

DF/HCC Operations for Human Research
EDC Receipt**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 5.1.

3. PROCEDURE:**3.1. OHRS Receipt and Scientific Review Committee (SRC)**

- 3.1.1. The PI and Study Team complete a New Project Application and submit it to OHRS, indicating if EDC eCRF forms are needed.
- 3.1.2. OHRS receives the application and creates an OnCore record, assigning a protocol number and populating OnCore with the information provided in the application.
- 3.1.3. OHRS sends an email notification to EDC leadership, copying Salesforce, to indicate that the protocol will require EDC eCRF build.
- 3.1.4. Salesforce automatically creates an inactive case for the protocol and assigns a service tier to the protocol (see Appendix 5: Protocol Tiering Algorithm).
 - 3.1.4.1. The service tier is assigned using an algorithm in Salesforce that gathers protocol information from OnCore.
 - 3.1.4.1.1. Tier 1 studies are those that do not require InForm EDC build and are returned to the Study Team with instructions on how to utilize RedCap (see Appendix 3).
 - 3.1.4.1.2. Tier 2 and 3 are assigned to a Designer for eCRF build after SRC approval or conditional approval is received.
 - 3.1.4.1.3. Tier 2 and Tier 3 studies that are also PRI studies are flagged for attention so that the EDC team is aligned with the rest of the activation timeline.
- 3.1.5. The protocol goes to SRC and a decision is made.
 - 3.1.5.1. The Salesforce case will remain inactive until the protocol receives SRC approval or conditional approval. Inactive cases will still appear in the EDC backlog but have not yet been assigned and activated for the EDC team to begin work.

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3.1.5.2. When the protocol is approved or conditionally approved, the Salesforce case will automatically update to active.

3.1.6. At this point the protocol exists in the EDC backlog. EDC leadership will review the protocol in Salesforce and can adjust the tier, if needed. EDC leadership will also indicate if work is required by the EDC team.

3.2. EDC Process

3.2.1. After the study has received approval or conditional approval and the status of the case in Salesforce has updated to active, Salesforce assigns the case to a Designer based on disease experience and Designer workload.

3.2.2. Biostatistics receives a notification providing the name and contact information of the Designer (via automatic notification from Salesforce). The Biostatistics contact will assign the protocol to a Biostatistician, by emailing the Designer with the Biostatistician's name and email address. The Designer will update the Biostatistician assignment in Salesforce when received.

3.2.3. The Designer will enter all key stakeholders in Salesforce to receive notifications throughout the process. All stakeholders, including the assigned Biostatistician, will receive an automatic introductory email from Salesforce.

3.2.3.1. The introductory email contains an overview of the EDC process, instructions, and expectations for scheduling the Project Initiation Meeting (PIM), PIM requirements, and next steps.

3.2.3.2. The introductory email also asks the PI to confirm the Lead CRC and/or Project Manager to ensure that the EDC team has the correct contact populated as the Study Team Representative.

3.2.4. If the study received "Conditional Approval," the assigned Designer reviews the SRC meeting minutes to see if any substantive structural changes were requested to the protocol so that those can be incorporated in the eCRF build.

3.2.5. The Designer reviews the protocol. Based on this review:

3.2.5.1. If significant changes are needed, the protocol must be amended and re-submitted to SRC before the Designer proceeds with study build. The study will go into blocked status until it is ready to proceed.

