WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM 7: PHYSICAL EXAM

Guidelines for completing Form 07, "Physical Exam." Note that not every question is detailed in these QxQ's, but only those requiring further explanation than that listed on Form 07.

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.
3. Participants should remove all clothing, except underwear. Shoes should be removed; thin socks may be worn, if participant desires. Paper or lightweight cotton gowns should be worn during the entire 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 physical exam. Remember to verify with the participant the date of her birth. Record the actual time you began the physical 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: GENERAL PHYSICAL CHARACTERISTICS AND BODY HABITUS

A1a. Weight: A balance scale should be used, and all weights should be recorded in pounds (LBS). The scale should be level and on a firm surface (not a carpet). Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. The participant should be instructed to stand in the middle of the platform of the balance scale with head erect and eyes looking straight ahead. Adjust the weight on the indicator until it is balanced. The weight should be recorded in pounds to the nearest 1.0 lb. Please do not make any conversions from kilograms. Have the participant step off the scale, reset the balance to zero and repeat. If measures differ by more than 1.0 lb., repeat a third time. Always record the first measure that most closely matches the third measure. For example, if only two measures were taken (i.e., the first and second measures were within 1.0 lb. of one another) record the first measure taken. If three measures were taken and the second and the third are within 1.0 lb. of each other, record the second measure. If three measures were taken and the first and the third measure were within 1.0 lb. of each other, record the first measure.

A1b. Indicate if the participant is attending an odd- or even-numbered visit. Beginning at visit 21, height will be measured once per year only, at even-numbered visits. If participant is attending an even-numbered visit, proceed to measure height as described in A1c below. If participant is attending an odd-numbered visit, skip to question A3b.

A1c. Height: Participant should stand with head in Frankfort horizontal plane, shoulders relaxed, arms at sides, legs straight, and feet flat. The participant should take a deep breath and stand as tall as possible. Enter the height of the participant in inches. Round off to the nearest whole number and write in the numeric value. Please do not do any conversions.

NOTE: Frankfort horizontal plane is described by NHANES as: "The head is in the Frankfort plane when the horizontal line from ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard."

A3b. Indicate if the participant is pregnant. If she is, skip to Section B.

A5. The visual assessment section of the physical exam includes clinician rating of fat distribution and other changes according to a scale with the following gradations: normal, mild, moderate and severe. Surveys in previous studies used a subjective rating system that was based on the opinion of the observer. While there are no absolute criteria, the WIHS study is providing a series of photographs with some gradations and descriptions (see WIHS website and below) to assist in the examination of the participant. The photographs and descriptions should be viewed as a guide to the evaluation. Some of the findings are similar to those found in people without HIV infection. If the participant fits into the average of the people that are seen, then choose **Normal**.

For this portion of the exam, participants should wear a loose fitting hospital gown. The exam should be performed with the participant standing. The legs should be relaxed with both feet flat on the ground and the arms should be relaxed on either side. When examining the various body sites, please make sure the area can be well visualized. For instance, when examining the chest, please have the participant remove the top part of the gown, so that the chest can be well visualized.

The following are definitions for mild, moderate, and severe used in a separate study looking at fat redistribution (HIV Outpatient Study (HOPS)):

Mild:	Only seen if looked for
Moderate:	Easily seen
Severe:	Obvious immediately

Described below are specific descriptions for each of the points (other than normal) on the 7-point scale associated with each area of the body listed.

Questions A5a, A5f, A5g concern the chest, upper back, and neck, respectively. Please use the following guidelines for all three of these locations:

Severely fat:	Fat obviously bulging outward; may have prominent folds
Moderately fat:	Prominent amount of fat
Mildly fat:	More fat than average on exam
Mildly wasted:	Little fat; musculature and veins may be visible
Moderately wasted:	Very little fat; musculature and veins may be prominent
Severely wasted:	Virtually no fat present; muscle bellies, tendons and bones may stand out

Questions A5b (abdomen) **and A5c** (waist) focus on the lower torso. **Question A5b** focuses on the amount of subcutaneous fat present in the abdomen, both anteriorally and laterally. **Question A5c** refers to the general shape of the abdomen, or waist, and not the amount of fat in the abdomen.

