



Title:	Documentation and Records		
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1 Purpose

The University of North Carolina at Chapel Hill (UNC-Chapel Hill) prepares and maintains adequate documentation of the IRB's activities. All records are accessible for inspection and copying by authorized representatives of the FDA, OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

2 Procedure

2.1 IRB Operations Records

Records documenting the daily operations of the IRB include, but are not limited to:

1. Written operating procedures
2. IRB membership rosters
3. Training records documenting that investigators, IRB members, and IRB staff have fulfilled the UNC-Chapel Hill's human subject training requirements
4. IRB correspondence including reports to regulatory agencies
5. Convened IRB meeting minutes
6. Correspondence by the convened IRB
7. Federal Wide Assurances
8. IRB Registrations

2.2 IRB Study Records

The IRB maintains a separate IRB study record for each research application in UNC IRB Information System (IRBIS). IRBIS assigns each research study a unique identification number called an IRB Study number (e.g., 16-0010). Hard copies of study records generated prior to the initiation of IRBIS are archived at UNC's archival repository.

Accurate records are maintained of all communications to and from the IRB. Copies are uploaded to the study record in IRBIS. The UNC-Chapel Hill IRB study records includes, but is not limited to:

1. Research plan and all other documents submitted as part of a new study application

2. Research plan and all other documents submitted as part of a request for continuing review or closure of research application
3. Documents submitted and reviewed after the study has been approved, including modification requests, protocol/research plan exception requests, proposed advertisements, data and safety monitoring reports, and reports of new safety information
4. Copy of IRB-approved Consent/Assent/Parental Permission Documents
5. DHHS-approved sample consent form document and research plan, when they exist
6. Documentation of scientific or scholarly review (if applicable)
7. Documentation of type of IRB review. For exempt determinations and expedited review, this will include the category under which the review is allowed
8. For expedited review, documentation of any findings and determinations required by the regulations and study-specific findings supporting those determinations, including, but not limited to, waiver or alteration of consent, waiver of documentation of consent, research involving pregnant women, fetuses, and neonates, research involving prisoners, and research involving children. For research reviewed by the convened board these findings and determinations are recorded in the minutes.
9. For expedited review, documentation of the risk determination and period of approval. For research reviewed by the convened board these determinations are recorded in the minutes.
10. Documentation of review by another institution's IRB when appropriate
11. Documentation of reliance agreements
12. Documentation of complaints and any related findings and/or resolution.
13. Approval letters that include any requirements that the investigator must satisfy before beginning the study
14. Documentation of all IRB review actions
15. Notification of expiration of IRB approval to the investigator and requirements related to the expiration
16. Notification of Suspension or Termination of research
17. Notification of Unanticipated Problem Involving Risk to Subjects or Others.
18. Notification of Continuing Noncompliance and Serious Noncompliance
19. IRB correspondence to and from research investigators
20. All other IRB correspondence related to the research
21. For devices, documentation of determination by IRB of significant risk/non-significant risk
22. Documentation of audits, investigations, reports of external site visits

2.3 The IRB Minutes

Proceedings are written and available for review by the next regularly scheduled IRB meeting. Once accepted by the members, the minutes must not be altered by anyone including a higher organizational authority.

A copy of IRB-approved minutes for each IRB meeting will be distributed to the IO.

Minutes of IRB meetings must contain sufficient detail to show:

1. Attendance
 - a. Names of members or alternates present
 - b. Names of members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions
 - c. Names of alternates attending in lieu of specified (named) absent members. (Alternates may substitute for specific absent members or categories of members only as designated on the official IRB membership roster)
 - d. Names of consultants present
 - e. Names of investigators present
 - f. Names of guests present
 - g. Names of ex officio members

Note: The attendance list shall include those members present at the beginning of the meeting. The minutes will indicate, by name, those members who are not present for the discussion and vote. The vote on each action will reflect the numbers of members present for the vote on that item. Members who recuse themselves because of conflict of interest are listed by name and the reason documented.
2. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.
3. Business Items discussed
4. Continuing education
5. Actions taken, including separate deliberations, actions, and votes for each research study undergoing review by the convened IRB.
6. Vote counts on these actions (Total Number Voting; Number voting for; Number voting against; Number abstaining; Number of those recused)
7. Basis or justification for actions disapproving or requiring changes in research
8. Summary of controverted issues and their resolution

9. Approval period for initial and continuing reviews, including identification of research that warrants review more often than annually and the basis for that determination
10. Risk determination for initial and continuing reviews, and modifications when the modification alters the prior risk determination
11. Justification for deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
12. Study-specific findings supporting that the research meets each of the required criteria when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain informed consent altogether
13. Study-specific findings supporting that that the research meets each of the required criteria when the requirements for documentation of consent are waived
14. Study-specific findings supporting that the research meets each of the criteria for approval for vulnerable populations under any applicable Subparts.
15. Study-specific findings and required determinations justifying those determinations for research involving subjects with diminished capacity.
16. Significant risk/non-significant risk device determinations and the basis for those determinations.
17. Determinations of conflict of interest and acceptance or modification of conflict management plans.
18. Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research.
19. Review of interim reports, e.g., new safety information; modification requests; etc.
20. An indication that, when an IRB member or alternate has a conflicting interest (see Section 21.2) with the research under review, the IRB member or alternate was not present during the final deliberations or voting.
21. Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.

