

Attachment H **Updated/Revised** Informed Consent Materials

Advance Letter for Parents of Children aged 4-11 years

**1FROM THE DIRECTOR
NATIONAL CENTER FOR HEALTH STATISTICS**

Dear (name of parent who was interviewed on NHIS)

Thank you for your recent participation in the National Health Interview Survey. We are now asking a randomly selected group of families to answer additional questions about the emotional and behavioral health of children and teenagers and we need your help to make this study a success.

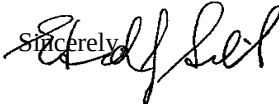
You will be asked questions about whether your child shows symptoms related to the five most common emotional and behavioral issues that children face. The interview will be conducted over the telephone by our research partner, RTI International, in Research Triangle Park, North Carolina. It will take about one hour to complete. Your answers may help improve our ability to describe and understand child and adolescent emotional and behavioral health issues in the United States and to make sure that people who need help can get it. We hope you will agree to participate.

I assure you that your participation is voluntary. You do not have to answer any questions that you do not want to answer, and you can stop the interview at any time. Whether or not you participate has no effect on any benefits you receive or will receive in the future.

The survey, conducted by the U.S. Department of Health and Human Services, is authorized by Section 306 of the U.S. Public Health Service Act [42 USC 242k]. Federal laws including the Confidential Information Protection and Statistical Efficiency Act and Section 308(d) of the Public Health Service Act [42 USC 242m (d)] protect your family's information and keep it confidential. The information you report in this survey will be used for research purposes only and will be reported in statistical form so you and your child cannot be identified. In about 6 months, when the study is done, we will contact you to tell you whether your child was experiencing an emotional or behavioral health issue at the time of the interview and to provide information about where you can get help if you want it.

If you would like to learn more about your rights as a respondent, please call the office of the Research Ethics Review Board at the National Center for Health Statistics, toll-free, at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol number 2010-11 Your call will be returned as soon as possible.

We appreciate your taking the time to talk to us. Thank you for your assistance.

Sincerely,


1Edward J. Sondik, Ph.D.
Director, National Center for Health Statistics
National Center for Health Statistics

P.S. In appreciation for your time and effort, we have enclosed \$5. We will send an additional \$25 in cash after the interview is completed.

Advance Letter for Parents of Children aged 12-17 years

**FROM THE DIRECTOR
NATIONAL CENTER FOR HEALTH STATISTICS**

Dear (name of parent who was interviewed on NHIS)

Thank you for your recent participation in the National Health Interview Survey. We are now asking a randomly selected group of families to answer additional questions about the emotional and behavioral health of children and teenagers and we need your help to make this study a success.

You will be asked questions about whether your child shows symptoms related to the five most common emotional and behavioral issues that children face. With your and your child's permission, we would also like to ask (Sample Child's name) about (his/her) feelings.

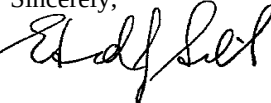
The interview will be conducted over the telephone by our research partner, RTI International, in Research Triangle Park, North Carolina. It will take you about one hour and your child about 45 minutes to complete but the interviews can be done at different times. Your answers may help improve our ability to describe and understand child and adolescent emotional and behavioral health issues in the United States and to make sure that people who need help can get it. We hope you will agree to participate.

I assure you that your and your child's participation are voluntary. You and your child do not have to answer any questions that you do not want to answer, and you can stop the interview at any time. Whether or not you and your child participate has no effect on any benefits you receive or will receive in the future.

The survey, conducted by the U.S. Department of Health and Human Services, is authorized by Section 306 of the U.S. Public Health Service Act [42 USC 242k]. Federal laws including the Confidential Information Protection and Statistical Efficiency Act and Section 308(d) of the Public Health Service Act [42 USC 242m (d)] protect your family's information and keep it confidential. The information you report in this survey will be used for research purposes only and will be reported in statistical form so you and your child cannot be identified. In about 6 months, when the study is done, we will contact you to tell you whether your child was experiencing an emotional issue at the time of the interview and to provide information about where you can get help if you want it.

If you would like to learn more about your rights as a respondent, please call the office of the Research Ethics Review Board at the National Center for Health Statistics, toll-free, at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol number 2010-11 Your call will be returned as soon as possible.

We appreciate your taking the time to talk to us. Thank you for your assistance.

Sincerely,


Edward J. Sondik, Ph.D.
Director, National Center for Health Statistics
National Center for Health Statistics

P.S. In appreciation for your time and effort, we have enclosed \$5. We will send an additional \$25 in cash to you and a gift card for \$ 25 to your child when the interview is completed.

