

October 17, 2018

IRB Announcement – Changes to JeffTrial and IRB Submission Process 2

Hello all—

This communication provides clarification and updates to the previous communication of June 28 entitled “Changes to JeffTrial and IRB submission process.”

The types of studies requiring a JeffTrial record have been updated to include the following:

1. **All** trials with a **written** consent form (as defined in previous announcement available on IRB website at:
https://www.jefferson.edu/content/dam/tju/human_research/irb/announcements/general_announcements/20180628%20Announcement%20-%20Changes%20to%20JeffTrial%20and%20IRB%20Submission%20Process.pdf)
2. **Oncology trials** with **verbal consent**
3. **Rothman** Institute trials have separate criteria. They are only required to be in JeffTrial, if there is EPIC-billable activity in the trial.
4. If the trial does not meet the above criteria, a JeffTrial record is not required.

JeffTrial update requirements for study personnel:

1. IRB reviews
 - a. Complete IRB review details are required. The OHR staff no longer enter review information.
 - b. All reviews (initial, continuing, amendments, final reports) must be entered with appropriate dates.
2. Maintenance of study staff lists
 - a. Study team is responsible for ALL staff additions and stop dates in JeffTrial.
 - b. For trials in JeffTrial, an OHR-12C is no longer required to be submitted to the IRB. Study teams must make timely updates to the staff lists in JeffTrial. The OHR will be receiving the staff list updates from JeffTrial.
 - c. If your study is not required to be in JeffTrial, you are required to submit an OHR-12C to the OHR to remove personnel.

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