Appendix 6: Cognitive Interview/Usability Testing – Consent Script

Date(MM/DD/YY) ____/_____/_____

Hour ____:____ AM/PM
Interviewer name: _____
Respondent ID number: _____

[INTERVIEWER: READ BEFORE CONDUCTING INTERVIEW]
Introduction and Consent Script

NORC is conducting a research study looking at ways to improve survey questions. These questions will be used to gather information on children's health. This study is funded by the Maternal and Child Health Bureau at the U.S. Department of Health and Human Services.

Today you will be asked to complete a series of survey questions. We will talk with you about these questions and ask you to discuss your answers. You may be asked to answer some questions using an electronic device such as a desktop computer, a laptop computer, a tablet, or a smartphone. It is not necessary for you to have any particular computer skills. You must be 18 years of age or older to take part in this research study.

For this study, we will ask you to answer some questions about children's health conditions. While there is no direct benefit to you for participating in this survey, your feedback may help make improvements to the survey. There are no risks in participating in this research beyond those experienced in everyday life.

Your participation in this study is entirely voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer.

Today's interview will take about an hour to complete. You will receive $50 for participating. You will receive the $50 even if you skip some questions or cannot complete the interview. [FOR PREDICTIVE VALIDATION TESTING CONDITION: We will follow up with you by phone in about two weeks to confirm some of the answers you give in today's interview. This follow up interview will take about 20 minutes to complete.]

Your participation in this research is confidential. You will not be personally identified in any report of these interviews. Your name will not be associated with any information you provide.

The U.S. Department of Health and Human Services (DHHS) gave this study a legal document, called a Certificate of Confidentiality. This means that the Study cannot be forced by a court order or subpoena to give out information that might identify you in any court. We will only release your information if you request it.

Federally funded projects such as this one are sometimes audited or evaluated by the United States Government. If that happens, we cannot use the Certificate of Confidentiality to protect your information from staff conducting the audit or evaluation.

We would like to audiotape our discussion today. All of your comments are strictly confidential and will be used for research purposes only. Only authorized staff members from NORC who are working on this project will have access to recordings. These recordings will be stored in secure NORC servers at all times. We record interviews to allow for review of answers at a later date; however, this recording will be erased once the project has ended.

May I audiotape our conversation?
IF RESPONDENT DOES CONSENT, BEGIN RECORDING.
IF RESPONDENT DOES NOT CONSENT, *DO NOT* RECORD, AND EXPLAIN TO THE PARTICIPANT THAT THE INTERVIEW CAN CONTINUE WITHOUT RECORDING.

Do you have any questions? *INTERVIEWER: ANSWER ANY RESPONDENT QUESTIONS OR CONCERNS*.

If you have any further questions after today's interview, please contact us at [NORC 1-800 NUMBER]. If you have any questions regarding your rights as a study participant, please feel free to contact the chairman of the National Center for Health Statistics (NCHS) Research Ethics Review Board at [1-800 NUMBER].

Do you agree to participate in this study as I have described it?

FOR IN-PERSON INTERVIEW:
INTERVIEWER: INITIAL RESPONDENT CONSENT: _____

FOR TELEPHONE INTERVIEW:
INTERVIEWER: CHECK OFF THIS BOX IF PARTICIPANT EXPRESSED VERBAL CONSENT: □ YES

IF RESPONDENT DOES NOT CONSENT, THANK HIM/HER FOR HIS/HER TIME

[Flesh-Kincaid Grade Level: 8.9]

[PROVIDER RECORD CHECK CONSENT SCRIPT – USE FOR RESPONDENTS ASSIGNED TO THE CRITERION-BASED VALIDATION TEST CONDITION WHO DO NOT HAVE DOCUMENTATION TO VALIDATE DIAGNOSIS QUESTIONS.]

Date(MM/DD/YY) ____/_____/_____

Hour ____:____ AM/PM
Interviewer name: _____
Respondent ID number: _____

INTERVIEWER: UPON COMPLETION OF COGNITIVE AND USABILITY TESTING, PLEASE READ THE FOLLOWING:

Thank you for taking the time to participate in our study. As mentioned earlier, the goal of our research is to improve survey questions to help us develop better ways of gathering information on children's health. To help us make sure our questions are accurately collecting the information we need, we would like to have your permission to contact your child's primary health care provider.

With your permission, we'd like to send a letter to your child's health care provider asking to confirm the date and diagnosis of the special health care need of your child. For us, it is critical to have information from both you, and your child's health care provider. Let me explain how it works.

We'll send a letter to your health care provider explaining that we have talked with you, and that we need his or her confirmation of your child's diagnosis. Any information that the provider gives us will be separated from information that could be used to identify you or your child. Neither you nor your child will be identified as a participant in this study in any report.

