

WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATION
FORM L16: TREATMENT FORM

GENERAL INFORMATION

Affix the WIHS ID label in the space provided or record the Participant's ID number.

Record the WIHS study visit number.

Record the initials of the person completing the form.

The form version is pre-printed. Be sure that you are using a current version and that all unused, outdated versions have been discarded.

SECTION A.

- A1. Record the treatment date. For example, June 6, 1995 will be recorded as 06/06/95.
- A2. If this is a report of the Participant's first treatment, circle code "1" for "YES" and proceed to **A5**. If the answer is "NO", proceed to question **A3**.
- A3. If this is a report of a repeated treatment (example: topical application of TCA or podophyllin for condyloma acuminata), circle 1 for "YES" and proceed to **A3a**. If the answer is "NO" skip to **A5**.
- A3a. Record the total number of treatments not including this treatment.
- A4. Record the dates of prior treatments and clearly **specify** the method of prior treatments.
- A5a-g. Record the indication for treatment for each location listed in a-g. Please circle one code only for the most severe or the highest grade lesion that is being treated for each location. For example, if a Participant underwent a cervical cone biopsy after cervical biopsies demonstrating HPV and CINIII, it is important to circle code "7" for the most severe lesion. If the category is not listed, complete "g" for "Other" and clearly **specify** the indication.
- A5a-g. Record the indication for treatment for each location listed in a-g. Please circle one code only for the most severe or the highest grade lesion that is being treated for each location. For example, if a Participant underwent a cervical cone biopsy after cervical biopsies demonstrating HPV and CINIII, it is important to circle code "7" for the most severe lesion. If the category is not listed, complete "g" for "Other" and clearly **specify** the indication.
- A6. Circle "1" for "YES" or "2" for "NO" for each indication (a - f) on which treatment was based. If "f" ("Other") is coded as yes, clearly **specify** the indication in the space provided.
- A7a-f. Each site is listed at subquestions a-f on pages 4-6; subquestion "a" refers to the cervix, subquestion "b" refers to the vagina, etc. Within each subquestion, the various treatment modalities associated with each site are listed. The first treatment modality is "None/Observation". If this treatment is selected, circle code "1" for "YES" and skip to the next anatomical area/subquestion. For example, as shown at question A7a. 1, the skip instruction on the form indicates to skip to subquestion (b) - the vagina.
- If the "None/Observation" is coded as "2" for "NO", then each treatment within the grouping must be coded as "1" for "YES" or "2" for "NO".
- A7a-f. Each site is listed at subquestions a-f on pages 4-6; subquestion "a" refers to the cervix, subquestion "b" refers to the vagina, etc. Within each subquestion, the various treatment modalities associated with each site are listed. The first treatment modality is "None/Observation". If this treatment is selected, circle code

"1" for "YES" and skip to the next anatomical area/subquestion. For example, as shown at question A7a. 1, the skip instruction on the form indicates to skip to subquestion (b) - the vagina.

If the "None/Observation" is coded as "2" for "NO", then each treatment within the grouping must be coded as "1" for "YES" or "2" for "NO".

A7a-f. Each site is listed at subquestions a-f on pages 4-6; subquestion "a" refers to the cervix, subquestion "b" refers to the vagina, etc. Within each subquestion, the various treatment modalities associated with each site are listed. The first treatment modality is "None/Observation". If this treatment is selected, circle code "1" for "YES" and skip to the next anatomical area/subquestion. For example, as shown at question A7a. 1, the skip instruction on the form indicates to skip to subquestion (b) - the vagina.

If the "None/Observation" is coded as "2" for "NO", then each treatment within the grouping must be coded as "1" for "YES" or "2" for "NO".

A7g. If the appropriate site is not listed in a-f, circle "1" for "YES" or "2" for "NO" under "Other Location" at A7g. If A7g is coded as "YES", clearly **specify** the location and modality in the spaces provided. If A7g is coded as "NO", skip to **A8**.

A8. Record if the participant is part of another study. If "YES", **specify** the name and site of the study. If "NO", skip to **A9**.

A8a-b. Record the name of the study and the site at which the woman is participating in the other study.

A9. Report whether histologic evaluation (or biopsy) was obtained during this treatment procedure. If yes, please complete Form L15 for each specimen that was removed.

A10. Record whether a follow-up visit was scheduled for the Participant after this treatment. If "YES", circle "1" and proceed to A10a. If "NO" or "UNKNOWN", skip to **A11**.

A10a. Record the intended follow-up interval in weeks or months by completing the appropriate boxes and circling "1" for "WEEKS" or "2" for "MONTHS". Record the nature of the intended follow-up by circling only one of the options listed.

A11. Record whether or not the intended treatment was completed on this date by circling the appropriate response.

A12. Circle "1" for "YES" or "2" for "NO" to indicate how the information on this form was obtained. Sources of information include study personnel, chart abstraction, direct contact with provider, patient history or other.

By study personnel, we mean WIHS staff.

By chart abstraction, we mean information obtained from a Participant's medical record.

By direct contact with the provider, we mean the health care provider who performed the treatment has provided the information on this form (L16).

By patient history, we mean information provided by the Participant's self-report.

A13. Circle "1" for "YES" or "2" for "NO" to indicate the primary source of the information for the treatment of the Participant on this date (see A12 for the definitions of information sources listed).

A14. Print name of person who provides the treatment on this date.

A15. Record the name and address of the institution where treatment is being provided.