Attachment H Informed Consent Materials

Advance Letter for Parents of Children aged 4-11 years

FROM THE DIRECTOR NATIONAL CENTER FOR HEALTH STATISTICS

Dear (name of parent who was interviewed on NHIS)

In the next few weeks, you will be called to take part in an important follow-up study to the National Health Interview Survey about the mental health of children and teenagers. You were randomly selected from the respondents who answered questions about their children in the National Health Interview Survey.

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 mental health issues that children face. We will contact you about 6 months after the interview to tell you whether your child may be experiencing one of these five mental health issues and to 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 child and adolescent mental health issues in the United States and to make sure that people who need help can get it.

The interview will be conducted over the telephone and take about 45 minutes to complete.

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. Taking part has no effect on any benefits you receive or will receive in the future.

The survey is being conducted by the U.S. Department of Health and Human Services and is authorized by the Public Health Service Act [Secs. 306 & 2012 (a) (7)]. This and other federal laws 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.

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 #______. 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 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)

In the next few weeks, you will be called to take part in an important follow-up study to the National Health Interview Survey about the mental health of children and teenagers. You were randomly selected from the respondents who answered questions about their children in the National Health Interview Survey.

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 mental health issues that children face. With your permission, and your child's, we would also like to interview (name of Sample Child) about (his or her) feelings.

We will contact you about 6 months after the interview to tell you whether your child may be experiencing one of these five mental health issues and to provide information about where you can get help if you want it.

We hope you will agree to participate and will allow your child to participate, too. Once you have given us permission to ask your child to participate, we will also ask them whether they want to take part. Your and their answers may help improve our ability to describe and understand child and adolescent mental health issues in the United States and to make sure that people who need help can get it.

The interview will be conducted over the telephone and on average takes about 45 minutes to complete and about 45 minutes for your child to complete.

Your participation 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. Taking part has no effect on any benefits that you or your child receive or will receive in the future.

The survey is being conducted by the U.S. Department of Health and Human Services and is authorized by the Public Health Service Act [Secs. 306 & 2012 (a) (7)]. This and other federal laws 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.

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 #______. Your call will be returned as soon as possible.

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

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 mental 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 a mental 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 child and adolescent mental health 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 information with anyone and we are required by Federal laws to follow strict procedures to protect your information. Your information will only be used for statistical research and 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. 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. 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]

[Mich getting the parent who was interviewed for the Mills 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 mental 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.

Taking part in this survey is voluntary but we hope you will agree to participate. Your answers may help improve our ability to describe and understand child and adolescent mental health in the United States and to make sure that people who need help can get it.

The survey takes about 45 minutes to complete. 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 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 be used for statistical research only and will not affect your receipt of any benefits. To thank you for your time, we will send you \$25.

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. 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.

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. 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 AVAIBLE, 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 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)