

OMB #: 0925-0593
Expiration Date: xx/xxxx

JULY LAUNCH VERSION
VERSION 6/7/2010

ASSUME PRE-PREGNANCY VISIT WAS
ADMINISTERED UNLESS NOTED

Recruitment Strategy Substudy
Pregnancy Probability Group Follow Up
CATI Instrument

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

TABLE OF CONTENTS

CATI

1. PREGNANCY SCREENER.....
2. TRACING QUESTIONS.....

DOCUMENT HISTORY

DATE	VERSION	SUMMARY OF CHANGE/MILESTONE
5/20/2010	CATI_v1	Schoendorf draft with Graber's programming and operational content
5/20/2010	20100520	Formatted for IRB; modification of (STATUS) PPG_GROUP=5 language; yet to apply to all relevant instruments; add in tracing questions.
5/21/2010	20100520_jg_edits	Modified tracing items.
5/21/2010	20100521	Accepted Graber's comments; tweak of phone number item.
5/24/2010	20100521	INFORMAL SUBMISSION TO OMB
5/26/2010	20100526	Additional comments from Jessica
5/26/2010	20100526	INCORPORATE COMMENTS FROM OMB (no changes)
5/27/2010	20100527	Revised closing scripts
5/28/2010	20100527	Comments from SDSU
6/3/2010	20100603	Incorporated changes from Program Office Staff and checked for eligibility-related language
6/7/2010	20100607	Accepted changes from previous version
6/7/2010	20100607a	Incorporate changes from J. Slutsman
		<i>COMMENTS FROM HIRSCHFELD</i>
		<i>RECONCILE WITH DATA ELEMENTS TABLES</i>
		<i>FORMAL SUBMISSION TO OMB</i>
		<i>INCORPORATE COMMENTS FROM OMB</i>
		<i>SUBMIT TO NICHD IRB</i>
		<i>RECONCILE WITH DATA ELEMENTS TABLES</i>

NOTE: *Italics denote anticipated development stages*

CATI

PG001 / **(TIME_STAMP_1)** PROGRAMMER INSTRUCTIONS: ENTER DATE/TIME STAMP

PG002 Hello. My name is [INTERVIEWER FIRST AND LAST NAME] from the National Children's Study. It's been a few months since we have spoken with you.

We're following up with women of childbearing age and our first questions are always about pregnancy. We first want to know...

PG003 / **(PREGNANT)** Are you pregnant now?

YES	1	PG005	/	(PPG_DUE_DATE_1)
NO	2	PG004	/	(TRYING)
RECENTLY LOST PREGNANCY (MISCARRIAGE OR ABORTION)	3	PG010	/	(MED_UNABLE)
RECENTLY GAVE BIRTH	4	PG011	/	(STATUS)
UNABLE TO HAVE CHILDREN (E.G., HYSTERECTOMY, TUBAL LIGATION)	5	PG010	/	(MED_UNABLE)
REFUSED	-1	PG004	/	(TRYING)
DON'T KNOW	-2	PG004	/	(TRYING)

INTERVIEWER INSTRUCTIONS: ENTER "YES" EVEN IF R IS UNSURE THAT SHE IS PREGNANT

PROGRAMMER INSTRUCTIONS:

- IF (PREGNANT = 1); SET PPG_GROUP = 1 (PREGNANT AND ELIGIBLE)
- IF (PREGNANT = 3); SET PPG_GROUP = 3 (HIGH PROBABILITY-RECENT LOSS)
- IF (PREGNANT = 4); SET PPG_GROUP = 4 (OTHER PROBABILITY – NOT PREGNANT AND NOT TRYING)

- REFERENCE CODE LIST: PREGNANCY_TRYING_STATUS_CL1

PG004 / **(TRYING)** Are you currently trying to become pregnant?

YES	1	PG010	/	(MED_UNABLE)
NO	2	PG010	/	(MED_UNABLE)
RECENTLY LOST PREGNANCY (MISCARRIAGE OR ABORTION)	3	PG011	/	(STATUS)
RECENTLY GAVE BIRTH	4	PG011	/	(STATUS)
UNABLE TO HAVE CHILDREN (E.G., HYSTERECTOMY, TUBAL LIGATION)	5	PG010	/	(MED_UNABLE)
REFUSED	-1	PG010	/	(MED_UNABLE)
DON'T KNOW	-2	PG010	/	(MED_UNABLE)

INTERVIEWER INSTRUCTIONS: DO NOT DEFINE "TRYING TO BECOME PREGNANT"

PROGRAMMER INSTRUCTIONS:

- IF (TRYING = 1); SET PPG_GROUP = 2 (HIGH PROBABILITY - TRYING TO CONCEIVE)
- IF (TRYING = 3); SET PPG_GROUP = 3 (HIGH PROBABILITY-RECENT LOSS)
- IF (TRYING = 4); SET PPG_GROUP = 4 (OTHER PROBABILITY – NOT PREGNANT AND NOT TRYING)

- REFERENCE CODE LIST: PREGNANCY_TRYING_STATUS_CL1

PG005 / **(PPG_DUE_DATE_1)** [Congratulations.] When is your baby due?

