Recruitment Strategy Substudy

Low-Intensity Pregnancy Visit 1 CATI Questionnaire

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DOCUMENT HISTORY

DATE	VERSION	SUMMARY OF CHANGE/MILESTONE
5/24/2010	NA	HAUGEN AND SCHOENDORF determined
		questions to be included in the Low-Intensity CATI
		Pregnancy Screener
5/25/2010	20100525	HASHEMI incorporated questions into desired format
5/26/2010	20100526-bjh	HAUGEN made revisions and provided comments when necessary
5/27/2010	20100526-bjh_jj	INCORPORATE VARIABLE SOURCES
5/27/2010	20100527	IRB TEAM added interview instructions to confirm
		that consent script was administered; added closing
		script; inserted skip pattern to CS007
6/2/2010	20100602	Comments from NCS PO
6/2/2010	20100602	INFORMAL SUBMISSION TO OMB
6/3/2010	20100603	INCORPORATE COMMENTS FROM OMB
		HIGHLIGHT LANGUAGE PERTAINING TO
		ELIGIBILITY (TO BE CORRECTED)
6/7/2010	20100607	INCORPORATE CHANGES FROM J. PARK
6/7/2010	20100607a	INCORPORATE CHANGES FROM J. SLUTSMAN
6/7/2010	20100607a	FORMAL SUBMISSION TO OMB
6/16/2010	20100616	GRABER COMMENTS
6/25/2010	20100624	Integrated changes from Slutsman, Schoendorf, and Park
7/1/2010	20100701	Additional revisions incorporated
7/14/2010	20100714	Accept format changes
7/15/2010	20100714	SUBMISSION TO OMB
		INCORPORATE COMMENTS FROM OMB
		SUBMIT TO NICHD IRB
		RECONCILE WITH DATA ELEMENTS TABLES

NOTE: Italics denote anticipated development stages

CATI

INTERVIEWER-COMPLETED QUESTIONS

[COMPLETION OF LOW-INTENSITY CONSENT MUST BE OBTAINED FIRST; ASSUME COMPLETION OF LOW-INTENSITY CATI PREGNANCY SCREENER OR RETURN OF PPG SELF-ADMINISTERED QUESTIONNAIRE]

(TIME_STAMP_1) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

[IF ADMINISTRATION OF QUESTIONNAIRE OCCURS DURING A SEPARATE EVENT FROM THE CONSENT ADMINISTRATION, ADD INTRODUCTORY STATEMENTS APPROPRIATE FOR INCOMING OR OUTGOING CALLS]

OPTION 1: INBOUND CALL TO STUDY CENTER FROM CONSENTED PARTICIPANT

Thank you for calling the National Children's Study. (TIME_STAMP_2)

OPTION 2: OUTBOUND CALL FROM STUDY CENTER TO CONSENTED PARTICIPANT

(FEMALE_1) Hello, my name is [DATA COLLECTOR'S NAME]. I'm calling from the [LOCAL STUDY CENTER NAME]. I'd like to speak with [NAME OF CONSENTED WOMAN]. Is she available?

YES1	(TIME STAMP 2)
NO2	
REFUSED1	• - /
DON'T KNOW2	(BEST_TTC1)

PROGRAMMER INSTRUCTION: PRELOAD NAME OF CONSENTED PARTICIPANT

(BEST_TTC_1) What would be a good time to reach her?

INTERVIEWER INSTRUCTIONS: ENTER IN HOUR AND MINUTE VALUES; AND SELECT AM OR PM

H H M M	
REFUSEDDON'T KNOW	

(BEST_TTC_2)

	AM
	REFUSED1 DON'T KNOW2
(BEST	_TTC_3)
	AFTER TIME REPORTED
(PHON	NE) Is this a good phone number to reach [NAME]? YES
PI	ROGRAMMER INSTRUCTION: PRELOAD NAME OF CONSENTED PARTICIPANT
(РНО	NE_NBR) Would you please tell me a telephone number where she can be reached?
	_ - _ - _ - _ -1 REFUSED1 DON'T KNOW
	_UNAVAIL) Thank you again for speaking with me today. Please ask her to call us a AL SC TOLL-FREE NUMBER].
	VIEWER INSTRUCTION: END INTERVIEW AND DISPOSITION CASE AS OPRIATE

(TIME_STAMP_2) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

[WHEN SPEAKING TO CONSENTED PARTICIPANT]

PS002.We are asking women of childbearing age a few questions about pregnancy. Not all women who answer these questions will be able to take part in the National Children's Study <u>now</u>, but almost every woman who answers these questions will have a chance to take part in some way in the future. We first want to know....

