DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Inspections by Regulatory Authorities	Policy #: CRP-1024
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DEPARTMENT: DHR Health Institute for Research & Development	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21

Purpose:
Inspections are similar to audits. Inspectors are either employed by state or federal government regulatory authorities, have the regulatory authority to issue and revoke licenses and to regulate the conduct of clinical research. The purpose of this policy is to describe the steps to prepare for a FDA inspection, what to do during and after an FDA inspection.

Applies To:
This policy applies to the following potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

Definition:
- **A. FDA Inspection** - The act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority (ies) to be related to the clinical trial and that may be located at the site of the trial, , or at other establishments deemed appropriate by the regulatory authority (ies).
- **B. OHRP Compliance Evaluations** – OHRP conducts for-cause evaluations occur in response to OHRP's receipt of substantive written allegations or indications of non-compliance with the HHS regulations. Sources of such allegations or indications of noncompliance include, but are not limited to, research subjects and their family members, individuals involved in the conduct of research such as investigators and study coordinators, institutional officials, and research publications.

Policy:
Study team members and research records shall be accessible for inspection and copying by authorized representatives of the regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.

Procedure:
- **A. Notice of Inspection:** FDA inspectors may or may not give notice of inspection to the research site. If the inspection is scheduled, the Principal Investigator or designee should fill out form FDA Inspection Notification form to gather important information about the inspection. When the site is aware of an impending inspection, the Principal Investigator or designee should contact the following:
  - **a.** Sponsor of the research study

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B. Preparation for inspection: It is good practice to review the study documents using the FDA Inspection Checklist. The Principal Investigator should make arrangements for a comfortable work area for the duration of the inspection.

C. During the inspection – Upon arrival of the Inspector(s), a designated study team member should inspect the Notice of Inspection (Form 482). Within the institution premises, the FDA inspector should be accompanied by a study team member at all times. The study team should cooperate fully but should not volunteer any unsolicited information.

Usually the inspector will request for files to review, starting with the "general" study materials, including the regulatory documents binders, signed informed consent forms, and specific patient records. Study finances and personnel records are not usually included in the standard inspection.

The Principal Investigator or designee should set aside time each day to talk with the Inspector, as well as be available for questions that may arise. An escort should be assigned to the Inspector and should be available to the Inspector at all times.

FDA Inspectors may be allowed to take photocopies of documents. It is good practice to maintain a log of all the documents that were copied and maintain another set of the documents that were copied. This would be helpful to provide a response to any Form 483 or Warning Letter that might be issued.

D. Exit Interview - The Inspector will usually hold an exit interview at the conclusion of the inspection. The Principal Investigator, research team, and other individuals as appropriate should be notified of the time and place and expect to attend. During this exchange, if serious deficiencies have been found during the inspection, an Inspectional Observations form 483 will follow from the regional office, listing the deficiencies. If no deficiencies are found, or the Inspector has comments that she or he believes are not serious enough to warrant a 483, no form will be issued.

E. Response to FDA 483 - The PI or designated shall draft a response to an FDA 483. The PI is also responsible for sending the written response to the FDA. The written response should include specifics:

a. Determine if a finding was an oversight/one-time occurrence; or systemic, where a change of procedure is indicated.
b. Delineate corrective actions: including justification of why the proposed response will remediate the issue; and a realistic timeline for correction.
c. If the PI disagrees with an observation: respond factually, providing clear and verifiable evidence.
d. Address each particular observation or finding, point by point.
e. The reply should be sent within two weeks. Keep a copy of the final signed response in your office.

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To request an EIR (establishment inspection report) - The FDA inspector will file an EIR within approximately 30 days. This report is subsequently available through FOI. It may be requested from:

Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5600 Fishers Lane
Rockville, MD 20857

Institutional follow up - Please provide a copy of the **final** establishment inspection report (EIR) and/or the Inspectional Observation Form 483 upon receipt by the designated staff of the DHR Health Institute for Research & Development.