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Re: Electronic IRB Approval Memos

The following briefly explains the timing and content of documentation generated in the OHSU electronic Institutional Review Board (eIRB) system.

Electronic Signatures:

The IRB Chair's electronic signature in the eIRB system is equivalent to and replaces the need for a physical signature on a paper document. The eIRB fulfills the 21 CFR part 11 electronic signature requirements through system controls for identification, limited access, system privileges, audit trails and policies.

Approval Dates:

For full board studies, the protocol approval date listed on the IRB memo reflects the date of the IRB meeting. The effective approval date of the other study documents reflects the date the IRB Chair determined that the board required changes (if applicable) were incorporated into the study documents. The protocol expiration date will never be more than 1 year after the IRB meeting. For expedited studies the approval date is the date that the IRB Chair or designated reviewer determined that the study protocol and associated documents could be approved.

IRB approval of study documents:

The IRB includes a list of the approved study documents in the memo for industry sponsored studies. The names of the documents are sometimes changed when they are uploaded in the eIRB so they are shorter or can be more easily categorized.

Availability of approved study documents:

After final board approval, the IRB staff electronically stamp and upload the final approved documents into the study documents bin in the eIRB. It can take several days for the documents to be available to the study team while this process takes place. The date of document availability in the eIRB system is the date associated with the activity of "post processing complete".