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Transferring Subjects between Research Sites

By Townsend N. Barnett, Jr.

Study subjects may transfer from one research site to another for various reasons, such as:

- The subject is permanently relocating away from the site (Site A).
- The subject is temporarily relocating away from Site A, e.g., for the winter.
- Site A is no longer willing or able to conduct the study, e.g., because the investigator is retiring.
- The sponsor is terminating the study at the site, e.g., because of regulatory noncompliance.

If another site (Site B) is able and willing to take over the subject, then the subject can be transferred. In some cases, it is may be necessary and practical to initiate a new site. If there are no suitable sites, then the subject cannot continue in the study and must be withdrawn according to protocol procedures.

A seamless transfer ensures that the subject's safety and state of mind are protected, his or her participation in the study continues, and data completeness and integrity are preserved. Inform all parties at each step. Written documentation is essential to address the subsequent questions that are likely to arise.

1. The sponsor identifies, contacts and arranges for transfer to Site B.
2. If appropriate, the sponsor introduces Site A to Site B.
3. The sponsor and the sites review and, if necessary, modify their respective clinical trial agreements.
4. Site A or the sponsor notifies Site A's IRB/IEC (institutional review board/institutional ethics committee) of the pending transfer.
5. Site B or the sponsor notifies Site B's IRB/IEC of the pending transfer.
6. Site B obtains IRB/IEC approval for the transfer, if required.
7. Site A and Site B comply with their respective IRB/IEC's transfer requirements and processes.
8. Site A and/or Site B obtains the subject's verbal agreement to the transfer.
9. Site B obtains the subject's signature on Site B's informed consent form, HIPAA authorization, and appropriate medical release forms. It gives the subject contact and other appropriate information. It informs Site A in writing that the subject has signed the informed consent form.
10. The subject authorizes, in writing, transfer of the subject's study records (including copies of completed source documents and case report forms, as well as documents relevant to the subject's medical care) from Site A to Site B. Site A retains the original documents. Either site can obtain this authorization and give a copy to the other site.
11. Site A ships the subject's study records to Site B by a reliable, secure and traceable method.

12. Site A provides a written or verbal report to Site B about the subject's medical condition, progress in the trial, and contact information, including primary care physician, if appropriate. Both sites document the communication in writing.
13. Site B reviews the subject's documentation for completeness and clarity. If it has any questions, it asks Site A. Both sites document the communication in writing.
14. Conduct of the study and responsibility for the subject's safety transfer when the subject signs Site B's informed consent form. Each site is responsible for the accuracy of, and queries on, its own data. If a source document or case report form is only partially complete on date of transfer, both sites will be responsible for their respective documentation.
15. Site B registers the subject with IVRS system. The subject's identification and randomization numbers do not change.
16. Site A inventories and packages any study drug and other materials to be shipped to Site B, with the assistance of the site monitor.
17. Site A ships the subject's study drug and other materials, with a packing list, to Site B according to sponsor and site standard operating procedures, including temperature monitoring/maintenance measures. Ship by a reliable, secure and traceable method. Both sites document the shipment. If there is any doubt regarding shipment of the subject's study drug between sites, the sponsor sends a new supply of study drug to Site B.
18. Site B verifies that materials received match the packing list and compliance with temperature monitoring/maintenance measures.
19. The sponsor and Site A generate and resolve relevant data queries as soon as possible. If the study is terminating at Site A, the sponsor conducts the close-out visit as soon as possible. Monitoring reports and other site management documentation should clearly reflect the subject's transfer.

If the subject transfer is temporary, the above process is very similar, except inform all parties of the plan for the return transfer. Site A may keep its study drug for accountability at the end of the study.

Author

Townsend N. Barnett, Jr. is Director, Clinical Quality Assurance at UCB. Contact him at 1.919.767.2521 or townsend.barnett@ucb.com.

