

Form Approved
OMB No.
Expiration Date:

Attachment 20

Clinic Appointment Packet Materials

<<Clinic Appointment Letter for Adult Subjects>>

(Reading level: 7.8)

<<Registry Clinic Appointment Letter for Adult Subjects>>

Date:

Dear

Thank you for taking part in the Centers for Disease Control and Prevention's (CDC) research study. The study is called the *Registry of Unexplained Fatiguing Illnesses and Chronic Fatigue Syndrome (CFS)*. Abt Associates Inc. is working with CDC to collect data about fatiguing illnesses and CFS. By studying CFS, we hope to understand how CFS changes over time and what makes it get better or worse.

Your appointment is scheduled for

Day/Date:

Time:

Location: CDC Study Clinic
Address and phone here

This packet contains:

- A consent form copy
- Two questionnaires
- Saliva collection tubes and instructions
- An overnight urine collection kit
- A schedule of activities
- Directions to the clinic and
- A checklist of what you need to bring to your appointment.

Please review these materials before your appointment. During your visit to the clinic, a clinic staff member will review and discuss the consent form with you. You will be asked to sign it. Your signature means you agree to join this study. By signing this form, you also agree to the collection of blood and urine specimens at the clinic.

Please do not eat or drink anything (except water) after midnight the night before your appointment. On the day of your appointment, please plan to spend about eight hours with us in the clinic. Remember to bring your saliva tubes, overnight urine specimen, and completed questionnaires.

When you come to the clinic, we will verify your identity and then make sure you are eligible for our study. There are four reasons why a study participant would not qualify:

(1) the person is younger than 12 or older than 59 years; (2) the person's body mass index is too high for this study; (3) the person shows signs of a current infection or illness (for example, a fever); or (4) the person has been pregnant within the last 12 months.

During your clinical evaluation, we will collect blood and urine samples. The samples will be submitted for routine laboratory tests. These tests are outlined in the enclosed consent form. An interviewer will also ask you to complete interviews and questionnaires. All of the information you provide will be kept private. Information will be reported only in summary form. To help cover your costs of participation, you will be reimbursed \$400.

In a few days, your scheduling coordinator will call to review these materials. If you have any questions or concerns, she will be able to help you.

If you have any questions about your rights in this study, you may call the CDC Deputy Director for Science toll-free at 1-800-584-8814. Please be prepared to leave a message, and your call will be returned. If you have any other questions about this research study, or, if you think that you have been injured in this study, please call Dr. James Jones at the CDC. Dr. Jones' number is: 1-404-639-1412. Please note that this call may be a toll call.

Very truly yours,

Scott Royal, Ph.D.
Project Director
Abt Associates, Inc.

(Reading level: 8.0)

<<Registry Pilot Study Clinic Appointment Letter for Adolescent Subjects>>

Date:

Dear Parent of Adolescent

Thank you for letting your child be part of the Centers for Disease Control and Prevention's (CDC) research study. The study is called the *Registry of Unexplained Fatiguing Illnesses and Chronic Fatigue Syndrome (CFS)*. Abt Associates Inc. is working with CDC to collect data about fatiguing illnesses and CFS. By studying CFS, we hope this research will lead to more effective diagnosis and treatment.

Your appointment is scheduled for

Day/Date:

Time:

Location: CDC Study Clinic
Address and phone here

This packet contains:

- A parental permission form
- An assent form for your child
- Two questionnaires
- Saliva collection tubes and instructions
- A urine specimen collection kit
- A schedule of activities
- Directions to the clinic and
- A checklist of what to bring to your appointment

Please review these materials before your child's appointment and complete the questionnaires for your child. During your visit to the clinic, a clinic staff member will review and discuss the permission form with you. You will be asked to sign it. Your signature means you allow your child to join this study. By signing this form, you also allow your child to provide blood and urine specimens.

Please do not have your child eat or drink anything (except water) after midnight the night before the appointment. On the day of the appointment, please plan to spend about 6 ½ hours with us. Remember to bring your child's saliva tubes, overnight urine specimen, and completed questionnaires.

When you come to the clinic, we will verify your child's identity and then make sure he/she is eligible for our study. There are four reasons why an adolescent would not qualify: the child (1) is younger than 12 years; (2) has a body mass index that is too high for this study; (3) shows signs of a current infection or illness (for example, a fever); or (4) has been pregnant within the last 12 months.

During the clinical evaluation, we will collect blood and urine samples from your child. The samples will be submitted for routine laboratory tests. These tests are outlined in the enclosed permission form. An interviewer will also ask your child to complete interviews and questionnaires. All of the information your child provides will be kept private. Information will be reported only in summary form. To help cover your costs of participation, you will be reimbursed \$300 and your child will receive \$100.

In a few days, your scheduling coordinator will call to review these materials. If you have any questions or concerns, she will be able to help you.

If you have any questions about you or your child's rights in this study, you may call the CDC Deputy Director for Science toll-free at 1-800-584-8814. Please be prepared to leave a message, and your call will be returned. If you have any other questions about this research study, or, if you think that your child has been injured in this study, please call Dr. James Jones at the CDC. Dr. Jones' number is: 1-404-639-1412. Please note that this call may be a toll call.

Very truly yours,

Scott Royal, Ph.D.
Project Director
Abt Associates, Inc.