TITLE: Data Management of PI-Initiated Therapeutic Protocols		
SOP #: DATA-100 *(formerly QA-717)*	**Page:** 1 of 4	**Effective Date:** 1/14/16

1. POLICY STATEMENT:

The Office of Data Quality (ODQ) and the Clinical Trials Research Informatics Office (CTRIO) are jointly responsible for managing clinical research data for PI-initiated therapeutic protocols, as outlined in this policy.

2. BACKGROUND:

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

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. CTRIO EDC Team
3.6. CTRIO Director
3.7. ODQ Data Quality Team
3.8. ODQ Director

4. DEFINITIONS:

None

5. PROCEDURE:

5.1. Data for all PI-initiated therapeutic protocols is submitted on case report forms (CRFs).

5.1.1. In circumstances where the Sponsor 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 Director for Administration or the CTRIO EDC Team Lead.

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

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. Electronic data capture (EDC) the following procedure should be used:

5.4.1. The CTRIO EDC team is responsible for building the electronic case report forms (eCRFs) in accordance with DATA-101, and management of 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. The designated research team member, typically the study coordinator, collects medical information from source documentation and enters the required data onto eCRFs.

5.4.3. The ODQ Data Quality team reviews system generated queries and responses, and issues manual queries within the EDC application if data requires additional clarification.

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

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.

5.6. 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 Overall PI.

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

TITLE: Data Management of PI-Initiated Therapeutic Protocols		
SOP #: DATA-100 *(formerly QA-717)*	**Page:** 4 of 4	**Effective Date:1/14/16**

8. RELATED FORMS & TOOLS:

Protocol Data Request Form

Version: 5
Effective Date: 1/14/16
Last Reviewed Date: 12/8/2015