

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

General Instructions:

1. All dates should be recorded in the MM/DD/YY format.
2. Times should be recorded in HH:MM format. Remember to use leading zeros, e.g., 08:00.

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. **AFTER COMPLETING THE EXAM, COMPLETE THE LESION CHART (LOCATED AT QUESTION A19) FOR ANY LESIONS PRESENT.**
- 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.

UTERINE EXAMINATION

A13. If the participant has no uterus, skip to question A14.

ADNEXAL EXAMINATION

A14. If the participant has no adnexae, skip to question A15.

PROMPT: IF PARTICIPANT HAS HAD A HYSTERECTOMY SINCE HER LAST STUDY VISIT, PLEASE VERIFY THAT SHE REPORTED IT ON F23 DURING HER INTERVIEW. CHECK WITH THE INTERVIEWER TO ENSURE THAT AN ASCERTAINMENT TRACKING CHECKLIST (ATC) WAS COMPLETED AND THAT MEDICAL RECORD RELEASE WAS OBTAINED.

GYNECOLOGICAL EXAM & ABNORMALITY/LESION CHART

The following are definitions of the numbered regions on the abnormal lesion chart at question A19:

The *labia majora* (locations 1 and 2) extend from the area of the *clitoris* (13) posteriorly to the *perineum* (7 and 8). The lateral aspects are covered with pubic hair. The inner aspects of the labia majora are not hair bearing, but may have prominent sebaceous glands. The labia majora are separated from the *labia minora* (3 and 4) by the interlabial sulcus. The labia minora are covered by keratinized squamous mucosa and extend from the region of the clitoris to the *introitus* (5 and 6).

Anteriorly, covering the pubic synthesis, is the *mons pubis* (15). Lateral to the pubis are the *inguinal regions* (9 and 10). The inner *thighs* (11 and 12) are lateral to the hair-bearing regions of the labia majora.

The *urethra* (14) and periurethral region is located between the clitoris and vagina introitus and is demarcated laterally by the inner aspects of the labia minora.

The *perineum* (7 and 8) is the region located between the vaginal introitus and anus.

The perianal region is the area immediately surrounding the external anal sphincter and is arbitrarily divided into four quadrants: upper left, lower left, lower right and upper right (27, 28, 29 and 30). The internal anal canal (31) is examined via anoscopy (anal colposcopy). The region beyond the perianus blends with the inner thighs (11 and 12).

A19. Indicate whether or not any abnormalities or lesions were found during the GYN exam. Indicate the locations of those abnormalities on the diagram by circling the numbers. If no abnormalities or lesions were present, code “2” indicating “NO,” and skip to question A44.

A19a. Record the total number of locations where external genitalia, vaginal or cervical lesions are present. This number must be consistent with the number of locations circled at question A19 and reported in questions A20–A43.

PROMPT: IF THE TOTAL NUMBER OF LOCATIONS WITH LESIONS IS GREATER THAN FOUR, PLEASE USE A COPY OF PAGE 4 OF THE FORM AND INSERT IT AFTER PAGE 4.

A20. **LOCATION #1.** Using the two-digit location codes provided at question A19, enter the appropriate location code for location #1. If the location code recorded is “31” (three or more locations), specify all affected locations in the space provided.

A21–A25: Indicate whether the lesion type present at location #1 is a wart, ulcer, rash, mass or other lesion type.

- A25. If there is lesion present at location #1 that is not a wart, ulcer, rash or mass, specify what it is on the line provided in question **A25**.
- A26–A31: **LOCATION #2**. Using the two-digit location codes provided at question A19, enter the appropriate code for location #2. If the location code recorded is “31,” specify all affected locations. Complete questions A27–A31, following the above instructions for questions A21–A25.
- A32–A37: **LOCATION #3**. Using the two-digit location codes provided at question A19, enter the appropriate code for location #3. If the location code recorded is “31,” specify all affected locations. Complete questions A33–A37, following the above instructions for questions A21–A25.
- A38–A43: **LOCATION #4**. Using the two-digit location codes provided at question A19, enter the appropriate code for location #4. If the location code recorded is “31,” specify all affected locations. Complete questions A39–A43, following the above instructions for questions A21–A25.
- 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.
 - iii. Assess whether there are increased wbcs (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 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 located at B11a, b, c, d and/or e. If no warts are noted, skip to question **B12**.
- B12. If any other cervical 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.