

Attachment C

National Health and Nutrition Examination Survey (NHANES) Electronic Digital Signature to Document Consent Description

Eligibility: All NHANES participants who currently sign hard copy consents/assents.

Informed Consent: No additional consents other than the regular NHANES consents are needed.

Exclusion Criteria: None.

Project Procedures: NHANES participants who sign consent/assent forms will be provided the ability to sign electronically rather than sign paper copies. There are no changes to the consent protocol currently in place, except that the signature will become electronic. A blank copy of the consent form(s) will be left with each respondent. If the respondent requests a copy of a printed form(s) with all of the information captured electronically, this would be provided. One signature will be obtained at the beginning of the SP or Family interview that will cover the two consents. The e-Consent would include the following household consent forms:

- a. Home Interview Consent (check box to link survey records with other records – yes/no)
- b. Parental/Guardian Permission to Audio Record the Home Interview (16-17 year olds) (check box for parent/guardian to agree or not agree to audio recording 16-17 year olds' SP interview)

The change from hard copy signature to electronic signature does not increase the burden to respondents for the consent process.

Respondent Selection RIQ E-Consent Questions

Phase 1 E-Consent Scenarios

Scenarios covered

SP Age: 0-15, 16-17 minor, 16-17 emancipated, 18+

Respondent: Proxy – parent/guardian, adult 18+, 16-17 year old minor & emancipated

Signed electronically previously: No & yes

Interpreter: No & yes

Witness required: No & Yes

Agree to e-sign: yes & no

RIQ INSERT SPECIFICATIONS

BOX INSTRUCTION:

HAS RESPONDENT SIGNED A HOME INTERVIEW FORM PREVIOUSLY (RESPONDENT PREVIOUSLY SELECTED IN RIQ.006)?

NO, CONTINUE TO HOME INTERVIEW INSTRUCTION SCREEN
 YES, SKIP TO NEXT SERIES OF QUESTION IN QUESTIONNAIRE. (CURRENTLY IF ALREADY SIGNED THE FI DOES NOT REMIND THE RESPONDENT - FI JUST CODES YES HAVE FORM AND CONTINUES.)
 IF 16-17 YEAR OLD SP AND NOT EMANCIPATED MINOR, CONTINUE (SHOULD NOT HAVE PREVIOUSLY SIGNED FORM).

RIQ.new HOME INTERVIEW INSTRUCTION SCREEN

HAND RESPONDENT COPY OF HOME INTERVIEW CONSENT FORM IN THE LANGUAGE HE/SHE READS.
 REVIEW KEY POINTS WITH RESPONDENT OR READ CONSENT FORM OUT LOUD IF NECESSARY.
 ANSWER ANY RESPONDENT QUESTIONS. (PRESS NEXT TO CONTINUE)

BOX INSTRUCTION:
 IF SP INTERVIEW, SKIP TO LINKAGE SCREEN.
 IF FAMILY INTERVIEW AND RESPONDENT HAS NOT CONSENTED TO ANY OTHER QUESTIONNAIRE AND THERE ARE SP QUESTIONNAIRES WITH NO CONSENTS YET, CONTINUE.
 IF FAMILY INTERVIEW AND RESPONDENT HAS NOT CONSENTED TO ANY OTHER QUESTIONNAIRE AND THERE ARE NO MORE SP QUESTIONNAIRES TO CONSENT TO, SKIP TO BOX 2.

RIQ.new WILL RESPONDENT BE CONSENTING TO SP QUESTIONNAIRES?

YES 1
 NO 2 (BOX 2)

RIQ.new LINKAGE SCREEN (REPLACES CURRENT QUESTION RIQ.085)

EXPLAIN THE LINKAGE CHECK BOXES AND ASK PERSON CONSENTING TO RECORD HIS/HER LINKAGE CHOICE BELOW.

We can do additional health research by linking the interview and exam data for {SP} to vital statistics, health, nutrition, and other related records. May we try to link these survey records with other records?