Question A5d focuses on the shape of the face; please use the following guidelines:

Severely fat:	Moon facies
Moderately fat:	Rounded
Mildly fat:	Shifting to round when looked for
Mildly wasted:	Fat loss visible on side of face when looked for
Moderately wasted:	Deep indentations of fat loss on side of face
Severely wasted:	Obvious, very deep indentations on side of face with virtually no fat present; muscle and bones may stand out

Question A5e (cheeks) refers to the area just lateral to the nose and mouth. Please use the following guidelines when evaluating the participant:

Severely fat:	Cheeks bulging
Moderately fat:	Cheeks fuller
Mildly fat:	Cheeks look fuller when looked for
Mildly wasted:	Lines of loss visible in cheeks when looked for
Moderately wasted:	Deep indentation in cheeks
Severely wasted:	Obvious, very deep indentations in cheeks with no fat present; muscle and bones may stand out

Questions A5h and A5i concern the arms and legs, respectively. Please note that prominent indentations may be visible, especially above the elbows on the arms and above the knees on the thighs. The arms should be relaxed on either side and not flexed when examined and the legs should be relaxed with both feet flat on the ground when examined. Focus on the right extremities as anthropometric measurements are generally performed on the right. If this is not possible, examine the left extremities and make a note that the left extremities were examined. The following are guidelines for the scale points for these items:

Severely fat:	Fat obviously bulging outward; may have prominent folds
Moderately fat:	Prominent amount of fat
Mildly fat:	More fat than average on exam
Mildly wasted:	Little fat; musculature and veins may be visible
Moderately wasted:	Very little fat; musculature and veins may be prominent
Severely wasted:	Virtually no fat present; muscle bellies, tendons and bones may stand out.

Question A5j focuses on the buttocks and the following guidelines should be used:

Severely fat:	Fat obviously bulging outward; may have prominent folds
Moderately fat:	Prominent amount of fat
Mildly fat:	More fat than average on exam
Mildly wasted:	Little fat; musculature and veins may be visible
Moderately wasted:	Very little fat; musculature and veins may be prominent
Severely wasted:	Virtually no fat present; muscle bellies, tendons and bones may stand out

A6. This question is to assess overall clinical impression of lipodystrophy and should be asked of all participants. Please indicate whether or not the participant exhibits any signs of lipoatrophy (peripheral fat loss) or lipohypertrophy (central fat accumulation). The term "lipodystrophy" has been used to describe patients who have any signs of either lipoatrophy or lipohypertrophy, or those who have both lipoatrophy and lipohypertrophy. These body fat changes occur in some patients on antiretroviral medications and it is unclear whether these changes are separate clinical entities or represent different manifestations of the same syndrome. The changes commonly reported include:

Lipoatrophy (peripheral fat loss)

* facial wasting (nasolabial or cheek area)
* loss of gluteal fat
* loss of subcutaneous fat in arms with prominence of arm veins and muscles in more severe cases
* loss of subcutaneous fat in legs with prominence of leg veins and muscles in more severe cases

Lipohypertrophy (central fat gain)

* dorsocervical fat pad enlargement (buffalo hump)
* supraclavicular and/or axillary fat pads
* abdominal girth enlargement
* breast hypertrophy

If the participant exhibits one or more signs of peripheral lipoatrophy, circle "YES" to question a, otherwise circle "NO". If the participant exhibits one or more signs of central fat accumulation, circle "YES" to b, otherwise circle "NO."

PROMPT:

- IF **PARTICIPANT IS POST-PARTUM AND NOT BREASTFEEDING**, DO NOT DO BODY MEASURES, SKINFOLDS OR BIA UNTIL PARTICIPANT IS ONE YEAR POST-DELIVERY.
- IF **PARTICIPANT IS POST-PARTUM AND BREASTFEEDING**, DO NOT DO BODY MEASURES, SKINFOLDS OR BIA UNTIL PARTICIPANT IS SIX MONTHS POST-DELIVERY. DO NOT DO CHEST GIRTH MEASUREMENTS UNTIL PARTICIPANT IS ONE YEAR POST-DELIVERY.

PLEASE RECORD A RESPONSE OF "-1" FOR THESE QUESTIONS AND RECORD REASON IN COMMENTS FIELD AFTER QUESTION A24.

