IRBNews

Office for the Protection of Human Research Subjects *May 2016*

Policy Changes

- Big news!
  Beginning very soon, informed consent documents will be stamped electronically within IRBManager.

  Investigators will notice that the IRB approval stamp will now be in the form of a line across the bottom of the consent form. This line will indicate the approval and expiration date of the document, just as the current stamp does. As always, researchers must use only copies of the most recently approved consent document when obtaining consent. If you have any questions, be sure to contact the IRB.

- Record Keeping
  IRB Policy regarding the required period of record keeping for both research and IRB records has changed. Both the VA and HIPAA require a six year period of record retention*. For non-VA studies, the current five year record retention period is being changed to a requirement for six years retention for research records. This will help ensure consistency for records retention for all studies.

  Unless your ICD specifically indicates that records will be destroyed after five years, then you do not need to submit a modification to change the record retention time. You will need to retain your study records for **six years from the end of the calendar year in which the study is closed, or longer if other requirements apply (like FDA or sponsor).** We will remind you of this requirement in the study closure letter when you submit a study closure request.

Miscellaneous Policy Changes

Introduction to IRB Policies was revised to clarify that references throughout policies to "VA studies" refer to studies that meet the criteria at the James H. Quillen VAMC.

*See Policies for details for VA requirements

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