

Opportunities for HPTN Laboratory Sub-studies

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Examples of approved ancillary laboratory studies

HPTN 033

Seroincidence study for hepatitis C (HCV) infection in the HPTN 033 cohort in China

HPTN 039

Effect of acyclovir on HIV drug susceptibility

Notification of Testing of HPTN Stored Specimens for the HPTN PLG

HPTN MOP under SOP #5:

http://www.hptn.org/Web%20Documents/Policy_and_Procedures/HPTNstoredSpecimen_7_2003.pdf

- **Notification Date**
- **Name and contact information for proposing HPTN Investigator**
- **Name and contact information for non-HPTN collaborating Investigator**
All non-HPTN investigators must complete an HPTN Materials Transfer Agreement. If applicable, please attach a copy of the signed agreement.
- **HPTN study in which specimens proposed for testing were collected**
- **Study sites from which specimens are requested**
- **Rationale and purpose of proposed testing**

- **Has the Chair (or Co-Chairs) of the main study listed in item 3 approved this proposal?**

Yes ⇒ Please retain documentation on site.

No ⇒ Please defer this notification and the proposed testing until approval has been obtained.

- **Have the following been completed?**

(a) All primary study endpoints ascertained

(b) All protocol-specified testing involving the stored specimens at issue performed (including QC/QA testing)

(c) All protocol-specified data analyses finalized

Yes ⇒ Please retain documentation on site.

No ⇒ Please defer submission of this notification and the proposed testing until all primary endpoints have been ascertained, all protocol-specified testing involving the stored specimens at issue has been completed, and all protocol-specified data analyses have been completed and considered final. Or, if the Protocol Chair (or Co-Chairs), Statistician, and Central Lab Representative has approved an exemption to these requirements.

- **Have specimens from participants who did not consent to long term storage for possible future research testing been discarded?**

Yes ⇒ Please retain documentation on site.

No ⇒ Please defer submission of this notification and the proposed testing until the specimens of non-consenting participants have been discarded.

- **Name of laboratory(s) at which the proposed testing will be performed**
- **Test(s) proposed to be performed**
- **What specific type and quantity of specimens will be tested?**

- **Will the results of the proposed testing be linked to data collected in the main study (e.g., demographics, HIV risk behaviours, clinical and lab outcomes) for purposes of analysis and publication?**

- **Is the proposed testing considered research subject to IRB/IEC review?**

Yes ⇒ Has approval been obtained from all responsible
been obtained.

No ⇒ Please retain documentation on site.

- **Will results of the proposed testing be provided to the participants who provided the specimens?**

Yes

No ⇒ Please retain documentation on site of IRB/IEC approval of whether or not results will be provided to participants.

- **Are supplemental HPTN funds required to complete the proposed testing?** Yes ⇒ Please specify amount and purpose of funds requested: \$ _____

