Investigator Standard Operating Procedures

SOP No. 105: Vendor Selection

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<tr>
<td>Author:</td>
<td>Office of Human Research</td>
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This SOP pertains to: All Investigators (or Sponsor-Investigators) within Memorial Healthcare System and the vendors they ultimately select to perform aspects of the research trial on their behalf.

Responsibility for executing this SOP: Investigator and Designated Research Personnel

Approved By (Sign & Date):

Senior Vice President & Chief Medical Officer, MHS

Approved By (Sign & Date):

Chief Medical Research Officer, OHR

1 PURPOSE

This procedure describes the process for the selection of an outside contractor or vendor for performing certain activities associated with the conduct of human subject research within Memorial Healthcare System (MHS) e.g. records retention, central laboratory, translation services, CRO, etc.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES

If the Investigator is the sponsor for the study, then he/she is ultimately responsible for all human subject research-related work conducted on his/her behalf by an outside contractor or vendor. The sponsor-Investigator is responsible for:

a) Complying with all Memorial Healthcare System requirements for acquiring goods and services from vendors.

b) Transferring responsibility (Reference SOP 103 Investigator Responsibility and Delegation of Authority) of any or all obligations or functions for conducting human subject research to one or more vendors, if approved by the sponsor and in compliance with the contract. The responsibilities that are transferred must be documented in writing, and a copy forwarded to the Office of Human Research (OHR), along with the corresponding protocol and other relevant study documents.

c) Providing the vendor with all protocol(s), applicable standard operating procedures (SOPs) and related training on these SOPs, Good Clinical Practice (GCP), Conflicts of Interest, and other relevant regulatory requirements (Reference SOP 104 Study Team Training).

d) Determining whether a particular vendor has the requisite skills, facilities and resources for conducting the contracted activities.

e) Verifying that the vendor has adequate SOPs if the vendor’s own procedures are to be used in the conduct of contracted activities instead of the Investigator’s procedures.
3 SPECIFIC PROCEDURES

3.1 Institutional Vendor Requirements

a) The Investigator may occasionally require the services of an outside vendor or agent to provide or perform certain clinical study-related goods or services. The Investigator or designee should contact Memorial Healthcare System’s Supply Chain Management Department to vet the required vendor or agent services.

b) The Investigator or other designated individual should first determine the need for a vendor or agent for particular goods or service.

c) The Investigator or designee should consult with all appropriate individuals (contract officials and content experts) to develop a list of deliverables expected from the vendor or agent as well as criteria by which to select the vendor.

d) An outside vendor or agent is not considered an employee but rather an independent contractor.

e) Vendors and agents may perform such services as:
   - Conduct required laboratory testing
   - Manage aspects of a clinical study such as monitoring and data collection and/or analysis
   - Manufacture product components or finished products
   - Provide other related consulting services

f) Vendors may not begin providing services until they have been approved through the necessary channels.

3.2 Regulatory Agency Aspects

a) As a general rule, Investigators should keep the OHR informed about the vendors they select, the selection criteria and process they use, and the vendor’s overall performance in completing the project.

b) The Investigator or designee should consult with the OHR about the applicable regulations that pertain to the conduct and completion of key activities specified in the aforementioned list of deliverables.

c) The Investigator or designee must ensure that the prospective vendor and/or agent has the skills, facilities and resources to complete the activities in compliance with existing regulations.

d) The Investigator or designee will promptly alert the OHR if a prospective vendor has received any recent Warning Letters or whether any employee of the vendor is disqualified or restricted or debarred by FDA from performing the desired services.

e) After conducting these assessments and procedures, the Investigator or designee must follow Memorial Healthcare System procedures for executing the contract process.

3.3 Vendor or Agent Audits

a) As applicable, the Investigator or designee should request the OHR’s assistance to secure an Auditor to assess a prospective vendor’s or agent’s compliance with the
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relevant regulations and/or guidelines, e.g. Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), or Good Clinical Practices (GCP).

b) If the vendor’s or agent’s own SOPs are to be used in the conduct of any activities to be delegated, the designee should also request that the Auditor review the vendor’s and agent’s SOPs for adequacy and regulatory compliance.

c) The Auditor should conduct the compliance assessments before a contract is signed for new vendors of critical activities.

d) The Investigator or designee and the OHR should establish a schedule for periodically auditing new (non-critical activities) and existing (all critical activities) vendors.

e) The Sponsor-Investigator or designee should provide a file copy to the OHR of all audit reports, listing objective observations and auditor perceptions on strengths and weaknesses, and maintain those reports in the appropriate section of the Regulatory Master File (Reference SOP 504 Routine Monitoring Visits).

4 REFERENCES TO OTHER APPLICABLE SOPS

- 103 Investigator Responsibility and Delegation of Responsibility
- 104 Study Team Training
- 504 Routine Monitoring Visits

5 ATTACHMENTS

None

6 APPLICABLE REGULATIONS AND GUIDELINES

- Transfer of Obligations to a Contract Research Organization (CRO) (21 CFR 312.52)
- General Responsibilities of Sponsors (21 CFR 312.50 and 812.40)
- Quality Assurance and Control (ICH E6 section 5.1)
- Contract Research Organizations (ICH E6 section 5.2)
- Trial Management, Data Handling and Record Keeping (ICH E6 section 5.5)
- Allocation of Responsibilities (ICH E6 section 5.7)