PS004.(PREGNANT) IF ADULT IS KNOWN TO BE PREGNAN you pregnant now?	IT, ADD [Just to confirm,] Are
YES	1
	GO TO (TIME_STAMP_3); SET (PPG_FIRST) = 1
NO, NO ADDITIONAL INFORMATION PROVIDED	
(IF VOLUNTEERED BY RESPONDENT) NO, RECENTLY LOST PREGNANCY (MISCARRIAGE/	ABORTION)3
	GO TO (TIME_STAMP_3); SET (PPG_FIRST) = 3
NO, RECENTLY GAVE BIRTH	4 GO TO (TIME_STAMP_11); SET (PPG_FIRST) = 4
NO, UNABLE TO HAVE CHILDREN (HYSTERECTOMY	<pre>7, TUBAL LIGATION) 5 GO TO (TIME_STAMP_11); SET (PPG_FIRST) = 5</pre>
	1 (TIME_STAMP_5) 2 (TIME_STAMP_5)

CURRENT PREGNANCY INFORMATION

(TIME_STAMP_3) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

PROGRAMMER INSTRUCTIONS:

- IF (PPG_FIRST) = 1 THEN GO TO (CP000) THEN TO (DUE_DATE)
- IF **(PPG_FIRST)** = 3 THEN GO TO (CP001A)

CP000. We'll begin by asking some questions about you, your health, and your health history. First, I'll ask about your current pregnancy.

CP001A. I'm so sorry to hear that you've lost your baby. I know this can be a hard time.

INTERVIEWER INSTRUCTIONS: USE SOCIAL CUES AND PROFESSIONAL JUDGMENT IN RESPONSE

PROGRAMMER/INTERVIEWER INSTRUCTION:

- IF SC HAS PREGNANCY LOSS INFORMATION TO DISSEMINATE, OFFER TO RESPONDENT AND GO TO CP001C/(LOSS_INFO).
- OTHERWISE GO TO CS007/(END2).

YES NO		1 (CS007) /(END2). 2 (CS007) /(END2).	
CP002 /(DUE _	DATE) What is your	current due date?	
REFUS DON'T INTERVIEWER INSTRUC • ENTER A TWO DI	KNOW CTION: IGIT MONTH, TWO DIG AS DETERMINED TO B		ID
APPROPRIATE M 0 IF DATE IS INTERVIEW MORE THA 0 IF DATE IS INTERVIEW OCCURREI 0 IF VALID DO REPORTED	ED DUE DATE AGAINS IESSAGE: MORE THAN 9 MONTH VER INSTRUCTION: "Y IN 9 MONTHS FROM TO MORE THAN 1 MONTH VER INSTRUCTION: "Y D MORE THAN A MONTH UE DATE WAS PROVID D; GO TO (KNOW_DAT	ST CURRENT DATE; DISPLAY HS AFTER CURRENT DATE, DISPLAY YOU HAVE ENTERED A DATE THAT IS ODAY. RE-ENTER DATE." H BEFORE CURRENT DATE, DISPLAY YOU HAVE ENTERED A DATE THAT TH BEFORE TODAY. RE-ENTER DATE DED, SET (DUE_DATE) = YYYYMMDD A TE) O TO CP004 (DATE_PERIOD)	E."
CP003/(KNOW_DATE)	How did you find out	your due date?	
HAD DOC REF	AN ULTRASOUND TO TOR OR OTHER PRO\ WITHOUT A USED	1 (DATE_PERIOD) FIGURE IT OUT. 2 (DATE_PERIOD) VIDER TOLD ME. N ULTRASOUND 3 (DATE_PERIOD) -1 (DATE_PERIOD) -2 (DATE_PERIOD)	
CP004/(DATE_PERIOD). What was the first day of your last menstrual period?			
		MONTH:	

CP001C/**(LOSS_INFO)**. DID RESPONDENT REQUEST ADDITIONAL INFORMATION ON COPING WITH PREGNANCY LOSS?