Body Measurements:

Body measurements should always be taken on the right side of the body (unless for a specific reason such as casts or amputations). Any marks that need to be made on the participant's skin should be made with a cosmetic pencil (waxed base), such as an eyeliner pencil. The measuring tape should be flexible but non-stretchable (i.e., Gulik type) and measurements should be recorded to the nearest 0.1 cm. For post-partum women who are not breastfeeding, do not take body measurements until one year post-partum. For women who are breastfeeding, do all of the measurements beginning six months post-partum, except for the chest/breast measurement.

NOTE: All measurements should be taken two times. If the difference between the measures exceeds 0.7 cm, repeat the measure a third (and final) time.

Each question in this section has a subquestion asking if the value exceeds 0.7 cm. If the first two values do not exceed this limit, record the measurements on lines #1 and #2 and circle "NO" for the subquestion. A third measurement does not need to be taken or recorded on line #3, and you should skip to the next body measure.

If the difference between the first two values exceeds 0.7 cm, a third measurement must be taken. Record measurements #1 and #2 on their respective lines and answer, "YES" to the subquestion. Take the third measurement and record on line #3.

NOTE: If a body measure is above the measurable limits of the measuring tape (i.e., > 150), "151" should be entered into the field for that body measure.

A7. Upper Arm Girth: Have the participant stand erect with feet together and the right arm flexed 90° at the elbow with the palm facing up. The examiner is positioned behind the participant. Using a tape measurer, mark a point halfway between the lateral projection of the acromian process of the scapula (bump on the backside of shoulder) and the interior part of the olecranon process (elbow). Next, the participant stands with the right elbow relaxed so that the right arm hangs freely to the side. The examiner stands facing the participant's right side. The measuring tape is placed around the upper arm at the marked point perpendicular to the long axis of the upper arm. The tape is held so that the zero end is held below the measurement value. The tape rests on the skin surface, but is not pulled tight enough to compress the skin. The arm circumference is recorded to the nearest 0.1 cm.

A8. Chest Girth: The chest girth is measured at the level of the fourth costo-sternal joints, which laterally corresponds to the level of the sixth ribs. The fourth costo-sternal joint can be located by a two-handed palpitation method whereby the examiner places both the index fingers on the superior surfaces of the clavicles, while the thumbs locate the first intercostal space. The index fingers then replace the thumbs, which are lowered to the second intercostal spaces. This procedure can then be repeated until the fourth cost-sternal joint is located. The ribs and their costal cartilages are followed medially to their articulations at the sternum, and this point is marked. The participant should be standing with the feet at the shoulder width. The arms are slightly away from the body to allow placing the tape around the chest. The measuring tape should be placed horizontally at the marked point. Once the tape is in place, the arms can be lowered to their relaxed position. Take the measurement at the end of a normal expiration. The chest girth is recorded to the nearest 0.1 cm.

A9. Waist Girth: The study participant is in a standing position. The participant is asked to hold up her gown. The examiner stands behind the participant and palpates the hip area for the right iliac crest (see Appendix A). The examiner marks a horizontal line at the high point of the iliac crest and then crosses the line to indicate the midaxillary line of the body. The pants and underclothing of the participant must be lowered slightly for the examiner to palpate directly on the hip area for the iliac crest. The examiner then stands on the participant's right side and places the measuring tape around the trunk in a horizontal plane at this level marked on the right side of the trunk. Make sure that the tape is parallel to the floor and that the tape is snug, but does not compress the skin. The measurement is made at minimal respiration to the nearest 0.1 cm.

A10. Hip Girth: The study participant stands erect with feet together and weight evenly distributed on both feet. The participant is holding up the examination gown. The examiner places the measuring tape around the buttocks. The tape is placed at the maximum extension of the buttocks (see Appendix B). The examiner then adjusts the sides of the tape and checks the front and sides so that the plane of the tape is horizontal. The zero end of the tape is held under the measurement value. The tape is held snugly but not tight. The examiner takes the measurement from the right side.

