***FDA Inspections***

1. **PURPOSE**

This Standard Operating Procedure (SOP) describes the procedures, processes, and responsibilities for the preparation, conduct and follow-up of FDA inspections.

**(MANDATORY LANGUAGE)**

1. **SCOPE**

This SOP applies to all research personnel involved in the implementation and coordination of a clinical trial, including the Principal Investigator (PI), Study Coordinators, and other research professionals. This includes all research team members who have contributed to research data, procedures, assessments, analysis, or product accountability which may be inspected by the FDA.

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*[Optional: Insert any additional details necessary to further define the scope of this SOP.]*

1. **POLICY**

FDA Regulation

Per 21 Code of Federal Regulations Part 312.68, *An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62* (Investigator recordkeeping and record retention).

In addition, 21 CFR 812.145 states that an investigator who has authority to grant access shall permit FDA employees to enter and inspect any establishment where devices are held, used or implanted, to inspect and copy all records relating to an investigator and may provide access to records that provide subject identity.

University of Michigan Medical School Institutional Review Board (IRBMED)

The University of Michigan Institutional Review Board (IRB) indicates that Investigators and research staff are expected to cooperate with evaluations, inspections, and audits performed by authorized internal oversight authorities, including the IRB, etc. Cooperation is also expected for external reviews (e.g., by Entities such as industry sponsors or Government Agencies such as the FDA, NCI or NIH Office of Research Integrity).

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**Additional Regulations or Policies ☐ N/A**

*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply]*

1. **DEFINITIONS**

Establishment Inspection Report (EIR): This is a comprehensive report prepared by the FDA inspector after the inspection.

FDA FORM 483: The FDA Form 483 Inspectional Observations is used by FDA Investigators to record their observations of noncompliance with regulations and is issued at the end of the inspection (audit).

SPONSOR-INVESTIGATOR: An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed.

STUDY DOCUMENTATION: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

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*[Optional: Insert any additional definitions for technical or special terms used within the Standard Operating Procedure that may not be familiar to the lay reader]*

Note: Many of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 21-Sep-2015 and are subject to change. Please see the [IRBMed Glossary](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/glossary) for the most current definitions and additional guidance.

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1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator**

An individual filling the role of the Principal Investigator (PI) is *accountable for the accuracy and completeness of clinical trial documentation and ensuring the research team members are available and prepared for an inspection*. The PI shall be responsible for the following activities:

* Maintains readiness in anticipation of an inspection, as the FDA may conduct an inspection at any time with or without advanced notice
* Ensures participating research sites in multi-site trials comply with inspection responsibilities (when acting as the lead PI)
* Notifies all necessary parties of impending FDA inspection as soon as practicable, including:
	+ Medical School Office of Regulatory Affairs
	+ Research team members including all Investigators on the clinical trial, Study Coordinators, etc.
	+ Sponsor in those cases where the PI is not the Sponsor-Investigator of the investigational new drug application (IND), or investigational device exemption (IDE)
	+ IRBMED
	+ Other departments integrally involved in the conduct of the study such as Research Pharmacy, BEU, MCRU, etc.
* Ensures the availability of clinical trial documentation for the FDA Investigator ’s review
* Facilitates the availability of applicable staff to the FDA Investigator during the visit
* Meets with Investigator(s) while onsite, and verifies their credentials
* Works with Medical School Office of Regulatory Affairs, or other U-M entities to respond in writing to any FDA findings, and if necessary, to any subsequent correspondence that requires response. This may include providing a corrective and preventative action plan.
* Provides a copy of the inspection report (e.g. Establishment Inspection Report (EIR)) and any other documentation and correspondence from or to the FDA, to the applicable oversight committees or U-M Offices (i.e. U-M Office of Regulatory Affairs, etc.)
* Delegates activities to other research team members, as appropriate

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*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator]*

**Study Coordinator/Designee**

An individual filling the role of Study Coordinator is responsible for preparing for the FDA inspection and for providing ongoing support to the FDA Investigators during the visit including the following activities:

* Ensures that all the requested clinical trial-related records and documentation are available to investigators
* Arranges physical space for the FDA Investigator
* Makes or oversees the making of any copies the FDA investigator requests, while keeping at least one additional copy of all copies made for the FDA Investigator
* Provides and oversees the FDA Investigator’s access to the clinical record as necessary
* Arranges the appropriate welcoming and accompaniment of the FDA Investigator throughout the investigation, including any badging, if necessary
* Notifies non-research staff in the clinic(s) or affected areas when and where an FDA inspection will occur
* Works with the PI and Medical School Office of Regulatory Affairs in responding to any FDA findings

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*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator/Designee]*

**Additional Roles and Responsibilities**  **☐ N/A**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SOP]*

1. **PROCEDURE**

**Visit Preparation**

*[Describe the process for preparing for a FDA Inspection, including notifying the Office of Regulatory Affairs, research staff and other applicable entities (e.g. the Sponsor, IRBMED, Health System Legal Office) about the upcoming visit, and working with the Office of Regulatory Affairs on visit preparation.]*

**Participation in the FDA Inspection**

*[Describe the process for preparing the records for review, granting access to the records, and ensuring the appropriate personnel are available to the FDA Investigator(s)]*

**Follow up from the Inspection**

*[Describe the processes for preparing, maintaining and disseminating responses to FDA queries and Form 483 findings, (including all correspondence regarding the inspection)]*

**Additional Procedures** **☐ N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

FDA - Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

FDA Inspections of Clinical Investigators:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf>

University of Michigan Medical School Office of Research - ORIO Guidance: Miscellaneous Information:

[http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting/other-reportable-information-or-occurrence-orio/orio-guidance-miscellaneous-information](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting/other-reportable-information-or-occurrence-orio/orio-guidan)

University of Michigan - Office for Human Research Compliance Review (OHRCR):

http://research-compliance.umich.edu/office-human-research-compliance-review-ohrcr

University of Michigan Office of Regulatory Affairs:

<http://www.med.umich.edu/medschool-regulatory/index.htm>

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*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

*[Optional: Insert any additional SOP appendices]*