

**WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM L14: COLPOSCOPY RESULTS**

SECTION A. COLPOSCOPY

- A1. This form must be completed for all participants for whom colposcopy is indicated. If the participant refuses the colposcopy, simply indicate such and no further information is required. However, if the colposcopy is not done for a reason other than refusal, skip to **Question A1d** to record why it was not done.
- a. Record the date the colposcopy is performed: the month, day, and year. Example: June 6, 1995 will be recorded as 06/06/95.
 - b. Enter the initials of the colposcopist(s) performing the evaluation. If more than one colposcopist is involved, record all the individuals.
 - c. Indicate whether a WIHS colposcopist performed the colposcopy or not. If not, complete an *ATC / ACSR ATC*, recording the date and location of the non-WIHS colposcopy. Skip to **Question A2**.
 - d. If the colposcopy was not done for a reason other than refusal, record the reason why and end the form.
- A2. Account for each item in **Questions A2a** through **A2h** by circling code "1" or "2." Circle "YES" for the applicable indication(s) for colposcopy. Circle "NO" for all others. If the colposcopy is being performed regardless of past history or Pap smear result, code Question A2g as "YES." If no category aptly describes the indication for the participant, circle "YES" for Question A2h and write out the indication in the **specify** field.
- A3. Circle "YES" for the types of colposcopy that were performed and "NO" for those that were not performed. Refer to the procedures under the Colposcopy/Biopsy Protocol. Whenever a colposcopy is performed, determine the date of the participant's last menstrual period and verify, by history or testing, whether the participant is pregnant or not. If the participant is pregnant, this will alter the biopsies that may be performed since endocervical curettage is contraindicated in pregnancy.

NOTE: Question A3e should only be coded "YES" if an anoscope (special instrument) is used to perform anoscopy, otherwise Question A3e should be coded as "NO."

- a–e. Circle the areas examined by colposcopy.

NOTE: The WIHS Colposcopy Protocol recommends that **all** these areas be included.

PROMPT: IF RESPONSES TO QUESTIONS A3a AND A3b ARE BOTH "NO," SKIP TO QUESTION A10.

- A4. If the cervix is not present, circle "2" and skip to **Question A10**.
- A5. To begin colposcopy of the cervix, insert a speculum that is large enough to allow visualization of the cervix. In multigravid patients, this may require a large speculum. Determine the adequacy of the colposcopic examination by noting the squamocolumnar junction throughout its circumference. If the entire squamocolumnar junction is not visible, insert an endocervical speculum and manipulate as needed to attempt to completely visualize the squamocolumnar junction. Code exam adequacy as "satisfactory" by circling "1" to indicate "visualization of the entire squamocolumnar junction and complete visualization of any colposcopic abnormalities" (i.e., there are no lesions extending beyond visualization into the endocervical canal); or circle "2" to indicate that an "endocervical speculum was

used to visualize squamocolumnar junction;" or circle "3" to indicate that the "entire squamocolumnar junction was not visualized."