YES..... 1
 NO..... 2

- CAPI INSTRUCTION:
- o DEFAULT SCREEN LANGUAGE TO ENGLISH, BUT INCLUDE A DROP DOWN LIST FOR THE FI TO CHOOSE THE LANGUAGE OF THE HARDCOPY CONSENT FORM (THE LANGUAGE THE PERSON CONSENTING READS). THIS INCLUDES ENGLISH, SPANISH, CHINESE TRADITIONAL, CHINESE SIMPLIFIED, KOREAN AND VIETNAMESE.
 - o DISPLAY YES/NO OPTIONS AS RADIO BUTTON, ALLOWING ONLY ONE CHOICE.

- o DISPLAY OMB NUMBER IN UPPER RIGHT OF SCREEN.

BOX 2 INSTRUCTION –
 IF FAMILY INTERVIEW SKIP TO HARDCOPY CONSENT LANGUAGE SCREEN.
 IF SP INTERVIEW AND IS SP 16-17 YEARS OLD AND MINOR (NOT EMANCIPATED)
 (EMANCIPATION PREVIOUSLY RECORDED IN *11RIQ.020?
 IF YES, CONTINUE.
 IF NO, GO TO ADULT RESPONDENT OR PARENT/GUARDIAN OF NON-
 EMANCIPATED 16-17 YEAR OLD SIGNATURE SCREEN

RIQ.NEW PARENT/GUARDIAN PERMISSION TO AUDIO RECORD 16-17 YEAR OLD SCREEN (REPLACES CURRENT RIQ.210)

GIVE PARENT/GUARDIAN PERMISSION TO AUDIO RECORD HOME INTERVIEW FORM TO PARENT/GUARDIAN IN THE LANGUAGE HE/SHE READS.

REVIEW THAT WE WOULD LIKE TO AUDIO RECORD THE SP'S INTERVIEW OR READ CONSENT FORM OUT LOUD IF NECESSARY

ANSWER ANY QUESTIONS.

CONTINUE 1
 NOT OFFERING RECORDING.....2 (SKIP TO ADULT R OR PARENT/GUARDIAN OF 16-17 YEAR OLD SCREEN)

NOTE: COLLECT WHY NOT OFFERING RECORDING LATER IN RIQ SECTION OF INTERVIEW.

RIQ.NEW I have read the Parent/Guardian Permission to Audio Record the Home Interview.

I agree to have my child's interview recorded for quality control 1
 I do not agree to have my child's interview recorded for quality control purposes 2

CAPI INSTRUCTION:

- o DEFAULT SCREEN LANGUAGE TO ENGLISH, BUT INCLUDE A DROP DOWN LIST FOR THE FI TO CHOOSE THE LANGUAGE OF THE HARDCOPY CONSENT FORM (THE LANGUAGE THE PERSON CONSENTING READS). THIS INCLUDES ENGLISH, SPANISH, CHINESE TRADITIONAL, CHINESE SIMPLIFIED, KOREAN AND VIETNAMESE.
- o DISPLAY RESPONSE OPTIONS AS RADIO BUTTONS, ALLOWING ONLY ONE CHOICE.
- o DISPLAY OMB NUMBER IN UPPER RIGHT OF SCREEN.

RIQ.new ADULT RESPONDENT OR PARENT/GUARDIAN OF NON-EMANCIPATED 16-17 YEAR OLD SIGNATURE SCREEN (USED FOR ALL INTERVIEWS)

CAPI INSTRUCTION:

