Note: Number pages sequentially (01, 02, 03) for each regimen. **Page** ☐☐

HPTN 052 (096) ITX-1 (400)

Index ID

☐☐☐ – ☐☐☐ – 0 0 – ☐

Site Number / Index Number / Partner / Chk

Index Antiretroviral Treatment Regimen Log

Instructions: *When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.*

PART A

1. Regimen Start Date: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐
2. Visit Code at which regimen was started: ☐☐☐.☐
3. This regimen is: *peripartum* ☐ *initial/primary* ☐ *secondary* ☐ *salvage* ☐
4. **REGIMEN MEDICATIONS:**
   Record codes for all medications in the regimen.

	Med Code	Dose (mg)	Frequency			
			qd	*bid*	*tid*	*qid*
4a.	☐☐	☐☐☐☐	☐	☐	☐	☐
4b.	☐☐	☐☐☐☐	☐	☐	☐	☐
4c.	☐☐	☐☐☐☐	☐	☐	☐	☐
4d.	☐☐	☐☐☐☐	☐	☐	☐	☐
4e.	☐☐	☐☐☐☐	☐	☐	☐	☐

5. Initials and date of staff member completing Part A: _____ Staff Initials / Date

PART B

6. Regimen Stop/ Modification Date: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐
7. Visit Code at which regimen was stopped or modified: ☐☐☐.☐

	Medication Status				Stop/Mod Codes	
	no change	*dose / freq. change*	*stopped*	*held*	*primary*	*secondary*
4a.	☐	☐	☐	☐	☐☐	☐☐
4b.	☐	☐	☐	☐	☐☐	☐☐
4c.	☐	☐	☐	☐	☐☐	☐☐
4d.	☐	☐	☐	☐	☐☐	☐☐
4e.	☐	☐	☐	☐	☐☐	☐☐

8. Were any of the above stop/ modification codes reported as an AE?..... *yes* ☐ *no* ☐ → ***If no, go to item 9.***
   8a. Record AE Log page(s). ☐☐☐ ☐☐☐ ☐☐☐
9. Initials and date of staff member completing Part B: _____ Staff Initials / Date

Index Antiretroviral Treatment Regimen Log (ITX-1)

Complete this form when the index participant starts a treatment regimen and each time a treatment regimen is stopped or modified. Parts A and B should be initialed and dated separately.

Item-specific Instructions:

- **Item 1:** The regimen start date refers to the date the participant received the ART prescription.
- **Item 3:**
  - A peripartum regimen is defined as the regimen given to pregnant women on the delay arm, prior to ART initiation. Do not mark this box if the woman has already initiated ART.
  - An initial/primary regimen is the first regimen started, not due to pregnancy. Participants remain on the initial/primary regimen, regardless of modifications, until a change is made due to virologic failure.
  - A secondary or salvage regimen is defined as a change in medication due to virologic failure.
- **Item 4:** Record the medication code for each medication in the participant's regimen. Refer to Atlas for current Medication Code List. ***Note****: During the study, this medication code list may be updated as new ARTs become available. Existing codes will not change, but new codes may be added. Please refer to the SSP appendices for medication code additions. If a drug used at your site is not listed, contact the SCHARP Project Manager for a new code.*
- **Dose: Record the total milligrams for one dose.**
  - A dose is the number of pills prescribed at an interval (e.g., two 150 mg pills bid equals two doses per day of 300 mg).
  - If a medication is being held by the clinician record "0000" as the dose for that medication.
  - For combination drugs, such as Combivir, line through the dose boxes and date and initial.
- **Frequency:**
  qd - once daily bid - two times daily tid - three times daily qid - four times daily

Stop/Modification Code List

Laboratory/Clinical Toxicities

33 Rash
34 Allergic Reaction
35 Anemia
36 Bleeding
37 CNS related symptoms
38 Diarrhea
39 Fatigue
40 Fever
41 Headache
42 Hepatoxicity
43 Hyperamylasemia
44 Hyperbilirubinemia
45 Hypercreatinemia
46 Hyperglycemia
47 Hypertriglyceridemia
48 Hyperuricemia
49 Myalgia
50 Myositis
51 Nausea
52 Neuropsych/mood
53 Neutropenia
54 Pancreatitis
55 Peripheral neuropathy
56 Renal colic
57 Renal insufficiency
58 Renal stones
59 Thrombocytopenia
60 Vomiting
61 Neuropathy
62 Elevated creatinine phosphokinase (CPK)
63 Abdominal pain

Clinical Event or Progression

70 Requires prohibited medication
71 Pregnancy
72 Pregnancy ended
73 Weight change
74 Virologic failure
75 Toxicity endpoint specified by protocol
76 AE
77 Lipodystropy
78 Other protocol-specified reason (specify)

Clinician/Subject Requests

80 Clinician decision
81 Subject/guardian decision
82 Compliance issue

Death

90 Death

Other

98 Study Termination
99 Other