DAY: <u> </u> D D
YEAR:
REFUSED
CONFIRM DATE. IF DATE IS CORRECT, ENTER 'DON'T KNOW'." O IF DATE IS AFTER CURRENT DATE, DISPLAY INTERVIEWER INSTRUCTION: "YOU HAVE ENTERED A DATE THAT HAS NOT OCCURRED YET. RE-ENTER DATE." O IF VALID DATE WAS PROVIDED, CALCULATE DUE DATE FROM THE FIRST DATE OF LAST MENSTRUAL PERIOD AND SET (DUE_DATE) (YYYYMMDD) = (DATE_PERIOD) + 280 DAYS; GO TO (KNEW_DATE)
CP004a /(KNEW_DATE). DID RESPONDENT GIVE DATE?
RESPONDENT GAVE COMPLETE DATE
(TIME_STAMP_4) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP
CP005/(HOME_TEST). Did you use a home pregnancy test to help find out you were pregnant?
YES
CP008/(BIRTH_PLAN). Where do you plan to deliver your baby?
In a hospital,

	Some other place?	• • • • •
	REFUSED DON'T KNOW	1 (CP010) /(PN_VITAMIN)
CP009.	What is the name and address of the place where y baby?	you are planning to deliver you
	NAME OF BIRTH HOSPITAL/BIRTHING CENTER (B	IRTH_PLACE)
	STREET ADDRESS (B_ADDRESS_1)/(B_ADDRESS	5_2)
	CITY (B_CITY)	73
	_ _ STATE ZIP CODE	(0)
	(B_STATE) (B_ZIPCODE)	
	REFUSED DON'T KNOW	1 2
	PN_VITAMIN) . In the month before you became p nultivitamins, prenatal vitamins, or folic acid?	regnant, did you regularly take
	YES NO REFUSED DON'T KNOW	1
CP012 /(PREG_VITAMIN). Since you've become pregnar multivitamins, prenatal vitamins, or folic acid?	nt, have you regularly taker
0	YES	2 1
DV003/ (DATE_VISIT). What was the date of your most rece you've become pregnant?	nt doctor's visit or checkup since
		MONTH: <u> </u>
	M M DAY:	<u> _</u>
	D D	1 1 1

$\mathsf{Y} \quad \mathsf{Y} \quad \mathsf{Y} \quad \mathsf{Y}$

	HAVE NOT HAD A VISIT
DV013.	At this visit or at any time during your pregnancy, did the doctor or other health care provider tell you that you have any of the following conditions?
	INTERVIEWER INSTRUCTIONS: RE-READ INTRODUCTORY STATEMENT AS NEEDED
	(DIABETES_1) Diabetes?
	YES
care pro	[At this visit or] at any time during your pregnancy, did the doctor or other health vider tell you that you had]
	(HIGHBP_PREG) High blood pressure?
	YES
	(URINE) Protein in your urine?
	YES 1 NO 2 REFUSED -1 DON'T KNOW -2
	(PREECLAMP) Preeclampsia or toxemia?
Ob	YES
	(EARLY_LABOR) Early or premature labor?
	YES

DON'T KNOW2
(ANEMIA) Anemia or low blood count?
YES
(NAUSEA) Severe nausea or vomiting (hyperemesis)?
YES
(KIDNEY) Bladder or kidney Infection?
YES
(RH_DISEASE) Rh disease or isoimmunization?
YES
(GROUP_B) Infection with a bacteria called Group B strep?
YES
(HERPES) Infection with a Herpes virus?
YES
(VAGINOSIS) Infection of the vagina with bacteria (bacterial vaginosis?
YES
(OTH_CONDITION) Any other serious condition?

YES	
NO REFUSED	-
DON'T KNOW	
DV014. (CONDITION_OTH)	
SPECIFY	
REFUSED	1
DON'T KNOW	2
MEDICAL HISTO	ORY
(TIME_STAMP_5) PROGRAMMER INSTRUCTION:	INSERT DATE/TIME STAMP
MC001. This next question is about your health when you are not	pregnant.
MC002./(HEALTH)Would you say your health in general is	
Excellent,	1
Very good,	2
Good,	
Fair, or	4 5
REFUSED	-1
Poor?REFUSEDDON'T KNOW	-2
MC103./(HEIGHT_FT) ./(HT_INCH). How tall are you without shoe	es?
T cot.	
REFUSED	
DON'T KNOW	-2
PROGRAMMER INSTRUCTIONS:	
INCLUDE A SOFT EDIT IF HEIGHT_FT > 7 OR <	
 IF HEIGHT_FT IS PROVIDED INCLUDE A SOFT IF HEIGHT_FT IS NOT PROVIDED INCLUDE A SOFT 	
MC104./(WEIGHT). What was your weight just before you became	e pregnant?
<u> </u>	