- DEFAULT SCREEN LANGUAGE TO ENGLISH, BUT INCLUDE A DROP DOWN LIST FOR THE FI TO CHOOSE THE LANGUAGE OF THE HARDCOPY CONSENT FORM (THE LANGUAGE THE PERSON CONSENTING READS). THIS INCLUDES ENGLISH, SPANISH, CHINESE TRADITIONAL, CHINESE SIMPLIFIED, KOREAN AND VIETNAMESE.
- CHECK BOX LABELED 'OFFICE USE ONLY: H' FOR FI TO CHOOSE IF RESPONDENT REFUSES TO SIGN ELECTRONICALLY BUT WILL SIGN HARDCOPY
- REFUSED BUTTON LABELED 'RF' FOR IF RESPONDENT REFUSES TO CONSENT. IF REFUSED, DISPLAY THE FOLLOWING MESSAGE: "EACH RESPONDENT FOR HOUSEHOLD

QUESTIONNAIRE MUST SIGN A HOUSEHOLD INTERVIEW CONSENT FORM BEFORE THE INTERVIEW CAN BE ADMINISTERED" (FUNCTIONS LIKE CURRENT RIQ.080-081).

- DO NOT ALLOW INSTRUMENT TO MOVE FORWARD WITHOUT A SIGNATURE, RF BUTTON OR HARDCOPY SIGNATURE ENTERED.
- DISPLAY "YES we may link these survey records with other records" if RIQ.new linkage question = 1.
- DISPLAY "NO we may not link these survey records with other records" if RIQ.new linkage question = 2
- IF SP IS 16-17 YEARS OLD, AND AGREED TO HAVE CHILD'S INTERVIEW RECORDED, DISPLAY "AGREE to have my child's interview recorded for quality control."
- IF SP IS 16-17 YEARS OLD, AND DID NOT AGREE TO HAVE CHILD'S INTERVIEW RECORDED, DISPLAY "DO NOT AGREE to have my child's interview recorded for quality control."
- COLLECT DATE AND TIME STAMP WHEN SIGNATURE IS CAPTURED.
- ABOVE SIGNATURE BOX, DISPLAY "I have read the Home Interview Consent Form {and Parent/Guardian Permission to Audio Record Home Interview Form}. I agree to proceed with the interview." BELOW ALLOW ADEQUATE SPACE FOR RESPONDENT TO SIGN. DISPLAY "and Parent/Guardian Permission to Audio Record Home Interview Form" IF PARENT PERMISSION TO AUDIO RECORD 16-17 YO SCREEN IS ANSWERED 1/YES OR 2/NO.
- DISPLAY OMB NUMBER IN UPPER RIGHT OF SCREEN.

BOX INSTRUCTION – IF RESPONDENT REQUESTED HARDCOPY SIGNATURE, SKIP TO HARDCOPY SIGNATURE SCREEN.

IF SP IS 16-17 MINOR (NOT EMANCIPATED) CONTINUE.

IF RESPONDENT SIGNED ELECTRONICALLY AND IS NOT 16-17 YEAR OLD MINOR, SKIP TO WITNESS/INTERPRETER REQUIRED QUESTION.

RIQ.new 16-17 YEAR OLD SP (NON EMANCIPATED) SIGNATURE SCREEN

CAPI INSTRUCTION:

