UMKC
Office of Research Services

4. Documentation and Records

4.1 Policy

The University shall prepare and maintain adequate documentation of IRB activities. All related research records must be 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.

4.2 Definitions

The following definitions apply throughout this Guidance document:

Research records (or "Investigator Records"): consists of records (as well as case histories or any data) prepared, created, gathered, or maintained by a PI, investigator or research staff for research under the auspices of the institution.

Research data (Raw Data): research data is recorded information regardless of the form or media on which it may be recorded. It may include laboratory workbooks, notes, technical data, questionnaires, case histories, synthetic compounds, cell lines, mapping information, plant, animal, chemical compounds or any other materials and/or information required to replicate or verify the results of an experiment or other scholarly exercise.

4.3 IRB Records

IRB records include, but are not limited to:

- Written operating procedures. (See section 1.9).
- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany
- the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
- Records of continuing review activities, including the rationale for conducting continuing
- review of research that otherwise would not require continuing review as described in
- §__.109(f)(1).
- Copies of all correspondence between the IRB and investigators.
- IRB membership rosters, (see section 2.7).
- Statements of significant new findings provided to subjects, as required by §__.116(c)(5).
- The rationale for an expedited reviewer's determination under §__.110(b)(1)(i) that
- research appearing on the expedited review list described in §__.110(a) is more than minimal risk.
- The RCO maintains accurate records listing research investigators, IRB members, and IRB staff that have fulfilled the human subject training requirements. Electronic copies of documentation are maintained in the official IRB.
- IRB correspondence (other than protocol related).
- IRB study files (see section 4.4.1 for information included in study files)
- Documentation of exemptions (see section 4.7).

- Documentation of convened IRB meetings minutes (see section 4.6 for information included in the minutes).
- Documentation of review by another institution's IRB when appropriate.
- Documentation of cooperative review agreements, e.g. Memoranda of understanding (MOU).
- Federal wide assurances.
- Quality assurance reviews.

Regulations & Guidance: DHHS 45 CFR 46.109; 45 CFR 46. 110;45 CFR 46.115(a)-(b); 45 CFR 46.116; FDA 21 CFR 56.115(a)-(b); AAHRPP II.3.A.

4.4 Procedures

4.4.1 IRB Study Files

The RCO will maintain an electronic study file for each IRB study submission that is submitted for review.

All communications to and from the IRB are maintained. IRB study files include, but are not limited to:

- Protocol and all other documents submitted as part of an initial IRB application.
- Protocol and all other documents submitted as part of:
- Continuing Reviews
- Final Reports
- Adverse Event Reports and Unanticipated Problem reports
- Amendments
- Copy of the IRB-approved consents/assents.
- IRB reviewer checklists
- Documentation of type of IRB review.
- Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §__.109(f)(1).
- The rationale for an expedited reviewer's determination under §__.110(b)(1)(i) that research appearing on the expedited review list described in §__.110(a) is more than minimal risk.
- Documentation of any approvals required by the regulations and protocol-specific findings supporting those approvals, including: waiver or alteration of the consent process, research involving pregnant women, fetuses, and neonates, research involving prisoners, and research involving children.
- Documentation of all IRB review actions.
- Notification of expiration of IRB approval to the PI and instructions for submitting relevant continuing review materials.
- Notification of suspension of research.

- Copies of approval letters and forms that describe what PIs must have before beginning the study.
- Documentation of audits, investigations, reports of external site visits.

Regulations & Guidance: FDA 21 CFR 56.115(a).

4.5 IRB Membership Roster

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

- Name;
- Gender;
- Earned degrees;
- Affiliated or non-affiliated (neither the member nor an immediate family member of the member may be affiliated with the University) status;
- Status as scientist or non-scientist. For purposes of this roster, IRB members with research experience are designated as scientists. Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research;
- Indications of experience, such as board certifications or licenses sufficient to describe each member's principal anticipated contributions to IRB deliberations;
- Representative capacities of each IRB member; which IRB member is a prisoner representative (as required by Subpart C of 45 CFR part 46);
- Role on the IRB (e.g., IRB Chair, IRB Vice-Chair, etc.). and alternate member status.
- The RCO must keep the IRB membership list current. IRB records include a curriculum vitae ("CV"), and education of each IRB member. The RCO Director must promptly report changes in IRB membership to all applicable Federal agencies.

Regulations & Guidance: FDA 21 CFR 56.115(a).

4.6 The IRB Minutes

Actions by a duly convened IRB must be reduced to writing and available for IRB members. IRB minutes will be submitted to all members for comments and revisions. Once presented to the IRB at a subsequent IRB meeting and thereafter accepted by the Chair, the minutes must not be altered by anyone including a higher institutional authority.