___ / ___ / _____		PG011	/	(STATUS)
M M D D Y Y Y Y				
REFUSED	-1	PG006	/	(DATE_PERIOD)

DON'T KNOW -2 PG006 / (DATE_PERIOD)

INTERVIEWER INSTRUCTIONS: ENTER A TWO DIGIT MONTH, TWO DIGIT DAY, AND A FOUR DIGIT YEAR.

PROGRAMMER INSTRUCTIONS:

SOFT EDIT:

- IF DATE IS MORE THAN NINE MONTHS AFTER CURRENT DATE, DISPLAY, "You have entered a date that is more than nine months from today. Confirm date and re-enter it."

HARD EDIT:

- IF DATE IS MORE THAN TEN MONTHS AFTER CURRENT DATE, DISPLAY, "You have entered a date that is more than ten months from today. Re-enter date."
- IF DATE IS MORE THAN 1 MONTH BEFORE CURRENT DATE, DISPLAY, "You have entered a date that occurred more than a month before today. Re-enter date."

IF DATE IS COMPLETE, SET (PPG_DUE_DATE_2) TO DATE PROVIDED; ELSE GO TO (DATE_PERIOD)

PG006 / (DATE_PERIOD) What was the first day of your last menstrual period?

___ / ___ / _____ PG011 / (STATUS)

M M D D Y Y Y Y

REFUSED -1 PG007 / (WEEKS_PREG)

DON'T KNOW -2 PG007 / (WEEKS_PREG)

INTERVIEWER INSTRUCTIONS: ENTER A TWO DIGIT MONTH, TWO DIGIT DAY, AND A FOUR DIGIT YEAR.

PROGRAMMER INSTRUCTIONS:

HARD EDIT:

- IF DATE IS MORE THAN TEN MONTHS BEFORE CURRENT DATE, DISPLAY, "You have entered a date that was more than ten months before today. Confirm date. If this date is correct, enter 'Don't Know' to continue with duration questions."
- IF DATE IS AFTER TODAY'S DATE, DISPLAY "You have entered a date that has not occurred yet. Re-enter date."

IF DATE IS COMPLETE, CALCULATE DUE DATE FROM FIRST DATE OF LAST MENSTRUAL PERIOD, WHERE (PPG_DUE_DATE_2) = (DATE_PERIOD) + 280 DAYS); ELSE GO TO (WEEKS_PREG)

PG007 (WEEKS_PREG) How many weeks pregnant are you now? If you're not sure, please make your best guess.

___ PG011 / (STATUS)

NUMBER OF WEEKS

REFUSED -1 PG008 / (MONTHS_PREG)

DON'T KNOW -2 PG008 / (MONTHS_PREG)

PROGRAMMER INSTRUCTIONS:

- SOFT EDIT: IF >43
- HARD EDIT: IF <1 OR >44

IF DATE IS COMPLETE, CALCULATE DUE DATE FROM NUMBER OF WEEKS PREGNANT, WHERE (PPG_DUE_DATE_2) = TODAY'S DATE + (280 DAYS - (WEEKS_PREG)*7); ELSE GO TO (MONTHS_PREG)

PG008 / (MONTHS_PREG) About how many months pregnant are you? If you're not sure, please make your best guess.

— —		PG011	/ (STATUS)
NUMBER OF MONTHS				
REFUSED	-1	PG009	/ (TRIMESTER)
DON'T KNOW	-2	PG009	/ (TRIMESTER)

PROGRAMMER INSTRUCTIONS:

- SOFT EDIT: IF >10
- HARD EDIT: IF <1 OR >12

IF DATE IS COMPLETE, CALCULATE DUE DATE FROM NUMBER OF MONTHS PREGNANT, WHERE (PPG_DUE_DATE_2) = TODAY'S DATE + (280 DAYS – (MONTHS_PREG)*30 - 15) ; ELSE GO TO (TRIMESTER)

PG009 / (TRIMESTER) Are you currently in your First, Second, or Third trimester?

1 ST (1 to 3 months pregnant)	1	PG011	/ (STATUS)
2 ND (4 to 6 months pregnant)	2	PG011	/ (STATUS)
3 RD (7 to 9 months pregnant)	3	PG011	/ (STATUS)
REFUSED	-1	PG011	/ (STATUS)
DON'T KNOW	-2	PG011	/ (STATUS)

PROGRAMMER INSTRUCTIONS:

REFERENCE CODE LIST: TRIMESTER_CL1

CALCULATE DUE DATE FROM (TRIMESTER),

- IF (TRIMESTER = 1) THEN: (PPG_DUE_DATE_2) = TODAY'S DATE + (280 DAYS – 46 DAYS))
- IF (TRIMESTER = 2) THEN: (PPG_DUE_DATE_2) = TODAY'S DATE + (280 DAYS – 140 DAYS))
- IF (TRIMESTER = 3) THEN: (PPG_DUE_DATE_2) = TODAY'S DATE + (280 DAYS – 235 DAYS))
- IF (TRIMESTER = -1 OR -2) THEN: (PPG_DUE_DATE_2) = TODAY'S DATE + (280 DAYS – 140 DAYS))

PG010 / (MED_UNABLE) Do any of the following apply to you? Have you had:

- A hysterectomy,
- Both ovaries removed,
- Your tubes tied,
- Gone through menopause or
- Any other medical reason why you cannot become pregnant?

