1.0 POLICY

1.1 Policy Statement

1.1.1 It is UA policy that the IRB maintain written documentation of all discussions and decisions concerning research studies conducted within its jurisdiction. In addition, adequate documentation will be maintained relative to discussions and decisions of all expedited procedures, as well as all communication between the IRB and study investigators or research staff.

1.1.2 The Office for Research Compliance (ORC) shall maintain complete documentation for all research applications. Study files must maintain all the following documentation: copies of all research applications (including scientific evaluations), approved sample informed consent documents, data safety monitoring board/committee reports, progress reports submitted by the Investigators, and reports of adverse events and unanticipated problems; all correspondence between the IRB and the investigators, records of continuing review activities, and statements of significant new findings provided to participants, reports of injuries to participants, and reports of protocol violations. (POLICY: IRB Record Keeping and Management.)

1.1.3 Before the meeting is called to order, the IRB Chair will determine that a quorum is present. Consistent with federal regulations, a quorum is defined as a simple majority of members, one of whom is a nonscientist and one who represents an unaffiliated member. If proposals require a prisoner representative or a licensed physician with liability coverage, their presence will be verified. If proposals involve participants likely to be vulnerable to coercion or undue influence, the IRB Chair will verify that at least one IRB member knowledgeable about or experienced in working with such participants will be present at the meeting. If a quorum is not present, the meeting will be cancelled and rescheduled. If required members are absent, the proposal must be tabled and rescheduled for another meeting. (Meetings by telephone are also an option.)

1.1.4 The Director of Research Compliance (DRC) shall maintain minutes of all IRB meetings. Once approved by IRB members at a subsequent IRB meeting, minutes may not be altered.

1.1.5 Minutes will be recorded using a template and will include the following:

1.1.5.1 Summary of discussion regarding controverted issues (e.g., level of risk, identification and management of investigator COI) and their resolution;
1.1.5.2 Modifications required by the Board;

1.1.5.3 When a member replaces a primary member;

1.1.5.4 For continuing review, the approval period.

1.1.5.5 The names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.

1.1.5.6 Documentation of required determinations (e.g., waiver of informed consent, waiver of documentation of informed consent, or justification of research with children, prisoners, pregnant women, fetuses, or neonates) along with protocol-specific findings that justify the determination;

1.1.5.7 Discussion of applicable regulatory criteria;

1.1.5.8 Member attendance at each convened meeting;

1.1.5.9 Information about members entering or leaving the room;

1.1.5.10 Determination of the study’s category of risk per CFR 45.

1.1.6 IRB minutes will additionally document:

1.1.6.1 Separate deliberations, actions, and votes for each protocol undergoing a review by the convened board, as well as for each protocol undergoing review of modification by the convened board;

1.1.6.2 Votes on actions including number of members voting For, Against, or Abstaining;

1.1.6.3 The names of IRB members who abstained from voting or who were absent during vote casting;

1.1.6.4 The names of IRB members who absent themselves from the meeting due to a conflict of interest;

1.1.6.5 The basis for requiring change in research;

1.1.6.6 The basis for disapproving research;

1.1.6.7 The rationale for significant or non-significant risk device determinations;

1.1.6.8 For DHHS studies, a justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent;

1.1.6.9 For FDA studies, documentation of the rationale for significant risk/non-significant risk determinations;
1.1.6.10 Determination of the degree of risk, as well as a determination of the approval period appropriate to the degree of risk and protocol specific findings;

1.1.6.11 Approval of research contingent on specific minor conditions by an IRB Chair or the IRB’s designee must be documented in the minutes of the first IRB meeting after the date of the approval.

1.1.6.12 The topic of any IRB education or other communication of the ORC with board members relevant to quality improvement or activities related to maintenance of AAHRPP accreditation.

1.1.7 IRB minutes will not:

1.1.7.1 Contain information extraneous to review of human subjects;

1.1.7.2 Reference only the regulatory criteria when specific documentation of certain determinations is required (i.e., wavier or research involving children).

1.1.8 Routing of IRB Minutes

1.1.9 IRB- approved minutes are routed to the Vice President for Research for informational purposes.

1.1.10 A list of IRB members, and their qualifications and affiliations will be maintained. IRB records will also include a resume or curriculum vitae for each IRB member.