Parental Consent Script for Parents of Children 4-8 years of age

[After getting the parent who was interviewed for the NHIS on the phone]

Hello, my name is _____. I am calling on behalf of the National Center for Health Statistics. Recently you took part in the National Health Interview Survey conducted by the Census Bureau. At that time, you answered questions about {CHILD'S NAME} health. We are asking some parents and children to take part in another survey. You may have received a letter about this.

Today's survey is about the most common emotional and behavioral health concerns in children and teenagers. They are anxiety, depression, and oppositional defiance, attention deficit, and conduct disorders. This study includes children who do and do not have these conditions.

We won't know until the end of the study—around [date range]--if the symptoms you report today suggest that {sample child} may have one of these problems. If your child shows symptoms of a mental health issue, we will call you with these results. We will report these results to you only if your child shows symptoms of an emotional or behavioral health issue. At that time, we will also provide information about where you can get help if you want it.

We hope you will agree to participate. Your answers may help improve our ability to describe and understand the emotional and behavioral health of children and adolescents in the United States and to make sure that people who need help can get it.

The survey takes about one hour to complete.

Taking part in this survey is voluntary. You may choose not to answer any questions you don't wish to answer, or end the interview at any time. We will not share your confidential information with anyone and we are required by Federal laws to follow strict procedures to protect your information. I can describe these laws if you wish. Your information will only be used for statistical research. Participation will not affect your receipt of any benefits.

READ IF NECESSARY: The Public Health Service Act is Volume 42 of the US Code, Section 242k. The collection of information in this survey is authorized by Section 306 of this Act. Through the National Center for Health Statistics, the confidentiality of your responses is assured by Section 308d of this Act and by the Confidential Information Protection and Statistical Efficiency Act. Would you like me to read the Confidential Information Protection provisions to you?

IF RESPONDENT WOULD LIKE TO HEAR PROVISIONS, READ: The information you provide will be used for statistical purposes only. In accordance with the confidential information protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents of the National Center for Health Statistics. By law, every employee of the National Center for

Health Statistics and its collaborating agencies and contractors who work on this survey have taken an oath and is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both, for the willful disclosure of ANY identifiable information about you or your household members.

This interview will be recorded for quality control purposes. At the end of the study, the recordings will be destroyed.

Is now a good time to complete this interview?

[IF "YES,"PROCEED]

[IF "NO," ASK FOR BEST DAY AND TIME OF DAY TO CALL BACK. MAKE A NOTE OF THIS INFORMATION; THANK THE INDIVIDUAL FOR HER OR HIS TIME AND HANG UP].

Are you in an area where you can answer these questions privately?

[IF "YES,"PROCEED]

[IF "NO," TELL THE RESPONDENT WE WOULD LIKE THEM TO BE ABLE TO ANSWER THE QUESTIONS IN AS PRIVATE A SETTING AS POSSIBLE]

Do you have any questions?

{IF YES, ANSWER THEM; IF NOT, SAY}

OK, let's get started.

[CONDUCT INTERVIEW]

Those are all the questions I have about your child.

Confirm phone number will be the same in XX months.

{RECORD ANSWER}

Thank you on behalf of the National Center for Health Statistics for the time and effort you've spent answering these questions. If you have any questions about this survey, you may call my supervisor toll-free at 1-xxx-xxx-xxxx. If you have questions about your rights as a survey participant, you may call the Research Ethics Review Board at 1-800-223-8118. Say you are calling about Protocol number 2010-11. Within (insert time period) you will receive \$25 for your participation in this survey. (confirm the address). Thank you again.

Parental Consent Script for Parents of Children 12-17 years of age

[After getting the parent who was interviewed for the NHIS on the phone]

Hello, my name is _____. I am calling on behalf of the National Center for Health Statistics. Recently you took part in the National Health Interview Survey conducted by the Census Bureau. At that time, you answered questions about {CHILD'S NAME} health. We are asking some parents and children to take part in another survey. You may have received a letter about this.

Do you remember getting the letter?

Yes

No

(The letter said) Today's survey is about the most common emotional and behavioral health concerns in children and teenagers. They are anxiety, depression, and oppositional defiance, attention deficit, and conduct disorders. This study includes children who do and do not have these conditions.

We won't know until the end of the study—around [date range]--if the symptoms you report today suggest that {sample child} may have one of these problems. If your child shows symptoms of a mental health issue, we will call you with these results. We will report these results to you only if your child shows symptoms of an emotional or behavioral health issue. At that time, we will also provide information about where you can get help if you want it.

We hope you will agree to participate. Your answers may help improve our ability to describe and understand the emotional and behavioral health of children and adolescents in the United States and to make sure that people who need help can get it.

