TITLE: Case Report Form Development		
POLICY #: DATA-101	**Page:** 1 of 3	**Effective Date:** 9/30/22

1. POLICY STATEMENT:

For investigator-sponsored trials (ISTs) that require Case Report Forms (CRFs), protocols will be tiered and prioritized to determine how eCRFs will be developed. The Research Informatics for Operations (RIO) will develop electronic case report forms (eCRFs) in InForm for therapeutic ISTs or other trials at the request of the DF/HCC DSMC/DSMB.

2. BACKGROUND:

InForm eCRF development cannot commence until after full or conditional SRC approval. User Acceptance Testing (UAT) and Final Testing of eCRFs will be required prior to deployment. Any post-production changes will follow OHRS protocol amendment requirements and be supported by the RIO EDC team. eCRFs need to be retired and moved out of the production environment at study completion.

3. RESPONSIBLE PERSONNEL:

3.1. Study Team
3.2. Biostatistician
3.3. Principal Investigator (PI)
3.4. RIO Solutions Architecture Technology (SAT), Electronic Data Capture (EDC) teams
3.5. Office of Data Quality (ODQ) Data Quality Team
3.6. Office for Human Research Studies (OHRS) Submission Intake Staff
3.7. Persistent (3rd Party Support Vendor)

4. DEFINITIONS:

4.1. User Acceptance Testing (UAT): is one of the last phases of the eCRF testing process. During UAT, actual users test the eCRF to make sure it can handle required tasks in real-world scenarios, according to design and data collection specifications.

5. POLICY:

5.1. **Tiering and Prioritization**

5.1.1. RIO-EDC is notified of interventional ISTs that require CRFs upon submission of the New Project Application (NPA) in the iRIS (Protocol Review Management System) system

5.1.1.1. Tier 1 studies are single patient IND studies, non-interventional studies, and non-therapeutic studies. For tier 1 studies, the lead site study team will be responsible for development and maintenance of the CRFs (e.g., in RedCap or other EDC system).

5.1.1.2. Tier 2 (single-site, single-arm interventional studies) and tier 3 (multi-site or multi-arm interventional studies) are serviced by the RIO EDC team and eCRFs are built in InForm. Within these service tiers, RIO EDC uses a prioritization framework for both initial, as well as amendment eCRF development and deployment activities.

5.2. **Tier 2 and Tier 3 eCRF Development**

5.2.1. RIO-EDC team begins development after SRC approval (or conditional approval).

5.2.1.1. The EDC Designer, Biostatistician, PI, and at least one Lead Site Research Manager or Lead Clinical Study Coordinator are required to attend one or more form review meetings during the eCRF development.

5.2.1.2. The PI, biostatistician and Lead Clinical Coordinator are responsible for providing feedback and answering questions from the RIO-EDC designer in a timely manner so development of the CRFs can proceed as planned.

5.2.1.3. If the study team is unresponsive the project will be escalated to the respective lead site Clinical Trial Office (CTO) for further action.

5.2.2. RIO completes deployment into the production or "live" environment once the eCRFs have been built and all testing has been completed.

5.2.2.1. RIO requires that key stakeholders complete User Acceptance Testing (UAT) and approve the eCRFs prior to deployment.

5.3. **Data Set Finalization and InForm eCRF Retirement**

5.3.1. Once a protocol is approved for study completion by ODQ and OHRS, the eCRFs will be retired and moved out of the production environment

5.3.2. ODQ will approve finalization of eCRFs prior to IRB study completion. ODQ will notify the RIO EDC team when the eCRF can be moved out of the InForm production environment.

5.4. **Maintenance and Support**

5.4.1. To receive InForm support from RIO, users must send an email to dfciinform@dfci.harvard.edu or submit support tickets using ServiceNow, addressed to "InForm – DFCI".

5.4.2. Changes to the InForm eCRFs require submission of a protocol amendment form to OHRS. The submitter must indicate if the amendment requires RIO EDC eCRF changes and include clear, detailed information about the changes required to support timely eCRF amendments processing. Change requests that are not the result of an amendment (i.e. design flaws) may be submitted directly to the RIO EDC team or InForm support by emailing dfciinform@dfci.harvard.edu.

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:

None

8. RELATED RESOURCES:

DATA-OP-3: EDC Receipt
DATA-OP-4: Project Initiation Meeting
DATA-OP-5: InForm eCRF Development
DATA-OP-6: InForm User Acceptance Testing
DATA-OP-7: InForm Final Testing
DATA-OP-8: InForm Deployment
DATA-OP-9: Data Set Finalization and InForm eCRF Retirement
DATA-OP-10: InForm Ticket Support
DATA-OP-11: Post-Production Change Requests