

**WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM 8: GYNECOLOGICAL EXAM**

Indicators for the beginning and end of all subforms have been added to the form. This has been done for data entry purposes only and will not affect how the form is completed.

PARTICIPANT INFORMATION

This section at the beginning of the form should be completed before beginning the gynecological exam. Record the actual time you began the gynecological exam in the space provided for "Time Module Began" and the actual time you ended the exam in the space denoted "Time Module Ended."

SECTION A: GYNECOLOGICAL EXAM

A number of vaginal and cervical specimens are collected during the GYN exam. Refer to the Gynecological Exam section of the WIHS Manual of Operations for the order and method of collection and tests to be performed.

Optional: Prior to inserting a clean vaginal speculum, examine the thighs, pubis, vulva, perineum, and perianal region for abnormalities. Beginning with visit 23, results of the external exam will not be recorded on F08; however, any abnormalities or lesions discovered during the gynecological exam should be noted in Question A19 and on the participant's chart.

A6. Assess vaginal discharge character and circle all appropriate response codes. **More than one code may be circled.**

CERVICAL EXAMINATION

PROMPT: IF A7 = 1 (PARTICIPANT HAS A CERVIX), PROCEED TO QUESTION A8. IF A7 = 2 (PARTICIPANT HAS NO CERVIX) AND IT IS AN EVEN-NUMBERED VISIT, SKIP TO QUESTION A14. IF A7 = 2 AND IT IS AN ODD-NUMBERED VISIT, SKIP TO QUESTION A16.

A8. If the cervical exam was done, circle "1" and proceed to **Question A9**. If the cervical exam was not done, circle "2," specify the reason why in 25 characters or less and skip to **Question A12**.

A9a. Assess the presence and severity of any cervical lesions.

A10. Assess the presence of cervical exudate. If there is no cervical exudate, circle "2" and skip to **Question A12**.

NOTE: BEGINNING WITH VISIT 23, THE BIMANUAL EXAM WILL BE COMPLETED ANNUALLY, AT EVEN-NUMBERED VISITS. IF PARTICIPANT IS BEING EXAMINED AT AN ODD-NUMBERED VISIT, SKIP TO QUESTION A16.

A12. If participant is too obese to detect cervical motion tenderness, circle response "3," unable to obtain.

UTERINE EXAMINATION

A13. If the participant has no uterus, skip to **Question A14**. If participant is too obese to detect whether or not the uterus is present, circle "3," unable to obtain, and skip to **Question A14**.

ADNEXAL EXAMINATION

A14. If the participant has no adnexae, skip to **Question A15**. If participant is too obese to detect whether or not adnexae are present, circle "3," unable to obtain, and skip to **Question A15**.

A15. If participant is too obese to detect a cul-de-sac mass, circle “3,” unable to obtain.

PROMPT: IF PARTICIPANT HAS HAD A HYSTERECTOMY SINCE HER LAST STUDY VISIT, PLEASE VERIFY THAT SHE REPORTED IT ON F23 DURING HER INTERVIEW.

GYNECOLOGICAL EXAM & ABNORMALITIES/LESIONS

- A19. Indicate whether or not any abnormalities or lesions were found during the GYN exam. If no abnormalities or lesions were present, code “2” indicating “NO,” and skip to **Question A44**.
- A20. Indicate the total number of lesions found during the GYN exam.
- A21. Indicate the type of lesions present during the GYN exam. Each lesion type has a yes/no indicator. The types of lesions are wart, ulcer, rash, mass, vesicle, or other. If other, please specify the type of lesion present.
- A44a. Perform the Wet Prep/Saline Mount according to the Lab Procedures Manual.
- i. Assess the presence or absence of Trichomonas.
 - ii. Assess the presence or absence of clue cells. If clue cells are present, indicate whether the percent of clue cells observed is <20% of cells or ≥20% of cells.
 - iii. Assess whether there are increased wbc's (i.e., whether wbc:epithelial cells is greater than 1:1).
- A44b. Perform the KOH Mount according to the Lab Procedures Manual.
- i. Assess the presence or absence of yeast.
 - ii. Assess the presence or absence of amine odor.

SECTION B: CLINICAL IMPRESSION

- B3. If overall clinical impression of this participant/exam is normal, circle “1” = “YES” and **END** form.
- B8. If herpes is present, indicate whether or not **Question B8a, b** or **c** best describes this herpes episode. If no herpes is noted, skip to **Question B11**.
- B11. If warts are present, indicate whether or not the warts are at any of the listed locations in **Question B11a, b, c, d** and/or **e**. If no warts are noted, skip to **Question B12**. If wart(s) are noted at any of the listed locations in a through e, then, for each wart noted, indicate if it was previously assessed in WIHS (and is unchanged, worsened or improved) or if it is new. Follow the instructions in italics on the form to determine whether or not a colposcopy is indicated.
- B12. If any other abnormality is present, specify what that abnormality is on the line provided.
- B19. Indicate whether colposcopy is indicated for the participant based on exam findings.

PROMPT: ANY FINDINGS SUGGESTIVE OF SEXUAL OR PHYSICAL ABUSE ARE TO BE FOLLOWED UP BY THE CLINICIAN AND REFERRED TO THE APPROPRIATE REFERRAL SOURCES (i.e., LOCAL SOCIAL SERVICE AND/OR LAW ENFORCEMENT AGENCY).

PROMPT: COMPLETE "TIME MODULE ENDED" ON PAGE 1 OF THE FORM.

PLEASE NOTE: ANY NECESSARY ADDITIONAL COMMENTS SHOULD BE WRITTEN IN THE SPACE PROVIDED ON THE LAST PAGE.