IRB Submission Flow Diagram

8/5/16

**STEP 0 - Creating a new study record**

When you are ready to submit a new study to the IRB, you must first create a new study record in JeffTrial.

The workflow in JeffTrial is divided into two categories: oncology and non-oncology. For oncology research, contact the CRMO to determine whether they or you will create the JeffTrial study record. For non-oncology research, you will create the JeffTrial study record.

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**STEP 1 - Submitting a transaction**

After you have created a new study record in JeffTrial, you are ready to submit transactions for that study, including the initial review. (Creating a study record in JeffTrial is not the same as submitting a transaction.)

To submit a transaction, you must upload documents to the Portal. To do this, log in to the Portal, go to “Create an IRB Submission,” and choose the type of transaction you are making from the drop-down menu. Then, upload all necessary documents for that transaction and click on the appropriate button (Save or Send).

Also, at this time you should deliver the applicable number of paper submission copies to the IRB: 3 copies for full reviews, expedited and exempt reviews do not require paper copies.
STEP 2 - Creating a transaction record

Immediately after you make your Portal submission, you must create a transaction record in your JeffTrial study record. A transaction record is a record of the submission, review and vote for a given transaction.

In the transaction record, you complete only two fields: 1) Submit Date, which is the date of your Portal submission, and 2) Review Reason, which is the type of transaction you are submitting. OHR staff will complete the record once the transaction has been reviewed by the IRB.

This is the end of your JeffTrial process.

STEP 3 - Assigning a transaction

Once your Portal submission is reviewed by IRB staff and paper copies are received, you will receive an email stating that the submission has been ACCEPTED or REJECTED with additional requirements noted. If the submission has been REJECTED, you may go back in to modify it as necessary.

Once your submission is ACCEPTED, you will receive a subsequent email indicating the date of the meeting to which your submission has been assigned for review.
STEP 4 – Reviewing transaction & receiving IRB approval

The IRB will review your submitted transaction on the assigned date, and you will be notified of its status in 1-2 weeks following the meeting.

If your transaction was APPROVED, the approval letter and stamped materials will be emailed to you.

If your transaction was APPROVED with administrative revisions, you must address revisions and provide to OHR. The approval letter and stamped materials will be emailed to you following review and acceptance of your responses.

If your transaction was NOT APPROVED, you must resubmit it to the same committee and address revisions in your response. Your resubmission must be uploaded to the Portal (see Step 1).