

Frequently Asked Questions about IRB Approval Memos

Why doesn't the IRB Chair physically sign the IRB memos?

The OHSU Institutional Review Board (IRB) Chair does not manually sign memos generated by the eIRB because the electronic signature is equivalent to a handwritten signature. (see OHSU's eIRB System: 21 CFR Part 11 Compliance, Approval Signatures, and Approval Stamps – http://www.ohsu.edu/xd/about/services/integrity/policies/upload/21cfr11.pdf)

Why doesn't the approval date of the study documents match the protocol approval date on the memo?

The IRB can grant approval of a study for no more than one year after the date of the convened board meeting per federal regulations. Therefore, the expiration dates will always be 364 days after the date of the board meeting unless the IRB determines that the study should be reviewed sooner. When the IRB requires changes to the consent form or other documents, the effective approval date for those documents reflects the date the IRB/Chair determined that the board required changes were incorporated in the document(s).

My consent forms were approved on Friday but they weren't available for me to use until Tuesday. Is this a problem?

No, this brief delay shouldn't be a problem for the conduct of the study because study staff still have access to the most recent stamped consent form in the eIRB until the new forms are available. This short delay is no longer than sending items in campus mail. If the risk and/or procedures have changed significantly from the previous version of the consent <u>and</u> the investigator needs to implement those changes for all subsequent participants the study team should wait until the new consents are available to enroll new subjects. If the changes are not significant new and currently enrolled subjects can be reconsented at their next scheduled study visit, as appropriate.

How can I determine what date the IRB approved documents were made available in eIRB? The date of document availability in the eIRB system is the date associated with the activity of "post processing complete".

Why aren't all of the submitted documents listed on the approval memo?

For industry-sponsored studies, the approved study documents submitted within the Initial Review Questionnaire will be listed on the approval memo. For non-industry-sponsored studies, the documents will not be listed unless requested at the time of IRB submission.

The Sponsor wants to know why the names of the documents on the IRB approval memo don't match the titles on their documents.

Sometimes the document titles are changed by users in the eIRB system when they are uploaded, so the titles are shorter or so they can be categorized more easily. You can always verify that the correct versions of the documents were approved by looking in the eIRB.

Version Date: 02/22/2012