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Outsourcing Study-Related Functions to External Service Providers - Tips for Study Conduct

Background

Principal investigators (PIs) of research studies may engage external service providers to perform study-related functions, which may include recruitment procedures such as identifying potential subjects, obtaining consent from subjects, or collecting study data (e.g. conducting surveys).

Even though study functions have been outsourced, PIs still hold the overall responsibility to ensure that their research study complies with applicable research policies and regulatory requirements. In accordance with Good Clinical Practice (GCP) requirements, PIs must also ensure that the study information is recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

Tips and Recommendations

Documentation of Outsourced Functions

It is crucial that the site staff and service provider(s) are clear on the delineation of their respective responsibilities in the study, to ensure a smooth delivery of the study objectives. As such, the types of study functions being outsourced to an external vendor should be clearly documented. Documentation can be in the form of a service agreement between the site and the service provider.

Documentation of Appropriate Training

Prior to study initiation, all individuals involved in the study must be appropriately trained to ensure that they have adequate understanding of the applicable research policies, regulatory requirements, protocol-related procedures and/or site-specific processes. The PI is responsible for ensuring adequate training of study team members and all staff engaged by the external service provider. Depending on the study requirements, trainings may be conducted on a regular or ad hoc basis. All trainings conducted should be properly documented and records maintained in the investigator file.

Maintenance of Appropriate Study Documentation

The PI should communicate with the service provider on the need to maintain appropriate documentation relating to the outsourced study activities. The source documents to be created and maintained by the service provider should be clearly specified. For example, the signatures of all staff engaged by the service provider to discharge one or more outsourced study functions must be maintained on a signature specimen sheet or study delegation log. This document may be maintained either by the site or service provider, to ensure that the outsourced study-related tasks and associated documentation remain attributable.

Similar to essential documents maintained at the trial site, all study-related documents maintained by the external vendor should adhere to the principles of good documentation practice. These documents should be kept confidential and be accessible only by authorised individuals from the service provider company. Study team members from the site should be provided access to these documents during the course of the study, for verification, audits and/or other authorised purposes. At appropriate intervals during the study or by the end of the study, all original essential documents maintained by the service provider relating to the study should be returned to the site. The site will be required to retain these documents, together with all other study-related essential documents, for the minimum retention period as required by applicable institutional and regulatory policies.

Appropriate Oversight

A communication plan should be established between the PI and external service provider to ensure that the site is kept updated on the progress of outsourced study functions. This is to ensure that study expectations continue to be met, and in the event of any deviations identified, allow for the timely implementation of appropriate corrective actions.

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References

- *PCR SOP 501-A02: Responsibilities of the Research Team*
- *PCR SOP 501-B03: Study Initiation*