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## HPTN058 Data Communiqué # 9

### HPTN058 第9号数据通告

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May 6, 2011 2011年5月6日

**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.**

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这是 HPTN058 临床试验官方研究文件。请打印并转给相关工作人员阅读，并存档于 HPTN058 研究特定程序（SSP）手册“通告”表。这份文件是 SSP 手册的一部分。

### Instructions for Final Visit at China Sites

中国现场末次随访的说明

**As instructed in a memo, dated May 2, 2011, from Dr. David Metzger, participants at the China sites should be terminated after they have completed Visit 104. This is their final study visit. However, participants who missed Visit 104 can return to the clinic and should be terminated only after completing their last study visit or when the site has completed all visits for all subjects, whichever occurs first.**

作为来自 David Metzger 博士，日期为 2011 年 5 月 2 日在备忘录中的说明，在中国现场的参加者必须在他们完成第 104 周随访后终止。这是他们的末次研究访问。然而，104 周失访的参加者返回了门诊只有当他们完成最后的研究访问后或当本基地已完成所有受试者的随访，无论哪一个先发生，必须被终止。

Following are instructions from SCHARP on how to complete CRFs depending on when participants come to the clinic for their final visit.

以下为来自 SCHARP 的说明关于当参加者为了他们的末次访问而来到门诊时如何完成 CRFs。

- 1. Participant has already completed Visit 104, but was not terminated 参加者已完成第 104 周访问，但未终止**
  - a. Do not perform Visit 130. It is not necessary to bring the participant back to the clinic, to complete the termination process. The clinician may wish to see the participant again after Visit 104 was completed but any additional data collected should only be recorded in the participant chart.不要完成第 130 周访问。不必要让参加者为完成终止程序返回门诊。在参加者完成第 104 周随访后，临床医生可能希望再次看到参加者，但是收集到的额外的数据必须记录在参加者记录里。
  - b. Terminate the participant as follows: 按下列程序终止参加者：

- If applicable, complete pregnancy outcome on a PO-1 CRF. 若适用，在一张 PO-1 CRF 表格上填写妊娠结果。
- Review AE logs to make sure they are either resolved or, if unresolved, mark the “Continuing at end of study participation” box in Item #6. 回顾 AE 日志以确定他们是否被解决或，若未解决，标记在项目#6 “研究结束后持续”处的框内。
- Complete an ESI-1 CRF. 填写一张 ESI-1 CRF 表格。
- Complete a Termination form (TM-1). 填写一张终止表格 (TM-1)。
- Fax all CRFs to DataFax as soon as possible. 尽快地传真所有的 CRF 表格给 DataFax。

## 2. Participant comes within Visit 104 window 参加者在第 104 周访问窗口期内随访

- a. When a participant comes to the clinic for this final visit, perform all required procedures. 当一位参加者来到门诊参加这次最终的随访，完成所有必要的程序。
- b. Complete the HTR-1, RA 1-8, SIA-1, UTR-1, LLF-1 and ESI-1 CRFs using **visit code 104.0**. 使用**随访代码 104.0** 填写 HTR-1、RA 1-8、SIA-1、UTR-1、LLF-1 和 ESI-1 CRF 表格。
- c. If applicable, complete pregnancy outcome on a PO-1 CRF. 若适用，在一张 PO-1 CRF 表格上填写妊娠结果。
- d. Review AE logs to make sure they are either resolved or, if unresolved, mark the “Continuing at end of study participation” box in Item #6. 回顾 AE 日志以确定他们是否被解决或，若未解决，标记在项目#6 “研究结束后持续”处的框内。
- e. Complete a Termination form (TM-1). 填写一张终止表格 (TM-1)。
- f. Fax all CRFs to DataFax as soon as possible after the visit is completed. 随访完成后，尽快地传真所有的 CRF 表格给 DataFax。

