3. effectiveness - analyze consent forms reading level and make suggestions for improve readability.

X. IRB RECORD REQUIREMENTS

IRB Membership Roster

A current roster of IRB members and their areas of expertise may be found on the HSPPO website. The roster is updated as committee membership changes.

Committee Members Coming and Going

If a committee member arrives late note that they have arrived and if the number of voting members has been affected.

Committee members will leave the room for three reasons, please record as follows:

1. Committee member left the room due to a conflict of interest.
2. Committee member left the room for a personal break and will be returning
3. Committee member left the meeting for good and will not be returning.

Meeting Minutes

Members and alternates of IRBs receive minutes of full board meetings and monthly reports of IRB business for their respective board. Minutes include written notification of all new projects approved (full board and expedited), projects determined to be exempt, continuing reviews (full board and expedited), modifications (full board and expedited), and reportable adverse experience.

Minutes are generated that record the following information:

1. attendance at each meeting including voting and non-voting members or attendees;
2. The IRB was advised at the meeting on (current full board meeting-month/day/year) of all expedited research proposals approved by this procedure since the last full board meeting on (month/day/year).
3. actions taken by the board including initial and continuing review of research;
4. the vote on actions taken including the number for, against, with reason for the against vote, to defer, and abstaining (The IRB chair, as a matter of policy votes only to ensure a quorum or to break a tie vote. If not voting, the chair will be listed as abstaining in the recording of each vote.),
5. notation when a member declares a conflict to interest and leaves the room and when the member returns (the minutes will state the reason the member left the room),
6. notation when a member leaves the room for reasons other than a conflict of interest and when the member returns,
7. the basis for requiring changes in or disapproving research;
8. the length of time of an approval;
9. a written summary of the discussion of controverted issues and their resolution;
10. specific comments relevant to inclusion/exclusion of certain populations;
11. amendments or modifications that require full board review;
12. documentation and review reports of adverse reactions reports;
13. Report from the Institutional Biosafety Committee (IBC) on research involving human subjects;
14. Report from the Radiation Safety Committee (RSC) on research involving human subjects; and

15. in addition to the review of pending applications, meeting minutes may include information regarding expedited approvals, modifications, terminations, emergency/single patient use, adverse experiences, and any other business appropriate for board meetings.

DHHS regulations at 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. OHRP recommends that when approving such a waiver for research reviewed by the convened IRB, these findings be documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

Similarly, where HHS regulations require specific findings on the part of the IRB, such as:

1. approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR46.117(c)];
2. approving research involving pregnant women, human fetuses, or neonates (see 45CFR 46.204-207);
3. approving research involving prisoners (see 45 CFR 46.305-306); or
4. approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings.

OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record.

Study File and Minutes Maintenance

The HSPPO maintains file copies of all research proposals reviewed, scientific evaluations, if any, approved sample informed consent documents, progress reports, UPIRTSOs, local serious adverse event reports, emergency use reports, budget and accounting records (if required for IRB review, these records are available from other offices within the OEVPR), statements of significant new findings provided to subjects (if any), meeting minutes showing attendance, action taken, vote with number of members voting for, against, to defer, or abstaining, the basis for requiring changes in or disapproving research, a written summary of the discussion of controversial issues and their resolution, and other correspondence pertaining to IRB operations.

IRB meeting minutes, once approved, are forwarded to the Executive Vice President for Research. These minutes include findings and actions, decisions to approve, disapprove, or require modifications to secure IRB approval of research activities and any other business the IRB considers necessary to report.

Reports of suspension or termination of research not conducted in accordance with the regulations, statutes and principles or IRB's requirements, or occurrences that have been associated with an event that is unexpected, related or possibly related to participation in the research, and suggests that the research places subjects or others at a greater risk of harm than was previously known or suspected will be included. Observations of, or having a third party observe, the consent process, observations of, having a third party observe, the conduct of the research may also be included.

Privacy Board actions and concerns related to University of Louisville investigators' adherence to the HIPAA Privacy Rule as it relates to research will be reported when these issues appear before the Privacy Board.

Record Retention by the IRB

Electronic records on human subjects research are maintained by the HSPPO for a minimum of three years after notice of study closure and records relating to research which is conducted shall be retained for at least three years after the completion of the research (45 CFR 46.115, 21 CFR 56.115).

The HSPPO maintains a permanent record of all closed project files on four external hard-drives held in the HSPPO and the AVPR office that supervises the HSPPO (studies closed since August, 2003) or in BRAAN2. Access to the hard-drive records is limited to HSPPO staff, IRB members, and individuals who have official reasons for reviewing the files. The four hard-drives are stored in a locked area in the HSPPO and the AVPR office. The AVPR office is in a different building separate from the HSPP office. If requested, the records shall be accessible for inspection and copying by authorized representatives of the OHRP and FDA at reasonable times and in a reasonable manner.

Data Retention when Subjects Withdraw/are Withdrawn from Human Subjects Research

For a variety of reasons, a subject enrolled in a research study may decide to withdraw from the research, or an investigator may decide to terminate a subject's participation in research regardless of whether the subject wishes to continue participating. In these circumstances, questions sometimes arise about: (1) whether the investigator may use, study, or analyze already collected data about the subject who withdraws from the research or whose participation is terminated by the investigator; and (2) whether the investigator can continue to obtain data about the subject and if so, under what circumstances. The guidance below addresses these and related questions. OHRP recommends that investigators plan for the possibility that subjects will withdraw from research and include a discussion of what withdrawal will mean and how it will be handled in their research protocols and informed consent documents.

When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.

If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents would be required.

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the