Note: Number events sequentially (01, 02, 03). Number each page with the same event number. **Event Number** ☐☐

HPTN 052 (096) IWT-1 (415)

Index ID

☐☐☐ – ☐☐☐ – 0 0 – ☐

Site Number | Index Number | Partner | Chk

Index When to Start

diagnosis code

1. Record diagnosis code for this event: ☐☐

1a. Specify diagnosis: _____

confirmed *probable*

1b. Indicate if diagnosis is confirmed or probable:..... ☐ ☐

yes *no*

1c. Is this an AIDS-defining illness? ☐ ☐

1d. Indicate the Visit Code at which this event was first reported: ☐☐☐.☐

1e. Was this event recorded on the Index Adverse Events Log? *yes* ☐ *no* ☐ → *Record AE Log Page #* ☐☐☐

1f. Diagnosis status: *new* ☐ *recurrent* ☐

dd *MMM* *yy*

1g. Date event started: ☐☐ ☐☐☐ ☐☐

1h. Date of diagnosis: ☐☐ ☐☐☐ ☐☐

1i. Outcome:

- ☐ Continuing
- ☐ Resolved
- ☐ Death

1i1. Date of outcome: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

- ☐ Continuing at end of study participation

2. Is diagnosis a clinical event with a code of 30–44?..... *yes* ☐ *no* ☐

→ ***If yes, end of form. Fax only page 1 to SCHARP DataFax.***

Comments: _____

_____

☐ ☒ ☐ ☐ 16-JAN-13

0 1 Language

Staff Initials / Date

Index When to Start (IWT-1)

The Index When to Start CRF collects data on HIV/AIDS-related illnesses, WHO Stage 2 and 3 Clinical Events, and other targeted conditions, according to LOA #1 to version 3.0 of the protocol. Fax the form within 3 weeks of first becoming aware of the event.

Events listed in Appendix IV as HIV/AIDS-related illnesses (codes 01–28) and Other Targeted Medical Conditions (codes 50–63) require completion of all pages of the CRF. All other events (codes 30–44) require completion of page 1 only; any pertinent information related to the diagnosis (e.g., diagnosis confirmed via test) may be recorded on the Comments line.

Event Number: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Index When to Start pages after faxing, unless instructed by SCHARP.

Item 1 Diagnosis Code: Refer to the Code Lists below. If a diagnosis is later found to be incorrect, draw a line through the diagnosis code and record the correct code.

HIV/AIDS-related Illnesses (WHO Stage 4, severe bacterial infections and pulmonary TB) **Code List**

01 Bacterial infections, severe (WHO Stage 3) (e.g., pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
02 Bacterial pneumonia, recurrent, severe (≥ 2 episodes in 12 months)
03 Oesophageal candidiasis (or candidiasis of bronchi, trachea, or lungs)
04 Cervical carcinoma, invasive, confirmed by biopsy
05 Chagas' disease
06 Cryptococcosis, extrapulmonary including meningitis
07 Cryptosporidiosis, chronic intestinal (> 1 month duration)
08 Cytomegalovirus disease (retinitis or infection of other organs)
09 Encephalopathy, HIV-related
10 Herpes simplex, chronic (orolabial, genital, or anorectal site, > 1 month duration), or bronchitis, pneumonitis, esophagitis, or visceral at any site
11 Isosporiasis, chronic intestinal (> 1 month duration) (confirmatory diagnostic testing required)
12 Kaposi's sarcoma
13 Leishmaniasis, atypical, disseminated
14 Lymphoma, Burkitt, immunoblastic, primary central nervous system/ cerebral, B cell non Hodgkin (confirmatory diagnostic testing required)
15 *Mycobacterium avium* complex (MAC)
16 *M. kansasii*, disseminated or extrapulmonary
17 *Mycobacterium tuberculosis*, pulmonary (WHO Stage 3)
18 *Mycobacterium tuberculosis*, extrapulmonary
19 Mycobacterial infection, other species or unidentified species, disseminated or extrapulmonary
20 Mycosis, disseminated, extrapulmonary histoplasmosis
21 Mycosis, disseminated, coccidiomycosis
22 Penicilliosis, disseminated
23 Pneumocystis pneumonia
24 Progressive multifocal leukoencephalopathy (PML)
25 Septicemia, recurrent, including non-typhoidal *Salmonella*
26 Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy
27 Toxoplasmosis of brain/central nervous system
28 Wasting syndrome due to HIV (involuntary weight loss >10% of baseline body weight) associated with either chronic diarrhea (≥ 2 loose stools per day ≥ 1 month) or chronic weakness and documented fever ≥ 1 month (MAC)

WHO Stage 2 and 3 Clinical Events Code List (excluding pulmonary TB and severe bacterial infections; see HIV/AIDS-related Illnesses Code List above)