- DEFAULT SCREEN LANGUAGE TO ENGLISH, BUT INCLUDE A DROP DOWN LIST FOR THE FI TO CHOOSE THE LANGUAGE OF THE HARDCOPY CONSENT FORM (THE LANGUAGE THE PERSON CONSENTING READS). THIS INCLUDES ENGLISH, SPANISH, CHINESE TRADITIONAL, CHINESE SIMPLIFIED, KOREAN AND VIETNAMESE.
- CHECK BOX LABELED 'OFFICE USE ONLY: H' FOR FI TO CHOOSE IF RESPONDENT REFUSES TO SIGN ELECTRONICALLY BUT WILL SIGN HARDCOPY
- REFUSED BUTTON LABELED 'RF' FOR IF RESPONDENT REFUSES TO CONSENT. IF REFUSED, DISPLAY THE FOLLOWING MESSAGE: "EACH RESPONDENT FOR HOUSEHOLD QUESTIONNAIRE MUST SIGN A HOUSEHOLD INTERVIEW CONSENT FORM BEFORE THE INTERVIEW CAN BE ADMINISTERED" (FUNCTIONS LIKE CURRENT RIQ.080-081).
- DO NOT ALLOW INSTRUMENT TO MOVE FORWARD WITHOUT A SIGNATURE, RF BUTTON OR HARDCOPY SIGNATURE ENTERED.
- DISPLAY "YES we may link these survey records with other records" if RIQ.new linkage question = 1.
- DISPLAY "NO we may not link these survey records with other records" if RIQ.new linkage question = 2
- IF SP IS 16-17 YEARS OLD, AND PARENT AGREED TO HAVE CHILD'S INTERVIEW RECORDED, DISPLAY "PARENT AGREED to have my interview recorded for quality control."
- IF SP IS 16-17 YEARS OLD, AND PARENT DID NOT AGREE TO HAVE CHILD'S INTERVIEW RECORDED, DISPLAY "PARENT DID NOT AGREE to have my interview recorded for quality control."
- COLLECT DATE AND TIME STAMP WHEN SIGNATURE IS CAPTURED.
- ABOVE SIGNATURE BOX, DISPLAY "I have read the Home Interview Consent Form. I agree to proceed with the interview." BELOW ALLOW ADEQUATE SPACE FOR RESPONDENT TO SIGN
- DISPLAY OMB NUMBER IN UPPER RIGHT OF SCREEN.

RIQ.new WITNESS/INTERPRETER REQUIRED SCREEN

IS A WITNESS/INTERPRETER SIGNATURE REQUIRED?

- WITNESS 1
- INTEPRETER..... 2 (INTERPRETER SIGNATURE SCREEN)
- NO 3 (PRINTED HARDCOPY FORM REQUESTED SCREEN)

RIQ.new WITNESS SIGNATURE SCREEN

CAPI INSTRUCTION:

- DISPLAY IN ENGLISH
- WITNESS MUST SIGN ELECTRONICALLY IF RESPONDENT DID.
- DO NOT ALLOW INSTRUMENT TO MOVE FORWARD WITHOUT A SIGNATURE
- COLLECT DATE AND TIME STAMP WHEN SIGNATURE IS CAPTURED.
- ABOVE SIGNATURE BOX, DISPLAY, "I observed the interviewer read this form to the RESPONDENT NAME and {he/she} agreed to participate by electronically signing or marking." BELOW ALLOW ADEQUATE SPACE FOR WITNESS TO SIGN.
- SKIP TO RIQ.NEW (PRINTED HARDCOPY FORM REQUESTED SCREEN).

RIQ.new INTERPRETER SIGNATURE SCREEN

CAPI INSTRUCTION:

- DISPLAY IN ENGLISH
- INTERPRETER MUST SIGN ELECTRONICALLY IF RESPONDENT DID.
- DO NOT ALLOW INSTRUMENT TO MOVE FORWARD WITHOUT A SIGNATURE
- COLLECT DATE AND TIME STAMP WHEN SIGNATURE IS CAPTURED.
- ABOVE SIGNATURE BOX, DISPLAY, "I interpreted this form to the RESPONDENT NAME and {he/she} agreed to participate by electronically signing or marking." BELOW ALLOW ADEQUATE SPACE FOR INTERPRETER TO SIGN.

RIQ.new PRINTED HARDCOPY FORM REQUESTED SCREEN

DID RESPONDENT REQUEST A COPY OF THE CONSENT FORM(S) WITH HIS/HER SIGNATURE PRINTED BE MAILED?

