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OHR and JeffTrial

JeffTrial is the new university-wide research protocol management system. One part of its functionality is to act as the data repository for all clinical research studies conducted in the Jefferson network. JeffTrial will replace the legacy IRB database and will be used by researchers as well as OHR, the CRM0 and JCCCR to create a robust data repository for clinical research studies in all phases of development.

In particular, OHR will use JeffTrial to manage study data pertaining to IRB review actions, including new studies, amendments, continuing reviews and final reports. Of note, the initial data entry for a study will now become the responsibility of the researcher. This means that whenever you enter JeffTrial to update a study record, it will already be in existence in the system.

As of September 9, 2013, the legacy IRB database will be deactivated and all existing data in it will have been migrated into JeffTrial. At that time, the legacy database will be locked and no new data can be entered into it. However, it will remain active indefinitely as a backup for retrospective data queries.

This document will review OHR’s part in the JeffTrial workflow, and all data points that are pertinent to OHR’s role in study record management in JeffTrial.

JeffTrial Workflow

Let’s begin with an overview of the workflow in JeffTrial for a new study submission, from the regulatory coordinator’s creation of a new study record in JeffTrial to OHR’s entry of data pertaining to the transaction following its review:

1. The Regulatory Coordinator* creates a new record in JeffTrial. (*The Regulatory Coordinator, or REG, is the designated role in JeffTrial for a user who has the ability to create and manage study records on the research side.) JeffTrial generates an internal protocol number for every new record created.

2. Following the creation of the JeffTrial record, the REG then goes to the IRB Portal to upload documents for the new study submission. At this time, the REG also will enter the Submit Date and Review Reason for the transaction into the JeffTrial record. The Submit Date is the date that the transaction is submitted to the Portal, and the Review Reason is the type of transaction submitted (Change Review, Continuing Review, Facilitated Review, Initial Review, Other).

3. When the study submission is made to the Portal, the OHR data coordinator is notified by automated email. The data coordinator checks the application for completeness, and uses the JeffTrial protocol number provided in the Portal
submission to access the JeffTrial record in order to review certain information (e.g., key personnel, sponsor, IND/IDE, etc.).

4. At this time, the data coordinator also assigns the IRB number and enters it into the JeffTrial record. The IRB number now links the study record in JeffTrial with all subsequent Portal submissions for that study.

5. The data coordinator, after completing preliminary review of the IRB application, notifies the REG by automated email with one of the following messages:
   
   a. Application is accepted for review.
   
   b. Application is accepted for review pending completion of appropriate CITI training for research personnel indicated.
   
   c. Application is not accepted for review. Please provide the following materials (required materials listed).
   
   d. Application is not accepted for review. You have not created this record in JeffTrial. Please do this now and notify OHR once completed.

6. When all required actions and/or documents have been completed and provided, the data coordinator accepts the application for review, makes some necessary notations in the transaction record in JeffTrial, and assigns the application to an IRB agenda. Once that agenda is finalized, the data coordinator notifies the IRB members by automated email that review materials are available in the Portal for the next IRB meeting.

7. In advance of the meeting, IRB members access the Portal to review their materials.

8. Following IRB review of the study submission, OHR personnel enter pertinent information into the appropriate JeffTrial record (e.g., review date, approval/disapproval, IRB committee, review comments, etc.) This data entry will be discussed in greater detail on the next page.

**Workflow for all other transactions**

For the most part, the workflow for all other IRB transactions (amendments, continuing reviews, final reports) is the same, except that there will be additional data points in JeffTrial that may require entry or modification based on the transaction. For instance, a continuing review approval will necessitate modification to the current expiration date, whereas an amendment that changes and removes personnel and adds an additional sponsor will necessitate changes to those particular fields in JeffTrial.

This data entry also will be discussed in greater detail.
Getting Started

To access JeffTrial, you must first log in. Please refer to the “Introduction to JeffTrial” training document for instructions.

All JeffTrial users are assigned at least one user role. Each role allows a unique set of privileges for the user. All OHR personnel have been assigned the role of ADMIN. The ADMIN role allows the user to view all study records in JeffTrial, and to enter data into and make modifications to certain fields. The ADMIN role will also allow certain reports to be created.

Your user role appears next to your name in the header at the top of the screen after you have logged in to JeffTrial. (If you have more than one user role, you can use the drop down menu next to your name to choose the pertinent role for the task at hand.)

Searching for a Study Record

Note in the above screenshot the search field at top of the menu bar on the left side of the screen where the user can enter the JeffTrial protocol number or IRB number in order to locate the pertinent study record.
When a match is found, click on the hyperlinked protocol number or IRB number to pull up the study record:
Note that there is a one-to-one match between the JeffTrial ID number and the IRB number.

**OHR Data Coordinator Role: In Detail**

Once the data coordinator has received the Portal submission and the JeffTrial protocol number, she can access the JeffTrial study record to review and enter certain information.

The data coordinator can review any relevant information in the JeffTrial record that will allow her to assess completeness of the Portal submission.

This may include:

[Starting with the Main category at the top of the vertical menu, and working from left to right through the tabs]

*Details tab:* Department, Investigator Initiated Protocol, Investigational Drug, etc.
Management tab – CCRRC review status
Staff tab – Protocol staff

Sponsor tab – Sponsor names and roles.
And moving down the vertical menu:

*Treatment* – Modalities, drugs or devices used in study. Study arms and brief descriptions.
**Institution** – Other institutions, including network sites, involved with the study. Those using TJU IRB are indicated in the “Uses Research Center IRB” column with a “Y” for Yes.
Once these items are reviewed by the data coordinator, she will enter the IRB number in the Main>Management tab, if the study is new.

