Post-Production Change Requests

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 5.4.2

3. PROCEDURE:

3.1. Change Request Receipt

3.1.1. Post-production eCRF change requests can be received two ways:

3.1.1.1. Protocol Amendment: The Study Team submits an amendment form to OHRS and indicates on the amendment form if EDC eCRF changes are required. The Study Team includes information about the eCRF changes needed in the amendment form.

3.1.1.2. Ticket: The EDC team identifies a ticket that requires post-production eCRF changes.

3.2. Change Request Initiation: Protocol Amendment

3.2.1. EDC Leadership and Salesforce receive an email notification from OHRS that eCRF changes are required.

3.2.1.1. Salesforce receives the email notification and a post-production change case is automatically opened.

3.2.2. Salesforce assigns the case to the Designer who built the eCRFs during initial eCRF build. If that Designer is no longer available, Salesforce assigns the case to a Designer based on experience and workload.

3.2.3. An introductory email is sent to the PI, Study Team Representative, Biostatistician, and Customer Experience Specialist informing them of the post-production change request process and next steps.

3.3. Change Request Initiation: Ticket

3.3.1. The EDC team member on ticket rotation identifies a post-production eCRF change request ticket.

3.3.2. The EDC team member on ticket rotation assigns the case to the Designer who built the eCRFs during initial eCRF build. If the Designer is no longer available, the case is assigned to a Designer based on experience and workload.

3.4. **Change Request Implementation**

3.4.1. The Designer reviews the protocol amendment form or the ticket information in Salesforce and determines if a user requirements meeting is needed.

3.4.1.1. A user requirements meeting will be needed for complex changes, and any changes that are unclear based on the submitted ticket or amendment form.

3.4.1.2. If a user requirements meeting is needed, the Customer Experience Specialist schedules a meeting with the PI, Biostatistician, Designer, and Study Team Representative via email.

3.4.1.3. The Customer Experience Specialist, PI, Biostatistician, Designer, and Study Team Representative attend the user requirements meeting to discuss the requested changes and answer any questions.

3.4.1.4. After the user requirements meeting is held, the process proceeds with step 3.4.2. below.

3.4.2. The Designer completes the eCRF/Rule Change Specification Form, emails it to the Study Team and Biostatistician, and updates the status of the task in Salesforce to indicate that the eCRF Change Specification Form is complete.

3.4.2.1. Salesforce sends an automatic notification to the PI, Study Team Representative and Biostatistician that the eCRF/Rule Change Specification Form is ready for review.

3.4.3. The PI, Study Team Representative and Biostatistician review the eCRF/Rule Change Specification Form.

3.4.3.1. If the PI, Study Team Representative and Biostatistician have any comments or questions on the eCRF/Rule Change Specification Form, they provide their comments and questions to the Designer via email. The Designer replies to these questions and comments iteratively until everyone agrees.

3.4.3.2. Once all comments or questions have been addressed, the PI, Biostatistician and Study Team Representative provide their approval by responding to the Salesforce email with their approval.

3.4.3.2.1. Once both approvals have been received, the Designer will mark the status of the task as complete and begin eCRF changes.

3.4.4. The Designer implements changes to the eCRF based on the approved specifications.

3.5. **Final eCRF Signoff, Final RIO Testing, and Deployment**

3.5.1. The Designer determines if Final eCRF Signoff is needed.

3.5.1.1. Final eCRF Signoff will be needed for complex changes, changes to the structure of the study, form rules, addition of any forms, etc.

3.5.1.2. If Final eCRF Signoff is needed, the Designer follows all steps outlined in the operation for Final eCRF Signoff (see DATA-OP-4 Final eCRF Signoff).

3.5.2. The case then moves to Final RIO Testing and all steps are completed (see DATA-OP-5 Final RIO Testing).

3.5.3. The following steps are completed to move the case into deployment.

3.5.3.1. EDC Manager assigns deployment to RIO staff member based on experience and workload. The assigned RIO staff member receives a notification from Salesforce that the eCRF changes are ready for deployment.

3.5.3.2. The RIO staff member deploys the eCRF changes in InForm.

3.5.3.3. The RIO staff member changes the status of the case in Salesforce to “deployed”.

3.5.4. The PI, Study Team Representative, Biostatistician, Customer Experience Specialist, and RIO staff member receive an automatic notification from Salesforce that the changes have been completed and the case is closed.

Appendix 1: Post-Production Change Requests Workflow