DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH

TITLE: Data Management of Investigator-Sponsored Therapeutic Protocols		
POLICY #: DATA-100	**Page:** 1 of 4	**Effective Date:** 9/1/21

1. POLICY STATEMENT:

The Research Informatics for Operations (RIO) supports systems for the management of clinical research data collected on investigator-sponsored protocols. The Office of Data Quality (ODQ) is responsible for monitoring data submission compliance.

2. BACKGROUND:

This policy does not apply to protocols where data are sent to an external sponsor or contract research organization (CRO) for capture and analysis (including Cooperative group studies and most industry-sponsored protocols).

3. RESPONSIBLE PERSONNEL:

3.1. Sponsor-Investigator
3.2. Principal Investigator (PI)
3.3. Study coordinator
3.4. DF/HCC Associate Director for Administration
3.5. RIO EDC Team
3.6. RIO Director
3.7. ODQ Data Quality Team
3.8. ODQ Director

4. DEFINITIONS:

None

5. POLICY:

5.1. This policy applies to all trials where a DF/HCC-managed system is used to collect and maintain the protocol data on case report forms (CRFs). Data for all investigator-sponsored, therapeutic protocols must be captured on CRFs.

5.1.1. In circumstances where the Sponsor-Investigator wants the data to be managed outside of the DF/HCC, a waiver must be approved by the RIO Director or the RIO EDC Team Lead.

5.2. CRF data are submitted according to the protocol schedule and as instructed on the CRF itself.

Commented [SC1]: Section 5.5. revised to clarify that for all investigator-sponsored studies, a data request must be submitted and approved by ODQ prior to sharing with a 3rd party or publishing.

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5.3. For research utilizing DF/HCC InForm or other centrally-managed DF/HCC electronic data capture (EDC) systems:

5.3.1. The RIO EDC team is responsible for building the electronic case report forms (eCRFs) in accordance with DATA-101 and managing access and training. The ODQ Data Quality team assures the accuracy and timeliness of data collection in the eCRFs.

5.3.2. The research team is responsible for collecting information from source documentation and accurately transcribing the required data into the CRFs.

5.3.3. The ODQ Data Quality team reviews system generated queries and responses, and issues manual queries within the EDC application if data requires additional clarification. Monitors may also issue queries when performing source data verification.

5.3.4. The research team is expected to respond to all queries within two weeks.

5.4. It is the responsibility of the Sponsor-Investigator or designee to monitor the data submission compliance of all sites participating on the trial within and external to DF/HCC.

5.4.1. After finalization of the CRFs, RIO develops a protocol-specific Missing Forms Report (MFR) according to the protocol guidelines, and the time points on the CRFs for submission requirements.

5.4.2. The Sponsor-Investigator or designee is responsible for monitoring data compliance on the MFR and notifying all participating sites of the status of data entry.

5.5. Prior to any publication, sharing, presentation, or official reporting of data to regulatory authorities, a data request must be submitted and ODQ must approve the release of the CRF data. Data requests submitted to ODQ must be approved by the Sponsor-Investigator and assigned biostatistician. ODQ requires the data to be clean (i.e., data entry complete, data discrepancies and queries resolved) before certain types of requests can be fulfilled.

5.6. In the event of significant data concerns, such as but not limited to continuing inaccurate safety and response data, continuing non-compliance of data submission or suspected fraudulent data, ODQ will inform the Sponsor-Investigator.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 11 – Electronic Records; Electronic Signatures
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:

DATA-OP-12: How to View Missing Forms Information in OnCore