Stage 2

30 Moderate, unexplained weight loss (< 10% body weight)
31 Upper respiratory tract infections, recurrent (sinusitis, tonsillitis, otitis media and pharnygitis)
32 Herpes zoster
33 Angular cheilitis
34 Oral ulcerations, recurrent
35 Papular puritic eruptions
36 Seborrhoeic dermatitis
37 Fungal nail infections

Stage 3

38 Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis
39 Unexplained severe weight loss (> 10% body weight)
40 Unexplained chronic diarrhea
41 Unexplained persistent fever
42 Oral candidiasis, persistent
43 Oral hairy leukoplakia
44 Unexplained anemia

Other Targeted Medical Conditions Code List

50 Diabetes mellitus
51 Lipodystrophy
52 Dyslipidemia
53 Malaria
54 Sensory peripheral neuropathy
55 Hypertension
56 Myocardial infarction
57 Coronary artery disease, not myocardial infarction
58 Congestive heart failure, not HIV cardiomyopathy
59 Stroke
60 Malignancy, newly diagnosed, excluding squamous cell and basal cell cancer of the skin
61 Renal insufficiency
62 Liver disease
63 Lactic acidosis

Item 1d: Record the visit code at which the event or illness was first reported.

Item 1f: Recurrent is defined as an event that recurs after it has clinically resolved after treatment.

Item 1g: Date event started is the date on which issues or symptoms related to the event started. At minimum, month and year are required.

Item 1h: Date of diagnosis is the date on which the confirmed or probable diagnosis was made. If a diagnosis is later found to be incorrect, draw a line through the diagnosis date and record the date of the correct diagnosis.

Item 1i: At the participant's Termination visit, the "Resolved" box must be marked and the date recorded for each event or illness OR the "Continuing at end of study participation" box must be marked.

Note: Number events sequentially (01, 02, 03). Number each page with the same event number. **Event Number** ☐☐

HPTN 052 (096) IWT-2 (416)

Index ID

☐☐☐ – ☐☐☐ – 0 0 – ☐

Site Number | Index Number | Partner | Chk

Index When to Start

Diagnosis Code ☐☐

3. Complete the information below for each abnormal laboratory result that supports or confirms the diagnosis.

OR ☐ No laboratory results to report. → ***Go to item 4.***

	Test Code	Date Specimen Obtained (dd / MMM / yy)	Laboratory Value	Units Code
3a.	☐☐☐☐	☐☐ / ☐☐☐ / ☐☐	☐☐☐☐☐☐☐.☐☐☐	☐☐
3b.	☐☐☐☐	☐☐ / ☐☐☐ / ☐☐	☐☐☐☐☐☐☐.☐☐☐	☐☐
3c.	☐☐☐☐	☐☐ / ☐☐☐ / ☐☐	☐☐☐☐☐☐☐.☐☐☐	☐☐
3d.	☐☐☐☐	☐☐ / ☐☐☐ / ☐☐	☐☐☐☐☐☐☐.☐☐☐	☐☐
3e.	☐☐☐☐	☐☐ / ☐☐☐ / ☐☐	☐☐☐☐☐☐☐.☐☐☐	☐☐
3f.	☐☐☐☐	☐☐ / ☐☐☐ / ☐☐	☐☐☐☐☐☐☐.☐☐☐	☐☐

4. Were any other diagnostic tests used to establish/ confirm this diagnosis? ..... *yes* ☐ *no* ☐

→ ***If yes, go to item 4b.***

4a. If no, how was the diagnosis made?

Specify: _____

_____

→ ***Go to item 5.***

Index When to Start (IWT-2)

Diagnosis Code: Record the code reported in item 1 on page 1.

Items 3a–3f Test Code: Refer to the Master CRF Appendices Notebook or on ACTG's DMC Website (http://fstrf.org/ACTG) for Appendix 76 for a complete list of codes.

ALB	albumin	CRET	creatinine (ULN)	K	potassium
ALP	alkaline phosphatase	FHDL	fasting HDL	MCV	mean corpuscular volume
ALT	(SGPT) (ULN)	FTC	fasting total cholesterol	NA	sodium
AST	(SGOT) (ULN)	FTG	fasting triglycerides	P	phosphate
CFLD	calculated fasting LDL	GLOC	glucose	PLAT	platelets
CL	chloride	HCO3	bicarbonate	RBC	red blood cells
CO2	carbon dioxide	HGB	hemoglobin	TBIL	total bilirubin (ULN)
				WBC	white blood cells

Items 3a–3f Units Code: For laboratory tests listed in the DAIDS Toxicity Tables where Conventional and/or Standard International Units (IU) are identified, the result value must be reported in one of the units of measurement listed in the table. If a different unit of measurement is reported by the laboratory the result value must be converted to either the conventional or standard units listed in the DAIDS Table.

