HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

8.1 IRB MINUTES

RESPONSIBLE OFFICE: HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENT (HRPPD) **EFFECTIVE DATE: June 7, 2021**

I. POLICY STATEMENT

A. This procedure outlines the responsibilities of the Human Research Protection Program Department (HRPPD) and the IRB for documentation of convened IRB proceedings according to applicable regulations such as:
- 45 CFR 46.115, §46.116(c), §46.116(d), §46.117(c);
- 21 CFR 56.115, §56.109(c)(1);
- 21 CFR 50.24;
- 32 CFR 219.115, §219.116(c), §219.116(d), §219.117(c);
- 45 CFR 164.512(i)(2)

II. SCOPE

A. This policy and procedures applies to the Human Research Protection Program Department (HRPPD) Staff, IRB, and the Institutional Official

B. Summary of Responsibilities include:

1. HRPPD staff records the discussion, deliberations and decisions of the convened IRB in minutes in accordance with applicable federal, state and local regulations.
2. HRPPD staff are responsible for documentation of minutes and reports to the convened Board of IRB decisions that occur outside a convened meeting under the rules and regulations applicable to IRB review of human subjects' research.
3. All IRB minutes are reviewed and approved by the IRB Chair where recommendations for changes are allowed. Once the minutes are accepted by the Board at a subsequent IRB meeting they may not be altered by anyone, including any higher authority. If comments or clarifications are required to be added to minutes after approval by the IRB Chair, the original version will be maintained and the revised version will go through the same review and approval process.
4. Minutes are accessible to review by the Institutional Official in eIRB.

III. PROCEDURES FOR POLICY IMPLEMENTATION

A. The HRPPD maintains electronic agendas based on the requests, reports, and studies that will be reviewed by the convened IRB.

B. The HRPPD maintains minutes of all convened IRB meetings documenting when applicable:

1. That the meeting was convened with members appropriately representing regulatory requirements (i.e., quorum) and the general perspective of participants.
2. Attendance at the meeting. Including:

a. The name of the members present and whether the member is serving as a primary or alternate. For alternates, the name of the member being represented is included.

b. The names of members not present or represented

c. Members and Consultants with a conflict are documented in the minutes as being absent with an indication that a conflicting interest was the reason for the absence.

d. The names of members or alternate members attending via videoconference or teleconference. Those members will have received all pertinent material before the meeting to ensure they are able to actively and equally participate in all discussions

e. The name of any consultants, guests, or other non-member in attendance.

3. The result of the IRB vote for approval or changes to the previous meeting minutes.
4. Separate deliberations with pertinent discussions of each action/protocol.
5. Record of votes: Votes for, against and abstentions for protocol approval are documented in the meeting minutes. Abstentions are counted as votes against the motion, as a majority is required for a motion to pass.
6. Additional comments to include thorough documentation of unique questions or concerns, recusal of investigators/members/consultants from discussion and vote, or other unique information that may be deemed valuable.
7. IRB determinations (e.g., approved as submitted, approved contingent upon revisions or clarifications, deferred, disapproved) and decisions. Where appropriate, protocol-specific findings are documented supporting determinations. Other required determinations and protocol-specific findings justifying those determinations include:

    a. Whether requests for waiver or alteration of the consent process meet applicable regulatory criteria.

    b. Whether requests to involve pregnant women, fetuses, and neonates meet applicable regulatory criteria

    c. Whether requests to involve prisoners meet applicable regulatory criteria

    d. Whether requests to involve children meet applicable regulatory criteria

    e. Significant risk/non-significant risk device determinations - The rationale for determining that risk associated with using a medical device in a study significant or non-significant.

8. Summary of discussion on controverted issues and their resolution
9. For initial and continuing review, the approval period. For modifications, if the Board voted to shorten the approval period, it should be noted.

10. The basis for requiring changes in or disapproving research
11. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS approved sample consent document.
12. The level of risk determined by the IRB.
13. 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 at the request of the IRB. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

C. The HRPPD Staff creates an Expedited Report which is an electronic record of all IRB decisions that occur outside a convened meeting documenting, when applicable:

1. The report demonstrates that determinations were made as required by the regulations and that protocol-specific findings, where applicable, are documented justifying those determinations (including for example that modifications are minor or that study is eligible for expedited review and the applicable expedited review category depending on the reason for review outside a convened meeting);
2. Description of actions taken by the designated reviewer should be reported to the next convened IRB.

D. After review, record keeping is in accordance with the 8.3 RECORDKEEPING.

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS
32 CFR 219 - PROTECTION OF HUMAN SUBJECTS (DOD)

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
January 2019	HRPP	Revision to reference 2019 common rule
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures