JeffTrial Initial Protocol Registration
MDG Coordinator Training

Kimmel Cancer Center
8/19/2013
Ver. 1.0
Role of the MDG Coordinator

The MDG Coordinator will be required to enter basic protocol information into JeffTrial. This is the first step in registering a protocol in JeffTrial.

After the MDG Coordinator receives a protocol from a PI, the protocol will be reviewed at an MDG. If approved, the MDG Coordinator will register the protocol in JeffTrial and send an approval notice to the PI.

This section will describe the process of initially entering a protocol into JeffTrial.

Entering New Protocols

To create a new protocol in JeffTrial, navigate to the PC Console. This can be found under "Protocols", located in the horizontal menu bar. After opening the PC Console, click on the "New Protocol" tab, located at the bottom of the vertical tab on the left.

Protocols (menu bar) → PC Console → New Protocol (vertical tab)
Clicking “New Protocol” will bring up the following screen:

When creating a new protocol, the MDG Coordinator must enter the following required fields, which are denoted with asterisks (*):

- **Protocol No.**: This number is auto-generated by JeffTrial
  - Write this number down and record it in the final MDG meeting minutes as it is the only protocol identifier at this point
- **Library**: Always choose ‘Oncology’.
- **Department**: The ‘Department’ selected should represent the institutional funding body for the study. Fiduciary reporting is available base on this field.
- **Title**: The full title of the protocol. Enter a short title if the full title is not known at this point.
- **Age**: Indicates the age of subjects on the protocol. Options are ‘Adult’, ‘Children’, or ‘Both’.
- **Investigator Initiated Protocol**: Indicates whether the PI initiated the protocol. Options are ‘Yes’ or ‘No’.
• **Protocol Type:** Indicates the type of protocol and will be used for reporting purposes
  - **Basic Science:** Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.
  - **Diagnostic:** Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.
  - **Health Services Research:** Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
  - **Other:** Not in other categories
  - **Prevention:** Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
  - **Screening:** Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
  - **Supportive Care:** Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant’s health or function. In general, supportive care interventions are not intended to cure a disease.
  - **Treatment:** Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in the previous versions of the guidelines.

• **Investigational Drug:** Options are ‘Yes’, ‘No’, or ‘N/A’

• **Accrual Information:** Check the “Not Applicable” box. This will be completed after the protocol is submitted to the CCRRC.

• **Primary Completion Date:** Enter date five (5) years from the current date then click the “Anticipated” radio button. This field is used for ClinicalTrials.gov.
  - The shortcut “yr+5” can be entered to automatically calculate the date

• Click [Submit] to save the information
Entering MDG Approval Information

To enter the MDG approval information, navigate to the “Reviews” vertical tab within the PC Console, click “Other External Committee Actions”, then click [Update].

Protocols (menu bar) → PC Console → Reviews (vertical tab) → Other External Committee Actions (horizontal tab)
The MDG Coordinator must enter the following information:

- **Committee**: MDG
- **Committee No.**: Enter the name of the MDG
  - For example, GU, LUNG, HEME, etc.
- **Review Date**: Date of the MDG meeting
- **Action**: Approved
- **Action Date**: Date of approval
- **Comment**: Enter the reason for approval
  - For example, “The committee needs an adjuvant clinical trial”
- Click [Add] to add the review to the protocol
- Click [Submit] to save the information

**Notifying CCRRC of MDG Approval**

After entering the protocol information into JeffTrial, the MDG Coordinator should send an email notifying the PI and the CCRRC (ccrrc@jefferson.edu) that the protocol was approved by the MDG. The email should contain the **Protocol No.** automatically generated by JeffTrial.