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

TITLE: Data Management of ~~PI-Initiated~~Investigator-Sponsored Therapeutic Protocols		
POLICY #: DATA-100	**Page:** ~~1~~1 of ~~4~~4	**Effective Date:** ~~1/14/16~~1/31/19

Commented [FNR1]: Clarifications throughout to reflect current ODQ and RIO processes. Merged in DATA-103 information. Changes to section 5.5 and 5.6 regarding MFRs and data requests. Language regarding paper CRFs removed, no longer relevant.

1. POLICY STATEMENT:

~~The Office of Data Quality (ODQ) and the~~The Research Informatics for Operations (RIO) ~~are jointly responsible~~supports systems for ~~managing~~the management of clinical research data ~~for PI-initiated therapeutic~~collected on investigator-sponsored protocols~~, as outlined in this policy.~~. The Office of Data Quality (ODQ) is responsible for monitoring data submission compliance.

2. BACKGROUND:

~~Cooperative group studies, most industry-sponsored protocols, and any other protocols for which~~This policy does not apply to protocols where data are sent to an external sponsor or contract research organization (CRO) for capture and analysis ~~are not included in this process.~~(including Cooperative group studies and most industry-sponsored protocols).

3. RESPONSIBLE PERSONNEL:

3.1. Sponsor
3.2. Overall 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 ~~PI-initiated~~investigator-sponsored, therapeutic protocols ~~is submitted~~must be captured on ~~case report forms (~~CRFs~~).~~.

Version: ~~5~~6
Effective Date: ~~1/14/16~~1/31/19
Last Reviewed Date: ~~12/8/2015~~11/13/18

5.1.1. In circumstances where the Sponsor-Investigator wants the data to be managed outside of the DF/HCC, ~~an exception requires~~ a waiver ~~that~~ must be approved by the ~~DF/HCC Associate~~ RIO Director ~~for Administration~~ or the RIO EDC Team Lead.

5.2. CRF data are submitted according to the protocol schedule ~~or~~and as instructed on the CRF ~~or in the EDC application~~itself.

~~5.3.~~ For ~~paper Case Report Forms the following procedure should be used:~~

~~5.3.1. Each protocol is assigned to an ODQ Data Analyst who organizes the data collection process, manages the Ingres database, and assures the quality of the data that are being collected for accurate reporting, interpretation and verification. The Data Analyst maintains documentation for each assigned protocol.~~

~~5.3.2. The designated research team member, typically the study coordinator, collects medical information from source documentation and transcribes the required data onto case report forms (CRFs) in black ballpoint pen. All corrections to the CRFs should be made according to good documentation practices and in compliance with DOC-101.~~

~~5.3.3. The designated research team member submits the original copy of the CRF to the ODQ Data Analyst for data review and entry into Ingres. The designated research team member must keep a copy of all completed CRFs for the research file.~~

~~5.3.4. When data arrive in the ODQ office, the CRFs are date-stamped, and before data is entered in Ingres, the ODQ Data Analyst reviews the data and performs logic checks on the CRFs. The ODQ Data Analyst reviews CRFs for legibility, data consistency and proper use of values.~~

~~5.3.5. When any data element is unclear, the ODQ Data Analyst will query the designated research team member electronically. A copy of the query and the reply is maintained by the ODQ Data Analyst.~~

~~5.3.6. All queries must be answered by the designated research team member within two weeks of the issued query. The ODQ Data Analyst will perform corrections in the database (if applicable). The CRF is the written record documenting information that has been entered into the database.~~

~~5.4.~~5.3. ~~Electronic~~electronic data capture (EDC~~) the following procedure should be used:~~):

~~5.4.1.~~5.3.1. The RIO EDC team is responsible for building the electronic case report forms (eCRFs~~), and management of~~) in accordance with DATA-101 and managing access and training for EDC systems. The ODQ Data Quality team assures the accuracy and timeliness of data collection in the eCRFs.

~~5.4.2.~~5.3.2. The ~~designated~~ research team ~~member, typically the study coordinator, collects medical~~is responsible for collecting information from source documentation and ~~enters~~accurately transcribing the required data ~~onto eCRFs~~into the CRFs.

~~5.4.3.~~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.

~~5.4.4.~~5.3.4. The ~~designated~~ research team ~~member must answer~~is expected to respond to all queries within ~~2 weeks of issuance. Queries may be either closed or re-opened by ODQ. This cycle repeats until the query is resolved~~two weeks.

~~5.5. Requests for data are first approved by the Overall PI, and then sent to ODQ. The Protocol Data Request Form is completed and emailed to odqdatamanagement@dfci.harvard.edu. Requests for data already entered into the database must be made at least two weeks in advance. Requests for data maintained in Ingres (paper CRFs) that has not been entered into Ingres must be made at least four weeks in advance.~~

5.4. It is the responsibility of the Sponsor and Overall PI 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 lead site study team is responsible for monitoring data compliance on the MFR and notifying all participating sites of the status of data entry.

5.5. Data requests submitted to ODQ must be approved by the Overall PI 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 ~~exist~~, 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 ~~and~~ Investigator, Overall PI, and lead site clinical trials office.

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-1: DATA Requests

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