	Pounds	
	REFUSEDDON'T KNOW	
F	PROGRAMMER INSTRUCTIONS: INCLUDE A SOFT ED	OIT IF WEIGHT < 90 OR > 400
MC110.	The next questions are about medical conditions or he now or may have had in the past .	alth problems you might have
MC003/ ((ASTHMA). Have you ever been told by a doctor or other had asthma?	r health care provider that you
	YES	1 2 -1 -2
MC004/ ((HIGHBP_NOTPREG). (Have you ever been told by a provider that you had)	a doctor or other health care
	Hypertension or high blood pressure when you're not p	regnant?
	YES NO	-1
MC005/ (DIABETES_NOTPREG) (Have you ever been told by provider that you had)	a doctor or other health care
	High blood sugar or Diabetes when you're not pregnant	?
	YES NO REFUSED DON'T KNOW	2 (THYROID_1) -1 (THYROID_1)
MC005a	/(DIABETES_2) Have you taken any medicine or received diabetes in the past 12 months?	red other medical treatment for
	YES	2 (DIABETES_3) -1 (DIABETES_3)

MC005b/(DIABETES_3) Have you ever taken insulin?
YES 1 (THYROID_1) NO 2 (THYROID_1) REFUSED -1 (THYROID_1) DON'T KNOW -2 (THYROID_1)
MC006/ (THYROID_1) (Have you ever been told by a doctor or other health care provider that you had) Hypothyroidism, that is, an under active thyroid?
YES
MC006a/(THYROID_2) Have you taken any medicine or received other medical treatment for a thyroid problem in the past 12 months?
YES
MC012A. This next question is about where you go for routine health care.
MC012/(HLTH_CARE). What kind of place do you usually go to when you need routine o preventive care, such as a physical examination or check-up?
Clinic or health center
HEALTH INSURANCE

(TIME_STAMP_6) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

14

HI000.Now I'm going to switch to another subject and ask about health insurance.

HI001/(INSURE) Are you currently covered by any kind of health insurance or some other kind of health care plan?
YES
HI002.Now I'll read a list of different types of insurance. Please tell me which types you
currently have.
INTERVIEWER INSTRUCTIONS: RE-READ INTRODUCTORY STATEMENT AS NEEDED
(Do you currently have)
(INS_EMPLOY) Insurance through an employer or union either through yourself or another family member?
YES
(INS_MEDICAID) Medicaid or any government-assistance plan for those with low incomes or a disability?
YES
INTERVIEWER INSTRUCTIONS: PROVIDE EXAMPLES OF LOCAL MEDICAID PROGRAMS
(INS_TRICARE) TRICARE, VA, or other military health care?
YES

(INS_IHS) Indian Health Service?	
YES	1
NO	
REFUSED	
DON'T KNOW	-2
(INS_MEDICARE) Medicare, for people with certain	disabilities?
YES	1
NO	2
REFUSED	
DON'T KNOW	-2
(INS_OTH) Any other type of health insurance or health	alth coverage plan?
YES	1
NO	2
REFUSED	-1
DON'T KNOW	-2
HOUSING CHARACTERIS	TICS
(TIME_STAMP_7) PROGRAMMER INSTRUCTION:	INSERT DATE/TIME STAMP
HC004/(AGE_HOME). Can you tell us, which of these categories when your home or building was built?	es do you think best describes
2001 TO PRESENT	1
1981 TO 2000	
1961 TO 1980	3
1941 TO 1960	4
1940 OR BEFORE	5
REFUSED	
DON'T KNOW	-2
HC007/(MAIN_HEAT)Which of these types of heat sources be	est describes the main heating
fuel source for your home? Is it	st describes the main heating
Electric	1
Gas – Propane or LP	
Oil	3
Wood	
Kerosene or Diesel	
Coal or Coko	6

	Solar Energy	8 9 -5 -1	(HC012) /(COOLING) (MAIN_HEAT_OTH) (HC012) /(COOLING) (HC012) /(COOLING)
HC012	HC007A. (MAIN_HEAT_OTH) SPECIFY	nds of c	cooling systems do you
	Window or wall air conditioners,	6	1 2 3 4 -5 (COOLING_OTH) -1 -2
HC012A	/(COOLING_OTH) SPECIFY REFUSED DON'T KNOW		
HC033.	Now I'd like to ask about the water in your home.		
HC034 /(WATER_DRINK). What water source in your home do drinking:	you us	e most of the time for
O _K	Tap water, Filtered tap water, Bottled water, or Some other source? REFUSED DON'T KNOW	2 3 -5 (WA 7 -1	ΓER_DRINK_OTH)

	SPECIFY
	REFUSED1 DON'T KNOW2
	TOBACCO AND ALCOHOL USE
	(TIME_STAMP_8) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAM
DA011/	(CIG_NOW)Currently, do you smoke cigarettes?
	YES 1 NO 2 (DA027)/(DRINK_NOW) REFUSED -1 (DA027)/(DRINK_NOW) DON'T KNOW -2 (DA027)/(DRINK_NOW)
DA012/	(CIG_NOW_FREQ). Do you smoke cigarettes
	Every day
DA013 <i>I</i>	(CIG_NOW_NUM).On days that you smoke, how many cigarettes do you smoke per day?
	_ NUMBER PER DAY
	REFUSED1 DON'T KNOW2
)	INTERVIEWER/PROGRAMMER INSTRUCTIONS: • IF RESPONDENT ANSWERS 1 OR LESS PER DAY, ENTER "1." • INCLUDE SOFT EDIT IF RESPONSE > 60 • IF RESPONSE IS IN PACKS, CALCULATE 20 CICARETTES DEP DACK

DA027/(DRINK_NOW). How often do you currently drink alcoholic beverages?