A11. Thigh Girth: First, have the participant sitting with her right knee bent at a 90° angle. Mark the nearest border of the patella (knee cap). A measuring tape is placed at the superior aspect of the inguinal crease which is easily located if the hips are in the sitting position. No pressure is to be applied at the inguinal crease; however, folds of fat tissue may have to be lifted on some obese participants to measure at the crease. The exam gown should be lifted. The tape is extended along the midline of the thigh to the line just proximal to the patella (see Appendix C). The examiner should make a mark (+) at the mid point of the thigh with a cosmetic marker. Next, have the participant stand with her right leg just in front of her left leg and her weight shifted back from her left leg. The examiner should demonstrate this instruction. The edge of the examining table may be used for the participant to hold onto to maintain balance. The examiner stands on the participant's right side and the measuring tape

is placed around the midthigh at the marked point. The tape is positioned perpendicular to the long axis of the thigh with the zero end of the tape held below the measurement value. The tape rests firmly on the skin without compressing the skin. The thigh circumference is measured to the nearest 0.1 cm.

A12. Dorsocervical fat pad:

a. The presence or absence of abnormal fat deposition in the dorsocervical region should be noted. Circle "1" if fat deposition is present; "2" if absent. Skip to **A13** if absent.

b. If present, record the clinician's impression of the severity of the fat deposition.

- **Mild**: Mild signs noted only after close inspection by the clinician.
- **Moderate**: Signs of fat maldistribution are noticed by the clinician without specifically looking for them.
- **Severe**: Signs of fat maldistribution are easily noted by casual observers or the clinician.

A13. The clinician performing the body measures should record his/her initials in question A13.

Skin Fold Measurements:

General Instructions:

- Make sure the participant's skin is dry and she is not overheated before taking any of the skinfold measures.
- All skinfolds should be measured with the Harpenden skinfold calipers.
- The measurements are taken on the right side of the body.
- Show the participant the calipers you will be using and allow the participant to feel the "pinch" on her hand (the area between the thumb and the index finger is a good place for this). Point to the four sites where the measurements will be performed.
- The fold of the skin and underlying subcutaneous adipose tissue should be firmly grasped between the examiner's left thumb and forefingers, pulling the skinfold away from the body. The amount grasped depends upon the thickness of the subcutaneous adipose tissue. The examiner grasps enough skin and adipose tissue to form a distinct fold that separates from the underlying muscle.
- The sides of the skinfold should be roughly parallel. The more fat under the skin, the thicker or wider the fold may be. Pulling the skinfold away from the body is usually easier in thin persons compared to obese persons. It can also be somewhat uncomfortable for the participant. Explaining to the participant what you are doing will make her feel more at ease.
- Hold the caliper in your right hand, perpendicular to the skinfold, and with the dial face up.
- The skinfold is grasped 2.0 cm above the place the measurement is to be taken and is held with the thumb and forefinger. This is important to prevent the pressure of the caliper heads from being affected by pressure from the fingers.
- The jaws of the calipers are placed at the marked level, perpendicular to the length of the fold, and the skinfold thickness is measured to the nearest 0.1 mm while the fingers continue to hold the skinfold.
- Take care not to place the caliper heads too far into the skinfold. The caliper heads should be placed on the actual double fold of the skin's thickness.
- During each measurement maintain the pressure of the fingers.

- Release the lever of the caliper and read the dial after approximately 3–4 seconds. Waiting longer than 4 seconds may result in inaccurate, smaller readings.
- Wait at least 15 seconds between each repetition so that the skinfold is allowed to "flatten," or return to normal, between readings
- If a participant is obese it may be difficult to pull the skinfold and/or the skinfold may be too thick for the calipers. Sometimes, skinfolds may be difficult to measure. For example, if a skinfold is too tight to be measured, a "0" should be recorded in the space for that skinfold on the form. If a skinfold is above the measurable limits of the calipers (i.e., > 50), "51" should be entered into the recording space for that skinfold.
- Practice the measurements until you are completely comfortable with them. It takes practice to become skillful and to be able to grasp the thickness of the skinfolds.
- If the participant refuses the skinfold measures, enter "-7 " in each of the response boxes for questions A13–A16.

NOTE: At a minimum, all skinfold measurements should be done in duplicate. If the difference between the measures exceeds 2 mm, repeat the measure a third (and final) time.