Do you have any questions? *INTERVIEWER: ANSWER ANY RESPONDENT QUESTIONS OR CONCERNS*.

Can we have your authorization to contact your child's health care provider?

INTERVIEWER: IF RESPONDENT CONSENTS, PLEASE ADMINISTER PROVIDER RECORD CHECK CONSENT FORM AND HIPAA AUTHORIZATION.
IF RESPONDENT DOES NOT CONSENT, THANK THEM FOR THEIR TIME

[PROVIDER RECORD CHECK CONSENT FORM AND HIPAA AUTHORIZATION]

RESPONDENT ID NUMBER: _____

Respondent's name_____
Address _____ Apt. _____
Home Phone ( )_____ Cell Phone ( )_____
City _____ State _____ Zip Code_____

Child's Name_____
Date of Birth_____

Your child's primary health care provider contact Information

_____

_____

_____

NORC requests your permission to obtain information from your health care provider about your child's health condition(s). This information will be used only by authorized personnel from NORC at the University of Chicago. This information is being asked with the purpose of making improvement to the National Survey of Children's Health. The information will be scanned and stored on NORC's secure server and the hard copy (if provided by fax, letter or any other written means) will be destroyed. The findings from examination of your child's health-related information will only be released in a summary form that does not identify individuals who participate in the study.

This permission form also serves as a HIPAA Authorization Form for the Use and Disclosure of Health Information. It is required by the Health Insurance Portability and Accountability Act of 1996 (known as HIPAA) [(11)] in order to collect protected health information from your/your child(ren)'s medical and health records to use in the National Survey of Children's Health Redesign study. Protected health information (PHI) is any identifiable health information about your/your child(ren)'s past, present, or future physical or mental health condition or payment for health care. Examples of PHI are medical and dental records, billing records, x-rays, ultrasound, and laboratory reports.

If you sign this form, you agree that you are voluntarily participating in the study and you authorize the health care providers identified above to release your/your child(ren)'s PHI to members of the research team.

I, _____, grant permission to NORC to contact my child's health care provider named above and obtain information related to my child's health status.

_____ _____
Signature of Individual Granting Permission Date

If you have any further questions after today's interview, please contact us at [NORC 1-800 NUMBER]. If you have any questions regarding your rights as a study participant, please feel free to contact the chairman of the National Center for Health Statistics (NCHS) Research Ethics Review Board at [1-800 NUMBER].

[1] Health Insurance Portability and Accountability Act: 42 U.S.C. 1320d-2 and 1320d-4 and the implementing regulation, 45 CFR 164.508, require a detailed authorization for your health care provider to disclose health information from your records for research purposes

Consent Script for Phone Follow Up (Predictive Validation Test Condition ONLY)

Hello, my name is _____. I am calling on behalf of the Maternal and Child Health Bureau at the U.S. Department of Health and Human Services. On [INSERT DATE OF INTERVIEW] you participated in an interview where we asked you questions about your child's health conditions. We are following up to confirm some of the answers you provided.

Before we get started, I wanted to remind you that taking part in this research is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer. The survey questions that follow will take about 20 minutes to complete.

Your participation in this research is confidential. You will not be personally identified in any report of the study findings. Your name will not be associated with any information you provide.

A Certificate of Confidentiality has been obtained from the Federal Government for this study. This certificate helps to insure your privacy. It means that the researchers cannot be forced to disclose information that may identify you. We can only release your information if you request it.

In order to review my work, this call will be recorded and my supervisor may listen as I ask the questions. Only authorized staff members from NORC who are working on this project will have access to recordings. These recordings will be stored in secure NORC servers at all times. This recording will be erased once the project has ended.

[IF RESPONDENT OBJECTS TO RECORDING, STOP THE RECORDING AND EXPLAIN TO THE PARTICIPANT THAT THE INTERVIEW CAN CONTINUE WITHOUT RECORDING.]

Do you have any questions? *INTERVIEWER: ANSWER ANY RESPONDENT QUESTIONS OR CONCERNS*.

If you have any further questions after today's interview, please contact us at [NORC 1-800 NUMBER]. If you have any questions regarding your rights as a study participant, please feel free to contact the chairman of the National Center for Health Statistics (NCHS) Research Ethics Review Board at [1-800 NUMBER].

Do you agree to participate in this study as I have described it?

[ADDITIONAL INFORMATION PROVIDED AT END OF SURVEY:]

If you have any questions or concerns about the study, please feel free to contact us at [NORC 1-800 NUMBER]. If you have questions about your rights as a survey participant, you may call the chairman of the National Center for Health Statistics (NCHS) Research Ethics Review Board at [1-800 NUMBER]. Thank you again.

[Flesh-Kincaid Grade Level: 8.7]