

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

JULY LAUNCH VERSION
VERSION 7/14/2010

ASSUME PRE-PREGNANCY VISIT WAS
ADMINISTERED UNLESS NOTED

Recruitment Strategy Substudy

***Enhanced Household,
Provider-Based & Two-Tier***

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.

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- 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 |
| 6/7/2010 | 20100607a | FORMAL SUBMISSION TO OMB |
| 6/10/2010 | 20100610 | Graber changes |
| 6/18/2010 | 20100618_TCA | Tracked changes accepted |
| 6/25/2010 | 20100625 | Incorporated comments from Slutsman, Schoendorf and Park |
| 6/29/2010 | 20100629 | Revised |
| 7/14/2010 | 20100714 | Accept format changes |
| 7/15/2010 | 20100714 | SUBMISSION TO OMB |
| | | <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 | / | (DATE_PERIOD) | |
| M M D D Y Y Y Y | | -1 | PG006 | / | (DATE_PERIOD) |

REFUSED -2 PG006 / (DATE_PERIOD)
DON'T KNOW

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:

- IF VALID DATE IS PROVIDED IN (PPG_DUE_DATE_1), SKIP TO (STATUS)

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 PREGNANT = 3 START QUESTION WITH "I'm sorry for your loss. I have just a few more questions."
- IF (MED_UNABLE = 1); SET PPG_GROUP = 5 (INELIGIBLE- UNABLE TO CONCEIVE)
- REFERENCE CODE LIST: CONFIRM_TYPE_CL1

PG011 / **(STATUS)**

| | | | | |
|--|--|-------|---|-----------------------|
| IF PPG_GROUP =1; PREGNANT AND ELIGIBLE | Thank you for taking time to answer these questions. [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 | PG012 | / | (TIME_STAMP_2) |
|--|--|-------|---|-----------------------|

XXX's local toll free National Children's Study office.

IF PPG_GROUP =2; HIGH PROBABILITY - TRYING TO CONCEIVE Thank you for taking time to answer these questions. 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. PG012 / (TIME_STAMP_2)

IF PPG_GROUP =3; HIGH PROBABILITY- RECENT LOSS [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; OTHER PROBABILITY - NOT PREGNANT AND NOT TRYING Thank you for taking time to answer these questions. 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. PG012 / (TIME_STAMP_2)

IF PPG_GROUP =5; INELIGIBLE- UNABLE TO CONCEIVE Thank you for taking time to answer these questions. 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. 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. / (END)
NO 2 TR002. / (PHONE_NBR)
REFUSED -1 TR004. / (END)
DON'T KNOW -2 TR004. / (END)

TR002. / (PHONE_NBR) What is the best phone number to reach you?
ENTER PHONE NUMBER AND CONFIRM.
|_|_|_|_| - |_|_|_|_| - |_|_|_|_|_| (PHONE_TYPE)
RESPONDENT HAS NO TELEPHONE 1 TR004. / (END)
REFUSED -1 TR004. / (END)
DON'T KNOW -2 TR004. / (END)

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

CONFIRM IF KNOWN.

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

TR004. **(END)** Thank you taking the time to answer our questions. **(TIME_STAMP_3)**

TR005. / **(TIME_STAMP_3)** PROGRAMMER INSTRUCTIONS: ENTER DATE/TIME STAMP