



HPTN058 Data Communiqué #2

02 January, 2009

This is official study documentation for the HPTN058 clinical trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN058 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

The following are clarifications and reminders on how to complete items in DataFax CRFs

CLARIFICATIONS

- **DSM-IV Diagnostic Worksheet (DSM-1)**

- If , in the **Introductory Question** (top of page 1), the answer to any of the three drugs is ‘no’, do not mark the ‘no’ box in the subsequent questions (1-7). Leave them blank.
- If none of the of the 7 criteria were met for any of the three drugs (i.e. the drug was not used during the specified time period), leave the Total Score box blank (do not enter a ‘0’)

Introductory Question <i>(Read only one aloud to the participant)</i>	Opiates/ Heroin	Benzodi- azepines	Alcohol
[] At Enrollment Visit: In the past 12 months, did you take any of the following drugs more than once to get high, to feel better, or to change your mood?	yes no	yes no	yes no
[] At 6-Month Follow-up Visit: In the past 6 months, did you take any of the following drugs more than once to get high, to feel better, or to change your mood?	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/>

Total Score	Opiates/ Heroin	Benzodi- azepines	Alcohol
Of the seven criteria, how many were met?.....	<input type="text" value="5"/>	<input type="text"/>	<input type="text"/>

- **Leading zeros** are required when filling out boxes that require numerical data.

Examples:

1. ALT: U/L

2.

7. In the last 6 months, how many different times were you in...

7a. jail?.....

of times

→

If > 0, how many days total?

- **Questions with “OR” option.** If a question requires one answer OR another, provide only one of the two possible responses.

Example:

1. What is your date of birth? **OR** Age: years (estimate OK)

dd *MMM* *yy*

Leave blank

- **Risk Assessment (RA-1)** – Following skip patterns. Make sure you follow the instructions lead by arrows.

Examples:

7. In the last 6 months, how many different times were you in...

7a. jail?..... →

of times **If > 0, how many days total?**

Incorrect:
There is no need to include zeros since the answer is '0'.

11. In the last 6 months, did you...

11a. smoke marijuana?..... →

yes no

If yes how many times in the last month?

Incorrect:
No need to include zeros since the answer is 'no'

Contact Huguette Redinger (redinger@ssharp.org) for questions regarding this Communiqué.