WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
PREGNANCY PROTOCOL
PREGNANCY FORM (PR01)

Visit Number:

All forms completed during the participant's regular core visit (including PRNOTI, PR01 and PR02) will be labeled with the current visit number tag (i.e., visit 11, visit 12, etc.).

If, however, a participant is scheduled to return during her third trimester for an exta visit within the same core visit window, the forms completed at this visit (PR01, F22, F08, F08a, F31, C60, C65, F10, F29, L01, L03 and L04), will be labeled by adding a ".1" to the current visit number (i.e., visit 11.1, visit 12.1, etc.). This will allow data collected during the extra third trimester visit to be distinguished from data collected during the regular core visit during analyses.

In either case, a copy of this form should be forwarded to WDMAC for data entry. Forms can be faxed to Johanna Goderre at 410-614-7125 or mailed to:

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SECTION A: GENERAL INFORMATION

A1. Circle code 1 if the Clinician is completing the form based on interview/discussion with the participant. Circle code 2 if the OB Designee is completing the form based upon abstraction of the participant's medical records. Clinicians proceed to question A2; OB Designees skip to question A4.

A2. **CLINICIAN**: Indicate whether this is the participant's first or second visit during this pregnancy.

A3. **CLINICIAN**: Record the date of interview with the participant in MM/DD/YY format. Skip to question A6.

A4. **OB DESIGNEE**: Record whether the medical record was obtained. If no, code 2 (NO) and specify the REASON records were unobtainable. After specifying REASON, **END**.

A5. **OB DESIGNEE**: Record the date of the chart review in MM/DD/YY format.

A6. a. Record whether the gestation of pregnancy was determined by Last Menstrual Period (LMP). If YES, enter the date of the participant's LMP and the Estimated Date of Confinement (EDC) as determined by the LMP. If NO, skip to question A6b.

i. LMP = last menstrual period (first day of last period). Clinicians should have a calendar available to aid the participant in determining the date she began her last menstrual period.

ii. Due date (EDC = estimated date of confinement) based on LMP. To calculate, add nine months (or subtract three months) from month of LMP and add seven days to day of LMP.

Example: LMP = 10/21/99; EDC = 7/28/00

b. Record whether the gestation of pregnancy was determined by exam within first 20 weeks. 20 weeks is roughly 4.5 months. If YES, enter the date of the exam and the number of completed weeks of gestation at the time of the exam. If NO, skip to question A6c.

i. Date of exam before 20 weeks.

ii. Clinician can calculate with a pregnancy wheel by taking starting point at LMP and finding date of 1st exam on wheel.

c. Record whether the gestation of pregnancy was determined by ultrasound. If YES, enter the date of the ultrasound and the number of completed weeks of gestation at the time of the ultrasound. If NO, skip to question B1.

i. Date of ultrasound before 20 weeks.

ii. Clinician can calculate with a pregnancy wheel by taking starting point at LMP and finding date of ultrasound on wheel.

SECTION B.

PROMPT: ALTHOUGH APPLICABLE TO BOTH CLINICIAN AND OB DESIGNEE, THE FOLLOWING QXQ SPECIFICATIONS ADDRESS THE CLINICIAN. SOME SKIP INSTRUCTIONS MAY DIFFER BETWEEN CLINICIAN AND OB DESIGNEE. CLINICIANS SHOULD CIRCLE <-8> IF THE PARTICIPANT DOES NOT KNOW THE ANSWER TO A QUESTION. OB DESIGNEES SHOULD CIRCLE <-8> IF THE REQUESTED INFORMATION IS NOT CONTAINED ON THE PARTICIPANT'S CHART.

B1. **Incompetent cervix requiring placement of cerclage**

Ask "**Have you ever been told you had an incompetent cervix and needed a stitch put in the cervix to keep the pregnancy inside the uterus?"**

Incompetent cervix is suggested by a past obstetrical history significant for second trimester loss characterized by painless cervical dilatation. The patient will frequently be found to have membranes protruding through the cervix or will have significant cervical dilation on exam. An emergency cerclage may be performed in some circumstances at the time of dilatation, or may be performed electively around the end of the first trimester in a subsequent pregnancy. A cerclage involves the placement of a suture to hold the cervix shut. It is usually placed under spinal anesthesia at about 12–13 weeks if placed electively, and rarely placed beyond 26 weeks in an emergency. It is rarely placed through abdominal surgery.

