JeffTrial IRB Submission
Regulatory Coordinator Training

Kimmel Cancer Center
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Ver. 1.0
Role of the Regulatory Coordinator

The Regulatory Coordinator will be required to enter basic information into JeffTrial to be submitted to the IRB.

This section will describe the process of entering IRB information into JeffTrial at the time of IRB submission.

Find the Protocol to be Submitted

To enter the information to be submitted into JeffTrial to be submitted to the IRB, navigate to the PC console. This can be found under “Protocols”, located in the horizontal menu bar. After opening the PC Console, type the Protocol No. in the “Select Protocol” search bar, located at the top of the vertical column on the left.
Adding Protocol Staff

To add study staff to the protocol, navigate to the “Staff” horizontal tab, which can be found within the “Main” vertical tab in the PC Console. Notice that the Principal Investigator and the Regulatory Coordinator fields have already been populated. Click [Update].

Protocols (menu bar) → PC Console → Main (vertical tab) → Staff (horizontal tab) → [Update]
To enter study staff:
- In the “Role” field, type the name of the staff’s role on the study, or click the drop down arrow to display a list of available study roles. Enter the following roles, if applicable:
  - Affiliate Coordinator
  - Affiliate Principal Investigator
  - Co-Investigator/Treating Physician
  - Data Manager
  - Data Monitor
  - Medical Monitor
  - Network Protocol Coordinator
  - Protocol Coordinator
  - Statistician
- In the “Staff Name” field, type the name of the study personnel.
- In the “Start Date” field, enter today’s date OR use the date trained on the delegation of authority log.

Click [Add].

To remove study staff:
- Click [Update]
Click [Edit] next to the name of the staff member to be removed

Complete the following fields:
- **Stop Date**: Enter the date the staff member is no longer working on the study
- **Stop Reason**: Enter the reason the staff member is no longer working on the study, if available
- Check the box under ‘Delete?’
- Click [Submit]
Adding IND/IDE Information

To add IND/IDE information, navigate to the “IND/IDE” horizontal tab, which can be found within the “Main” vertical tab in the PC Console. Click [Update]. Click [Add] on the following screen.

Protocols (menu bar) → PC Console → Main (vertical tab) → IND/IDE (horizontal tab) → [Update] → [Add]
Complete the following fields:

- **ID**: Enter the investigational drug identifier
- **Holder Type**: Select the holder type of the IND from the drop-down menu
- **Holder Name**: Enter the name of the holder of the IND
- **Grantor**: Choose the name of the FDA center to which the IND was submitted
- **Submit Date**: Enter the date the IND was submitted to the FDA
- **FDA Approval Date**: Enter the date the FDA approved the IND
- **Expiration Date**: Enter the expiration date of the IND
- **Expanded Access**: Indicate whether the IND is approved for expanded access (i.e. compassionate use). If this information is unavailable, leave the field blank.
- **Exempt (if applicable)**: Indicates whether the IND is Exempt
- **Click [Save]**

Click [Submit].

Follow the same steps if the study uses an IDE.
Entering Preliminary IRB Information

To add IRB information, navigate to the “IRB” horizontal tab, which can be found by going to the PC Console and then clicking on the “Reviews” vertical tab. Click [Add].

Prior to entering IRB information, ensure that the protocol has been approved by the CCRRC. This can be done by looking at the Protocol Status, which should say CCRRC Approval.

Protocols (menu bar) → PC Console → Reviews (vertical tab) → IRB (horizontal tab) → [Add]
The “Update IRB Review” page will appear. Click [Create]:

![Image of the Update IRB Review page]

- **Review Information**
  - Review Date
  - Submitted Date
  - Committee
  - Review Reason
  - Review Type

- **Summary**
  - 4000 character(s) remaining

- **Comments**
  - Global
  - Required
  - Deleted

- **Details**
  - Add

- **Reviewers**
  - Add

- **Communications**
  - Add

- **Notes**

No records found.
Complete the following fields:

- **Review Information**:
  - **Submit Date**: Enter the date the protocol is submitted to the IRB via the IRB Portal and/or paper copy (six copies will be required in the future)

- **Details**:
  - Click [Add]
  - **Type**: Indicates the document type, this mirrors the IRB document list and cannot be amended without prior approval from the IRB. (if one is missing please place a service request)
  - **Amendment No.**: Enter the amendment number, if applicable
  - **Version Date**: Enter the version date of the document
  - **Description**: Write whether the document is clean or tracked, and what type of document it is (i.e. clean pregnancy consent)—DO NOT write the word “current” this is to be used only for APPROVED STAMPED CONSENTS
  - **Global?**: Check if document will be used at all research institutions for a multi-site study.
  - **Comments**: This a free text field, however what is typed in here will not appear on the “Reviews” main page

- Click [Save]

Repeat the above steps for all documents that need to be added until all documents for that specific submission have been itemized. Do not attach documents until they are IRB approved.

****If you have multiple consents that are not in the drop down box, select the OHR-8 universal consent, and in the description box write the type of consent that is being submitted example: clean- pregnancy, tracked-molecular testing, etc. *****

### Uploading IRB Approval Letters

Once a study is IRB approved, the regulatory coordinator will upload the approval letter into the IRB Submission Package, which is entered by the IRB AFTER a submission transaction has been accepted.

Do not attach documents UNTIL THEY ARE IRB APPROVED.
Attach IRB APPROVED STAMPED documents using “File”. Do not use URL.

- Click “Submit” at the bottom of the page
- This message will appear at the top of the page:
  
  Message: Record has been updated

Please read the following section carefully:

JeffTrial has the capability of releasing and unreleasing consent forms into the general system for others (who have access to the protocol) to locate the most current document from any place in the hospital or university behind the firewall.

When a document is released, it is accessible throughout JeffTrial in areas such as the “Documents/Info” tab and in “Document Search”.

When a document is unreleased, it will not be able to be searched for or located unless that staff person has access to the IRB reviews and is able to edit them.

The regulatory coordinator will have to upload the most current stamped consent and check off the “Release” box for others to find the document in “Document Search”.

To release a document:

1. Find the IRB transaction with the word “Clean” and the corresponding document
2. Remove the word “Clean” from the description box
3. Add “Current” in the description box—keep the other identifiers (i.e. pregnancy, treatment, blood, etc. for consents)
4. Attach the document using the steps above
5. Check off the “Release” box

All documents that are released can be found in the “Documents/Info” tab except for consents.
To unrelease a document:

1. Find the IRB transaction with the document to be unreleased
2. Delete the word “Current”
3. Uncheck the “Release” box

Opening a Protocol to Accrual

*Please verify that you have approval to open a study prior to completing this step

To open a study to accrual, navigate to the “Status” vertical tab within the PC console. Ensure that the Protocol Status says “IRB Initial Approval”.

Protocols (menu bar) → PC Console → Status (vertical tab)

After the CRA, the Data Monitor, and the Protocol Coordinator sign off on the study, the [Open] button will appear.
Click [Open] and then enter the date the study opened to accrual.

The Protocol Status has now changed to "Open to Accrual".