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The REG Role: Completing Basic Protocol Information

Users in JeffTrial have one or more roles assigned to them that allow various levels of access and functionality. All study coordinators (excepting Kimmel and JCCCR personnel) will be assigned to the REG role. REG stands for Regulatory Coordinator. This role will allow you to enter detailed protocol information, update and maintain IRB checklists, initiate IRB submissions, and create reports on your studies.

This training document pertains to researchers conducting non-oncology research. If you intend to conduct oncology research, you will need to contact the CRMO to obtain additional training, as the workflow in JeffTrial differs for oncology studies.

In this section, you will learn about entering detailed protocol information into JeffTrial for the purpose of IRB submission.

Service Requests
You may encounter situations where you cannot find the appropriate selection in certain drop-down menus, such as a personnel name, a sponsor, or a new investigational drug. In order to request the addition of new items or for any technical problem, you will need to make a service request. Instructions for how to do this are at the end of this training document.

Entering New Protocols
The process of making a submission to the IRB will now start with entering data into JeffTrial. The process of creating a new protocol within JeffTrial begins in the PC Console. The PC Console can be found under “Protocols”, located in the menu bar. (See the training document, “Introduction to JeffTrial.”) Once the PC Console is opened, click on the New Protocol tab located at the bottom of the vertical menu bar on the left side of the page:
Protocol → PC Console, New Protocol (Vertical Tab):

The New Protocol page is where the REG enters basic information about the protocol. The following is a screenshot preview of the New Protocol page:

New Protocol
When creating a new protocol record in JeffTrial, the REG should enter the following required fields shown on this page:

- **Protocol No.** - (This number is auto-generated by JeffTrial)
- **Library** – choose Non-Oncology
- **Organizational Unit** – choose Non-Oncology
- **Department** – select your department from the drop-down menu
- **Title** – Enter full study title
- **Short Title** – Appears in JeffTrial reports and on the public website.
- **Objectives** – Enter primary and secondary study objectives. Keep as brief as possible and use lay language.
- **Phase** – Enter study phase, or NA if not applicable.
- **Scope** – Choose Local or National
- **Age** – choose Adults, Children, or Both
- **Investigator Initiated Protocol** – Yes or No
- **Protocol Type** – Epidemiological, Genetic, Interventional, Observational, or Treatment. Choose the type that most closely matches the study. (*See below for explanations.)
- **Multisite Trial** – Yes or No
- **Investigational Drug** – N/A, Yes or No
- **Protocol Target Accrual** – This is the total projected accrual for TJU and affiliates under TJU IRB approval. The Target Accrual Number displays in the top header of most pages of the study record.
- **RC Total Accrual Goal (Upper)** – This is the projected accrual goal for TJU alone, not including affiliates under TJU IRB approval.
- **Accrual Duration (Months)** – Enter the accrual period in months. Estimate if not specifically known.
- **Primary Completion Date** – Enter expected study completion date. Estimate if not specifically known. Always check off “Anticipated.”

All other fields should be left blank.

Click [Submit] once this page has been completed.
*Explanations for Protocol Type*

**Interventional:** Clinical Research Category in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

**Observational:** Clinical Research Category in which the studies focus on cancer patients and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

**Epidemiological and behavioral studies:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, such as surveillance, risk assessment, outcome, environmental, and behavioral studies.

**Genetic:** Laboratory-based studies using specimens to assess disease risk, clinical outcomes, response to therapies, etc.

**Main (Vertical Tab)**

After completing the New Protocol page and clicking [Submit], it then becomes the Details page of the Main vertical tab. The Main vertical tab contains several different horizontal tabs where the REG can further complete basic protocol information. The horizontal tabs in left to right order are: Details, Management, Staff, Sponsor, IND/IDE, and CT.GOV/CTRP (the CT.GOV function will not be used initially).

We will now discuss each tab and the requisite data to be entered.

**Details**

The Details horizontal tab is where JeffTrial users can update and review the protocol detail information. As you can see in the screenshot below, the Details page contains all of the initial information completed by the REG on the New Protocol page:
Management

In the Management Details section under this horizontal tab, the REG should enter the following required fields

- **GCRC Participation** – Select No
- **Internal Account No.** – If the study has an 080 account number issued by Office of Research Administration, enter it here. (If the ORA account number is not yet available, leave the field blank; you can go back later to update this page.) If the study has no external funding, enter your departmental account number.
- **IRB No.** – Once all study materials for the new study submission have been received and accepted for review by the IRB, OHR staff will enter the IRB Control # in this field. Until that time, make sure that you record the Protocol No. from the Details page in a separate file for reference, as this is the easiest way to search for the record in JeffTrial.
Adding Management Groups to the Protocol

Next, you will need to select the appropriate Management Group for the protocol. Management Group refers to the TJU department or division that is conducting the study (e.g., cardiology, pulmonary, etc.). To add the appropriate management groups, click the [Select] button within the Administrative Groups section of the page:

Protocol → PC Console → Main (Vertical Tab) → Management (Horizontal Tab) → [Select]:
When you click the [Select] button, a pop-up window* will appear and you can then select the appropriate management group from the list by checking the appropriate select box and clicking on the [Add] button:

*Please note, you must deactivate your browser pop-up blocker to view this window.