B1a. Ask, "**Have you had the stitch removed that was placed to keep your cervix shut? Was it removed before you went into labor, during labor, or after you had the baby?"**

Record whether the cerclage was removed at anytime after placement – antepartum, intrapartum, or postpartum.

B2. **Bleeding < 28 weeks** – Indicate whether any vaginal bleeding occurred during pregnancy prior to 28 weeks gestation and prior to the onset of labor. Twenty-eight weeks is six months, two weeks. If not applicable, circle <-1>.

B3. **Bleeding ≥ 28 weeks** – Indicate whether any vaginal bleeding occurred during pregnancy at or after 28 weeks gestation and prior to the onset of labor. Twenty-eight weeks is six months, two weeks. If not applicable, circle <-1>.

B4. **Pregnancy induced hypertension**

Ask, "**Have you been told your blood pressure has been high during this pregnancy? Did you have high blood pressure before you got pregnant? Has anyone told you you had protein in your urine (not the same as a urine infection)? Has anyone told you you had pre-eclampsia or toxemia?"**

Pregnancy-induced hypertension is based on at least two measurements of blood pressure taken at least six hours apart in which:

- the blood pressure is > 140/90; or
- the systolic BP is > 30 mm Hg over the baseline BP; or
- the diastolic BP is >15 mm Hg over the baseline BP.

It differs from pre-eclampsia, or toxemia, in that there is no proteinuria or edema at this point, although patients with PIH may develop pre-eclampsia. Patients may well confuse PIH with pre-eclampsia.

Indicate if during the pregnancy, the participant's blood pressure was persistently ≥ 140/90 mm Hg OR if the participant experienced a rise in systolic pressure of ≥ 30 mm Hg and diastolic pressure ≥ 15 mm Hg from her first trimester blood pressure. In addition, the participant must not have proteinuria, AND there must be no known hypertension prior to pregnancy.

B5. **Chronic hypertension requiring treatment** – Record if the participant experienced high blood pressure > 140/90 mm Hg that began prior to pregnancy or in the first twenty weeks of pregnancy which is controlled with anti-hypertensive medication.

B6. Ask, "**Have you been told you had diabetes (or high sugar) during this pregnancy? Did you have diabetes before you got pregnant (not the same as having had gestational diabetes mellitus [GDM] before with another pregnancy)? If you have diabetes now with this pregnancy, are you just following a special diet, or are you injecting yourself with insulin, too?"**

Most pregnant women will receive a one-hour glucose challenge test (GCT) between 24–28 weeks gestation; some at high risk of gestational diabetes mellitus (GDM) will also be screened early in pregnancy.

Record whether the participant reports diabetes. If YES, proceed to B6a. If NO, skip to B7.

a. **Pre-gestational diabetes** – Indicate whether the participant's diabetes (hyperglycemia) occurred before pregnancy.

b. **Gestational diabetes** – Indicate whether the participant was diagnosed with diabetes during pregnancy by an abnormal three-hour glucose tolerance test. Criteria: two abnormal serum values from the following:

Fasting - 105, 1 hour - 190, 2 hour - 165, 3 hour - 145 OR abnormal 1 hour post 50 gram glucose load of > 200 mg/dl.

AND control of hyperglycemia with diabetic diet alone AND no history of elevated blood sugar prior to pregnancy.

c. **Insulin therapy during pregnancy** – Indicate whether the diagnosis was made by the same criteria as B6b AND hyperglycemia is controlled by the administration of insulin and diabetic diet.

B7. **Intrauterine growth retardation (suspected)**

Ask, "**Have you been told that the baby isn't growing well?"** or "**Have you been told that the baby is smaller than it should be?"** as well as, "**Have you had a sonogram to be sure?"**

Intrauterine growth retardation (now termed intrauterine growth restriction) is diagnosed when the estimated fetal weight and other sonographic parameters determine that the fetus falls below the tenth percentile for its gestational age. The patient may well not know or understand this term.

Indicate if intrauterine growth retardation is suspected. Diagnosis should be based on serial ultrasound and fundal height measurements.

B8. **Cystitis (requiring treatment)**

Ask, "**Have you been treated for a urinary tract infection during pregnancy?"**

Indicate if the participant required treatment for cystitis. Diagnosis should be based on positive bacterial clean catch urine culture of > 100,000 organisms/ml of a single type OR positive bacterial urine culture of organism in any amount from urine from sterile site (e.g., cathed specimen) OR in a patient who has symptoms of a urinary tract infection, > 100 organisms/ml of a single type.