Each question in this section has a subquestion asking if the value exceeds 2 mm. If the first two values do not exceed this limit, record the measurements on lines #1 and #2 and circle "NO" for the subquestion. A third measurement does not need to be taken or recorded on line #3, and you should skip to the next body measure.

If the difference between the first two values exceeds 2 mm, a third measurement must be taken. Record measurements #1 and #2 on their respective lines and answer, "YES" to the subquestion. Take the third measurement and record on line #3.

A14. Thigh Skinfold: The thigh skinfold is measured in the midline of the anterior aspect of the right thigh. This level has already been marked for the thigh girth measure (See Appendix C). The participant stands with her weight shifted back on the left leg with the right leg forward, knee slightly flexed, foot flat on the floor. Some of the women may need to hold onto the edge of the table to maintain their balance in this position. This is the same position used for measuring thigh girth. A fold of skin and subcutaneous tissue is grasped in the midline about 2.0 cm above the marked point. The jaws of the skinfold caliper are placed perpendicular to the length of the fold and the shaft of the thigh over the marked point. Skinfolds are recorded to the nearest 0.1 mm while the fingers continue to hold the skinfold.

A15. Tricep Skinfold: The participant stands erect with her feet together, shoulders relaxed, and arms hanging freely at her sides. The examiner stands behind the participant's right side. The point on the posterior surface of the right upper arm is located in the same area as the marked midpoint for the upper arm circumference. A fold of skin and subcutaneous adipose tissue is grasped with thumb and fingers approximately 2.0 cm above the marked level with the skinfold parallel to the long axis of the arm (See Appendix D). The jaws of the calipers are placed at the marked level, perpendicular to the length of the fold, and the skinfold thickness is measured to the nearest 0.1 mm while the fingers continue to hold the skinfold.

A16. Subscapular Skinfold: The participant stands erect with shoulders and arms relaxed at her sides. The examiner opens the back of the examination gown and palpates for the inferior angle (or triangle portion) of the right scapula. The examiner makes a cross (+) on the inferior angle of the scapula with cosmetic marker. The examiner gently grasps a skinfold with the index finger directly above (1 cm) and medial to the inferior angle of the scapula with the thumb reaching toward the spine. The skinfold forms a line about 45° below the horizontal

extending diagonally toward the right elbow (See Appendix E). The jaws of the caliper are placed perpendicular to the length of the fold about 2.0 cm lateral to the fingers with the top jaw of the caliper on the mark over the inferior angle of the scapula. The skinfold thickness is measured to the nearest 0.1 mm while the fingers continue to hold the skinfold.

A17. Suprailiac Skinfold: The participant stands and holds the right side of the examining gown up so that the waist and top of the right hip area is exposed. The iliac crest has already been marked for the waist circumference measurement. The examiner places his/her thumb (left) in line with the intersecting marks and picks up the skinfold with the thumb and fingers. The skinfold should slope downward and forward at a 45° angle extending toward the pubic symphysis (See Appendix F). The lower jaw of caliper is placed on the mark perpendicular to the skinfold about 2.0 cm medial to the fingers and the skinfold is measured to the nearest 0.1 mm while the fingers continue to hold the skinfold.

A18. The clinician performing the skin fold measures should record his/her initials in question A18.

Bioelectrical Impedance Analysis (BIA):

A19–A21: Ask these three questions before administering the BIA procedure.

A22–A23: *BIA General instructions:*

- ***BIA should not be done on pregnant women, on women who are overheated (as indicated by high body temperature), or on women who have a cardiac pacemaker or who have amputations other than fingers or toes.***
- There should be no portable electrical heater or other electronic device in use in the exam room and the exam table should be non-conductive.
- The battery should be kept current and the equipment should be calibrated weekly.
- If the participant refuses the BIA, enter "-7 " in each of the response boxes for questions A20–A21.