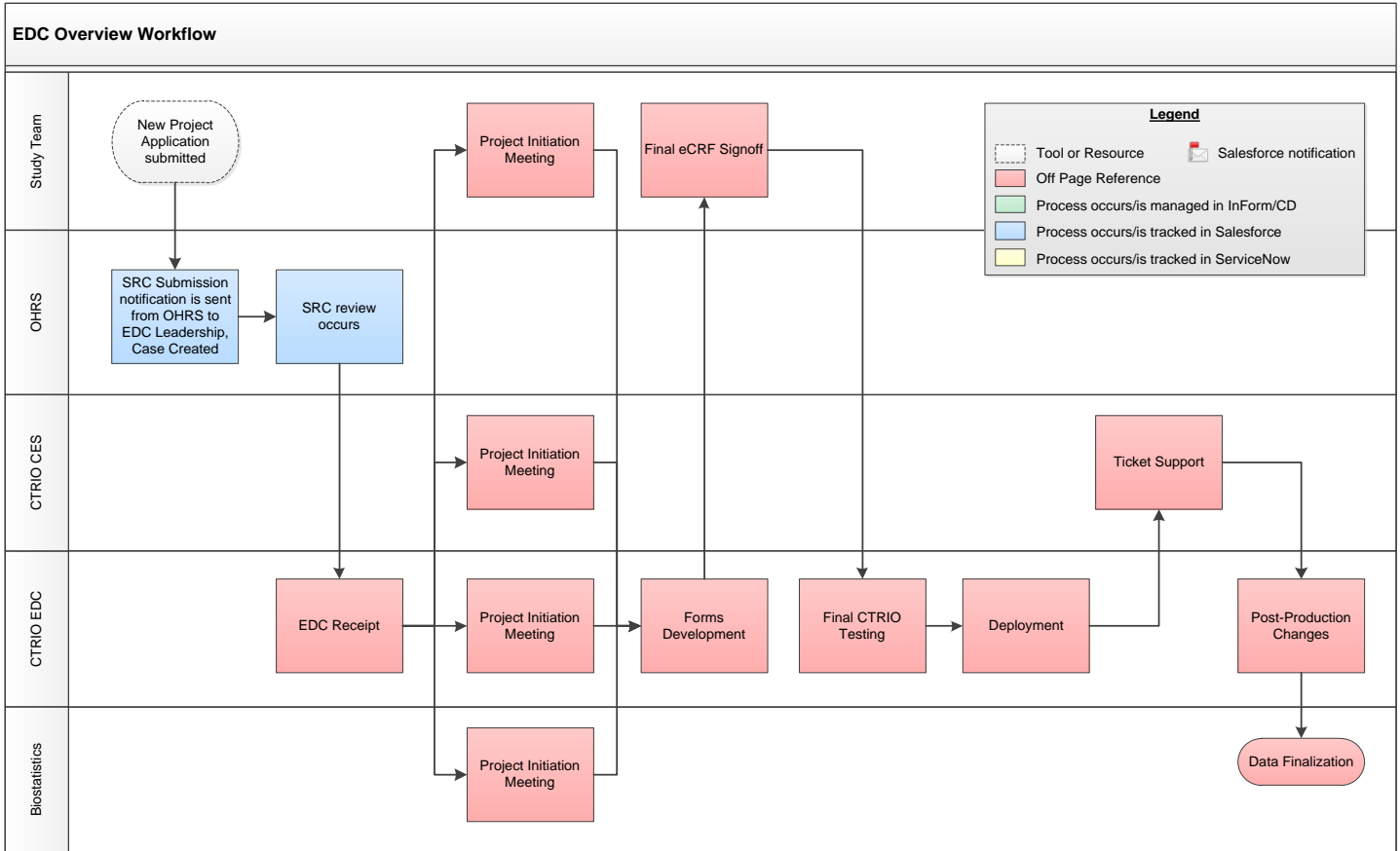
3.2.5.2. Insignificant changes will be documented on the Protocol Feedback Form for discussion with the PI, Biostatistician, and Study Team Representative at the Project Initiation Meeting.