B9. **Pyelonephritis**

Ask, "**Have you been hospitalized during the pregnancy for a urine infection that went up to the kidneys? Have you been given antibiotics in an IV for this infection?"**

In pregnant women, fever, flank pain with costovertebral angle tenderness, and occasional nausea and vomiting suggest pyelonephritis.

Indicate if the participant experienced pyelonephritis. Diagnosis should be based on clean catch urine culture of > 100,000 organisms/ml of a single type AND maternal fever greater than 101° F or 38.3° C and costovertebral angle (CVA) tenderness.

B10. **Other clinically significant antepartum infection(s)**

Ask, "**Have you had any infections during this pregnancy that required treatment of any kind?"**

Record if the participant has had any other antepartum infections other than those already listed. Infection(s) may be viral, bacterial, fungal or due to other agents such as mycoplasma, rickettsia. Diagnosis must be documented in a physician's note. If YES, circle code 1 and SPECIFY type of infection on the line provided. If NO, skip to question B11.

B11. **Other clinically significant obstetrical problems**

Ask, "**Have you had any other problems having to do with the pregnancy that have required special treatment or visits to special high risk doctors?"**

Record if the participant experienced any other obstetrical problems that occurred from conception to labor and delivery, such as placenta previa. (OB DESIGNEE: Do not include obstetrical problems that led to or were coincident with labor that resulted in delivery. This information will be collected on PR02, Section B: Intrapartum Complications.) If YES, circle code 1 and SPECIFY type of problem on line provided. If NO, skip to question B12.

B12. **Premature labor requiring parenteral tocolysis**

Ask, "**Have you been told you were in early or premature labor and were given special medicine to stop your labor?"** Many women may be hydrated by PO or IV to reduce uterine irritability; be certain the patient understands this would not just be fluids, but **"one of two different drugs, called magnesium sulfate, or terbutaline, which is sometimes also used for asthma."**

Record YES if the participant experienced regular uterine contractions after 20 weeks, and before 37 weeks, which were five to eight minutes apart or less PLUS one or more of the following:

- Progressive changes in the cervix.
- Cervical dilation of 2 cm or more.
- Cervical effacement of 80% or more.

If not applicable, circle code <-1>.

SECTION C. ANTEPARTUM MEDICATIONS

C1. **Antepartum antibiotics taken**

Ask, "**Have you taken any antibiotics, or medication for an infection, during your pregnancy?"**

Indicate whether any antibiotics were taken during pregnancy before the onset of labor. Examples include penicillin, erythromycin, cefazolin. Specify which antibiotics were taken. Do not include antibiotics given during labor and delivery. This information will be collected on PR02, Section B: Intrapartum Complications.

C2. **Antepartum glucocorticoids taken**

Ask, "**Have you taken any steroids, like prednisone, or a special injection to help the baby's lungs if you were having early labor?"**

Glucocorticoids given may include prednisone, for asthma or other conditions, and betamethasone, to improve fetal lung maturity in women in preterm labor or, in some cases, in women at high risk for preterm labor. Betamethasone is given at 6 mg IM q12h x 4 doses weekly from the time of preterm labor, or early 3rd trimester, up to 34 weeks in such patients.

Indicate whether glucocorticoids were taken during pregnancy before the onset of labor. Examples include hydrocortisone, prednisone, dexamethasone, betamethasone. Specify which

glucocorticoids were taken. Do not include glucocorticoids given during labor and delivery. This information will be collected on PR02, Section E: Intrapartum Medications.

C3. **Antepartum zidovudine or Combivir taken** – Record whether zidovudine (AZT) or Combivir (ATC + 3TC) was taken during pregnancy before the onset of labor. If YES, circle code 1 and proceed to C3a. If NO, skip to question C4.

a. Record the average number of doses taken per week in the last month. Use leading zeros.

b. Record the date during the pregnancy when the participant began to take zidovudine or Combivir in MM/DD/YY format. If the participant was taking zidovudine or Combivir before finding out she was pregnant and has not discontinued that use, please report the date of her last menstrual period in field C3b. Clinicians should have a calendar available to aid the participant in determining the date she began taking AZT or Combivir.

C4. Record any comments in question C4.