

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.