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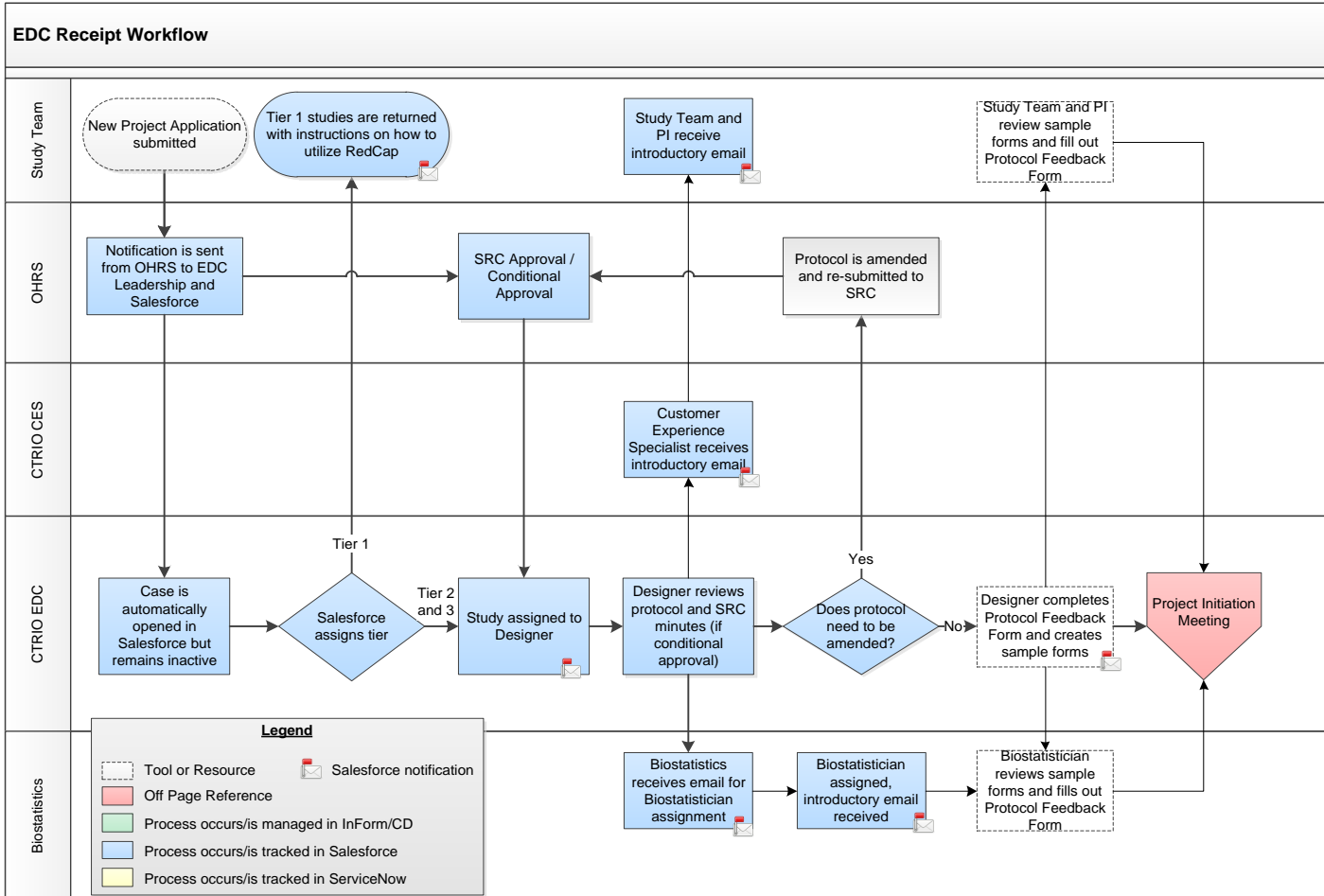
- 3.2.6. The Designer creates sample forms, as well as an accompanying Protocol Feedback Form, to capture any outstanding questions or comments for the PI, Biostatistician, and Study Team Representative.

Appendix 1: EDC Overview Workflow



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Appendix 2: EDC Receipt Workflow



Appendix 3: Tier 1 RedCap Study Instructions

Hello Researcher,

Thank you for your interest in capturing data for your clinical research. The RIO EDC team serves all therapeutic studies. Your study has been classified as a non-therapeutic study and therefore is applicable for entry in the RedCap database. Additional information about RedCap at DF/HCC can be found [here](#). If you have outstanding questions about your protocol and how to navigate the activation process, we have provided some helpful resources below.

Clinical Research Resources and Offices: <http://www.dfhcc.harvard.edu/research/clinical-research-support/>
Biostatistics: <http://www.dfhcc.harvard.edu/research/core-facilities/biostatistics/>

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The Protocol Feedback Form below should be prepared by the Designer for the Study Team and Biostatistician. The form should be used to answer questions such as:

- *Is the form required per protocol? Will the data captured on the form be used for analysis? It is not necessary to capture all data points collected on trial if they will not be used for research purposes. (For example, a Pregnancy form is not usually required even if pregnancy is tested on study **since the test is done for safety/eligibility and the data will not be analyzed.**)*
- *Is the visit necessary for the study? Do any forms need to be removed from the visit? Do any forms need to be added to the visit? Does the order of the forms in the visit need to be changed?*