1.1.11 The IRB will maintain written policies and procedures as described in the POLICY: IRB Record Keeping and Management.

1.1.12 For quality control and improvement, at least once a year the Director of Research Compliance (DRC) shall convene a subcommittee of the two IRB Chairs, 2 IRB members, and the two Research Compliance Specialists to review the adequacy of the IRB meeting minutes format and consider if and how it should be revised.

1.2 Objective

1.2.1 Implementation of this policy will provide a complete history of all IRB actions relative to its review of applications, including continuing reviews, amendments and adverse event reports, thus allowing a reconstruction of the history of all IRB actions related to the review and approval of a study and promoting UA compliance with UA and IRB policies, regulations, and accreditation standards.

1.3 Responsibility.

1.3.1 The Director of Research Compliance (DRC) has oversight responsibility for the recording, documentation and retention of all IRB board minutes and related study correspondence and the authority to delegate certain activities to DRC staff.
2.0 PROCEDURE

2.1 Minutes Recording and Preparation.

2.1.1 The Research Compliance Specialist (RCS) attending the convened IRB meeting records the meeting and drafts detailed notes to document IRB discussions and determinations of the IRB. The minutes will be prepared using a template to help assure inclusion of all necessary content and will include:

2.1.1.1 The location of the meeting, time of convening and of adjourning;

2.1.1.2 Documentation of attendance to include:

   2.1.1.2.1 Initial and continued presence of a majority of members (i.e., quorum), including at least one nonscientist and one community (unaffiliated) member. Members with conflicts of interest shall not be counted toward quorum for a particular application.

   2.1.1.2.2 The presence of a prisoner representative who receives all application materials and reviews all applications involving prisoners;

   2.1.1.2.3 Whether an alternate is voting and for whom he/she is voting;

   2.1.1.2.4 Entry and exits of members from the room, including whether a conflict of interest was the reason for an absence;

   2.1.1.2.5 Presence of a licensed physician for review of all FDA protocols.

2.1.2 Minutes on the review of each protocol include the following:

   2.1.2.1 The names of any IRB members excused from the meeting due to a conflict of interest during the discussion and vote on the study;

   2.1.2.2 Report of the recommendations of any consultant used, a statement of whether or not the consultant had any identifiable conflict of interest, and description of the nature of that conflict;

   2.1.2.3 Separate deliberations for each action taken by the IRB;

   2.1.2.4 A summary of the discussion of any controverted issues and their resolutions;

   2.1.2.5 The vote on these actions, including the number of votes for, against, or abstaining, and the name(s) of any abstaining member.

   2.1.2.6 In order to document the continued existence of a quorum, the ORC staff member records votes in the minutes using the following format:

       a. Approve
       b. Approve with revisions
c. Resubmit with revisions
d. Table
e. Disapprove
f. Abstain
g. Conflict

2.1.2.6.1 The RCS verifies that number of votes for each application (including abstentions) matches the number present in the room at the time.

2.1.2.7 The determination of the IRB regarding the length of the approval period and the frequency of continuation review based on the degree of risk or the risk/benefit ratio;

2.1.2.8 Name of the investigator and others attending the meeting (such as a consultant);

2.1.2.9 The basis for requiring changes in the research;

2.1.3 The level of risk determined by the IRB.

2.1.4 The recorder will write IRB meeting minutes impersonally and will not attribute opinions expressed by IRB members to them. Typically, the minutes only identify members by name when they recuse themselves from a particular review, leave the meeting for any reason, or abstain from voting.

2.1.5 When the IRB disapproves a protocol, the RCSs will document the basis for the disapproval in the minutes and document discussion of the controverted issues.

2.1.6 The IRB considers written comments and/or information provided by ad hoc or cultural consultants in the review process. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. The IRB will maintain documentation of written comments or reports in the protocol file. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

2.2 Alternates

2.2.1 IRB minutes document when an alternate IRB member replaces a voting IRB member and for whom the alternate is substituting.

2.2.2 When alternates substitute for a primary member, the alternate member receives and reviews the same material that the primary reviewer received or would have received.

