

June 28, 2018

IRB Announcement – Changes to JeffTrial and IRB Submission Process

Hello all—

Changes by the JeffTrial vendor have necessitated the following changes in the JeffTrial and IRB submission process:

As of Monday, July 2, only new studies that include written consent forms (i.e., consent forms requiring participant signature) will need a JeffTrial record to be created prior to IRB submission. This includes consent forms OHR-8, OHR-8A, OHR-8B, OHR8C, OHR-8D, OHR-8K, OHR-8S, or any other written consent form that would require participant signature, and whether or not study is being submitted to Jefferson or external/commercial IRB. (*Digital consent forms, where a written consent form is transposed into a digital document, are considered written consent forms. Abbreviated digital consent statements, as would be used for digital surveys, which require a simple click to proceed to the survey, are not considered written consent forms for the purpose of this process change.) Please contact JCRI@jefferson.edu if you have questions.

For active studies that meet the consent form criteria described above, the following changes in JeffTrial will be implemented:

- Study personnel will be responsible for updating ALL IRB review information in JeffTrial.
- Study personnel will also be responsible for updating the JeffTrial Study Staff List.
 - The NEW requirement is to ADD Study Staff, which should be done after appropriate OHR-12B approval.
 - Study Staff end dates, as noted below, now require submission of an OHR-12C.
- Protocol Initiation in JeffTrial:
 - Oncology trials will continue to follow the requirements defined by the Sidney Kimmel Cancer Center (SKCC).
 - Non-oncology trials will be created by JCRI.
 - Requests should be submitted at the time a sponsor provides study documents or when the protocol is completed for an investigator initiated trial.
 - To request new protocol creation, please complete the attached JeffTrial Protocol Record Request form and submit to JCRI@jefferson.edu along with the study protocol.

- You can also find the form on the JCRI webpage at: <https://www.jefferson.edu/university/research/clinical-research-institute/jefftrial.html> .
- JCRI will send the JeffTrial # to the study team identified on the form within 2 business days.

Please contact JCRI@jefferson.edu with any questions about the above changes.

- **As of Monday, July 2**, new studies that do not include a written consent form and all exempt studies **will no longer require a JeffTrial record to be created.** To submit to the IRB you will simply upload the electronic application in the Portal.
- **For active studies that meet the above criteria (3rd bullet)**, you will no longer need to manage the study record in JeffTrial. The study records will remain in JeffTrial, but the status will be updated by JCRI to “Terminated” with an effective date of 7/02/2018. No additional updates should be made in JeffTrial for these trials.

The following elements have been incorporated into the IRB submission process to assist you in determining whether studies need a record to be created in JeffTrial prior to IRB submission:

1. The following prompt has been added to the OHR-1:

CREATION OF JEFFTRIAL RECORD

[] If your study involves use of a consent form, you must contact JCRI@jefferson.edu for review and creation of a JeffTrial record prior to submitting to the IRB. Consent form documents include: OHR-8, OHR-8A, OHR-8B, OHR-8C, OHD-8D, OHR-8K, OHR-8S, or any other consent form that would require participant signature.

2. A similar prompt will be included in the Portal. Submissions that include written consent forms will not receive IRB review until a JeffTrial # is entered in the Portal
3. As JeffTrial no longer will serve as the IRB’s database, we have reactivated the OHR-12C to track removal of study personnel. This form becomes effective on **Monday, July 2**.
4. All IRB-approved studies will be tracked in the new IRB database that will be accessible on the right-hand side of the IRB website.

To facilitate this transition, please do not create a record in JeffTrial after 4PM on Friday June 29. You may resume creating JeffTrial records on Monday July 2 at 9AM.

This e-blast is jointly issued by OHR and JCRI.

Thank you,

Kyle Conner, MA, CIP