11	cubic microns	24	μKat/L	37	mm/hr	50	x 10^3/cu mm
12	fL	25	μL	38	million/mL	51	x 10^9/L
13	g/d	26	μmol/L	39	mmol/L	52	x 10^{12}/L
14	g/dL	27	mg/dL	40	ng/dL	53	x 10^3/μL
15	g/L	28	mg/g stool	41	ng/mL	54	x 10^6/μL
16	IU/L	29	mg/L	42	nmol/L	55	times viscosity of water
17	IU/mL	30	mg/24 h	43	% (percent)	56	tuberculin
18	kU/L	31	mEq/L	44	% saturation	57	units
19	microns	32	mIU/L	45	% total hemoglobin	58	U/g hemoglobin
20	μg/dL	33	mL/min	46	pg	59	U/L
21	μg/L	34	mU/$_3$mL	47	pg/mL	60	U/mL
22	μg/mL	35	mm^3	48	pmol/L	61	volume fraction
23	μIU/mL	36	mm Hg	49	seconds	98	no units identified on report

Note: Number events sequentially (01, 02, 03). Number each page with the same event number. **Event Number** ☐☐

HPTN 052 (096) IWT-3 (417)

Index ID

☐☐☐ – ☐☐☐ – 0 0 – ☐

Site Number | Index Number | Partner | Chk

Index When to Start

Diagnosis Code ☐☐

Complete the information below for each test. For diagnoses of tuberculosis, list all diagnostic tests regardless of result.

	Test Type	Result Code	Date Specimen Obtained/Test Done (dd-MMM-yy)	Specify Test, Site, Units	Specify Result
4b.	☐	☐	☐☐ ☐☐☐ ☐☐		
4c.	☐	☐	☐☐ ☐☐☐ ☐☐		
4d.	☐	☐	☐☐ ☐☐☐ ☐☐		
4e.	☐	☐	☐☐ ☐☐☐ ☐☐		
4f.	☐	☐	☐☐ ☐☐☐ ☐☐		
4g.	☐	☐	☐☐ ☐☐☐ ☐☐		

5. Was the index receiving any antiretroviral or other medications at the time of this diagnosis which are known or suspected to be related to the event?..... *yes* ☐ *no* ☐ → ***If no, go to item 6.***

Complete the information below for each medication.

	Drug Code	Relationship of diagnosis to Medication/Treatment *Mark only one.*	Action Taken with Medication *Mark only one.*
5a.	☐☐☐☐☐☐☐☐ specify: _____	☐ definitely related ☐ possibly related ☐ probably related ☐ probably not related	☐ dose reduced ☐ no change ☐ withheld ☐ permanently discontinued
5b.	☐☐☐☐☐☐☐☐ specify: _____	☐ definitely related ☐ possibly related ☐ probably related ☐ probably not related	☐ dose reduced ☐ no change ☐ withheld ☐ permanently discontinued

Index When to Start (IWT-3)

Diagnosis Code: Record the code reported in item 1 on page 1.

Items 4b–4g Test Type:

1	Culture
2	Antigen Assay
3	Antibody
4	Microscopy/pathology/biopsy
5	Radiology
6	Other laboratory
9	Other

Items 4b–4g Result Code:

1	Normal
2	Abnormal, consistent with reported event
3	Abnormal, not consistent with reported event
4	Inconclusive
5	Inadequate/insufficient
6	Result pending
9	Other

Items 5a–5b Drug Code: Refer to Appendix 3 or the Drug Code Lookup Program on ACTG's DMC Website (http://fstrf.org/ACTG) for drugs not listed below.

08180407	Abacavir Sulfate/ABC/Ziagen	08180415	FTC/Emtriva/emtricitabine
08180208	Aluvia (lopinavir/ritonavir)	08180043	Indinavir/IDV/Crixivan
08181205	Amprenavir/APV/Agenerase	08181218	Lexiva/Fosampreavir
08181214	Atazanavir/ATV/Reyataz	08180026	Lamivudine/3TC/Epivir
08180422	Atripla (efavirenz/emtricitabine/TDF)	08181208	Lopinavir/Ritonavir (LPV/RTV)/Kaletra
08180021	AZT/ZDV/Zidovudine/Retrovir	08181204	Nelfinavir/NFV/Viracept
08180412	Combivir (3TC/ZDV)	08180013	Nevirapine/NVP/Viramune
08180024	d4T/Stavudine/Zerit	08181203	Ritonavir/RTV/Norvir
08180414	DAPD/Amdoxovir/trimeric	08181209	Saquinavir soft gel/FTV/Fortovase
08180020	ddC/Zalcitabine/Hivid	08180030	Saquinavir/SQV/Invirase/R031-8959
08180007	ddI/Didanosine/Videx	08188804	T-20/pentafuside/enfuvirtide/ENF/Fuzeon
08180051	ddI ECDidanosine EC/Videx EC	08182002	TDF/Tenofovir/Tenofovir disoproxil fumarate/Viread
08180031	DLV/delavirdine mesylate/Rescriptor	08180418	Trizivir (3TC/ABC/ZDV)
08180804	Efavirenz/EFV/Sustiva/StocrinR	08180421	Truvada (tenofovir disoproxil/emtricitabine)
08180420	Epzicom (Abacavir/lamivudine)		