2.3 Specific Findings.
When the IRB makes specific findings at convened meetings, DRCs document these findings in the minutes of the meeting and include protocol-specific information justifying each finding. Examples of specific findings include, but are not limited to:

A. Alteration or Waiver of Informed Consent: When the IRB reviews a procedure that alters or waives the requirements of informed consent, the minutes document the determinations required by the federal regulations (45 CFR 46.116 & 117) and protocol specific-findings justifying their determinations.

B. Waiver of Documentation of Informed Consent: When the IRB reviews a procedure that waives the requirements for obtaining a signed informed consent document, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.116 & 117).

C. Research Involving Deception: When the IRB reviews research involving deception, the minutes document that the IRB made the findings in accordance with 45 CFR 46.116.

D. Research under FDA Purview: If a study that is under the purview of the Food and Drug Administration proposes waiver of the requirement for informed consent, the minutes note which regulation applies (e.g., 21 CFR 50.23 or 21 CFR 50.24). For other studies, the minutes document findings in accordance with 45 CFR 46.116.

E. Research Involving Prisoners: When the IRB reviews research involving prisoners, the minutes indicate that the research meets the findings required by 45 CFR 46.305(a) and represents one of the categories of research permissible under Health and Human Services (HHS) regulations required by HHS 45 CFR 46.306(a).

F. Research Involving Children: When the IRB reviews research involving children, the minutes document that the IRB made the findings in accordance with IRB policy and federal regulations (HHS 45 CFR 46 Subpart D 46.404-46.407).

G. Wards of the State or Other Agency: When the IRB reviews research involving children who are wards of the state or any other agency, institution, or entity, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.409).

H. Research Involving Fetuses, Pregnant Women, Neonates or Research on Transplantation of Fetal Tissue: When the IRB reviews research involving fetuses, pregnant women, neonates, or the transplantation of fetal tissue, the minutes must document that the IRB made the findings in accordance with federal regulations (45 CFR 46 Subpart B).

I. Research Involving Decisionally Challenged: When the IRB reviews research involving individuals who are determined to be cognitively impaired and/or lack decision-making capacity, the minutes document that the IRB made the
findings in accordance with federal regulations (45 CFR 46.111(b); 21 CFR 56.111(b)).

J. Investigational New Devices: The minutes will document the determination of the IRB regarding significant or insignificant risk for Investigational New Devices, and the rationale for that decision, in accordance with federal regulations [(21 CFR 812.3(m)].

2.4 Distribution of Minutes

2.4.1 The RCS prepares initial draft of the IRB minutes in time for the preparation meeting of the DRC, RCS, and IRB chair. These persons review the minutes and approve them to distribution to the IRB.

2.4.2 The RCS disseminates the minutes as part of the IRB agenda for the meeting at which the minutes are scheduled to be approved.

2.4.3 Each IRB member present during the convened meeting reviews the draft minutes, comments on revisions as appropriate, and votes on approval of the minutes.

2.4.4 The RCS files a copy of the final approved minutes in the IRB records.

2.4.5 The RCS places a copy of all written communications of IRB actions to investigators in protocol files.

2.4.6 The RCS distributes copies of approved minutes, to:

2.4.6.1 The Vice President for Research

2.4.6.2 The Director of Research Compliance,

2.4.6.3 Any others deemed appropriate by the DRC or the IRB.

2.4.7 ORC maintains copies of all IRB minutes in electronic format in the ORC database. Copies are maintained indefinitely.

3.0 REFERENCES

DHHS: 42 USC 498A(b)(1),(2)(c); 45 CFR 46.115(a)(2); 45 CFR 46.116(c)-(d); 45 CFR 46.117(c); 45 CFR 46.204,205,207; 45 CFR 46.305,306; 45 CFR 46.404,405,406,407,408; 45 CFR 46 Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects (Federal Register, Vol. 68, No. 119, pp.36929-36931, Friday, June 20, 2003; 45 CFR 46 Waiver of Emergency Research (Federal Register, Vol 61, No. 192, pp.51531-51533, October 2, 1996), OHRP Guidance on Written Institutional Research Board (IRB) Procedures

FDA: 21 CFR 50.51-56; 21 CFR 56.109(c); 21 CFR 56.115(a)(b)
4.0 RELATED SECTIONS

4.1 GUIDANCE: IRB Determinations and Motions

4.2 FORM: IRB Meeting Minutes Template