10 Documentation and Records

University of Virginia 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.

10.1 IRB Records

IRB records 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 University of Virginia's human subject training requirements
4. IRB correspondence including reports to regulatory agencies
5. IRB Study Records (Study Files) including correspondence with investigator and research team
6. Documentation of exemptions including exemptions related to emergency uses.
7. Convened IRB meeting minutes
8. Documentation of review by another institution's IRB when appropriate.
9. Documentation of cooperative review agreements, e.g., Memoranda of Understanding (MOUs).
10. Federal Wide Assurances.
11. IRB Registrations.
12. Documentation of complaints and any related findings and/or resolution.

10.2 IRB Study Files

The IRB maintains a separate IRB study file for each research application (study) that it receives for review. Research studies are assigned a unique identification number by the IRB Staff and entered into the IRB tracking system.

Accurate records are maintained of all communications to and from the IRB. Copies are filed in the study file. University of Virginia IRB maintains a separate file for each research study that 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 protocol/research plan violations, complaints, non-compliance, unanticipated adverse device events and unanticipated problems.
4. Copy of IRB-approved Consent/Assent/Permission Forms
5. DHHS-approved sample consent form document and research plan, when they exist
6. IRB reviewer forms (when expedited review procedures are used)
7. Documentation of scientific or scholarly review (if available).
8. Documentation of type of IRB review. For exempt determinations and expedited review, this will include the category under which the review is allowed.
9. 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.
10. 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.
11. Documentation of all IRB review actions.
12. Notification of expiration of IRB approval to the investigator and requirements related to the expiration.
13. Notification of suspension or termination of research.
14. Copies of approval letters and forms that describe any requirements that the investigator must satisfy before beginning the study.
15. IRB correspondence to and from research investigators.
16. All other IRB correspondence related to the research.
17. For devices, documentation of determination by IRB of significant risk/non-significant risk.
18. Reports of unanticipated problems involving risk to subjects or others.
19. Documentation of audits, investigations, reports of external site visits.

10.3 The IRB Minutes

Proceedings are written and available for review by the next regularly scheduled IRB meeting. After the review period for minutes has lapsed, the minutes must not be altered by anyone including a higher organizational authority.

A copy of the 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

    Note: The attendance list shall include those members present at the beginning of the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. 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 and any education provided.
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. Significant risk/non-significant risk device determinations and the basis for those determinations.
16. Determinations of conflict of interest and acceptance or modification of conflict management plans.
17. 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.
18. Review of interim reports, e.g., unanticipated problems or safety reports; modification requests; report of violation/deviations; serious or continuing non-compliance; suspensions/terminations, etc.
19. A list of research approved under expedited review procedures since the time of the last such report.
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.

10.4 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.
1. Earned degrees.
2. 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 University of Virginia.
3. 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.

4. Indications of experience, such as board certifications, licenses, and areas of practice sufficient to describe each member's chief anticipated contributions to IRB deliberations.
5. 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 University of Virginia research.
6. Role on the IRB (Chair, Vice-Chair, etc.)
7. Voting status
8. 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 IRB Director or designee will report changes in IRB membership to OHRP/FDA within 90 days of the change.

10.5 Documentation of Exemptions

Documentation of verified exemptions consists of the reviewer's citation of a specific exemption category as detailed in Section 6.

10.6 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.

10.7 Access to IRB Records

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

1. All IRB records are kept secure in locked filing cabinets or locked storage rooms. 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 HRPP Director, IRB Chairs/Vice Chairs, IRB members, IRB Directors, IRB staff, PAM and Education 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 IRB 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 files is prohibited.

10.8 Record Retention

In order to comply with the requirements of OHRP, FDA, and HIPAA, IRB records are maintained at the facility for at least three (3) years after completion of the research. If the study is regulated by HIPAA and a Waiver of HIPAA authorization was granted the file will be kept for six (6) years after completion of the research.

IRB records for approved research cancelled without participant enrollment will be retained at the facility for at least 3 years after closure.

After that time those records will be shredded or otherwise destroyed.