### 3. Participant missed visit 104 参加者于 104 周访问失访

- a. If a participant missed Visit 104, make every effort to have him/her return as soon as possible. 若一名参加者于 104 周访问失访，尽一切努力使他/她尽快返回。
- b. If the participant returns after Visit 104 extended window has closed but before Visit 130 window opens, follow the same instructions as in Item #2 above, and use **visit code 104.0** on the CRFs. 若参加者于 104 周访问扩展的窗口期结束后返回，但仍在 130 周访问窗口期打开之前，遵循上述项目#2 同样的说明，并在 CRF 表格上使用 **104.0 随访代码**。
- c. If the participant returns for Visit 130 but before Visit 156 window opens, follow the same instructions as in Item #2 above, and use **visit code 130.0** on the CRFs. In addition, complete a MV-1 for Visit 104. 若参加者为 130 周访问返回，但在 156 周访问窗口打开之前，遵循上述项目#2 同样的说明，并在 CRF 表格上使用 **130.0 随访代码**。另外，填写一张 104 周随访的 MV-1 表。
- d. If the participant returns for Visit 156 (up to 28 days after the Visit 156 target date), follow the same instructions as in Item #2 above, and use **visit code 156.0** on the CRFs. In addition, complete a MV-1 for Visits 104 and 130. 若参加者为 156 周访问返回（156 周访问目标日期后最多 28 天），遵循上述项目#2 同样的说明，并在 CRF 表格上使用 **156.0 随访代码**。另外，填写一张 104 周和 130 周随访的 MV-1 表。
- e. If the participant never returns, he/she can be terminated at the close of his/her Visit 156 window (up to 28 days after the Visit 156 target date) or at the time the last participant has completed the study at the site, whichever occurs first. Terminate the participant as in Item #1b. above. In addition, complete a MV-1 for Visits 104, 130 and 156. 若参加者未返回，他/她可于他/她的 156 周访问窗口结束时终止（156 周访问目标日期后最多 28 天）或当时最后一个参加者已完成本现场的研究，无论哪一个先发生。按照上述项目#1b 终止参加者。另外，填写一张 104 周、130 周和 156 周随访的 MV-1 表。

### 4. Participant missed visit 104 and has already been terminated 参加者于 104 周访问失访，已经被终止

- a. If a participant missed Visit 104 and has already been terminated, please delete the termination (TM-1) form (draw a line across the page and write 'DELETE' on it, date and initial) and fax the form to DataFax. Do not delete the TM-1 form if the reason for termination is death. 若一参加者于 104 周失访，且已经被终止，请删除终止表格（TM-1）（在页面上画一条对角线且写上‘DELETE’、日期和首字母缩写），并传真此表格至 DataFax。若终止的原因为死亡，不要删除 TM-1。
- b. Make every effort to have him/her return as soon as possible. 尽一切努力使他/她尽快返回。
- c. If the participant returns, follow the instructions in Item #3a. to 3d. above as appropriate. 若参加者返回，酌情按照上述项目#3a 到 3d 的说明完成访问。
- d. If the participant never returns, he/she can be terminated at the close of his/her Visit 156 window (up to 28 days after the Visit 156 target date) or at the time the last participant has completed the study at the site, whichever occurs first. Complete the termination process by completing or updating the CRFs listed in Item #1b. above. In addition, complete a MV-1 for Visits 104, 130 and 156. 若参加者未返回，他/她可于他/她的 156 周访问窗口结束（156 周访问目标日期后最多 28 天）或当时最后一个参加者已完成本现场的研究时终止，无论哪一个先发生。完成终止过程通过填写或更新上述项目#1b 列出的 CRF 表格。另外，填写一张 104 周、130 周和 156 周随访的 MV-1 表。

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If you have any questions regarding this Communiqué, please contact Project Manager, Huguette Redinger (redinger@ssharp.org).

若您对本通报有任何疑问，请联系项目经理 Huguette Redinger ([redinger@scharp.org](mailto:redinger@scharp.org))。