The survey takes about 45 minutes to complete. Taking part in this survey is voluntary. You may choose not to answer any questions you don't wish to answer, or end the interview at any time. We will not share your confidential information with anyone and we are required by Federal laws to follow strict procedures to protect your information. I can describe these laws if you wish. Your information will only be used for statistical research. Participation will not affect your receipt of any benefits.

READ IF NECESSARY: The Public Health Service Act is Volume 42 of the US Code, Section 242k. The collection of information in this survey is authorized by Section 306 of this Act. Through the National Center for Health Statistics, the confidentiality of your responses is assured by Section 308d of this Act and by the Confidential Information Protection and Statistical Efficiency Act. Would you like me to read the Confidential Information Protection provisions to you?

IF RESPONDENT WOULD LIKE TO HEAR PROVISIONS, READ: The information you provide will be used for statistical purposes only. In accordance with the confidential information protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents of the National Center for Health Statistics. By law, every employee of the National Center for Health Statistics and its collaborating agencies and contractors who work on this survey have taken an oath and is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both, for the willful disclosure of ANY identifiable information about you or your household members.

To thank you for your time, we will send you \$25.

Do you have any questions so far?

Yes

No

Because this is a parent and child survey, I would also like to ask similar questions of (name) about emotions, concentration, behavior and getting along with others. If you agree, we will ask your child if s/he would like to be interviewed. S/he has the same rights and protections as you and we will let him/her know this. That means s/he can choose not to participate, or to answer only some questions or stop the interview at any time.

We will also tell (child) that we won't share her/his answers with you. We will only tell you if we think there might be a problem, if s/he in danger or is about to harm himself/herself or others so that you can follow up.

So that (name) can answer questions freely, we will ask that s/he answer questions in as private a place as possible. We will send (name) a \$25 gift card.

We won't know until the end of the study—around [date range]--if the symptoms you and your child report today suggest that (child) may have one of these problems. If your child shows symptoms of a mental health issue, we will call you with these results. We will report these results to you only if your child shows symptoms of a mental health issue. At that time, we will also provide information about where you can get help if you want it.

This interview will be recorded for quality control purposes. At the end of the study, the recordings will be destroyed.

Is now a good time to complete this interview?

[IF "YES,"PROCEED]

[IF “NO,” ASK FOR BEST DAY AND TIME OF DAY TO CALL BACK. MAKE A NOTE OF THIS INFORMATION; THANK THE INDIVIDUAL FOR HER OR HIS TIME AND HANG UP].

Are you in an area where you can answer these questions privately?

[IF “YES,”PROCEED]

[IF “NO,” TELL THE RESPONDENT WE WOULD LIKE THEM TO BE ABLE TO ANSWER THE QUESTIONS IN AS PRIVATE A SETTING AS POSSIBLE]

Do you have any questions?

{IF YES, ANSWER THEM; IF NOT, SAY}

OK, let’s get started.

[CONDUCT INTERVIEW]

Those are all the questions I have about your child.

Thank you on behalf of the National Center for Health Statistics for the time and effort you’ve spent answering these questions. If you have any questions about this survey, you may call my supervisor toll-free at 1-xxx-xxx-xxxx. If you have questions about your rights as a survey participant, you may call the Research Ethics Review Board at 1-800-223-8118. PROTOCOL 2010-11. Within (insert time period) you will receive \$25 for your participation in this survey. (confirm the address). Thank you again.

May I now speak to (sample child)

If they say NO, thank them and confirm phone number will be the same in XX months and thank them again.

If they say, YES, ask to speak to the child.

IF THE CHILD IS NOT AVAILBLE, ASK FOR A NUMBER WHERE THEY CAN BE REACHED AND A GOOD TIME TO REACH THEM.

Child Assent

Thank you for agreeing to talk to me. Your mother/father said that you can take part in this special survey if you want to. I will be asking you about what you do, about how you feel and about any problems you may be having. This will take about 45 minutes. You can stop answering questions at any time. You do not have to answer questions if you do not want to. If you do take part, you will help us learn a lot about other kids in the United States.

We will not share the answers you give us to anyone, even your parents, unless we think you may harm yourself or others. Then we will tell your parents or someone else who can help you. Also, if we have concerns about you we might ask that your parents speak to your family doctor about this. We won't tell your parents exactly what you said, only that we are concerned about you.

Is this OK?

[IF "YES,"PROCEED; If "NO", thank them and end interview]

Are you in an area where you can answer these questions privately?