Note: Number events sequentially (01, 02, 03). Number each page with the same event number. **Event Number** ☐☐

HPTN 052 (096) IWT-4 (418)

Index ID

☐☐☐ – ☐☐☐ – 0 0 – ☐

Site Number | Index Number | Partner | Chk

Index When to Start

Diagnosis Code ☐☐

	Drug Code	Relationship of diagnosis to Medication/Treatment *Mark only one.*	Action Taken with Medication *Mark only one.*
5c.	☐☐☐☐☐☐☐☐ specify: _____	☐ definitely related ☐ possibly related ☐ probably related ☐ probably not related	☐ dose reduced ☐ no change ☐ withheld ☐ permanently discontinued
5d.	☐☐☐☐☐☐☐☐ specify: _____	☐ definitely related ☐ possibly related ☐ probably related ☐ probably not related	☐ dose reduced ☐ no change ☐ withheld ☐ permanently discontinued

6. Were specific treatments recommended or initiated to treat this diagnosis? ..... *yes* ☐ *no* ☐ → ***If no, go to item 7.***

6a. If yes, did this lead to an improvement in the condition? ..... *yes* ☐ *no* ☐

Complete the information below for each therapy.

	Drug Code	Specify
6a1.	☐☐☐☐☐☐☐☐	
6a2.	☐☐☐☐☐☐☐☐	
6a3.	☐☐☐☐☐☐☐☐	
6a4.	☐☐☐☐☐☐☐☐	
6a5.	☐☐☐☐☐☐☐☐	
6a6.	List any other treatments recommended, e.g. diet, exercise:	

7. Was any other information used to arrive at this diagnosis? *yes* ☐ *no* ☐ → ***If no, end of form.***

7a. If yes, specify: _____

☐ ☒ ☐ ☐ 16-JAN-13

0 1

Language

Staff Initials / Date

Index When to Start (IWT-4)

Diagnosis Code: Record the code reported in item 1 on page 1.

Items 5c–5d Drug Code: Refer to Appendix 3 or the Drug Code Lookup Program on ACTG's DMC Website (http://fstrf.org/ACTG) for drugs not listed below.

Items 6a1–6a5 Drug Code: Refer to Appendix 3 or the Drug Code Lookup Program on ACTG's DMC Website (http://fstrf.org/ACTG).

08180001	Acyclovir	08160008	Isoniazid
48160023	Ambroxol hydrochloride	08400014	Itraconazole
08121610	Amoxicillin trihydrate	08220009	Levofloxacin
08120401	Amphotericin B	56400004	Metoclopramide
08400001	Azithromycin	84041623	Metronidazole (topical)
08120614	Cephalexin	08040001	Metronidazole
08220002	Ciprofloxacin	08120406	Miconazole
08121203	Clarithromycin	88280009	Multiple Vitamins
08122803	Clindamycin HCL	48240001	N-acetylcysteine; acetylcysteine
28120801	Clonazepam	08120407	Nystatin (oral)
08260001	Dapsone	84040816	Nystatin (topical)
68320002	Depo-Provera (medroxyprogesterone acetate)	28089201	Paracetamol
84060010	Dexamethasone (topical)	08121601	Penicillin G benzathine
04120023	Dexchlorpheniramine maleate	08400009	Pentamidine isethionate
28080443	Diclofenac potassium	80120011	Pneumococcal vaccine, polyvalent
28080417	Diclofenac sodium	08160010	Pyrazinamide
28080457	Dipyrone	08200006	Pyrimethamine
08122403	Doxycycline hyclate	08160011	Rifampin
08160006	Ethambutol	12080826	Scopolamine
08160007	Ethionamide	08120206	Streptomycin sulfate
20040405	Ferrous sulfate	08240005	Sulfadiazine
08120402	Fluconazole	08400005	Sulfamethoxazole; comb.; trimethoprim; (co-trimoxazole)
88080006	Folinic acid		
08180046	Ganciclovir	80080002	Tetanus and diphtheria toxoids adsorbed (for adult use)
80120022	Hepatitis A vaccine	84360015	Trichloroacetic acid
80120057	Hepatitis A virus vaccine inactivated and Hepatitis B vaccine (recombinant)	08180022	Valacyclovir HCL
		08812001	Vitamin C
80120006	Influenza virus vaccine		