FDA Inspection Checklist

Protocol: _____

IRB#: _____

Investigator: _____

Date FDA Contacted Site: _____

	Notes and Action Items:
Information to collect from FDA inspector: ▪ FDA Inspector's Name: _____ ▪ FDA Inspector's Contact Information: _____ ▪ Name of study being inspected: _____ ▪ Specific study personnel to be available: _____ ▪ Specific documents to be available: _____ ▪ Date of inspection and expected duration: _____ ▪ Document any telephone conversations with the FDA Inspector	
Notify Appropriate Parties: ☐ PI ☐ All Key Study Personnel (listed on delegation Log and 1572) ☐ Staff in the facility or areas where research was conducted ☐ Sponsor (if applicable); if the PI is not the sponsor-investigator of the IND or IDE ☐ University Hospitals Clinical Research Center (UHCRC) 216-844-5936 ☐ Health Information Services (Medical records) 216-844-3555	
Before the Inspection: ☐ Ensure that all medical records for all subjects enrolled in the study are available. Inform Health Information Services that the records request is for an FDA inspection and **all** records must be available for the first day of the inspection. Records should not be de-identified. ☐ Reserve a room in a private area for the inspection: ☐ The room should not contain files or records that do not pertain to the inspection. ☐ A copy machine should be close to the room. ☐ FDA inspectors should not be located in/around patient care and research staff workspace areas during the inspection. ☐ The UHCRC may facilitate securing an appropriate location.	

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☐ Identify a person who will serve as escort and oversee the inspection:_____

- o The escort will serve as a guide and general contact person.
- o The escort must be readily available to the inspector at all times.

☐ Prepare a general overview of the study. This should be kept for the PI and study staff and should include:

- ☐ Study summary
- ☐ Adverse events
- ☐ Deaths
- ☐ Violations
- ☐ Deviations
- ☐ Copy of the study staff delegation log
- ☐ Sponsor contact and address (if applicable)
- ☐ IRB contact name, Chairperson, and address

☐ Ensure all study documents are available for review by the inspector:

- ☐ All informed consent forms
- ☐ All original source documents (including printed lab reports, ECGs, etc)
- ☐ Case Report Forms
- ☐ Regulatory binder (include all IRB and regulatory documents and sponsor correspondence)
- ☐ Test article accountability and storage records

☐ Review agreements/contracts for specific details regarding FDA inspections

☐ Review study documentation for:

- ☐ Comprehensiveness, accuracy and compliance.
- ☐ Weakness/gaps; correct those that can be corrected (i.e. file violations, draft notes-to-file, locate missing documents, etc.).
- ☐ Unresolved or outstanding issues; develop a corrective plan for any unresolved/ outstanding issues.
- ☐ Ensure all protocol training has been documented- if not, create Note to Files for ALL training and have PI sign off.
- ☐ Review the Institution's record retention requirements incase questions Arise.
- ☐ Keep all study documents and records ready and accessible, however do not volunteer a list of them to the inspector. Always wait for a specific request to provide information.

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During the Inspection:

- ☐ PI or designees must be available to meet with the inspector to receive and sign the FDA Form 482 "Notice of Inspection"
- ☐ The FDA inspector should present credentials upon arrival to the site. If he/she does not, make sure you ask to see ID prior to allowing access to confidential records.
- ☐ The FDA inspector will request a tour of the facility areas where the research took place. Notify staff in the study areas to be prepared for the visit and possible questions. The FDA inspectors must be accompanied by research staff at all times during the tour.
- ☐ Research staff will need to be available at all times to the FDA auditor. All staff should answer questions directly and honestly. **Listen carefully to the question and only answer what was asked.** If you are unclear of the question, ask the inspector to repeat or rephrase the question. Respond to queries promptly. It is acceptable to defer to the PI or other study staff if you don't know the answer.
- ☐ The standard procedure is that the inspector will request files for review. Provide the inspector only with files that have been requested.
- ☐ The inspector will request copies of some documents. Make a separate copy for yourself of any documents that are requested by the inspector. The Inspector's copies should be stamped "Confidential" and your copies should be stamped "Copy".
- ☐ The PI should designate an individual to take notes of activities and discussions during the inspection. Keep a log of the questions asked by the inspector.
- ☐ The PI should set aside time each day to talk with the inspector, as well as being available for any questions that arise.

After the inspection:

- ☐ The FDA inspector will hold an exit interview with the PI at the conclusion of the inspection. The escort, PI and any other appropriate staff should attend this interview. The purpose of this interview is to review the FDA's findings and deficiencies, if any. Any deficiencies will be noted on an FDA Form 483 and given to the PI. A copy of the report will be given to the PI.
- ☐ During the exit interview, the escort or designee will document the conversation, specifically noting observations, comments and commitments.

Maintain all research documentation on site until the Establishment Inspection Report (EIR) is received.

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Response to FDA Form 483 (if necessary):

- Contact the University Hospitals Clinical Research Center, Office of Research Compliance and Education for guidance. Carrie O'Neill can be reached at 216-286-2283.

☐ A response must be submitted for all FDA Form 483s.

☐ The written response should include the following information:

- ☐ Determination if a finding was an oversight/single occurrence or if it is a systemic problem requiring change of procedure/process.
- ☐ Describe corrective actions. This should include justification of why the proposed response would correct this problem and prevent it from reoccurring. Include a timeline for corrective actions.
- ☐ Address each specific finding, point by point
- ☐ The response must be sent to FDA within 30 days.

☐ Maintain all research documentation on site until the Establishment Inspection Report (EIR) is received.