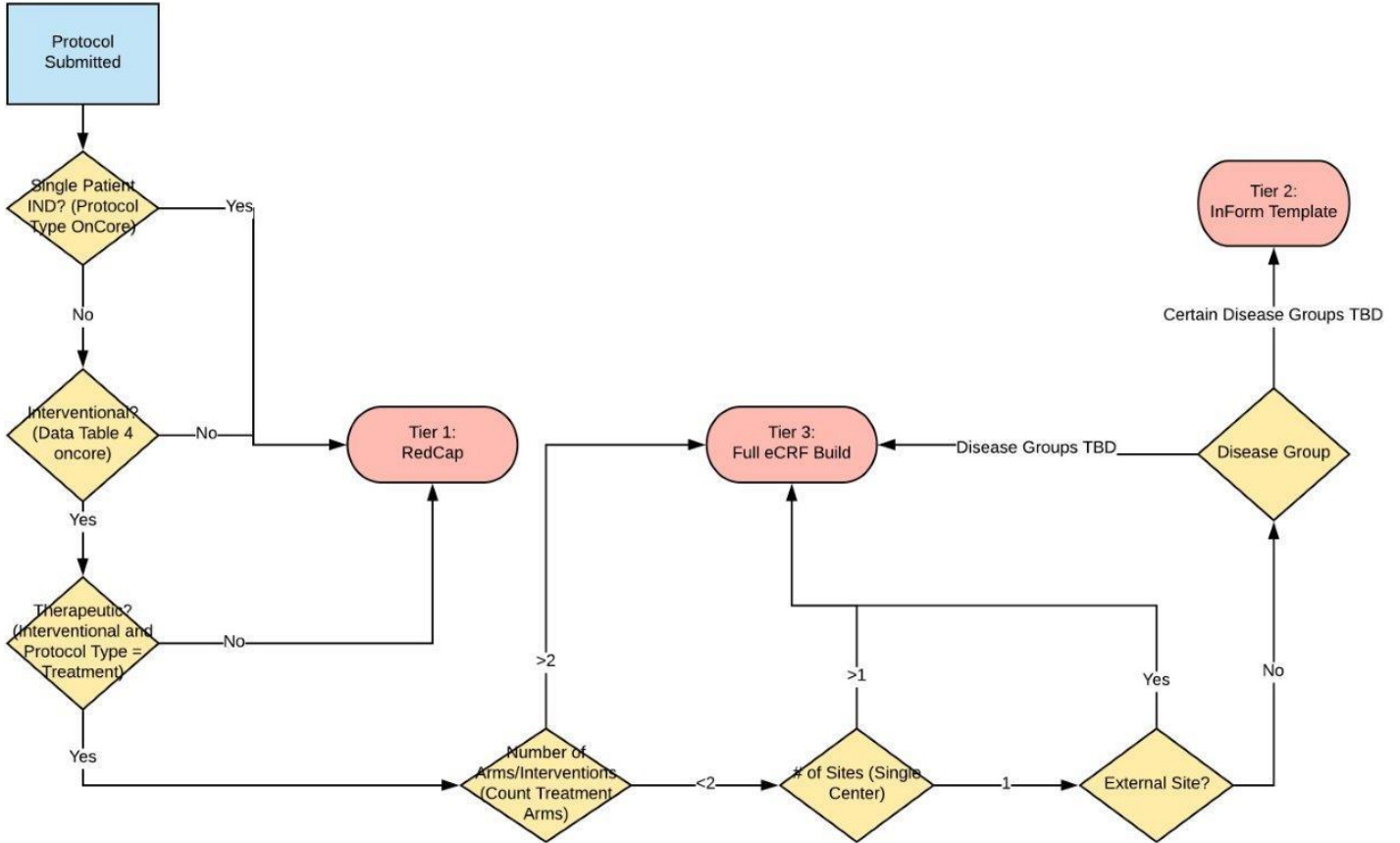
The first three rows below include examples that could be included by the Designer. The response column on the right is used by the Study Team Representative and Biostatistician and is discussed during the Project Initiation Meeting (PIM).

#	Form Name	Protocol Reference	Designer Question or Comment	Response
1	Lab Hematology	Section x.x p xx and SOE on p xx	<ul style="list-style-type: none"> • Please verify all fields, units, lengths of results (xx.x vs xxx.x, etc.). • Do we need both Absolute and differentials? 	
2	Medical History and Medical Conditions		<ul style="list-style-type: none"> • Are there any disease-specific medical conditions that should be listed here along with the standard options? 	
3	Date of Visit		<ul style="list-style-type: none"> • What is approximate maximum length of treatment for each course (in years)? 	
			<ul style="list-style-type: none"> • 	

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Appendix 5: Protocol Tiering Algorithm



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