Procedures:

1. The participant should remove her right shoe and sock. If, for some reason, the procedure must be done on the left side, then make note of it and on subsequent visits always use the left side.
2. The participant should lie on her back, without a pillow on the exam table, with her arm 30 degrees from her body and thighs not touching.
3. Remove jewelry on the electrode sites.
4. The sites where you will place the electrodes should be gently cleaned with an alcohol wipe, particularly if the skin is moist or covered with lotion. Allow alcohol to evaporate before placing electrodes.
5. Attach the electrodes (use whole electrode pads only) and patient cables as described below and as shown in the photographs provided by RJL. Attach the lead wires to the electrodes with the red leads attached to the wrist and ankle and the black leads attached to the hand and foot. In each case, the red alligator clip should be proximal and the black clip distal.
    - *Right wrist:* Draw an imaginary line on the dorsal surface bisecting the styloid processes of the ulna and radius. Place the center of the electrode along the middle of the imaginary line, and with the tab of the electrode facing out (away from the body).

- *Right hand:* Place the electrode below the knuckle and above the base of the middle finger, with the tab of the electrode facing out.
- *Right ankle:* Draw an imaginary line on the dorsal surface of the foot bisecting the medial and lateral malleoli of the ankle. Place the center of the electrode along the middle of the imaginary line with the tab of the electrode facing out.
- *Right foot:* Place the electrode at least four to five centimeters away from the electrode on the ankle, below the base of the second toe, with the tab of the electrode facing out.

6. The participant should remain motionless and relaxed with her arms and legs slightly apart, never touching any other part of the body. The arms should be bent slightly at the elbow with palms down. In cases where the participant's arms and legs cannot be properly spread (because the participant's body is large), the procedure should still be completed and a note made in the comments section. As long as there is no skin contact (the paper gown can be used to separate the arms from the trunk or the legs from each other), no interference with the proper flow of the current should take place.
7. Turn on the analyzer and when the measurements have stabilized, read and record the displayed Resistance (Rx) and Reactance (Xc) in the spaces provided in **A20**. If you were unable to obtain the reading for either of these two measures, select the "Can't obtain" box for the respective measure.
8. Turn off the analyzer. Double-check the leads and electrodes. Stabilize the participant, turn the leads back on, read and record the displayed Resistance and Reactance in the spaces provided in **A21**. Once again, check the "Can't obtain" box if you are unable to obtain a reading for either of these measures.
9. Unhook the leads and remove and dispose of the electrodes. Do not reuse the electrodes.

A24. The clinician performing BIA measures should record his/her initials in question A24.

Comments: Please note if the participant reports recently having had diarrhea, having thrown up, being diaphoretic or incontinent, or any other factors that may affect the BIA measurement.

SECTION B: SKIN EXAM

NOTE: AS YOU PROCEED WITH THE PHYSICAL EXAM, RESPONSES CIRCLED "YES" THAT ARE SHADED REQUIRE PROMPT REFERRAL FOR EVALUATION AND/OR TREATMENT. PLEASE REFER TO YOUR MANUAL FOR REFERRAL GUIDELINES.

B1a. Ask the participant if she has ever had an allergic skin reaction. It is defined as an adverse cutaneous reaction produced by ingestion, parenteral use, or local application of a drug, which may produce various morphologic patterns and types of lesions.

B2. Enter the total number of different location codes recorded in B3–B8. The value must be equal to the number of boxes completed in B3–B8 indicating where lesions are present.

B3–B8: Section B allows entry of up to six locations. Descriptive information recorded for each lesion type consists of two parts (a and b). For each location code mentioned at B2, complete one location code box describing the location and then enter the diagnosis of the lesion (i.e., complete sections a and b for each lesion location).

a. Using the location codes provided, enter the two-digit code that corresponds with the location of the lesion. If there are two locations at which the same type of lesion is found, each location should be recorded individually in a location box found in B3–B8. For example, if eczema is found on the back and legs (codes 07 and 08), record each of those location codes

in B3a and B4a. However, if the same type of lesion is found in three or more locations, use only one location box and record location code "14" (3 or more locations).

b. Using the diagnosis codes provided, enter the three-digit diagnosis code for the lesion. If the clinician does not know or cannot confirm the diagnosis, record "299."

Section B can accommodate up to six lesion locations. If the participant has less than six lesion locations, follow the **PROMPT** and skip to **C1**. **If more than six lesion locations are present, use a copy of page 6 for recording additional lesion locations.**

SECTION C: ORAL EXAM

NOTE: REFER PARTICIPANTS WITH ORAL LESIONS AS APPROPRIATE TO MEDICAL PROVIDERS.

C2. On the basis of the oral examination, enter YES or NO for each of the following:

a. Angular Cheilitis
- Found only in the corners (angles) of the mouth
- Erythema, fissures or linear ulcers
- If lesion can be attributed to recent injury, do not code as angular cheilitis

b. Pseudomembranous Candidiasis
- Yellow-white or white, loosely adherent plaque(s) located anywhere in the mouth
- Plaques must be adherent to the mucosa, but must wipe off

NOTE: If not certain that plaques are adherent, have the subject rinse. If plaques remain and can be wiped off, code as pseudomembranous candidiasis.

c. Erythematous Candidiasis
- Diffuse or irregular erythematous (redder than normal), macular patches on mucosal surfaces
- Dorsum (top) of tongue – irregular, depapillated (smooth) area or areas that may or may not be erythematous
- In any location – areas are not sharply defined

NOTE: Confirm with identification of fungal hyphae on KOH prep.

d. Hairy Leukoplakia
- White, slightly elevated, vertically corrugated surface alteration of the lateral (side) or ventral (undersurface) surface of the tongue

NOTES: 1) Vertical corrugations are essential to the coding of hairy leukoplakia. 2) When extending to the ventral aspect of the tongue, the white lesion may be flat and not corrugated – vertical corrugations must be present in an associated lesion on the lateral tongue.

e. Oral Papilloma/Wart
- Any papillary outgrowth(s) of the oral mucosa
- May be "cauliflower-like" or flat
- May be solitary or multiple
- Small to extensive

NOTE: Generalized papillary textured mucosa under a full or partial denture should not be recorded as oral Papilloma.

f. Other
- For any other oral lesion than those listed above, write in the lesion by description or name.

SECTION D: PHYSICAL FINDINGS IN THE BREASTS

D1a. Indicate if the participant is attending an odd- or even-numbered visit. Beginning at visit 21, the breast exam will be performed once per year only, at even-numbered visits, unless a semi-annual exam is clinically indicated. If participant is attending an even-numbered visit, perform the breast exam as described in D1b below. If participant is attending an odd-numbered visit, skip to Section E.

NOTE: If a semi-annual exam is clinically indicated and an exam is performed at an odd-numbered visit, the results will not be recorded on the F07 form. However, if abnormalities are found, the participant should be referred as appropriate to her medical provider.

D1b. Examine and record your overall assessment of the participant's breasts.

D9–D18: Be careful to record information from the LEFT and the RIGHT breasts separately and in the proper location on the form. If a breast mass is not found in a region, code "NO," and skip to the next region (do not complete sub questions "a" and "b"). If a mass is found, record the size of the mass in centimeters and indicate whether or not this is an old mass. Old mass is defined as:

Old Mass: A persistent, discrete lump or localized thickening in either breast that has been evaluated by a physician, mammogram, needle aspiration or biopsy and that was found to be a benign condition.

SECTION E: BLOOD PRESSURE MEASUREMENT

E1. BLOOD PRESSURE (MEASURE AND RECORD THREE TIMES USING DINAMAP MONITOR):

All blood pressure measurements in the WIHS will be collected using the same automated Dinamap monitor (Dinamap Procare Series, GE Medical Systems) for standardization purposes. Each site should purchase a sufficient number of Dinamap monitors so that all WIHS participants seen at all subsites will have their blood pressure measured using the Dinamap monitor.

The WIHS requires the collection of three seated blood pressure measurements from the participant's right arm, using an automated Dinamap blood pressure monitor. The pulse rate will be recorded with each blood pressure measurement from the Dinamap monitor. The Dinamap monitor should be set to automatically measure blood pressure at one-minute intervals.

The clinician should communicate appropriately with the participant regarding the purpose, time requirement and process of blood pressure measurement. Throughout the BP measurement, the clinician should keep the participant warm, relaxed and comfortable. The participant should be discouraged from reading, watching TV or talking, except to voice discomfort or confusion about instructions. The participant should be seated with both feet flat on the floor and with the back supported. Her right arm should be placed on the table in the proper position (i.e., at heart level with the arm slightly flexed and the palms facing upward). The participant's arm should be bare to above the point of the shoulder.

1. ARM MEASUREMENT

   The proper size cuff must be used to obtain accurate blood pressure (BP) readings.