**Staff**

The next horizontal tab is the Staff tab. Staff members are added at the protocol level here. This grants them access to the protocol you have just created. To add staff members associated with the protocol, click on the Staff tab in the horizontal menu:
Select the appropriate Role and then type in the first or last name of the person in the find-as-you-type field. If the staff name does not appear in the list, make a service request to have that person added. The start date does not have to be filled in immediately. It is recommended to be completed when the study delegation log is completed. Click [Add] to add the staff member to the protocol.

The following Roles are considered key personnel for the purposes of IRB review and approval:

- Principal Investigator
- Co-Investigator/Treating Physician
- Protocol Coordinator
- Regulatory Coordinator
- Other Staff (This would pertain to research nurses, students, and any other study personnel who don’t fall under the above roles.)

The following Roles, while not considered key personnel, can also be added to a study:

- Data Manager
- Data Monitor
- Medical Monitor
- Statistician
- Infusion Nurse

The remaining Roles that appear in the drop-down menu will most likely not be used at Jefferson.

A staff member may be listed multiple times, with different roles on a protocol. To edit a staff member's Role, Institution, Start/Stop date or Stop Reason, click on the...
Edit hyperlink for the appropriate staff person. Institutions available for selection are those associated with the protocol. Changing a staff member’s Institution on this page applies only to this protocol; it does not affect the default institution listed in the Staff Record.

If the protocol will utilize the same or a similar group of staff assigned to an existing protocol, you can select protocol staff by team. Click on [Select Team] to display a protocol selection field:

```
Protocol → PC Console → Main (Vertical Tab) → Staff (Horizontal Tab) → [Select Team]
```

When an IRB number is entered and the [Show Team] button is selected, a window will appear listing that study's staff list. You may select the entire list to copy over to the new protocol by clicking [Select All], or individual staff can be selected by individually clicking the 'Select' checkboxes.

**Sponsor**

The next horizontal tab is the Sponsor tab. Here, you can add the sponsor of the study. Simply click on the [Add Sponsor] button to the right side of the page to get started:

```
Protocol → PC Console → Main (Vertical Tab) → Sponsor (Horizontal Tab)
```

After clicking on the [Add Sponsor] button, a find-as-you-type field will appear where you can look for the correct sponsor(s):
Once you have selected a sponsor, you can click on the **edit** hyperlink to select its role for the study:

If the sponsor you are looking for is not listed in the find-as-you-type field, make a service request to add a new sponsor to the database.

For studies with multiple sponsors, add all sponsors and choose the Sponsor Role for each that most closely matches the appropriate role.

**IND/IDE Horizontal Tab**

The next horizontal tab is the IND/IDE tab. Please complete the following fields on this page:

- Investigational Drug – Yes or No
• Investigational Device – Yes or No

*Protocol ➔ PC Console ➔ Main (Vertical Tab) ➔ IND/IDE (Horizontal Tab)*

If you answer Yes to either of these questions, the screen expands after you click [Submit] to show the following tables that gather more information about IND/IDE:

Whether your study includes an investigational drug or device, the same 4 fields are required:
- **ID** – Enter the IND# (for investigational drug) or IDE# (for investigational device) issued by FDA.
- **Holder Type** – The choices are Industry, Investigator, NCI, NIH, and Organization. Choose Industry if the sponsor holds the number. Choose Investigator if the local PI or a non-TJU individual holds it. Choose Organization if TJU or another non-corporate entity holds the number.
- **Holder Name** - Enter the name of the individual, sponsor, or other entity that holds the IND or IDE number.
- **Exempt** – Applies when IND or IDE is not required because investigational drug or device meets FDA exemption criteria.
- **Comments** – In this field, type in the full name of the investigational drug or device.

Once these fields are completed, you must click [Save] and then [Submit].

**Treatment (Vertical Tab)**

The next vertical tab is called Treatment. In this tab, the REG will add study arms and study drug/device information.

To get started with this tab, add a step code (use “1”), select Registration and click on the [Add] button:

*Protocol ➔ PC Console ➔ Treatment (Vertical Tab) ➔ Details (Horizontal Tab)*

![PC Console Screenshot]
**Adding Arms to the Study**

Once you have added a protocol step, an **Arms** hyperlink will appear as shown above. By clicking on the hyperlink, you will be able to add a protocol arm.