	2-4 times a week
(TIME_STA	
	REFUSED1 (TIME_STAMP_9) DON'T KNOW2 (TIME_STAMP_9)
	V_NUM) . Currently , on days that you drink alcoholic beverages, how ou have per day?
	 NUMBER OF DRINKS
	DON'T KNOW2
	VER INSTRUCTIONS: SPONDENT ANSWERS LESS THAN 1 PER DAY, ENTER "1."
DA029 I(DRINK_NOV hours?	V_5) . Currently , how often do you have 5 or more drinks within a couple of
	Never
	REFUSED1 DON'T KNOW2
INTERVIEW REQUIREM	VER INSTRUCTIONS: FOLLOW LOCAL MANDATORY REPORTING IENTS.
(TIME_S	TAMP_9) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

EV000. We would now like to take a few minutes to ask some questions about your experience

(TIME_STAMP_10) PROGRAMMER INSTRUCTION: INSERT DATE/TIME

EVALUATION QUESTIONS

STAMP

in the study. EV001. How important was each of the following in your decision to take part in the National Children's Study? (LEARN) (How important was...) Learning more about my health or the health of my child? Not at all important......1 Somewhat important..... Very important......3 (HELP) (How important was...) Feeling as if I can help children now and in the future? Not at all important......1 Very important......3 (INCENT) (How important was...) Receiving money or gifts for taking part in the study? Not at all important......1 Somewhat important..... Very important......3 (RESEARCH) (How important was...) Helping doctors and researchers learn more about children and their health? (EN\ ay affect ch

Not at all important
(IR) (How important was) Helping researchers learn how the environment mildren's health?
Not at all important
MMUNITY) (How important was) Feeling part of my community?
Not at all important

(KNOW_OTHERS) (How important was) Knowing other women in the study?			
Not at all important			
(FAMILY) (How important was) Having family members or friends support my choice to part in the study?	tak		
Not at all important			
(DOCTOR) (How important was) Having my doctor or health care provider support my choice to take part in the study?			
Not at all important			
EV004. How negative or positive do each of the following people feel about you taking pa the National Children's Study?	rt in		
(OPIN_SPOUSE) Your spouse or partner			
Very Negative1Somewhat Negative2Neither Positive or Negative3Somewhat Positive4Very Positive5Not Applicable-7			
(OPIN_FAMILY) Other family members			
Very Negative1Somewhat Negative2Neither Positive or Negative3Somewhat Positive4Very Positive5Not Applicable-7			
(OPIN_FRIEND)Your friendsVery Negative1Somewhat Negative2Neither Positive or Negative3			

Very Positiv	Positive	
(OPIN_DR) You	r doctor or health care provider	
Somewhat Neither Pos Somewhat Very Positiv	ive	ces only
EV005/ (EXPER) been	IENCE). In general, has your experience with the	National Children's Study
	Mostly negative	
	PVE) . In your opinion, how much do you think the e the health of children now and in the future?	National Children's Study will
	Not at all	2 3
EV008./(INT_LE	ENGTH) Did you think the interview was	
	Too short	
EV009./(INT_ST	TRESS) Do you think the interview was	
	Not at all stressful	
EV0 this again?	10. /(INT_REPEAT) If you were asked, would you	participate in an interview like
	VES	1

O 2

CONCLUSION

(TIME_STAMP_11) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

PROGRAMMER INSTRUCITONS:

- IF PPG_FIRST = 3 GO TO (END2) ELSE GO TO (END1)
- CO001/(END1). Thank you for participating in the National Children's Study and for taking the time to answer our questions. We will contact you in about 6 months to ask you some more questions. If there are any other women in your household age [LOCAL AGE OF MAJORITY] 49, (please have her | she may) contact us at [STUDY CENTER TOLL-FREE NUMBER].
- CS007/(END2). Thank you for taking the time to answer these questions. Based on what you've told me, you are not eligible to take part in the study.

(TIME_STAMP_12) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP