## WOMEN'S INTERAGENCY HIV STUDY INTERIM EVENTS FORM

PARTICIPANT ID:	-    -  _		
FORM VERSION:	<u>1</u> 0/0_1 M_D	_ / <u>0</u> <u>0</u> <u>Y</u>	
DATE COMPLETED:	/	/Y	
FORM COMPLETED BY:		VISIT:	
1. HOW WAS INTERIM EV	ENT DATA OBTAI	NED?	
Active surveillance (via WIHS Interim Events Protocol)			
2. WIHS STAFF HEARD OF	THIS EVENT FRC	M WHAT SOURCE?	
Participant Family member of partic Friend of participant	ipant 2	Health care provider4Social service provider5Other6	

Specify:

### PROMPT: IF PARTICIPANT HAS DIED, COMPLETE QUESTIONS #1 AND #2 ABOVE AND END THE FORM. ALSO COMPLETE A DISENROLLMENT FORM, NOTE THE DEATH ON THE ATC, AND MAIL A MEDICAL RECORD RELEASE TO A FAMILY MEMBER FOR SIGNATURE.

### SECTION A. CANCER DIAGNOSES

For the following questions, I am going to use the words "health care provider" to mean any doctor, nurse, physician's assistant or nurse practitioner you go to for medical care.

A1. a. Since your (MONTH) study visit, have you been told by a health care provider that you had cervical cancer?

YES	1	
NO	-	<b>A2)</b>

b. Have you had surgery (been admitted to the hospital and had surgery in an operating room) to treat the cervical cancer?

YES	1
NO	2

c. Have you had a CAT or MRI scan of your abdomen (a big donut-shaped machine that takes special pictures)?

 d. Have you been told that you need to have either surgery or radiation therapy?

YES 1	_
NO 2	

A2. Since your (MONTH) study visit, have you been told by a health care provider that you had any other type of cancer, including skin cancer, lymphoma, Kaposi's sarcoma, Hodgkin's disease, breast cancer or cancer of the female organs – the ovaries or uterus?

YES	1	
NO	2	(A3)

2

2

2

2

2

What kind of cancer? Was it: [**READ**  $\mathbf{a} - \mathbf{i}$ ]

			NO/NEVI	ER
		YES	HEARD OI	F IT
a.	Breast cancer	1	2	<b>(b)</b>

- i. Have you had a lump removed by a surgeon (not a needle biopsy, but an incision resulting in stitches)?
  - YES .....1 NO .....2
- ii. Have you had a mastectomy (removal of entire breast)?
  - YES ..... 1 NO ..... 2
- b. Cancer of the ovary ..... 1
- c. Cancer of the uterus ..... 1
- d. Kaposi's Sarcoma (KS) . . 1
- e. Lymphoma ..... 1
- f. Lymphoma in the brain ... 1
- g. Hodgkin's disease ...... 1 2
- h. Skin cancer (not KS) .... 1 2
- i. Other cancer ...... 1 2 (A3)

SPECIFY:

A3. PLEASE RECORD THE TOTAL NUMBER OF CANCERS REPORTED AT THIS VISIT. DO NOT FORGET TO INCLUDE CERVICAL CANCER IF REPORTED IN QUESTION A1a, IN ADDITION TO ALL CANCERS REPORTED IN QUESTIONS A2a–A2i.

|\_\_\_| # CANCERS

### **PROMPT: IF QUESTION A3 = 00, SKIP TO SECTION B.**

## **BEGIN INTS1**

### PROMPT: FOR EACH CANCER INDICATED IN QUESTION A3, COMPLETE QUESTIONS A4–A5. THE NUMBER OF BOXES COMPLETED MUST EQUAL THE VALUE RECORDED AT A3. INDICATE THE LOCATION OF EACH REPORTED CANCER IN a, THEN COMPLETE b–f AS INDICATED FOR EACH. IF THE TOTAL NUMBER OF REPORTED CANCERS IS GREATER THAN TWO, PLEASE XEROX THIS PAGE AND INSERT THE COPY AFTER PAGE 3.

A4	a. LOCATION OF REPORTED CANCER:		
	PROMPT: REPLACE (LOCATION) WITH THE LOCATION WRITTEN IN A4a.		
	Now I'm going to ask you a few more questions about your (LOCATION) cancer diagnosis.	<u>YES</u>	NO
	b. Is this your first diagnosis of cancer?	1 (c)	2 (e)
	c. When your (LOCATION) cancer diagnosis was made, were you told that it had also metastasized or spread to another part of your body?	1 <b>(d)</b>	2 (A5)
	d. Spread to where?(A5)		
	e. Were you told that the cancer you are <u>now</u> reporting had metastasized or spread from the original cancer?	1 <b>(f)</b>	2 (f)
	f. Where was the original cancer? (A5)		

A5 a. LOCATION OF REPOR	RTED CANCER:
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	PROMPT: REPLACE (LOCATION) WITH THE LOCATION WRITTEN IN A5a.		
	Now I'm going to ask you a few more questions about your (LOCATION) cancer diagnosis.	<u>YES</u>	<u>NO</u>
	b. Is this your first diagnosis of cancer?	1 <b>(c)</b>	2 (e)
	c. When your (LOCATION) cancer diagnosis was made, were you told that it had also metastasized or spread to another part of your body?	1 <b>(d)</b>	2 ( <b>B</b> 1)
	d. Spread to where? (B1)		
	e. Were you told that the cancer you are <u>now</u> reporting had metastasized or spread from the original cancer?	1 <b>(f)</b>	2 <b>(f)</b>
	f. Where was the original cancer? (B1)		

### END INTS1

PROMPT: FOR EACH CANCER DIAGNOSIS REPORTED IN QUESTIONS A1a, A2 AND A2a-i, COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST (ATC).

a.

# ALSO, IF EITHER A4c/A5c OR A4e/A5e = YES, THEN COMPLETE ATC FOR METASTATIC CANCER.

#### **SECTION B. TUBERCULOSIS**

B1. The next few questions are about tuberculosis. I will refer to tuberculosis as TB for short. Since your (MONTH) study visit, have you had TB?

	YES NO			(B2)
Was	s it in your:	YES	NO	
	Lungs?	1	2	
	Other location?		2	(c)
	SPECIFY:			
c.	Did you have a chest X-ray?	1	2	
d.	Did you take medications for 3			
	months or more?	1	2	

# PROMPT: IF ANY OF QUESTIONS B1a-d = YES, THEN COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST.

B2. Not including the test you had for this study, since your (MONTH) study visit, have you had a skin test for TB?

YES	<pre>3&gt; (Section C)</pre>
When was the last time (most recent) you had a skintest for TB? I need the month and the year.	/

b. Were you told that the test was positive or showed that you had been exposed to TB?

YES	1
NO	2
DON'T KNOW	<-8>
DECLINED	<-7>

### PROMPT: IF QUESTION B2b = YES, THEN COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST.

### SECTION C. AIDS DEFINING ILLNESSES

C1. Since your (MONTH) study visit, have you had diarrhea (three or more soft or liquid stools per day), that lasted for more than one month?

C2. Since your (MONTH) study visit, has a health care provider told you that any diarrhea you may have had was caused by:

		NO/NEVER
	YES	HEARD OF IT
a.	Cryptosporidia1	2
b.	Microsporidia1	2
c.	Isospora1	2
d.	C-M-V1	2
e.	M-A-I1	2

C3. Since your (MONTH) study visit, has a health care provider told you that you had herpes simplex infection of the lungs or esophagus, (the tube between your mouth and your stomach)?

YES	 1
NO/NEVER HEARD OF IT	 2

C4. Since your (MONTH) study visit, has a health care provider told you that you had PCP, pneumocystis carinii pneumonia?

YES	 	 	1
NO/NEVER HEARD OF IT	 	 	2

C5. Since your (MONTH) study visit, has a health care provider told you that you had another type of pneumonia, lung infection? Do not answer yes if you were diagnosed only with bronchitis.

	YES	
a.	In the <b>past 12 months</b> , how many times has a heath care provider told you that you had pneumonia that required antibiotics, not counting PCP?	 # TIMES
b.	<b>Since your (MONTH) study visit</b> , how many times have you had pneumonia that required antibiotics, not counting PCP?	 # TIMES
c.	When was the last time you had pneumonia, not counting /    PCP? I need the month and the year.  M  Y	

### PROMPT: FOR EACH ILLNESS THE PARTICIPANT REPORTS IN QUESTIONS C2–C18 COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST.

C6. Since your (MONTH) study visit, has a health care provider told you that you had Candida or thrush, a yeast infection of the esophagus (the tube between your mouth and stomach) not just in your mouth?

YES	1
NO/NEVER HEARD OF IT	2

C7. Since your (MONTH) study visit, has a health care provider told you that you had Candida or thrush, a yeast infection of the lungs or airways (trachea or bronchi)?

YES	1
NO/NEVER HEARD OF IT	2

C8. Since your (MONTH) study visit, has a health care provider told you that you had an M-A-I infection which is sometimes called M-A-C or MAC?

YES	1
NO/NEVER HEARD OF IT	2

C9. Since your (MONTH) study visit, has a health care provider told you that you had Toxo infection, or toxoplasmosis of the brain?

YES	1
NO/NEVER HEARD OF IT	2

C10. Since your (MONTH) study visit, has a health care provider told you that you had C-M-V, cytomegalovirus:

	YES	NO	
a.	in either eye (retinitis)?1	2	
b.	in your blood? 1	2	
c.	in your intestine? 1	2	
d.	in your liver? 1	2	
e.	elsewhere in your body? 1	2	(C11)

SPECIFY: \_\_\_\_\_

C11. Since your (MONTH) study visit, has a health care provider told you that you had meningitis related to HIV?

YES 1	
NO/NEVER HEARD OF IT 2	(C12)

a. Were you told that this was Crypto, Cryptococcal meningitis?

YES ..... 1 NO/NEVER HEARD OF IT ..... 2

PROMPT: FOR EACH ILLNESS THE PARTICIPANT REPORTS IN QUESTIONS C2–C18

WIHS	5 ID #

### COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST.

C12. Since your (MONTH) study visit, has a health care provider told you that you had Cryptococcal infection:

		YES	NO	
a.	in your blood?	1	2	
b.	elsewhere in your body?	1	2	(C13)
	SPECIFY:			

C13. Since your (MONTH) study visit, has a health care provider told you that you had Histoplasmosis infection or Histo?

YES 1	
NO/NEVER HEARD OF IT	(C14)

- a. Where in your body? SPECIFY: \_\_\_\_\_
- C14. Since your (MONTH) study visit, has a health care provider told you that you had Cocci, coccidioidomycosis infection or Valley Fever?

YES	1
NO/NEVER HEARD OF IT	2

C15. Since your (MONTH) study visit, has a health care provider told you that you had wasting syndrome, in other words, severe weight loss?

YES	1	
NO/NEVER HEARD OF IT	2	(C16)

Have you had (CONDITION) that lasted for at least one month, during the same time that you experienced severe weight loss?

	YES	NO
a.	Chronic diarrhea (at least 3 loose stools	
	per day for greater than or equal to 30 days) 1	2
b.	Chronic weakness and documented	
	fever (for greater than or equal to 30 days) 1	2
c.	Were you told that [this symptom/these	
	symptoms] [was/were] due to HIV/AIDS 1	2

C16. Since your (MONTH) study visit, has a health care provider told you that you had dementia or encephalopathy, or that you had a memory problem or confusion caused by HIV?

YES ..... 1 NO/NEVER HEARD OF IT ..... 2

### PROMPT: FOR EACH ILLNESS THE PARTICIPANT REPORTS IN QUESTIONS C2–C18 COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST.

C17. Since your (MONTH) study visit, has a health care provider told you that you had an infection in the blood with a bacteria called salmonella?

YES	1	
NO/NEVER HEARD OF IT	2	(C18)

a. Have you had this more than once, since your (MONTH) study visit?

YES	•																	1	
NO																			

C18. Since your (MONTH) study visit, has a health care provider told you that you had PML, progressive multifocal leukoencephalopathy, a disease of the brain?

YES	 1
NO/NEVER HEARD OF IT	 2

### PROMPT: FOR EACH ILLNESS THE PARTICIPANT REPORTS IN QUESTIONS C2–C18 COMPLETE THE ASCERTAINMENT TRACKING CHECKLIST.

C19. Since your (MONTH) study visit, has a health care provider told you that you had herpes simplex with ulcers or sores lasting longer than one month?

YES ..... 1 NO/NEVER HEARD OF IT ..... 2

### **END FORM HERE**