And for all transactions (new, amendment, continuing review, final report), on the Reviews>IRB tab, she will enter:

1. **Review Date** – Assigned meeting date for the transaction
2. **IRB committee** – Choose appropriate TJU IRB, NCI CIRB, or if TJU is relying on another external IRB: Other IRB.
3. **Review Type** – Exempt, Expedited, Facilitated (when TJU relies on an external IRB), or Full.

Keep in mind that for any transaction, including a new study, the REG will have already entered the **Submit Date and Review Reason**. When the data coordinator goes to enter the above bulleted information on the Reviews>IRB tab, she will look for the most recent transaction that the REG has submitted, which will be listed first under the IRB Action History subheading on this page.

In order to add the required data points, the data coordinator will click Edit for this transaction:
This opens the transaction record for modification. Note that the header now says Update IRB Review:
The data coordinator also will go to the lower half of the transaction record in order to enter the following information into the Details tab:

1. First, she will click “Add” at the right side of the record to activate the fields.

![Image of a details tab with Add button highlighted]

2. Then, in the “Type” field at the left she will choose “IRB Submission Package” from the drop-down menu.

3. Finally, she will enter the date that the submission has been accepted for review in the “Date Received” field*, and then click “Save” followed by “Submit and Close” to save the completed transaction record and return to the Reviews>IRB screen.

![Image of the details tab with IRB Submission Package and a date entered]

(*The Received Date indicates the formal date of receipt by the IRB, as distinguished from the “Submit Date” in the top half of the transaction record, which is the date that the REG has made the submission, prior to it being reviewed for completeness by the data coordinator.)

This completes the data review and entry for the data coordinator at the beginning of the IRB submission process.

**Data Entry Following IRB Review: In Detail**

Following IRB review of any transaction (new study, amendment, continuing review, final report), the IRB Specialist will enter the following data points in the Reviews>IRB tab of the pertinent JeffTrial record:
• **Action** - Approved, Closed, Deferred, Disapproved, Exempted, Other. Some of these bear explanation:
  - **Closed** will be used to indicate approval of a Final Report.
  - **Deferred** – This is a rare event where the IRB cannot vote on the transaction for various reasons.
  - **Disapproved** – Not Approved in TJU parlance.
  - **Other** – A catchall category for a transaction that does not fit any of the other categories. Will rarely be used, if at all.

• **Action Date** – This is the date of the review. For transaction reviewed by the full committee, this is the meeting date. For expedited transactions, this is the date that the subcommittee member(s) reviewed the transaction.

• **Expiration Date** – This date is a year from the initial or continuing review approval date, unless specified differently, for instance, a 6-month approval period for a high risk study. Use existing expiration date for all amendment transactions, unless reviewed concurrently with a continuing review. Click on the calendar button to the right of the field to choose the date, or type in manually.

• **Summary** – This is a free text field. For amendments, enter a brief summary of the amendment. Also, use this field to describe any relevant or unusual details about the review that are not already captured in other fields.

In order to add the required data points, click Edit for the appropriate transaction. This opens the screen for this transaction. Note that the header says “Update IRB Review.”
(All of the information for these fields, excepting certain Summary information, can be derived from the IRB approval letter.)

Once these data points are entered, click Submit to save them. Click Close to return to the Reviews>IRB screen.

**For Initial Reviews**

One additional field to be completed for an initial review is the Annotations>IRB Risk field:

Select either minimal or greater than minimal based on the risk determination made by the IRB following an approval. This determination will be notated in the minutes.

Note that:
- **all** expedited studies are minimal risk.
- exempt studies and facilitated reviews do **not** require a risk designation.

Click [Submit] to save the data.

**Special Data Entry Points for Amendments**

Following approval of certain amendments, other information may need to be entered or modified in the JeffTrial record. Possible modifications include:
- Adding or removing sponsors
- Addition or deactivation of study personnel (see explanation below)
- Study title change
- IND/IDE status change
- Addition or removal of participating institutions (see explanation below)
- Age – For instance, addition of pediatric subject population
- IRB number – Change of number based on funding change

To make the necessary modifications, go to the appropriate vertical and horizontal menu tabs, make the appropriate changes by manual typing or choosing from a drop-down menu, and click Submit. You may first need to unlock the screen, in which case you first need to click Update. Then make the necessary changes and click Submit. One of these buttons will always appear in the lower right-hand corner of the screen.

**Changing Study Personnel**

Because the purpose of JeffTrial is to provide a complete history of the study, no information should be deleted from a study record, unless that information is incorrect. Therefore, protocol staff who have been removed from the study by amendment will not be deleted from the protocol staff record. Rather, their status will be changed.

Following are the steps for deactivating study personnel:

1. On Main>Staff tab, click Update in lower right corner of screen
2. An Edit function column will appear on the right side of the staff list table. Click Edit for the pertinent protocol staff member.
3. In the personnel record that appears, you will notice that a start date is entered. Enter in the Stop Date field the date of approval for the amendment removing this personnel.
4. In the Stop Reason field, enter “Removed by amendment.”
5. Click Submit. This will save the change and close the personnel record.

To change the role of a study personnel (for example, to change a co-investigator to a PI):

1. Once in the personnel record, click on the Add button on the right-hand side. This will create a new role field.
2. Choose the new Role for the study personnel from the drop-down menu.
3. Enter as the Start Date for the new role the date of approval for the amendment changing the personnel’s role.
4. As we have discussed, no records will be deleted. Therefore, the study personnel’s previous role will be retained. However, since this role is deactivated, a Stop Date
should be entered. The Stop Date for the old role is also the approval date for the amendment that changes the personnel's role.

See the series of screen shots below.
This completes the training document for OHR workflow.