

## FDA AUDIT CHECKLIST

***WHEN FDA CALLS TO SCHEDULE A SITE VISIT, OBTAIN THE FOLLOWING INFORMATION<sup>1</sup>:***

Call date		
Starting date		Expected Duration
FDA Investigator Contact Information	Name	
	Telephone	
	Title	
Additional FDA Investigators' Names?		

***ASK:***

<i>Who / what is being inspected? Wait for specific answers. Do not make suggestions.</i>		
	Clinical trial(s)/study	Details?
	Principal Investigator Co-Investigator(s)	
	Other	
<i>Why is the inspection being done? Wait for the answer. Do not make suggestions.</i>		
	Routine? (i.e. IND)	Details?
	Directed (for cause)?	
	Follow-up (i.e. 483; warning letter ?)	
	Other	
Does the FDA want specific personnel available?    no            yes→if yes, then list		
Who		When
Does the FDA want specific documents available? (List on separate sheet if needed)		
Does the FDA want any of these documents sent prior to their arrival?    no            yes→then:		
Address:		How?    overnight    registered    certified
		Delivery by when?

<sup>1</sup> Permission to adapt and use this form is granted by Emory University, Office of Research Compliance.

***IMMEDIATELY,  
CONTACT AND SEND NOTIFICATION TO THE FOLLOWING:***

🍏 **Sponsor** \_\_\_\_\_  
Phone: \_\_\_\_\_

🍏 **Principal Investigator (name)** \_\_\_\_\_  
Email: \_\_\_\_\_ Phone: \_\_\_\_\_

🍏 **Research Coordinator (name)** \_\_\_\_\_  
Email: \_\_\_\_\_ Phone: \_\_\_\_\_

🍏 **UTHSC-H Office of Research**  
**Catey Carter, RN, Clinical Trials Resource Coordinator**  
[Catharine.V.Carter@uth.tmc.edu](mailto:Catharine.V.Carter@uth.tmc.edu), Phone: 713-500-3524, Fax: 713-500-0335

The notification will be distributed by the Office of Research to:

- 1. UTHSC-H Office of Research Support Committees**  
**Cynthia Edmonds, Manager**  
[Cynthia.L.Edmonds@uth.tmc.edu](mailto:Cynthia.L.Edmonds@uth.tmc.edu), Phone 713-500-3977, Fax: 713-500-0319
- 2. UTHSC-H Office of Institutional Compliance**  
**Karen Parsons, Director of Institutional Compliance**  
[Karen.K.Parsons@uth.tmc.edu](mailto:Karen.K.Parsons@uth.tmc.edu), Phone: 713-500-3294, Fax: 713-500-0326
- 3. UTHSC-H Office of Auditing and Advisory Services**  
**Lois Pierson, Assistant Vice President, Internal Audit**  
[Lois.K.Pierson@uth.tmc.edu](mailto:Lois.K.Pierson@uth.tmc.edu), Phone: 713-500-3162, Fax: 713-500-3170

***Affiliate Institutions***

🍏 **Memorial Hermann Center for Clinical Innovation and Research**  
**Linda Brown, Clinical Research Education and Compliance Specialist**  
[Linda.Brown@memorialhermann.org](mailto:Linda.Brown@memorialhermann.org), Phone: 713-704-3430

🍏 **Harris County Hospital District**  
**Julie Thompson, PhD, RN, Director, Research & Sponsored Programs**  
[julie\\_thompson@hchd.tmc.edu](mailto:julie_thompson@hchd.tmc.edu), Phone: 713-566-6473

*At least one week before the scheduled visit, the Research Coordinator should complete the following activities<sup>2</sup>:*

Check		Comments
<b>Step 1</b>	<b>Gather and review study documents – detailed list follows</b>	
	Note any problems (e.g. missing or incorrect documents)	
<b>Step 2</b>	<b>Secure/reserve work space for FDA representative away from other study/clinical records and research staff</b>	
	Optional: Contact the Office of Research to reserve audit work space	
<b>Step 3</b>	<b>Coordinate with appropriate affiliate institutions to confirm plans for site visit support</b>	
<b>Step 4</b>	<b>Prepare the following documents:</b>	
<b>A. Study overview</b>		
	A general overview of the study	
	List of all personnel and delegated responsibilities	
<b>B. Subjects list</b>		
	List of all subjects enrolled, including name, study number, date enrolled and completed, medical record number	
	List of all subjects screened	
<b>C. Current Active Studies</b>		
	List of Principal Investigator’s current active studies	
<b>Step 5</b>	<b>Gather and organize the following documents:</b>	
<b>A. Organize all Regulatory Files by general heading arranged in chronological order (or reverse chronological order)</b>		
	Protocol, include all versions	
	Investigator’s Brochure, all versions	
	Informed Consent Form, all versions	
	Protocol Amendments	
	Form FDA 1572, all versions	
	CVs for PI and Sub-investigators listed on all versions of Form FDA 1572	

<sup>2</sup> Activity checklist is taken in part from “Pre-FDA Audit Checklist”; Pre-FDA Audit Investigator Site Preparations training class by GA International Donald Ashbrook and Robert Kagon; Nov. 13, 2002.

<b>B. Communications</b>		
	Sponsor Correspondence	
	CRO Correspondence	
	Monitoring Log	
<b>C. IRB Files</b>		
<i>note: pay attention to date of IRB notification and date of IRB acknowledgment &amp;/or approval</i>		
	Approval Letter (initial) for initial protocol with original informed consent	
	Amendment approval(s) with the approved informed consent	
	Approvals for:	
	Periodic or Annual Reports	
	Renewal Documents	
	Notification of:	
	Adverse Events	
	Deaths	
	Acknowledgement of:	
	IND Safety Reports	
	Study Termination	
	Final Summary	
<b>D. Laboratory</b>		
	Laboratory Certification and normal ranges	
	CV of laboratory director	
<b>E. Drug Accountability - drug log to include:</b>		
	Receipt of Drug	
	Dispensing	
	Return	
<b>F. Subject Documents</b>		
	Informed Consents for screened/enrolled subjects	
	Consents obtained prior to any study procedures?	
	Source documents for each subject enrolled (including labs, x-rays, scans, etc.)	

<b>Step 6</b>	<b>Complete the following review and note any issues to discuss with PI, CTO, ORC</b>	
<b>A. Review for each subject enrolled</b>		
	Review Inclusion/Exclusion Criteria	
	Document reason for excluded subjects	
	CRFs completed for each enrolled subject	
	Source documentation for all CRF entries	
	Data Clarification issues satisfied	
	Consent obtained for all subjects screened/enrolled	
	Verify correct version of informed consent signed	
	Confirm 'Notes to File' present as appropriate	
<b>B. Medical Records and/or Study Files</b>		
	Condition of subject at time of entry into the study (i.e. all inclusion/exclusion criteria met)	
	Exposure to Study Drugs	
	Concomitant medications	
	Laboratory reports	
	Diagnostic tests	
	Dose Modifications	
	Adverse Events/Deaths	
	Protocol Exceptions	
	Early Termination	