   - Ask participant to either remove her upper garment or to completely expose the right upper arm in order to perform the arm circumference measurement.

- In the standing position with the **right** forearm held horizontal, measure the arm length from the shoulder to the elbow. Mark the midpoint. (Arm circumference measurement is already being done in WIHS.)
- With the arm relaxed at the side of the body, place the tape measure horizontally, and draw snugly around the arm at the midpoint. Record the circumference.
- Consult the chart of arm circumference measurements and corresponding cuff sizes to choose the appropriate cuff. **Do not rely** on the markings on most BP cuffs – they may be incorrect!
- The left arm may be used if the BP is known to be higher in that arm, or in the presence of an anomaly or other circumstance prohibiting use of the right arm. Otherwise all BP measurements should be done on the right arm.

2. APPLYING THE BP CUFF

The cuff sizes used are:

Small adult: 17.1 – 25 cm
Regular adult: 25.1 – 33 cm
Large adult: 33.1 – 40 cm)
Thigh: (40.1 – 50 cm)

- Place the cuff directly on the skin, not over clothes.
- Palpate the brachial artery and place the midpoint of the length of the bladder over the brachial artery and the mid-height of the cuff at heart level.
- The lower edge of the cuff should be about one inch above the natural crease of the inner aspect of the elbow.
- Wrap the cuff snugly and secure firmly.
- The participant should be seated with both feet flat on the floor and with her back supported, and rest with her palm turned upward. Ask if the participant is relaxed, and, if necessary, help her to relax.

3. OBTAINING THE BP READINGS

The participant should be allowed to sit quietly for five minutes without talking. She should be seated comfortably, feet flat on the floor with her back supported. Ideally she should not have smoked or have had any caffeine within the 30 minutes prior to the BP determinations. After the five-minute waiting period, the clinician is to take three blood pressure measurements, with a one-minute wait between each measurement. The participant's arm should be passively raised overhead by the examiner for the first five seconds between each measurement. All measurements should come from the Dinamap.

1. Turn the Dinamap monitor on by pressing the blue "*on/off*" button on the lower right hand corner of the monitor. Then, press the light gray "*cycle*" button, which is below the green "*inflate/stop*" button on the upper right hand corner of the monitor. Make sure that the number "1" appears in the screen immediately to the left of the "*cycle*" button. This automatically sets the monitor to inflate, and then to re-inflate every one minute thereafter.
2. After the first blood pressure and pulse measurements appear on the screen, enter the systolic blood pressure, diastolic blood pressure and pulse onto the WIHS Physical Exam (F07) form. Please note that the pulse on the Dinamap monitor appears below the diastolic blood pressure.

3. After the cuff deflates, passively raise the participant's arm overhead for five seconds. Lower the arm gently.
4. Record the second blood pressure measurement and pulse, and again passively raise the participant's arm overhead for five seconds. Lower the arm gently.
5. Record the third blood pressure measurement and pulse, and then remove the cuff.

Always remember to turn off the monitor by pressing the blue button at the lower right hand corner of the monitor after all three blood pressure measurements are taken, otherwise the cuff will continue to inflate at one-minute intervals.

If, for some reason, you did not record the prior reading before the next blood pressure measurement was taken, you can press the gray "*history*" button after the blood pressure measurement is taken. The Dinamap monitor can store up to 25 blood pressure readings. If you would like to store just the three blood pressure measurements for the participant, clear all previous stored blood pressure measurements before taking the first blood pressure measurement. This can be done by pressing and holding the gray "*history*" button for two seconds. If you would like to print the blood pressure measurements, press the gray "*history*" button, followed by the gray "*print*" button, which is directly below the gray "*history*" button.

When the blood pressure is reported to the participant, the clinician should say, "Your average blood pressure today is …"

NOTE: IF BLOOD PRESSURE IS < 90/60 OR > 140/90, REFER PARTICIPANT TO MEDICAL PROVIDER.

PROMPT: COMPLETE "TIME MODULE ENDED" ON PAGE 1. THEN PROCEED TO FORM 8. ANY NECESSARY ADDITIONAL COMMENTS SHOULD BE WRITTEN IN THE SPACE PROVIDED ON THE LAST PAGE.