



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

HPTN 052 (096)

ITX-1 (400)

Index ID

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 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, re fax 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	PART B																																			
<p>1. Regimen Start Date: <input type="text"/><input type="text"/> <sup>dd</sup> <input type="text"/><input type="text"/><input type="text"/><input type="text"/> <sup>MMM</sup> <input type="text"/><input type="text"/> <sup>yy</sup></p> <p>2. Visit Code at which regimen was started: <input type="text"/><input type="text"/><input type="text"/><input type="text"/>.<input type="text"/>  <small>peripartum    initial/primary    secondary    salvage</small></p> <p>3. This regimen is: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>4. <b>REGIMEN MEDICATIONS:</b>  <small>Record codes for all medications in the regimen.</small></p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:10%;">Med Code</th> <th style="width:20%;">Dose (mg)</th> <th style="width:20%;">Frequency</th> <th style="width:20%;">Medication Status</th> <th style="width:20%;">Stop/Mod Codes</th> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><small>qd    bid    tid    qid</small></td> <td style="text-align: center;"><small>no change    dose / freq. change    stopped    held</small></td> <td style="text-align: center;"><small>primary    secondary</small></td> </tr> </thead> <tbody> <tr> <td>4a.</td> <td><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/></td> <td><input type="checkbox"/> <input 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Regimen Stop/Modification Date: <input type="text"/><input type="text"/> <sup>dd</sup> <input type="text"/><input type="text"/><input type="text"/><input type="text"/> <sup>MMM</sup> <input type="text"/><input type="text"/> <sup>yy</sup></p> <p>7. Visit Code at which regimen was stopped or modified: <input type="text"/><input type="text"/><input type="text"/><input type="text"/>.<input type="text"/></p> <p>8. Were any of the above stop/modification codes reported as an AE? ..... <input type="checkbox"/> <small>yes</small> <input type="checkbox"/> <small>no</small> <b>→ If no, go to item 9.</b></p> <p>8a. Record AE Log page(s). <input type="text"/><input type="text"/><input type="text"/> <input type="text"/><input type="text"/><input type="text"/> <input type="text"/><input type="text"/><input type="text"/></p> <p>9. Initials and date of staff member completing Part B: _____  <small>Staff Initials / Date</small></p>
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<p>5. Initials and date of staff member completing Part A: _____  <small>Staff Initials / Date</small></p>																																				

# 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

<b>Laboratory/Clinical Toxicities</b>	<b>45</b> Hypercreatinemia	<b>60</b> Vomiting	<b>76</b> AE
	<b>46</b> Hyperglycemia	<b>61</b> Neuropathy	<b>77</b> Lipodystrophy
<b>33</b> Rash	<b>47</b> Hypertriglyceridemia	<b>62</b> Elevated creatinine phosphokinase (CPK)	<b>78</b> Other protocol-specified reason (specify)
<b>34</b> Allergic Reaction	<b>48</b> Hyperuricemia	<b>63</b> Abdominal pain	<b>Clinician/Subject Requests</b>
<b>35</b> Anemia	<b>49</b> Myalgia	<b>Clinical Event or Progression</b>	<b>80</b> Clinician decision
<b>36</b> Bleeding	<b>50</b> Myositis	<b>70</b> Requires prohibited medication	<b>81</b> Subject/guardian decision
<b>37</b> CNS related symptoms	<b>51</b> Nausea	<b>71</b> Pregnancy	<b>82</b> Compliance issue
<b>38</b> Diarrhea	<b>52</b> Neuropsych/mood	<b>72</b> Pregnancy ended	<b>Death</b>
<b>39</b> Fatigue	<b>53</b> Neutropenia	<b>73</b> Weight change	<b>90</b> Death
<b>40</b> Fever	<b>54</b> Pancreatitis	<b>74</b> Virologic failure	<b>Other</b>
<b>41</b> Headache	<b>55</b> Peripheral neuropathy	<b>75</b> Toxicity endpoint specified by protocol	<b>98</b> Study Termination
<b>42</b> Hepatotoxicity	<b>56</b> Renal colic		<b>99</b> Other
<b>43</b> Hyperamylasemia	<b>57</b> Renal insufficiency		
<b>44</b> Hyperbilirubinemia	<b>58</b> Renal stones		
	<b>59</b> Thrombocytopenia		