- YES 1 (SKIP TO NEXT RIQ QUESTION)
- NO 2 (SKIP TO NEXT RIQ QUESTION)

CAPI INSTRUCTION: THIS QUESTION IS NECESSARY IF NOT ALL RESPONDENTS WILL RECEIVE A PRINTED COPY OF FORM FILLED OUT (CURRENTLY GETTING JUST BLANK HARDCOPY). IF NOT ALL RESPONDENTS WILL RECEIVE A PRINTED FILL OUT COPY OF THE CONSENT, THEN AN ELECTRONIC INDICATOR (VARIABLE/ALERT/FLAG?) WILL NEED TO BE SET TO KNOW WHICH RESPONDENTS REQUESTED THE PRINTED FORMS. IF EVERYONE IS MAILED A COPY OF THE CONSENT FORM WITH CHECK BOXES MARKED AND HIS/HER SIGNATURE, THEN THIS QUESTION CAN BE REMOVED.

RIQ.newXX HARDCOPY SIGNATURE SCREEN

ASK RESPONDENT TO SIGN TWO COPIES OF THE HOME INTERVIEW CONSENT FORM. HAVE RESPONDENT KEEP ONE COPY AND COLLECT ONE IN THE HH FOLDER AND RETURN TO FIELD OFFICE.

TO COMPLETE THE HARDCOPY FORM:

- PRINT NAME OF PERSON ANSWERING QUESTIONS
- CHECK BOXES REGARDING LINKING WITH OTHER VITAL RECORDS
- IF 16-17 YEAR OLD RESPONDENT ANSWERING FOR HIM/HERSELF, SP SIGNS FORM AND PARENT/GUARDIAN SIGNS FORM.
- IF 16-17 YEAR OLD EMANCIPATED MINOR, SP SIGNS FORM AND CHECK BOX FOR EMANCIPATED MINOR TO DOCUMENT THAT A PARENT/GUARDIAN SIGNATURE IS NOT REQUIRED.
- IF NOT 16-17 YEAR OLD RESPONDENT, SIGNED BY RESPONDENT WHO IS ANSWERING FOR CHILD 0-15, BY ADULT SP, OR PROXY FOR AN ADULT.
- SIGNED BY WITNESS/INTERPRETER (IF NECESSARY)
- SIGNED BY STAFF MEMBER
- RECORD HH & FAMILY ID
- CHECK QUESTIONNAIRE BOXES FOR ALL COMPLETED WITH RESPONDENT (SPS & FAMILY)
- RECORD NAMES OF ALL CHILDREN OR ADULT PROXY PARENT IS RESPONDING FOR ALONG WITH SP IDS

PRESS NEXT TO CONTINUE

RIQ.080 HAS RESPONDENT SIGNED THE HARDCOPY HOUSEHOLD INTERVIEW CONSENT FORM?
(CURRENT QUESTION)

CAPI INSTRUCTION:

IF 'NO' (CODE 2), DISPLAY THE FOLLOWING MESSAGE: "EACH RESPONDENT FOR HOUSEHOLD QUESTIONNAIRE MUST SIGN A HOUSEHOLD INTERVIEW CONSENT FORM BEFORE THE INTERVIEW CAN BE ADMINISTERED" AND RETURN TO RIQ.080.

IF REFUSED, EXIT INTERVIEW.

NOTE: IF INTERPRETER USED, RESPONDENT MUST SIGN FORM.

SET FORM TYPE VARIABLE TO HARDCOPY SO THAT ISIS E/S KNOWS A HARDCOPY FORM NEEDS TO BE IMAGE SCANNED.

YES..... 1
NO..... 2
REFUSED..... 7

Consent Signature Screen Example for Parent/Guardian of 16-17 year old SP

Language: OMB: 0920-0950

YES we may link these survey records with other records. AGREE to have my child's interview recorded for quality control.

I have read the Home Interview Consent Form and Parent/Guardian Permission to Audio Record Home Interview Form. I agree to proceed with the interview.

OFFICE USE ONLY: H

619-03-0025-01-01 HPQ v. 6.90/5.00 Home Interview Consent Form RIQnew

Annotations:

- Form Language Selection
- Check box text
- Signature box text (minor modifications to mention form(s) instead of "information above")
- Signature capture
- Check box for FI to indicate if person signing prefers to not sign electronically but hardcopy.
- Refusal button for FI to indicate refusal to consent