A copy of IRB-accepted minutes for each IRB meeting will be available and typically include the following:

- Names of IRB members present;

- Names of IRB members or IRB alternate members who are participating through videoconference, teleconference or other electronic means, and documentation that those not physically present have received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions;
- Names of absent IRB members;
- Names of alternates attending in lieu of absent IRB members. Names of consultants present, if applicable;
- Name of investigators or research staff present;
- Names of guests present;
- The initial 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 those members present for the vote on that item;
- The presence of a quorum initially and throughout the IRB meeting, including the presence of one member whose primary concern is in a non-scientific area;
- Business items discussed;
- Continuing education conducted;
- Actions taken, including separate deliberations, and votes (total number voting; number voting for; number voting against; number abstaining; number of those excused, number of those recused) for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB;
- Basis or justification for all IRB actions and/or decisions including required changes in research or disapproval;
- Summary of controverted issues and their resolution;
- Approval period for initial and continuing review protocols, including identification of research that warrants review more often than annually and the basis for that determination;
- Risk level of initial and continuing review approved protocols;
- Review of interim reports (e.g. AEs or safety reports; amendments; report of violations or deviations, etc.);
- Review of DSMB summaries;
- Review of DSM plans;
- Protocol-specific documentation that the research meets the required criteria for approval;
- When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB justifications and findings regarding IRB determinations stated in the Subparts or the IRB agreement with the findings and justifications as presented by the PI on IRB forms;
- The rationale for SR device/NSR device determinations;
- COI determinations;

- Special protections warranted in specific research projects for groups of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally-disabled persons, or economically- or educationally-disadvantaged persons, regardless of source of support for the research;
- A list of research approved since the last meeting utilizing expedited review procedures;
- Documentation of approval by the IRB Chair (or designee) of research contingent on specific minor conditions in the minutes of the first IRB meeting that takes place after the date of the approval;
- An indication that, when an IRB member has a COI (see section 2.8) with the research under review, the IRB member was not present during the deliberations or voting on the proposal, and that quorum was maintained. The name of the IRB member will be captured in the minutes as well as the reason for their departure.

Regulations & Guidance: 45 CFR 46.116(c)-(d)); 45 CFR 46.117(c); 45 CFR 46.204; 45 CFR 46.205; 45 CFR 46.206; 45 CFR 46.207; 45 CFR 46.305; 45 CFR 46.306; 45 CFR 46.404; 45 CFR 46.405; 45 CFR 46.406; 45 CFR 46.407; 45 CFR 46.408; 42 USC 498 a(b)(1); 42 USC 498 a(b)(2); 42 USC 498 a(c); FDA 21 CFR 50.51; 21 CFR 50.52; 21 CFR 50.53; 21 CFR 50.54; 21 CFR 50.55; 21 CFR 50.56; 21 CFR 56.109(c); 21 CFR 56.115(a); AAHRPP II.3.A.; and II.3.C.

4.7 Documentation of Exempt Determinations

Documentation of exempt determinations consists of the RCO staff member's citation of a specific exemption category and written concurrence of the activity.

4.8 Documentation of Expedited Reviews

IRB records for initial review by the expedited procedure must include:

- The specific permissible category;
- A description of action taken by the reviewer;
- The approval date; and
- Any determinations required by the regulations including protocol-specific findings supporting those determinations.

4.9 Access to IRB Records

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

- All paper IRB records are kept secure in locked filing cabinets or locked storage rooms. The Research Compliance Office is closed and locked when unattended.
- Access to IRB records, whether paper or electronic, is limited to the IO, IRB Chair, IRB members, Research Compliance Office staff, authorized institutional officials, and officials of Federal and state regulatory agencies (OHRP, FDA). Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are

provided access and may recommend additional procedures for maintaining security of IRB records.

- Records are accessible for inspection and copying by authorized representatives of Federal regulatory agencies during regular business hours.
- The Research Compliance Office staff will provide copies of records for authorized personnel if requested.
- All other access to IRB study files, paper or electronic, is prohibited.

4.10 IRB Record Retention

IRB records (as described in section 4.3) pertaining to research, must be stored securely. Paper records are stored in the Research Compliance Office.

IRB records must be retained for at least seven (7) years after completion of the research.

4.11 Investigator Records

PIs are required to maintain accurate, current and complete records of their human subject research activities. In general, PIs should establish and maintain a file for each study that has been reviewed by the IRB. These files should closely resemble the IRB's file structure on the study.

Within each study, PIs also should maintain a file for each subject who signs a consent document agreeing to participate in the study. These subject-specific files should include the original signed consent document and copies of case report forms, and any other correspondence between the PI and the subject, including:

- All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.

Research records must be retained for seven (7) years after the final report on the research project has been submitted, then destroyed. If the research is being done under a contract that requires a longer retention time, the contract retention time will apply. In instances where the principal investigator believes the records have continuing research value and/or when it is in the best interest of the University that data be retained for long or indefinite periods, records management and the investigator will develop a retention period that meets the needs of the University and the investigator. In instances where the research data must be retained for long periods of time (over 15 years) to aid subsequent research projects, then other storage media that has stable longevity capabilities can be used to retain the research information.

See Research Records all Departments Authorization NO. 00-018

4.12 Records for FDA-Regulated Studies

4.12.1 Investigational Drugs and Devices

Investigators are expected to maintain accurate, complete and current records with respect to studies involving investigational drugs consistent with FDA requirements found at 21 CFR 312.62(a)(b)(c). This includes the following:

- Disposition of drug: a PI is required to maintain adequate records of the disposition of the drug. This includes the following:
    - The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
    - The names of all persons who received, used, or disposed of each device.
    - Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

- Case histories: a PI is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each Individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms, supporting data, and medical records (e.g., physician progress notes, the Individual's hospital chart(s), and the nurses' notes). Such records shall include:
    - Documents, evidencing consent and, for any use of a device by the investigator without consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain consent. The case history for each Individual shall document that consent was obtained prior to participation in the study.
    - All relevant observations, including records concerning adverse device effects ADEs (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
    - A record of the exposure of each subject to the investigational device, including, the date and time of each use, and any other therapy.

Approved by: Lawrence Dreyfus, PhD
Name of University Institutional Official

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Signature of University Institutional Official Date