IRB Records and Retention

The IRB files shall be maintained in a manner that contains a complete history of all IRB actions related to a review and approval of a proposal, including continuing reviews, amendments, and adverse event reports.

The IRB shall maintain the following documents:

1. Copies of all research applications submitted, protocols, scientific evaluations, approved consent documents, Investigator Brochures, recruitment materials, any modifications to approved studies, data safety monitoring board reports, progress reports submitted by investigators, any emergency use reports, reports of injuries to subjects, adverse events / unanticipated problems, and protocol deviations.
2. The minutes of all IRB meetings.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A copy of each member's CV and a member roster documenting:
    - name;
    - earned degrees;
    - representative capacity;
    - indications of experience such as board
    - certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and
    - any employment or other relationship between each member and WHF (for example: full-time employee, part-time employee, member of board, stockholder, paid or unpaid consultant).
6. Any documentation of non-compliance or research misconduct
7. Statements of significant new findings developed during the course of the research that may relate to the subject's willingness to participate in the research.
8. Any budget or accounting records associated with the research.
9. Copy of the institution's current Federal-wide Assurance.
10. Copies of IRB registration submissions to OHRP that reflect changes in IRB membership.

The IRB shall retain all records regarding an application (regardless of whether it is approved) for at least three years after the disapproval or completion of the research. After three years the Principal Investigator will be contacted via written correspondence and asked for final disposition of the IRB file. If there is no reply after 30 days, the record will be destroyed. Note that records documenting that a request for waiver of HIPAA Authorization met all the requirements of 45 CFR 164.512(i.)(2)(ii) must be retained for 6 years from the completion of the research.

The IRB shall make all records accessible for inspection and copying by authorized representatives of the applicable federal agencies at reasonable times and in a reasonable manner.