- A6. If the colposcopic examination of the cervix is "within normal limits" circle "1," then skip to **Question A10**. If the exam has "abnormal findings" circle "2" and proceed to **Question A7**.
- A7a-f. Before the application of 3-5% acetic acid to the cervix, code the presence or absence of keratosis (leukoplakia) in **Question A7a** and inspect the cervix for friability, mucopus, or other evidence of inflammation (also see Question A10). Repeat acetic acid application as needed during the procedure. Inspect under colposcopic magnification (7.5-30X) using white light. Note the presence or absence of aceto-white epithelium in **Question A7b**. Inspect the cervix using the green filter and record whether punctation, mosaicism, or atypical vessels are noted in **Questions A7c through A7e**. If there is any other finding, circle "1" for **Question A7f**, and specify what was found; otherwise circle "2" at **Question A7f** and proceed to **Question A8**.
- A8. Based on the findings noted in **Question A7**, record the percentage of the transformation zone that is abnormal. If there is no abnormality of the transformation zone, circle code "1."
- A9. Based on the findings noted in **Question A7**, record the site and quadrants of **all** lesions noted to be abnormal by circling code "1" for "YES." All other questions should be coded as "2" for "NO."
- A10-14. These questions relate to visual and colposcopic evaluation of the lower genital tract including the cervix, vagina, vulva, perianal area and anus. After completion of colposcopy of the **cervix** with and without acetic acid, proceed to inspect the **vaginal** walls with the colposcope looking for inflammation, atrophy, or other abnormalities such as condyloma. Repeat vaginal examination after application of acetic acid. Note the site, number and location of any aceto-white lesions, mosaicism, punctation, papillomas, condylomas, or other abnormalities. After gross inspection of the **vulva**, apply gauze soaked with acetic acid to the vulva and **perianal** regions for three to five minutes. Inspect the vulva grossly and colposcopically. Note any pigmented lesions, aceto-white areas, or other lesions of the vulva or perianal region. Inspection of the perianal region requires gentle traction on the skin on the buttocks to allow adequate visualization of the area. **Anal** lesions, in this study, will be those found at time of anoscopy (see Section B, Anal Colposcopy).
- A10. After inspecting the vagina, cervix, vulva, perianal region, and anus visually and colposcopically before the application of acetic acid, note whether any evidence of inflammation exists such as erythema, friability or lesions. If there is evidence of inflammation circle "1" for "FOUND." Then for each location where inflammation is present, circle "1" for "YES." For locations that are not inflamed, circle "2" for "NO." If there is no evidence of inflammation in any areas circle "2" for "NOT FOUND" and skip to **Question A11**.
- A11. Note the presence of any polyps or papillomas of the vagina, cervix, vulva, perianal region, or anus. If there is evidence of polyps or papillomas circle "1" for "FOUND." Then for each location where polyps or papillomas are present, circle "1" for "YES" or circle "2" for "NO" for the locations where they are not present. If there is no evidence of polyps or papillomas circle "2" for "NOT FOUND" and skip to **Question A12**.
- A12. Note the presence of any condyloma acuminatum of the cervix, vagina, vulva, perianal region, or anus. If there is evidence of condyloma acuminatum circle "1" for "FOUND." For each location where condyloma acuminatum is present, circle "1" for "YES" or circle "2" for "NO" for the locations at which no evidence is present. If there is no evidence of condyloma acuminatum circle "2" for "NOT FOUND" and skip to **Question A13**.
- A13-14. Specify the type and location of any other lesions of the cervix, vagina, vulva, perianal region, and anus. Please be as precise as possible. If there is evidence of "Other" findings circle "1" for "FOUND."

Then for each location where the “Other” finding is present, circle “1” for “YES” or “2” for “NO.” If there is no evidence of any “Other” findings circle “2” for “NOT FOUND” and skip to **Question A15**.

A15. Indicate if a Pap smear was performed at the same time as this colposcopy.

A16. If a cervical biopsy (including an endocervical curettage) was performed, circle “1.” Indicate the type of cervical biopsy taken in **Questions A16a** through **A16e**. It is important to note if the participant refused the biopsy or if it was deferred to another date. If performed on another date, please complete another colposcopy form if the colposcopy was repeated, even if it was a limited colposcopy. In any event, please complete **Form L15**, the histopathology report.

Following are the indications for biopsy:

1. The presence of a lesion, even if it is felt to be low grade, including:
 - keratosis (leukoplakia)
 - aceto-white epithelium
 - punctation
 - mosaicism
 - atypical vessels
 - colposcopically suspect invasive cancer
 - exophytic or microcondylomatous lesions
 - pigmented vulvar or perianal lesions
2. If multiple or multifocal lesions are present on the cervix, biopsy the worst of the lesions (two to three lesions if indicated per anatomic site). Each biopsy is to be placed in an individual vial/container.
3. An ECC will be performed on every participant who has a colposcopy with indications #2, #3, or #5 as listed in the Colposcopy Protocol.
4. Do not perform an ECC on pregnant women.
5. In women who are pregnant, it is suggested to biopsy low-grade lesions.
6. In women who are pregnant, biopsy high-grade lesions.