To add a protocol arm, enter an arm code (e.g., A, B, C), type in a brief description of the treatment group, and click on the [Add] button.
Once you have added a protocol arm, a Modalities/Drugs/Devices hyperlink will appear as shown above. By clicking on the hyperlink, you will be able to add a study modality, drug or device:

**Modalities/Drugs/Devices**

![Modalities/Drugs/Devices](image)

To enter a study modality, drug or device, simply search for the modality, drug or device in the appropriate find-as-you-type field and click on the appropriate [Add] button. If the modality, drug or device you are looking for is not in the list, make a service request to have it added.

Click [Close] to close this screen and return to the Details → Protocol Arms screen.

**Institution (Vertical Tab)**

The next vertical tab is called Institution. In this tab, the REG can add any participating institution to the protocol.

To get started, click on the add button:
To add an institution, please follow this guide:

1. Click on the search button located to the right of the institution field. This will bring up a pop-up window (*disable pop-up blocker*) with a list of institution hyperlinks to choose from.
2. If adding Thomas Jefferson University, then simply click on the hyperlink and then click on save. If adding any other institution, check off whether or not it uses the research center IRB (TJU IRB).
3. Click [Save] for each institution you choose.
Making an IRB Submission

Once you have created the initial study record in JeffTrial, you are ready to make your initial and all subsequent submissions (amendments, continuing reviews, final report) to the IRB. To make a submission of any kind, you will upload the study documents to the IRB Portal. Your submission is then reviewed for completeness by OHR. When accepted for review, you are notified by automated email.

At this point, you will return to the study record in JeffTrial to add additional information pertaining to the submission you have just made.

To do this, open the IRB horizontal tab within the Reviews tab of the PC Console and click [Add]:

*Protocol ➔ PC Console ➔ Reviews (Vertical Tab) ➔ IRB (Horizontal Tab) ➔ [Add]*
You will then see the Update IRB Review page:

In the Review Information section, the REG is responsible only for entering the Submit Date and the Review Reason for the submission that has just been made.

The **Submit Date** is the date the submission is made to the IRB via the Portal and/or paper copy.

The **Review Reason** is the type of IRB submission. The options are: Amendment Review, Continuing Review, Facilitated Review (initial review of a study for which T/JU will rely on an external IRB), Final Review, and Initial Review. The Other category will be used by OHR for other administrative transactions that do not require formal IRB approval. (You do not need to create a review record for these.)

**Click [Create] once these fields are completed.** Click [Close] to close the window and return to the previous screen.

The information you have added becomes part of the history for this study submission. Following the IRB review of the submission, OHR staff will fill in additional fields for this transaction to provide a complete history. Various reports can be generated based on the data in this field.

The expected time for the transaction record to be updated by OHR following IRB approval is 5 business days.
Opening the Study

After receiving initial IRB approval, you are ready to open the protocol to accrual in JeffTrial.

To open the study for accrual, you will need to go to the Status vertical tab of the PC Console:

*Protocol $\rightarrow$ PC Console $\rightarrow$ Status (Vertical Tab) $\rightarrow$ Status (Horizontal Tab)*

If the IRB has approved your study, then you will see two changes to this page. First, you can see that the Protocol Status in the header has changed to IRB INITIAL APPROVAL. Second, you can find an [Open] button near the bottom right side of the page. Click on this button to open accrual.
Enter the date of the action and click [Submit].

Note that the Protocol Status in the header has now changed to OPEN TO ACCRUAL, and the action now appears at the top of the Protocol Status table.

**Metric Collection via the IRB Checklist**

Users of JeffTrial are encouraged to use the checklist function to track protocol related tasks or activities for metric collection purposes. Various checklists are located in the Status tab of the PC Console:

*Protocol → PC Console → Status (Vertical Tab) → Checklist (Horizontal Tab)*
Primarily, the REG will be using the IRB checklist. The checklist items are customizable. If you would like to make any new additions, make a service request.

When you receive new IRB metrics, open up the IRB checklist by clicking on the checklists button to the right and subsequently, clicking on the IRB vertical tab on the left hand side of the page.
To update any of the checklist items, simply click on the appropriate hyperlink to bring up the Checklist Item Communications page, where you fill in the date and any comments if necessary:
Making a Service Request

All requests for technical assistance, addition of data points or checklists, and suggestions should be made via the KCC Service Request website at:

https://black.kcc.tju.edu/isrticket/

A hyperlink to this website is also provided on the IRB homepage in the navigation bar on the left side of the screen.

Alternatively, you can reach the service request website from the Jefferson homepage via the click path:

http://www.jefferson.edu/ > Jefferson Kimmel Cancer Center > KCC Intranet > Service Request

Or from the KCC homepage via the click path:

http://www.kimmelcancercenter.org/ > KCC Intranet > Service Request.

You will receive a ticket number for your request which will allow you to track its progress.