are people with CFS from people with other fatiguing illnesses?
2. Among persons with CFS, how do their symptoms change over time?
3. What types of health care providers do people see for help with their fatigue?
4. What is the economic impact of CFS on individuals and families?

CDC is planning to extend this registry after this year. With your permission we may contact you again about your child in about a year. We would like to find out if your child's fatigue has gotten better, stayed the same, or gotten worse.

PROCEDURES

Taking part in this study is voluntary. If you and your child choose to join this study, you and your child can expect to spend about 6 to 7 hours at the clinic today. We will provide breakfast and lunch.

After we finish reviewing this permission form, you will decide if you want your child to join this study. If you permit your child to join and your child agrees, we will take your child's saliva and urine samples which you brought with you to clinic. We will test cortisol levels and other stress hormones in these samples. We will not test for illegal drugs or HIV. We will also take a sample of about 6 tablespoons of blood from a vein in your child's arm. He/She will be lying down when we draw the blood. We will test this blood for general blood

chemistry, hormones and other substances important to the immune system. Because food affects some of these tests, we have asked that your child not eat or drink before his/her appointment today. We will give him/her breakfast after we draw the blood. You are welcomed to have breakfast as well.

We will also ask your child to give another urine sample for routine tests. We will not test for illegal drugs or HIV. You and your child will be asked about your child's medical history and any medications that your child has taken in the last 2 weeks. A doctor will give your child a complete physical examination. Your child will be asked to disrobe to his/her underwear. You may stay in the room during the physical examination.

Your child and you will get a lunch break and lunch will be provided.

When you arrived at clinic, you were given the opportunity to review the questionnaires your child will be asked to complete. During the day, we will ask your child to complete paper questionnaires without assistance from you. This means you will be asked to wait in another room while your child completes these tasks. We will also ask your child to use a computer to answer questions. If your child has trouble reading, writing, or using a computer, he/she may ask a staff member to read the questions and record his/her answers. The questionnaires will cover such topics as fatigue symptoms, sleep, and general health. If your child is concerned about a question, your child may choose not to answer it for any reason. The questionnaires should take no longer than 1 and 1/2 hours to complete. However, your child may take as much time as he/she needs.

Your child will also be given a mental health assessment by a specially trained professional. When you arrived at clinic, you were given the opportunity to review this assessment. You may not be present during this interview. Again, some of the questions we ask are personal and may be upsetting. If your child is concerned about a question, he/she may choose not to answer it for any reason. The mental health assessment will take about 2 hours to complete.

We will provide snacks and caffeine-free drinks. We ask that your child not leave the clinic until your child completes the study or you or your child chooses to withdraw.

RISKS AND PROCEDURES TO MINIMIZE RISKS

We expect the risks to your child from being in this study will be rare, but we cannot rule them out. Possible risks include:

1. Risks from taking blood: Drawing blood may hurt a little. Bruising, bleeding, and rarely infection could occur where the needle enters your child's vein. To reduce these risks, blood samples are taken in a sterile manner by experienced staff.
2. Risks from the mental health assessment: Some of the questions we will ask your child are personal and may be upsetting. These questions may cause stress for your child and bring about painful memories or feelings. Research staff will be careful to avoid causing stress during these tests. Your child can choose not to answer any questions that cause him/her concern. An experienced, trained clinician will administer the mental health assessment. He or she will also be available to address any emotional or other difficulties that may arise when your child answers the survey questions. Occasionally, while conducting these interviews, we learn that a subject may be thinking about harming himself/herself. In such cases, the medical facility will provide support until offsite emergency psychiatric services are reached.

Being in this study may have other risks, of which we are not aware. If we become aware of more risks, we will inform you, and you may decide whether your child should continue in the study.

COSTS

The only cost to you for being in our study is the time you must spend and what it costs you to get here today. Similarly, the only cost to your child is the time he/she must spend on clinic activities.

Doctors at CDC will review all of your child's test results. Abt Associates will send you the results of your child's laboratory tests by mail when the results have been evaluated. You also may choose to have these results sent to your health care provider. If we find any results that might indicate a medical problem, we will contact you as soon as possible and advise you to have your child see a doctor. You would have to pay for that doctor's visit and recommended treatments yourself.

If you or your child have a medical or psychiatric emergency during your child's participation, CDC and Abt Associates will not pay for any treatment you or your child receive at that time or in the future. We believe that the chance of needing emergency care is very small. Should you or your child be harmed during this study, we will give you or your child emergency health and/or psychiatric care until formal care can be arranged. You or your insurer will be billed in the usual manner if such services are necessary. However, by signing this permission form and agreeing to be in this study, you are not giving up any of your rights or any of your child's rights.

BENEFITS

There may be no direct benefits to you or your child from joining this study. However, your child will be adding to the knowledge and understanding of fatiguing illness and CFS. We are planning to continue this study. If we do, persons taking part in this study may be chosen for future intervention trials designed to treat fatigue.

ALTERNATIVE TREATMENT

The current study does not offer standard or alternative treatments. Your child may see his/her own doctor for his/her symptoms at your own cost.

CONFIDENTIALITY

Answers to the questions we ask and your child's test results will be kept private to the extent allowed by law. However, please understand that information that would present a clear and present danger to the health and safety of a person if kept private, will be disclosed in accordance with Georgia law.

To protect you and your child's privacy, we will keep the records for your child under a code number rather than by name. We will keep the records in locked files and on computers that use passwords. Only people directly involved with this study will be allowed to look at them. Your name, your child's name, and other facts that might point to your child will not appear when we present this study or publish its results. However, Abt Associates will be able to link the code number to your child's name if needed. At CDC's request, Abt Associates may share identifying information with another contractor for the purpose of conducting a future study. Any staff with access to you or your child's information will be required to sign a confidentiality pledge. This pledge forbids them from sharing your personal information with anyone else.