Perform the ECC using a Kevorkian curette with an in-and-out motion twice around the circumference of the endocervix. Swish the curette in the preservative solution to wash off endocervical tissue. Remove any remaining clot or mucus with associated endocervical tissue from the cervix using forceps or endocervical brush and swish in solution.

Perform indicated cervical biopsies with colposcopic guidance using cervical biopsy forceps. Hemostasis may be achieved using Monsel's solution or silver nitrate.

Some institutions will be performing LEEP or laser procedures at the time of colposcopy using the “see and treat” technique. If this is being done, use appropriate technique to remove the specimen with as little thermal injury as possible. **Form L15** requests information regarding margins, if assessed.

NOTE: Each biopsy is to be placed in an individual vial/container to allow for individual pathologic inspection.

- a. Record if an ECC was performed.

- b. Record if a colposcopically directed punch biopsy was performed, including the number and location rounded to the nearest o'clock position. If this type of treatment was not performed, circle code "2" and skip to **Question A16d**.
- c. Record if a cervical excisional biopsy other than a punch biopsy was performed. Record the location rounded to the nearest o'clock positions. If this type of treatment was not performed, circle code "2" and skip to **Question A16d**.
- d. Record if a loop excision of the transformation zone was performed (LLETZ, LETZ, LEEP). Indicate if an ectocervical pass was performed and record the number of ectocervical passes.
- e. Record if a cervical cone biopsy was performed and note the method of conization. If a loop cone was performed, note the number of ectocervical passes and whether an endocervical core was performed.

A17. Document the overall impression of the cervix.

- a. Record the total number of cervical lesions.

A18. Record if non-cervical biopsies were taken. If no biopsies were taken, delayed or refused, skip to **Question A29**.

TYPE OF BIOPSIES TAKEN

A19. Perform indicated vaginal biopsies after local anesthesia using a combination of topical and sublesional injection using a small gauge needle (25–27 Ga). Use of anesthetic, such as 1% lidocaine with epinephrine may minimize bleeding. Hemostasis may be achieved using Monsel's solution or silver nitrate. Location codes for the biopsies are on page 9 of the form and require notation by recording the numbers designating anterior/posterior/right & left lateral and proximal/medial/distal third.

A20. Perform indicated vulvar biopsies using either a Keys punch, forceps, or LEEP after local anesthesia. Since this is a tender area, it is helpful to use a topical anesthetic such as 1% lidocaine with epinephrine prior to injection. The location codes for the sites of biopsy are listed on page 9 of the form.

A21. Perform indicated perianal biopsies as outlined under the QxQs for **Question A20**.

A22. If anal colposcopy or biopsies are performed, complete **Section B** of this form.

A23. Indications for an endometrial biopsy include postmenopausal bleeding, irregular bleeding after age 35, or as deemed appropriate by the physician. Location codes are not required for this question.

A24–A25. Specify any other biopsies performed and their locations using the location codes on page 10 of the form as needed. If the specific location biopsied is not listed on page 10 of the form, describe the type and location of the biopsy.

A26a–c. Record the total number of vaginal, vulvar and perianal lesions.

A27a–e. Record the maximum lesion size in centimeters for lesions located on the vagina, vulva, perianal region, anal, or any other location.

