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AAHRPP Elements I.5.A, II.2.C, II.2.D, II.2.E

POLICY

IRB members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore this material must provide IRB members with enough information about a study to assess if it adequately meets the IRB's criteria for approval.

Research submission requirements for new studies, continuing reviews and amendments are found on the IRB website.

The ERICA system uses a smart form application which requires specific information based upon the responses of the applicant (e.g. if an investigator indicates that the study will be a placebo-controlled trial, an additional page in the application will be required). Applications which are incomplete cannot be submitted electronically.

A submitted proposal will be scheduled for IRB review once the IRB staff determines that the information and materials submitted present an adequate description of the proposed research. A research proposal (and associated documents) is submitted via the ERICA electronic system. The submission by a Principal Investigator in ERICA is considered an electronic signature, legally valid as if the research proposal was submitted in paper format with a printed signature

If the IRB or IRB staff determines that the submitted information is not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. Incomplete submissions will not be reviewed by the IRB.

Complete submissions as outlined in the research submission requirements are made available to IRB members for expedited and convened review via the ERICA system.