

## 1. BACKGROUND:

This procedure applies to all DF/HCC studies that require RIO EDC developed Electronic Case Report Forms (eCRFs), principally Investigator Sponsored Trials (ISTs.)

## 2. ASSOCIATED DF/HCC POLICIES:

2.1. [DATA-101](#) Section 5.2.3

## 3. PROCEDURE:

### 3.1. Final eCRF Signoff Preparation

3.1.1. After the Designer has deployed the study to the InForm Quality Assurance (QA) environment, the Designer creates test users in InForm for Study Team members.

3.1.2. The Designer decides if study specific InForm training is required; studies with complicated features are candidates for this training.

3.1.2.1. If study specific training is required, the Designer creates a training plan for the study.

3.1.2.1.1. The Customer Experience Specialist works with the Study Team to schedule and complete the study specific training prior to initiating Final eCRF Signoff.

3.1.3. The Designer completes the Final eCRF Signoff Instruction Form template in Salesforce.

3.1.3.1. The Designer updates the status of the task in Salesforce to indicate that the eCRFs are ready for Final eCRF Signoff.

3.1.3.2. Salesforce sends an automatic email with the Final eCRF Signoff Instruction Form to the Lead Coordinator initiating Final eCRF Signoff and prompting approval when complete.

### 3.2. Final eCRF Signoff

3.2.1. The Lead Coordinator logs into the InForm QA environment using credentials provided in the Final eCRF Signoff Instruction Form and completes testing.

3.2.2. The Customer Experience Specialist works with the Lead Coordinator to answer any questions as he/she completes Final eCRF Signoff.

3.2.3. The Lead Coordinator completes the Final eCRF Signoff feedback form and emails it to the Designer, copying the Customer Experience Specialist and Salesforce.

**Version:** May 17, 2018

**Maintained by:** Research Informatics for Operations (RIO)

DF/HCC Operations for Human Research  
Final eCRF Signoff

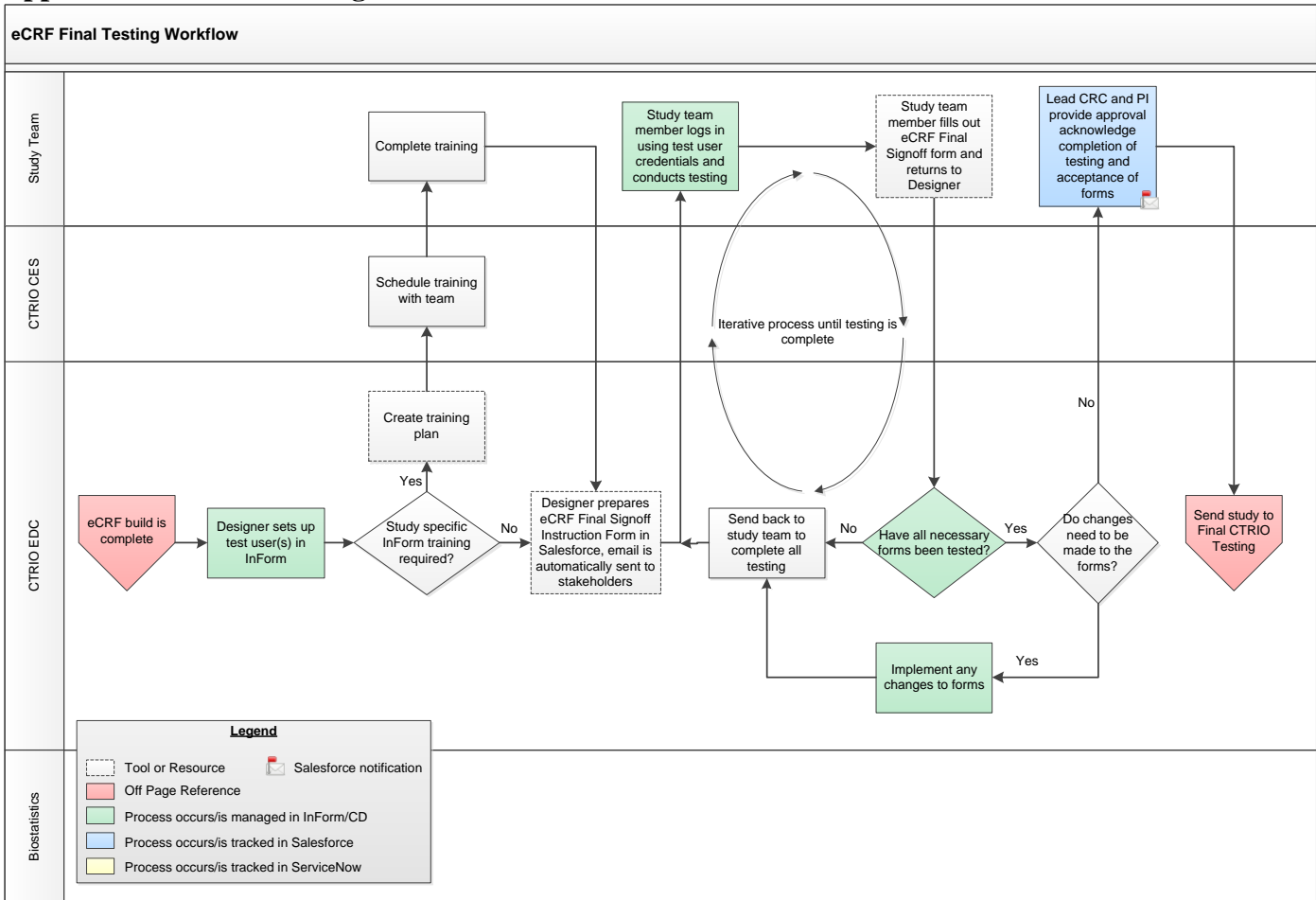
- 3.2.4. The Designer implements changes to the forms in response to the completed Final eCRF Signoff feedback form and updates the status of the task in Salesforce to indicate that Final eCRF Signoff is complete.
- 3.2.5. When all changes are complete, and forms are satisfactory to all, the Lead Coordinator provides final signoff by responding to the Final eCRF Signoff Salesforce email with their approval.
- 3.2.5.1. The Lead Coordinator will respond to the email with the following statement: “I have completed my review of the eCRF for ##-### per Final eCRF Signoff requirements. The eCRF meets all the requirements of the clinical team. I understand that any requests for changes in the production environment will affect data collection for the study. I am authorizing the EDC team to proceed with moving this study to the production environment.”
- 3.2.5.2. The Designer receives a notification when a response has been sent by the Lead Coordinator and monitors responses. When approval has been received, the Designer updates the status of the Final eCRF Signoff milestone to “complete” and promotes the case to the Final RIO Testing.

**Version:** May 17, 2018

**Maintained by:** Research Informatics for Operations (RIO)

## DF/HCC Operations for Human Research Final eCRF Signoff

### Appendix 1: Final eCRF Signoff Workflow



**Version:** May 17, 2018

**Maintained by:** Research Informatics for Operations (RIO)