TITLE Case Report Form (CRF) Design for PI-Initiated Protocols		
SOP #: DATA-101 *(formerly QA-715)*	**Page:** 1 of 4	**Effective Date:** 1/14/16

1. POLICY STATEMENT:

Case Report Forms (CRFs) are designed by the Clinical Trials Research Informatics Office (CTRIO) in collaboration with the Sponsor, Overall PI, designated study coordinator, ODQ Data Quality Team and Biostatistician for DF/HCC PI-initiated protocols. The CRF development and design process ensures that data elements required for research analysis are appropriately identified and electronic systems are in place for data storage.

2. BACKGROUND:

Case Report Forms (CRFs/eCRFs) contain clinical and other pertinent data collected during the trial process and represent the official documentation of trial results provided to the sponsor and regulatory authorities. CRFs allow research information to be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

3. RESPONSIBLE PERSONNEL:

3.1. Sponsor
3.2. Overall Principal Investigator (PI)
3.3. Study Coordinator
3.4. Biostatistician
3.5. CTRIO EDC Team
3.6. CTRIO EDC Team Lead
3.7. CTRIO Director
3.8. ODQ Data Quality Team

4. DEFINITIONS:

None

5. PROCEDURE:

5.1. CTRIO will be informed of proposed DF/HCC PI-initiated protocols going to Scientific Review Committee (SRC), Pediatric Scientific Review Committee (PSRC), and Institutional Review Board (IRB) Panel D. A member of the CTRIO EDC team will be assigned to the protocol as the study designer/developer.

5.2. The CTRIO EDC team will:

5.2.1. Review the proposed protocol.

5.2.2. Compile sample CRFs from existing form libraries.

5.2.3. Maintain documentation of the eCRF design process, key requirements, and decision points.

5.3. The study team will be responsible for notifying CTRIO in the event changes are made to the protocol that may impact CRF requirements.

5.4. After the trial is conditionally approved or approved by SRC/PSRC/IRB, the CTRIO EDC Team will:

5.4.1. Send template/draft eCRFs to the Sponsor or designee, Overall PI, designated study coordinator, and Biostatistician for review

5.4.2. Schedule a meeting with Sponsor or designee, Overall PI, designated study coordinator, and Biostatistician, if needed (may require extended timeframe)

5.4.3. The Biostatistics CRF Review Waiver may be submitted at this review.

5.5. The Sponsor or designee, Overall PI, designated study coordinator, ODQ Data Quality Team and Biostatistician will:

5.5.1. Review/Edit CRFs (Edits/Comments may be emailed or hand written and faxed or scanned)

5.5.2. Return comments to the CTRIO eDC team.

5.6. The CTRIO eDC team will:

5.6.1. Develop the CRFs including submitted edits

5.6.2. Send a copy of the CRFs to the Sponsor or designee, Overall PI, designated study coordinator, ODQ Data Quality Team, and Biostatistician (if applicable) for approval

5.7. The Sponsor, Overall Principal Investigator, designated study coordinator, ODQ Data Quality Team and Biostatistician (if applicable) must approve CRFs or submit further edits.

5.8. Additional Testing for Electronic Case Report Forms (eCRFs):

5.8.1. eCRFs will be made available for electronic testing by CTRIO, and the designated study coordinator.

5.8.2. Testing of eCRFs is done to verify that data can be properly entered and that the data elements are correctly captured. Testing also verifies that the data workflow allows for the correct process through a treatment course. Therefore data should be entered for at least one test subject on every form and on at least one form at each visit and follow-up.

5.8.3. Prior to final deployment, the CTRIO EDC Team performs final verification and validity checking. CTRIO performs final deployment of the EDC study.

5.9. Edit Checks will be developed by CTRIO in order to assist with the input of clean data.

5.9.1. Edit checks are logical, programmatic rules that generate automatic queries in the eCRF.

5.10. Electronic Case Report Forms (eCRFs) Deployment:

5.11. eCRFs/CRF must be finalized prior to protocol activation.

5.12. Prior to entering data onto eCRFs, users are trained within the appropriate system. Protocol specific data fields may be defined within the system on the eCRFs using help text or links to code lists.

5.13. Questions regarding any exceptions to the timelines and procedures above should be directed to the CTRIO EDC Team Lead.

5.14. **Procedure for eCRF Post Production Changes (eCRF Edits):**

5.14.1. eCRFs <u>may</u> be edited after the study has been deployed <u>IF</u>:

5.14.1.1. There was an error in the development of a form/data element.

5.14.1.2. IRB approved amendments require changes to data collection affecting eCRF design/data capture.

5.14.1.3. Exceptions may be approved by the CTRIO EDC Team Lead

5.14.2. Post production changes that either remove or add directions or data captured will go through the same process and sign-offs as initial design.

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 FORMS & TOOLS:

Biostatistics CRF Review Waiver