

**Children's Hospital and Health System, Inc.  
Administrative Policy and Procedure  
Children's Research Institute**

**SUBJECT: Institutional Review Board (IRB) Record Keeping**

**POLICY**

**I. Purpose:**

- A. To ensure the IRB's records provide sufficient evidence of adequate protection of human subjects participating in research activities reviewed and approved by the Children's Hospital of Wisconsin (CHW) IRB.

**II. Policy:**

- A. It is the responsibility of the IRB Coordinator to prepare, and maintain adequate documentation of IRB activities. All IRB activities must be documented and managed in accordance with this policy.
- B. All IRB activity, whether at a convened meeting or conducted under expedited / exempt review procedures shall be documented.
- C. General Documentation
  - 1. Membership Roster identifying primary and alternate members by 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 with CHW.
  - 2. A copy of the most recent Federal-wide Assurance submitted to OHRP.
  - 3. A copy of the most recent IRB Registration(s) submitted to OHRP and any related documentation.
  - 4. Policies and Procedures
  - 5. A copy of the Investigator's Handbook
  - 6. *Curricula vitae* of all active physician investigators and evidence of completion of training programs required by the IRB.
- D. Research files: A separate electronic file for each approved research project will be maintained on IRBNet. Each file should contain, at a minimum:
  - 1. All correspondence to/from the investigator, including IRB approval letters;

2. IRB application;
  3. A copy of the full protocol;
  4. Any scientific review reports and related documents;
  5. Any marketing materials;
  6. Investigator Brochures and/or Working Instructions, if applicable;
  7. FDA approval letters, if applicable
  8. A copy of the electronically stamped, approved informed consent(s);
  9. Progress reports submitted by the investigator;
  10. Reports of injuries to subjects and other adverse events reports;
  11. Summary of inquiries into protocol deviations or unanticipated problems reported by the principal investigator including the process, recommendations and any actions taken by the IRB Chair or designee and/or full IRB;
  12. Reports to government agencies and/or sponsors required under “IRB Reporting” policy
  13. A copy of the HHS grant application, if applicable;
  14. Records of continuing review activities;
  15. Statements provided to subjects of significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation;
  16. For Planned Emergency Research, a copy of a scientific publication of the results of the completed investigation, including demographic characteristics of the research population; and
  17. Any correspondence from Children’s Research Institute (CRI) or any CHW FWA affiliated institution.
- E. Meeting Minutes: The minutes of IRB meetings shall be written in sufficient detail to demonstrate the following:
1. Member attendance and participation, either physically or via conference call;
  2. Members who abstained from voting due to a potential or actual conflict of interest and confirmation that the member left the room during deliberations;
  3. Attendance of alternate members.
  4. For Planned Emergency Research, the affirmative vote and identity of the independent physician consultant to the IRB or IRB member not participating in the research and documentation that all of the determinations and findings required in the IRB policy “Planned Emergency Research” have been met;

5. Review of emergency use reports in accordance with IRB policy, "Emergency Use of Test Articles";
  6. Actions taken by the IRB, such as the review and approval of the minutes from previous meetings and any other "old business";
  7. The vote on actions taken including the total number of votes, the number of members voting for, against and the identity of those abstaining, as well as the reason for abstaining;
  8. Separate deliberations, actions and votes for each protocol undergoing initial or continuing review by the convened IRB;
  9. The basis for requiring changes in or disapproving research;
  10. Protocol specific information justifying altering or waiving the requirements for informed consent or for obtaining a signed consent form;
  11. Consideration of additional safeguards when vulnerable populations are involved;
  12. Summary of discussion of serious adverse events;
  13. Documentation of approval period and the determination of which protocols require continuing review more often than annually, as appropriate to the degree of risk;
  14. Documentation of level of risk.
  15. A written summary of the discussion of controverted issues and their resolution;
  16. Research studies determined exempt from review including the regulatory authority justifying the exemption;
  17. Research studies approved through the expedited review process including the regulatory authority justifying the expedited review; and
  18. Disposition of any disclosed financial conflicts of interest.
- F. Investigator Correspondence: The IRB shall communicate all IRB and administrative decisions, conditions and requirements in writing as soon as possible following a decision or a convened meeting to the principal investigator via IRBNet.
- G. Record Retention Period: Records relating to specific research which has been approved shall be retained for at least three (3) years after closure of the research study (i.e., after all follow-up has been completed and the principal investigator has provided a final report to the IRB). The IRB shall permanently maintain IRB membership rosters, written IRB policies and procedures, and minutes of IRB meetings.

- H. Accessibility: All records discussed above relating to specific research which has been IRB approved will be accessible for inspection and copying by authorized representatives of the federal government at reasonable times and in a reasonable manner.
- I. Disclosed financial conflicts of interest and supporting documentation gathered in the IRB's deliberations will be maintained in a separate file until such time as the IRB study file is no longer required to be maintained. Every effort will be made to maintain the privacy of these files within the limits imposed by applicable laws and regulations.

## **PROCEDURE**

### A. General Documentation

1. Whenever there is a change in the IRB membership, the IRB Coordinator will update the Membership Roster and prepare updated information for forwarding to OHRP by the Human Protections Administrator (HPA).
2. As per OHRP, renewal of IRB registration is required at the end of the three year effective period. Therefore, if there has been no change in the IRB membership during this time period, the IRB Coordinator must prepare the IRB registration renewal for filing by the HPA before expiration of this time period.
3. The IRB Coordinator will permanently maintain past Membership Rosters.

### B. Research Files

1. The IRB Coordinator will retain research files for at least three (3) years after completion of the research.
2. Research is complete when all research and follow-up activities have ended for all research participants involved in the study, and the principal investigator has provided a final report to the IRB.

### C. Meeting Minutes

1. The IRB Coordinator will prepare and review the meeting minutes. Any questions or issues regarding the minutes should be discussed with the IRB Chair or other IRB members for resolution prior to inclusion in the next month's agenda.
2. If IRB members request any changes to the minutes, the IRB Coordinator will make the requested changes. If major changes were made (i.e. missing a discussion item), the revised minutes will be provided to the IRB members at the next scheduled meeting.
3. Once approved by the the IRB, the IRB Coordinator will permanently maintain a record of the meeting minutes.

References:

- A. 21 CFR 56
- B. 45 CFR 46
- C. OHRP Guidance on Written IRB Procedures

Documentation (Documents & Forms):

- A. IRB Membership Roster
- B. OHRP Federal Wide Assurance

(Signed copy on file)

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Peggy Troy, President CHHS