Researchers from the CDC who are directly involved with this study may be present at the clinic. They will not be able to connect your name or your child's name to his/her information without your consent.

If you choose to have your test results sent to your child's doctor, he/she would be the only person outside of this study with whom we share those results.

REIMBURSEMENT

If your child completes the clinical evaluation and overnight urine collection, you will receive \$300 for the time you must take off and any personal costs for being in our study. Your child will receive \$100 for completing the evaluation. A portion of that reimbursement is being provided to you for the time it took to collect an overnight urine collection. If your child does not provide an overnight urine sample, your reimbursement amount will be decreased by \$25.00, and so will your child's. Though we hope that you will stay to the end of the day, you and your child are free to stop at any time and withdraw from the study. We will determine your child's eligibility for the clinical evaluation shortly after your arrival at clinic. If we find that your child is ineligible, he/she will not be asked to participate further. You will receive \$50 for your time and your child will receive \$25.

If, upon arriving at the clinic and reviewing the schedule of clinic activities with the study staff, you decide that your child will not join the study, you will receive \$50 for your time and your child will receive \$25. If you and your child decide to join the study and later withdraw before the end of the clinic day, you will receive \$150 and your child will receive \$50.

The amount you and your child receive will be mailed to you in the form of a check. If you choose not to answer some of the questions or do not agree to the storage or genetic testing of your child's blood (described on page 6), the amount we give you and your child will not be reduced.

CONTACT

If you have any questions about how the study works, contact Marjorie Morrissey, toll-free, at 1-866-710-9996. If you think that your child has been harmed as a result of this study, contact Dr. James Jones at (404) 639-1412. This may be a toll call. If you have questions about your child's rights as a participant in this research study, please contact the office of CDC's Deputy Associate Director for Science toll-free at 1-800-584-8814. Please leave a brief message including your name and phone number. Also, mention that you are calling in reference to CDC protocol #XXXX. Someone will return your call as soon as possible.

VOLUNTARY PARTICIPATION

You are free to let your child join the study or not. There is no penalty for choosing not to join this study. You and your child will not lose any benefits that you both normally get or could expect to get in the future. If you let your child join the study, you and your child are also free to stop taking part at any time. In that case, too, you and your child will not lose any benefits that both of you normally get. If for any reason the investigators believe that it would be unsafe for your child to continue the study, they will stop participation at that point. Such situations may include medical or emotional problems that might interfere with further assessment. If this occurs, you and your child will receive full payment for your time.

YOUR PERMISSION

I agree to let my child be in this study. I have been given a chance to ask questions. I feel that all of my questions have been answered. I have been told that allowing my child to be in this study is my choice. I have been told that after choosing to be in this study, my child and I may leave it at any time. I have been told that my child may choose not to answer any particular question. Furthermore, I have been told that by agreeing to let my child be in this study, I allow project staff to interview him/her about his/her background, medical history and mental health, and I agree to allow my child's blood to be drawn and urine to be collected for testing.

Based on the information given to me, including but not limited to the above, I agree to let my child participate in this study.

_____	_____	_____
Date	Time	Name of Adolescent
_____		_____
Printed Name of Parent or Guardian		Parent or Guardian's Signature

TEST RESULTS

You may choose to have your child's test results from this study forwarded to your child's health care provider. Please check one of the following options:

- Do not forward my child's test results to my child's health care provider.
- Please forward my child's test results to my child's health care provider.

Name of provider: _____

Address: _____

GENETIC TESTING

We will use part of the blood sample (about a tablespoon) to study genes and DNA. We understand that many people have concerns about blood being used for genetic testing. The tests that we will perform look for changes in genes that affect brain and blood chemicals. We are not aware of any genes that cause CFS. We will not be testing for known genes that cause specific diseases. The results of these tests should not affect you or your child's future employment or insurability. These results will be kept confidential to the extent legally possible. However, you may choose not to have your child's blood tested for genes and DNA and still allow him/her to be part of this study. Your decision will not affect you or your child's compensation.

Please check one box:

- I give permission for my child's blood to be tested for genes and DNA under the conditions outlined in this permission form.
- I DO NOT give permission for my child's blood to be tested for genes and DNA under the conditions outlined in this permission form.

Date

Name of Adolescent

Printed Name of Parent or Guardian

Parent or Guardian's Signature

STORAGE OF SAMPLES FOR FUTURE USE

We would like to store a small portion (about a tablespoon) of your child's blood sample for possible future studies of gene expression, as well as hormonal and immune systems. The samples will be stored with some information about your child, such as his/her age, race, sex, and information about your child's health. Any information that links your child to the specimen will be destroyed. However, you may choose not to have your child's blood stored for future studies and still let him/her be part of this study. Your decision will not affect your compensation or your child's compensation.

Please check one box:

- I give permission for my child's blood to be stored under the conditions outlined in this permission form.
- I DO NOT give permission for my child's blood to be stored under the conditions outlined in this permission form.

Date

Name of Adolescent

Printed Name of Parent or Guardian

Parent or Guardian's Signature

CONSENT TO BE RECONTACTED

We may wish to contact you again about future studies for your child. By giving consent to be contacted, your child does not have to take part in future studies. You are just giving us permission to contact you and invite your child to take part in other studies of CFS.

Please check one box:

- I give consent to be contacted about future studies as outlined in this permission form.
- I DO NOT give consent to be contacted about future studies as outlined in this permission form.

Date

Name of Adolescent

Printed Name of Parent or Guardian

Parent or Guardian's Signature