TITLE: Audits and Inspections		
POLICY#: AUD-100	**Page:** 1 of 3	**Effective Date:** 1/31/2020

1. POLICY STATEMENT:

DF/HCC research activities are subject to both internal and external audit and inspection.

Prompt notification of external audits and inspections is required to inform key associated leadership and study personnel.

2. BACKGROUND:

All audits/inspections strive to ensure the protection of human subjects and the quality and integrity of the data and information submitted to the Institutional Review Board (IRB), Sponsor, and regulatory authorities. DF/HCC has a vested interest in the quality of the research that is performed at the facility and in maintaining its collective reputation as an outstanding research community. Because of the center's structure and many sources of funding and support, it is critical for it to have an overall understanding of the workings and results of any external audits/inspections. This allows DF/HCC to develop systems to resolve problems when necessary.

3. RESPONSIBLE PERSONNEL:

3.1. Principal Investigator (PI)
3.2. Subinvestigator
3.3. Research Nurse
3.4. Study Coordinator
3.5. Office of Data Quality (ODQ) Audit Team
3.6. DF/HCC Audit Committee Chair
3.7. Clinical Trials Office Director
3.8. Institutional Official (IO)

4. DEFINITIONS:

4.1. **Clinical Trial Office**: The institutional entity that provides centralized administrative services that help support cancer clinical trials from initial proposal through study completion.

4.2. **External Audit**: An independent examination of research related activities and documents to determine whether the research related activities were conducted, recorded, and accurately reported according to the protocol, sponsor's procedures, and the applicable regulatory requirements. This may include but is not limited to examinations requested or directed by the Food and Drug

Administration (FDA), European Medical Association (EMA), National Institutes of Health (NIH), a National Cancer Institute (NCI)/Cooperative Group, regulatory authorities, a research sponsor, or their representatives.

4.3. **Institutional Official (IO)**: A senior official who, on behalf of a research institution, has the authority and responsibility for the oversight and administration of the institution's human subject research program.

5. POLICY:

5.1. Internal Audits

5.1.1. The Office of Data Quality (ODQ) performs internal audits of DF/HCC research activities. All protocols are eligible for auditing, regardless of sponsorship.

5.1.2. The PI must participate in the exit interview, unless an exception is granted by the auditor or inspector and a designee is appointed by the PI. The conduct of the exit interview is mandatory and failure to accommodate the meeting will result in notification sent to the DF/HCC Audit Committee chair and further action taken as deemed appropriate.

5.1.3. The Audit Committee (see COM-100) reviews the audit reports and written corrective action plans and approves or disapproves the audit rating and PI response. ODQ maintains documentation of the audit outcome, Audit Committee response and any required follow-up action.

5.2. External Audits and Inspections

5.2.1. The PI or designated research team member will notify the responsible clinical trials office within 1 business day of notification of any external group's plans to inspect or audit a protocol at that DF/HCC institution, providing the following details: date, time, location, and purpose of the inspection, as well as the identity of the auditors and the principal DF/HCC study contact.

5.2.2. In the event of a regulatory agency inspection, for example by Food and Drug Administration (FDA) or European Medical Association (EMA):

5.2.2.1. It is the responsibility of the PI and, when applicable, the responsible clinical trials office to ensure impending inspections are communicated

to the individuals listed on the DF/HCC External Regulatory Inspection Contact List. The responsible clinical trials office must also notify the appropriate IRB of record for the site. During the inspection, the PI, or designee, will prepare and distribute a written daily summary.

5.2.2.2. The PI or designated research team member will notify the sponsor as soon as possible. However, DF/HCC research teams are unable to host external sponsors, provide onsite space, or meet in person with sponsor representatives during a regulatory inspection. The research team may provide the sponsor with a copy of the daily summary upon request.

5.2.2.3. The PI or designated research team member is responsible for following AUD-OP-2.

5.2.3. The PI is solely responsible for responding to the audit or inspection report by the date indicated on the report.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 - Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED RESOURCES:

AUD-OP-1: Internal Auditing Procedures
AUD-OP-2: FDA and Other Regulatory Inspections
DF/HCC Guidance on Responding to Audit Findings
DFHCC External Regulatory Inspection Contact list