

GA 105

STANDARD OPERATING POLICY AND PROCEDURE FOR VENDOR SELECTION AND AGREEMENTS

SOP: GA 105 Version No.: Effective Date: XX/XX/XX	VENDOR SELECTION AND AGREEMENTS	Supersedes Document: XX/XX/XX
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1. POLICY

<<Sponsor>> may require the services of an outside contractor to perform such services as:

- Conduct required laboratory testing (a contract laboratory)
- Manage aspects of a clinical study such as monitoring and data collection and/or analysis (a contract research organization)
- Manufacture product components or finished products (a contract manufacturer)
- Provide consulting services (a regulatory affairs or quality assurance consultant)

When an outside vendor is used to provide such services, <<Sponsor>> shall comply with existing requirements that address requests for proposals (RFPs) for contracts. <<Sponsor>> shall ensure that the vendor complies with regulations that relate to the services that have been delegated to the contractor and that the vendor has the requisite skills and capabilities to perform the work. If appropriate, <<Sponsor>> also may conduct an audit or review of the proposed vendor before a contract is signed.

2. SCOPE

These policies and procedures apply to <<Sponsor>>, its employees, subcontractors and others who manage, oversee and conduct research regulated by FDA.

3. RESPONSIBILITY

<<Sponsor>> is ultimately responsible for all research-related work conducted on its behalf by a vendor and for complying with institutional/company requirements for acquiring goods and services from vendors.

<<Sponsor>> may transfer responsibility of any or all obligations or functions for conducting human subject research to a vendor, after determining the vendor has the requisite skills, facilities and resources for conducting the contracted activities and with appropriate documentation of the delegated activities.

<<Sponsor>> is responsible for 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 <<Sponsor>>'s procedures.

4. APPLICABLE REGULATIONS AND GUIDELINES

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

5. REFERENCES TO OTHER APPLICABLE SOPS

GA 101 Sponsor Responsibility and Delegation of Responsibility

PM 503 Documentation and Records Retention

QA 801 Quality Assurance Audits

6. ATTACHMENTS

GA 105-A: Vendor Audit Report Form

GA 105-B: Checklist Vendor's Qualifications to Engage in Regulated Activities

GA 105-C: (Sponsor's existing RFP template)

GA 105-D: (Sponsor's existing vendor contract template)

GA 105-E: Confidentiality Agreement Template

GA 105-F: Investigator Contract Template

7. PROCESS OVERVIEW

A. Institutional Vendor Requirements

B. Regulatory Aspects

C. Vendor Audits

8. SPECIFIC PROCEDURES

A. Institutional Vendor Requirements

#	Who	Task	Attachment	Related SOP
1.	<<Sponsor Designee>>	Determine the need for a vendor for particular goods or service.		GA 101
2.		Develop list of deliverables expected from the vendor.		
3.		Develop RFP.	GA 105-C: (Sponsor's Existing RFP Template)	
4.		Work with contract officials and content experts to develop criteria for vendor selection.		
5.		Work with contract and legal officials to develop vendor contract.	GA 105-D: (Sponsor's Existing Vendor Contract Template)	
6.		When RFP, has been finalized, release the RFP as required and select the vendor of choice by applying the selection criteria.		
7.				

Note:

B. Regulatory Aspects

#	Who	Task	Attachment	Related SOP
1.	<<Sponsor	Establish a file of acceptable vendors (based on prior	GA 105-B: Checklist: Ven-	

	Designee>>	performance or recent assessments) for key activities.	Vendor's Qualifications to Engage in Regulated Activities	
2.		Review applicable regulations that pertain to conduct and completion of key activities specified in the list of deliverables.		
3.		Through appropriate language in the RFP and contract, as well as site visits (vendor audit), ensure that prospective vendor has the skills, facilities and resources to complete the activities in compliance with existing regulations.	GA 105-A: Vendor Audit Report Form	
4.		Examine FDA website to determine if a possible vendor has received a recent Warning Letter or whether any employee of the vendor is disqualified or restricted by FDA from performing the desired services.		
5.		When appropriate, execute the contract process.		
6.		Maintain copies of all relevant contracts and supporting documents in the RMF.	PM 503-A: RMF Contents	PM 503
7.				
Note:				

C. Vendor Audits

#	Who	Task	Attachment	Related SOP
1.	<<Sponsor Designee>>	Assign a knowledgeable and qualified individual to audit the prospective vendor.		
2.		As applicable, assess vendor's compliance with Good Laboratory Practice (GLP), Quality System regulation and GCP.	GA 105-A: Vendor Audit Report Form	QA 801
3.		If the vendor's own SOPs are to be used in the conduct of delegated activities, review the vendor's SOPs for adequacy and regulatory compliance.		
4.		Conduct compliance assessments before a contract is signed for new vendors of critical activities.		
5.		Establish a schedule to fully audit new vendors and to periodically audit critical activities of existing vendors.		
6.		File audit reports, listing objective observations and auditor perception regarding strengths and weaknesses in appropriate section of the RMF.		PM 503
7.				
Note: FDA does not routinely examine a firm's audit reports. Refer to FDA Compliance Policy Guide 7151.02.				