

# Clinical Research Compliance Assessment Tool

<b>Facility:</b>	<b>Y or N</b>	<b>Date:</b>
<b>Department Name:</b>		<b>Auditor:</b>
<b>Research Director:</b>		<b>Facility Score:</b>
<b>Research Compliance Indicators</b>		<b>Comments</b>

I	Administration	
	1. Do you have a copy of the [facility's] SOP notebook?	
	2. Can you state what regulations, guidelines, policies & SOP's these are based upon?	
	2. Do you have written documentation of staff training on SOP's?	
	4. Have you written site specific SOP's or added a memo to the SOP notebook, re: utilizing SOP's as they stand?	
	5. Do you have a Delegation of Responsibilities list for research staff? Listed for site or per protocol?	
	6. Do you have a research orientation checklist?	
	7. Are study budgets being developed with the [appropriate parties]?	
	8. Are research pharmacy charges being negotiated with the Research Pharmacist?	
	9. Are sponsor payment checks being sent directly to [the appropriate department]?	

II	Initiation of Study	
	1. Is your site assessing protocol feasibility?	
	2. Are you involving all research team members in the feasibility review?	
	3. Are you utilizing the pre-study site visit checklist to prepare for and complete a visit?	
	4. Do you verify that all paperwork is in place before the visit (CFA, critical documents, etc.)?	
	5. Do you invite personnel from other departments to attend on-site study initiation meetings?	
	6. Do you have a means of documenting that all regulatory and institutional requirements have been met prior to subject enrollment?	

III	Protocol Management	
	1. Do you maintain a communication log? If so, where?	
	2. Do you send Confidentiality Agreements to the [appropriate department] for review?	
	3. Do you have written documentation of staff training on the IRB Policies and Procedures/HIPAA Guidelines?	
	4. Do you have a tracking system for IRB submission of your protocols?	
	5. Do you have a set system for monitoring study related documents?	
	6. Do you have a listing of regulatory documents to maintain?	
	7. Do you inform other departments of scheduled monitoring visits (Pharmacy, Radiology, IRB, etc.)?	
	8. Do you have a monitoring plan in place for other sites?	
	9. At study termination, do you review the study specific contract to verify deliverables having been met?	
	10. Do you keep investigational drugs/devices at your site? If no, where?	
	11. Are your investigational drugs/devices kept locked up and separate from standard of care items?	
	12. Do you maintain an investigational drug/device accountability log?	

IV	Management of Research Subjects	
	1. Do you practice that Informed Consent is a process and not a document? If so, how?	
	2. Do you have a plan for re-consenting research subjects as needed? When do you?	
	3. Do you have a monthly listing to Medical Records of enrolled research subjects?	
	4. Do you develop a written recruitment plan for each study?	
	5. Do you maintain screening logs?	
	6. Do you have a set practice in place for reviewing laboratory and other procedure results?	
	7. Are team members processing specimens at your site location?	
	8. Are applicable team members certified in the shipping of hazardous goods?	
	9. Do you have a consistent practice in place for providing source documentation?	

V	Data Management	
	1. Do you have site databases containing PHI?	
	2. Do you perform any self-monitoring for data integrity?	
	3. Do you utilize the Clinical Research Office for remote file storage/retrieval?	
	4. Do you notify the sponsor of storage arrangements?	

VI	Quality Assurance	
	1. Do you have a plan in place for handling non-FDA audits?	
	2. Do you know who to call first when you are notified of an FDA audit?	
	3. Are you familiar with the FDA Inspection Site Preparation check list?	
	4. Have you specifically reviewed the FDA Audit SOP with all research team members?	

<b>Persons Interviewed During Audit:</b>	<b>Total No's</b>
<b>Audit Reviewed With:</b>	<b>Facility Score (44 indicators)</b>