2.4 IRB Membership Roster

A membership list of IRB members will be maintained; it will identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list will contain the following information about members:

1. Name.
2. Earned degrees.
3. Employment or other relationship between each member and the organization (i.e., affiliated or non-affiliated). To be categorized as non-affiliated, neither the member nor an immediate family member of the member may be affiliated with the UNC-Chapel Hill.
4. Status as scientist or non-scientist. Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline are considered a scientist for the purposes of the roster, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline are considered a nonscientist.
5. Indications of experience, such as board certifications, licenses, and areas of practice sufficient to describe each member's chief anticipated contributions to IRB deliberations.
6. Representative capacities of each IRB member; including which IRB member(s) is a prisoner representative, and which IRB members are knowledgeable about or experienced in working with children, pregnant women, cognitively impaired individuals, and other vulnerable populations commonly involved in the UNC-Chapel Hill research.
7. Role on the IRB (Chair, Vice-Chair, etc.)
8. Voting status
9. For alternate members, the primary member or class of members for whom the member could substitute

The IRB office must keep the IRB membership list current. The OHRE Compliance Manager will report changes in IRB membership to OHRP/FDA within 90 days of the change.

2.5 Documentation of Exemptions

Documentation of verified exemptions consists of the reviewer's citation of a specific exemption category that the activity described in the investigator's request for satisfies the conditions of the cited exemption category as detailed in SOP 601.

2.6 Documentation of Expedited Reviews

IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category; that the activity described by the investigator satisfies all of the criteria for approval; the approval period and any determinations required by the regulations including study-specific findings justifying the following determinations:

1. Approving a procedure which waives or alters the informed consent process;
2. Approving a procedure which waives the requirement for documentation of consent;
3. Approving research involving pregnant women, human fetuses, or neonates;
4. Approving research involving prisoners;
5. Approving research involving children.

2.7 Access to IRB Records

The IRB has policies and procedures to protect the confidentiality of research information:

1. All IRB records are kept on a secure UNC server or in locked filing cabinets or locked storage rooms. Computers are password protected. Doors to the IRB Offices are closed and locked when the rooms are unattended.
2. Ordinarily, access to all IRB records is limited to the OHRE Director, IRB Chair, IRB members, IRB Managers, IRB Analysts, IRB staff, authorized organizational officials, and officials of federal and state regulatory agencies (e.g., OHRP and FDA). Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IO and the OHRE Director.
3. Records are accessible for inspection and copying by authorized representatives of federal regulatory agencies during regular business hours.
4. Records may not be removed from the IRB Office; however, the IRB staff will provide copies of records for authorized personnel if requested.
5. All other access to IRB study records is prohibited.

2.8 Record Retention and Disposition

The IRB records detailed above shall be retained and disposed of as per the Section 6.4, 6.10 and 6.11 of The University of North Carolina at Chapel Hill General Records Retention and Disposition Schedule.

For records not included in the UNC-CH General Records Retention and Disposition Schedule, refer to Federal retention requirements:

DHHS regulations require that, “records relating to research which is conducted shall be retained for at least 3 years after completion of the research.” [45 CFR 46.115(b)] If a protocol is cancelled without subject enrollment, IRB records are maintained for at least three years after cancellation.

FDA regulations require that sponsors and investigators of an Investigational New Drug (IND) retain “records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified.” [21 CFR 312.57(c)]

FDA regulations require that the investigator or sponsor of an Investigational Device Exemption (IDE) maintain the records “for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.” [21 CFR 812.140(d)]

2.9 Public Records request

Some of this documentation may be subject to public access under the North Carolina Public Records Act and/or the Federal Freedom of Information Act (FOIA). The Office of University Counsel should be consulted when a public records request is received.

3 References

21 CFR 46.115

21 CFR 56.115

21 CFR 312.57(c)

21 CFR 812.140(d)

UNC General Records Retention and Disposition Schedule published April 25, 2016 http://library.unc.edu/wp-content/uploads/2016/06/unc_ret_sched.pdf