TITLE: Case Report Form Development		
POLICY #: DATA-101	**Page:** 1 of	**Effective Date:** 7/2/18

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.

2. BACKGROUND:

InForm eCRF development cannot commence until after SRC approval and a Project Initiation Meeting. User Acceptance Testing 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) and Customer Experience Services (CES) 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. Protocols requiring CRFs are identified by the OHRS Submission Intake Staff and received by RIO. RIO classifies protocols by type to determine the suitable environment (e.g., InForm versus RedCap) and who will be responsible for CRF development.

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).

5.1.1.2. Tier 2 (single-site, single-arm therapeutic studies) and tier 3 (multi-site or multi-arm therapeutic 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. A Project Initiation Meeting (PIM) is required to ensure all necessary information is available before the RIO EDC team begins case report form development in InForm.

5.2.1.1. The EDC Designer, Biostatistician, PI, Lead Site Study Team, and CES PMO Specialist are required to attend the PIM.

5.2.2. RIO begins development after both SRC approval (or conditional approval), and completion of the Project Initiation Meeting (PIM).

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

5.2.3.1. 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 submit support tickets using ServiceNow, addressed to "InForm – DFCI". If the user does not have a Partners login, they send an email to dfciinform@dfci.harvard.edu.

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 may not be submitted directly to the RIO EDC team or InForm support.

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