A28. Record the total number of diagnostics biopsies performed, including both cervical and non-cervical biopsies. This is important because each biopsy will generate a separate **Form L15** (Histopathology Report) when pathology reports are available, which will be tracked by Apollo. **Do NOT include biopsies taken solely for ACSR donation.**

- a. Record the total number of biopsies delayed or refused, including both cervical and non-cervical biopsies.
- b. Record the total number of biopsies taken for specimen bank donation only, including both cervical and non-cervical biopsies. Include lesion and control tissue biopsies. As these will be donated to the ACSR, no **Form L15** will be expected.

The following are definitions of the numbered regions on the lesion chart on page 10 of the form:

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 are located between the clitoris and vagina introitus and are 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).

- A29. Record the overall clinical impression of the highest grade non-cervical lesion. If normal, skip to **Question A33**.
- A30a–e. Circle code “1” for “YES” to indicate the location(s) at which the highest grade non-cervical lesion was identified. Circle code “2” for “NO” for the other locations.
- A31. Circle the appropriate numbers on the diagram corresponding to the areas where all lesions are found on the vulva, perianal region, groins, or thighs.
- A32. Circle the appropriate numbers on the diagram corresponding to the areas where all lesions are found in the vagina.
- A33. Circle the appropriate response for the examiner's knowledge of the participant's HIV status at the time of colposcopy.
- A34. Indicate whether a follow-up visit was scheduled for any biopsies that were performed.
- a. If follow-up was scheduled, report the institution or physician with whom this was scheduled to allow for retrieval of any treatment results.

SECTION B. ANAL COLPOSCOPY

THIS SECTION MUST BE COMPLETED IF QUESTION A22 IS CODED AS “YES.”

- B1. Circle the appropriate response indicating whether anal colposcopy was performed. If the answer is “No,” “Delayed” or “Refused,” no further questions need to be answered on this form. If the answer is “Yes,” proceed to **Question B1a**.
- a. Record the date that the anal colposcopy is performed: the month, day and year. Example: June 6, 1995 will be recorded as 06/06/95.
- b. Enter the initials of the colposcopist(s) performing the evaluation. If more than one colposcopist is involved, record all the individuals.
- B2a–f. Account for each item in **Questions B2a** through **B2f** by circling codes “1” or “2.” Circle “YES” for the applicable indication(s) for anal colposcopy. Circle “NO” for all others. If the colposcopy is being performed regardless of past history or anal cytology result, code **Question B2e** as “YES.” If no

category aptly describes the indication for the participant, circle “YES” for **Question B2f** and write out the indication in the **specify** field.

- B3. Record whether any lesions were noted at time of anal colposcopy. If no lesions are seen, skip to **Question B8**.
- B4. An anoscopy is to be performed by gross visualization and colposcopic evaluation with and without acetic acid.
- a. Before the application of 3–5% acetic acid, record the presence or absence of keratosis (leukoplakia) and look for friability, erythema, or other evidence of inflammation.
 - b–g. Apply acetic acid as needed during the procedure. Inspect under colposcopic magnification (7.5–30X) using white light. Note the presence or absence of aceto-white epithelium in **Question B4b**. Next, inspect using the green filter and record whether punctation, mosaicism, atypical vessels, or condyloma are noted in **Questions B4c** through **B4f**.
- B5. Record the total number of lesions by circling the code corresponding to each number.
- B6. Record the maximum lesion size found during the anal colposcopy.
- B7. Report the location of the lesions by referring to the diagram and definitions printed at the bottom of page 14 on the form.
- a–b. Record the anterior and posterior positions by rounding to the nearest o’clock number. In other words, anterior encompasses from 9 o’clock through 3 o’clock and posterior from 3 o’clock through 9 o’clock
 - c–f. Record the locations by using the diagram.
- B8. Record whether a biopsy was performed. This can be performed by using a punch biopsy instrument after appropriate analgesia. Hemostasis can be assured using a silver nitrate stick. If no biopsy was performed, proceed to **Question B10**.
- B9. Record the number of anal biopsies that were performed.
- NOTE: This number should not include any biopsies performed in Section A.**
- B10. Record the anosopic impression by circling the appropriate number.