[IF "YES,"PROCEED]

[IF "NO," REMIND RESPONDENT THAT WE WOULD PREFER THEY ANSWER THE QUESTIONS IN AS PRIVATE A SETTING AS POSSIBLE]

Usually we record the interview so that we can check afterwards that we've got the right idea about what you tell us. So I have a tape recorder here. Is it OK if I use that?

[IF YES, PROCEED, IF NO, ASSURE THEM YOU WILL NOT TAPE RECORD, AND THEN PROCEED].

Do you have any questions?

{IF YES, ANSWER THEM; IF NOT, SAY}

OK, let's get started.

Back End Consent for Children

Those are all the questions I have. I'd like to thank you on behalf of the National Center for Health Statistics for the time and effort you've spent answering these questions. (TELL THEM HOW YOU WILL SEND INCENTIVE)

Reporting Back Results (Phone)

Hello,

I am _____

Recently, you took part in a study about child mental health. At the time of the interview you asked that we contact you if the information you gave us that day indicated your child may be at risk for a emotional or behavioral health problem. We agreed to contact you so that you could use the information to follow-up with your pediatrician or other health professional.

I am calling today to tell you that based on the answers you gave us that day, your child may be experiencing a mental health problem. Remember, these results are based on information from a single test and you may want to follow up with your pediatrician, family doctor or other mental health provider.

I have a list of mental health services in your area that you may contact. Would you like me to give you those phone numbers?

(Give them information)

Would you like me to send you a letter describing this information so that you can share it with your doctor or mental health professional?

YES confirm address

NO

I'd like to thank you on behalf of the National Center for Health Statistics for the time and effort you've spent on this survey. If you have any questions about this survey, you may call my supervisor toll-free at 1-xxx-xxx-xxxx. If you have questions about your rights as a survey participant, you may call the chairman of the Research Ethics Review Board at 1-800-223-8118. and mention Protocol number 2010-11.

Sample Letter to Be Sent if Parent Wants a Written Response

**National Health Interview Survey
Children's Mental Health Follow Up Study**

Date

Dear _____,

I am writing today to confirm what I told you in our phone conversation. Based on the answers you gave us on the day you were interviewed, your child may be experiencing an emotional or behavioral health problem.

Remember, these results are based on information from a single interview and do not mean that your child is definitely at risk for a mental health problem. We did find symptoms that suggest that your child *may* have a mental health problem. Please note that it is possible that a problem does not exist or that the problem has gone away since we conducted the interview.

You might want to contact your pediatrician or family doctor or a mental health professional to further discuss whether a problem exists. You can tell them that you and your child were interviewed over the telephone using the Child Adolescent Psychiatric Assessment or Pre-School Psychiatric Assessment tool developed by researchers at Duke University.

For your convenience, we have included a list of some mental health services in your area. These services are also listed at www.samhsa.hhs.gov under Treatment Locators on the left side of the screen.

(insert information of local mental health service providers)

If you would like to speak with someone immediately, you may contact a 24-Hour Helpline at **1-800-662-HELP** (1-800-662-4357).

I'd like to thank you on behalf of the National Center for Health Statistics for the time and effort you've spent on this survey.

Sincerely,

Heather Ringeisen, Ph.D.
Child Mental Health Study Director
RTI International

Thank you letter for parent

Dear Name,

Thank you for taking part in the National Health Interview Survey Child Emotional and Behavioral Health Follow-up Survey. The information that you gave about your child will help the US Department of Health and Human Services develop programs to promote the health of children in your state and throughout the United States.

In appreciation for your time and effort spent answering our questions, we have enclosed \$25. We have also enclosed two brochures on mental health services: *A Behavioral Thermometer* and *Treatment of Children with Mental Illness: Frequently asked questions about the treatment of mental illness in children*.

In about 6 months when the study is complete, we may contact you if the information you gave us that day indicated that your child may be at risk for an emotional or behavioral health problem. If you have any concerns about your child's health, please contact a health professional.

Thank you again for your help with this important research.

Sincerely,



Edward J. Sondik, Ph.D.
Director, National Center for Health Statistics
National Center for Health Statistics

Thank you letter for child

Dear Name,

Thank you for taking part in the National Health Interview Survey Child Mental Health Follow-up Survey. The information that you gave will help us to help other children just like yourself.

In appreciation for your time and effort spent answering our questions, we have enclosed a \$25 gift card. We have also included some information for you about mental health and some websites where you can go for more information about mental health issues and treatment.

Thank you again for your help with this important research.

Sincerely,

A handwritten signature in black ink, appearing to read "Ed Sondik". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Edward J. Sondik, Ph.D.
Director, National Center for Health Statistics
National Center for Health Statistics