YES	1	PG011	/ (STATUS)
NO	2	PG011	/ (STATUS)
REFUSED	-1	PG011	/ (STATUS)
DON'T KNOW	-2	PG011	/ (STATUS)

PROGRAMMER INSTRUCTIONS:

- IF (UNABLE = 1); SET PPG_GROUP = 5 (INELIGIBLE- UNABLE TO CONCEIVE)
- REFERENCE CODE LIST: CONFIRM_TYPE_CL1

PG011 / (STATUS)

IF PPG_GROUP =1 [Congratulations again on your pregnancy.] We would like to set up a time to talk about the National Children's Study. If you have any other questions before that time, please call xxx-xxx-xxxx, which is XXX's local toll free National Children's Study office. Thank you for taking time to answer these questions. PG012 / (TIME_STAMP_2)

IF PPG_GROUP =2 We will call you again in a couple of months to ask a few quick questions. If you find out that you're pregnant before our next call, please call xxx-xxx-xxxx, which is XXX's local toll free National Children's Study office. Thank you for taking time to answer these questions. . PG012 / (TIME_STAMP_2)

IF PPG_GROUP =3 [I'm so sorry to hear that you've lost your baby. I know this can be a hard time.] Because your address is in the study area, we may be back in touch at a later time to update your household information. If you have any other questions before that time, please call xxx-xxx-xxxx, which is XXX's local toll free National Children's Study office. Thank you for taking time to answer these questions. PG012 / (TIME_STAMP_2)

IF PPG_GROUP =4 We will call you again in a couple of months to ask a few quick questions. If you have any other questions before that time, please call xxx-xxx-xxxx, which is XXX's local toll free National Children's Study office. Thank you for taking time to answer these questions. PG012 / (TIME_STAMP_2)

IF PPG_GROUP =5 Based on what you've told me, we will not ask you to take part in the study at this time. We may be back in touch at a later time to update your household information. If you have any other questions before that time, please call xxx-xxx-xxxx, which is XXX's local toll free National Children's Study office. Thank you for taking time to answer these questions. PG012 / (TIME_STAMP_2)

INTERVIEWER INSTRUCTIONS: READ APPROPRIATE PPG SCRIPT

PROGRAMMER INSTRUCTIONS:

- DISPLAY SCRIPT BASED ON ASSIGNED PPG STATUS
- DISPLAY CORRECT SITE OFFICE TOLL-FREE NUMBER
- REFERENCE CODE LIST: PPG_STATUS_CL1

PG012 / (TIME_STAMP_2) PROGRAMMER INSTRUCTIONS: ENTER DATE/TIME STAMP TR001 / (BST_NMBR)

TR001. / (BST_NMBR) Just to confirm, is this the best phone number to reach you?

YES	1	TR004.	/	(TIME_STAMP_3)
NO	2	TR002.	/	(PHONE_NBR)
REFUSED	-1	TR004.	/	(TIME_STAMP_3)
DON'T KNOW	-2	TR004.	/	(TIME_STAMP_3)

TR002. / (PHONE_NBR) What is the best phone number to reach you?

ENTER PHONE NUMBER AND CONFIRM.
 |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

RESPONDENT PROVIDED TELEPHONE NUMBER	1	TR003		(PHONE_TYPE)
RESPONDENT HAS NO TELEPHONE	-8	TR004	/	(TIME_STAMP_3)
REFUSED	-1	TR004.	/	(TIME_STAMP_3)
DON'T KNOW	-2	TR004.	/	(TIME_STAMP_3)

TR003. / (PHONE_TYPE) Is that your home, work, cell, or another phone number?

CONFIRM IF KNOWN.

HOME	1	TR004.	/	(TIME_STAMP_3)
WORK	2	TR004.	/	(TIME_STAMP_3)
CELL	3	TR004.	/	(TIME_STAMP_3)
FRIEND/RELATIVE		4	TR004.	/	(TIME_STAMP_3)
OTHER		5	TR004.	/	(TIME_STAMP_3)
REFUSED		-1	TR004.	/	(TIME_STAMP_3)
DON'T KNOW		-2	TR004.	/	(TIME_STAMP_3)

TR004. / (TIME_STAMP_3) PROGRAMMER INSTRUCTIONS: ENTER DATE/TIME STAMP

TR005. Thank you for participating in the National Children's Study and for taking the time to answer our questions.