1 PURPOSE

1.1 This procedure establishes the process to record minutes for convened meetings.

1.2 The process begins when the meeting is called to order.

1.3 The process ends when the minutes are reviewed for Quality and any corrections are made if applicable.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Administrative and current procedural updates.

2.2 Vote counts updated for better understanding and clarity.

2.3 Revised minute approval process to allow full IRB Committee approval.

2.4 Revised to align with regulatory requirements, add references to citations and checklists, and remove additional descriptive text.

3 POLICY

3.1 Minutes are to comply with regulatory requirements.

3.2 IRB members may make corrections to the minutes.

3.3 The IRB Administration writes minutes and makes them available for review within the system of record.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Document in the minutes[1]:

- 5.1.1 Meeting attendance
  - 5.1.1.1 Record each voting member (regular members and alternates) present at the meeting at any time.
    - 5.1.1.1.1 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
  - 5.1.1.2 Record any non-voting attendees[2] present at any time.
  - 5.1.1.3 Record any non-members and guests present at any time.
- 5.1.2 List each business item that was discussed; document:
  - 5.1.2.1 Action taken by the IRB[3];
  - 5.1.2.2 The number of votes for, against, and abstaining;
  - 5.1.2.3 The basis for requiring changes in or disapproving research; and
  - 5.1.2.4 A written summary of the discussion of controverted issues and their resolution.
- 5.1.3 Regulatory determinations and review outcomes; ensure that corresponding completed checklists or equivalent are in the IRB system of record:
  - 5.1.3.1 The criteria for approval[4] have been met
  - 5.1.3.2 The Conflict of Interest Management Plan[5] has been accepted
  - 5.1.3.3 There are adequate provisions to obtain[6] and document[7] informed consent
  - 5.1.3.4 A waiver or alteration[8] of the consent process has been issued
  - 5.1.3.5 An exception from informed consent requirements for emergency research[9] has been issued

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[1] 45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)
[2] (45 CFR 46.107(e); 21 CFR 56.107(f))
[3] HRP-041 lists possible actions
[4] HRP-314; 45 CFR 46.111; 21 CFR 56.111
[5] HRP-055
[6] HRP-314b; HRP-090; 45 CFR 46.111(a)(4); 21 CFR 56.111(a)(4)
[7] HRP-091; 45 CFR 46.111(a)(5); 21 CFR 56.111(a)(5)
[8] HRP-410; 45 CFR 46.117(c); 21 CFR 56.109(c) and (d);
[9] HRP-419; 21 CFR 50.24

5.1.3.6 A waiver of written documentation[10] of consent has been issued

5.1.3.7 A waiver of HIPAA Authorization[11] has been issued

5.1.3.8 Children[12] have been approved as participants

5.1.3.9 Pregnant people, human fetuses,[13] or neonates[14] have been approved as participants

5.1.3.10 Prisoners[15] have been approved as participants

5.1.3.11 Determinations of Unanticipated Problems, Serious or Continuing Noncompliance, Suspension or Termination of IRB Approval [16]

5.1.3.12 Cognitively impaired adults have been approved as participants when the study is a clinical trial[17]

5.1.3.13 Significant/non-significant device determination [18]

5.1.4 Review of protocols granted approval using the expedited procedure [19]

5.2 Complete and retain "CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)."

6 MATERIALS

6.1 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)

7 REFERENCES

7.1 21 CFR §56.115(a)(2)

7.2 45 CFR §46.115(a)(2)

[10] HRP-411; 45 CFR 46.117(c); 21 CFR 56.109(c) and (d)
[11] HRP-441; 45 CFR 164.512
[12] HRP-416; 45 CFR part 46 subpart D and/or 21 CFR part 50 subpart D
[13] HRP-412; 45 CFR part 46, subpart B
[14] HRP-413; HRP-414; 45 CFR part 46, subpart B
[15] HRP-415; 45 CFR part 46, subpart C
[16] HRP-321; 45 CFR 46.103(b)(5) or 21 CFR 56.108(b)
[17] HRP-417; ICH E6 R2 4.8.13-4.8.15
[18] HRP-418; 21 CFR 56.108(a)(1); 21 CFR 812.66
[19] 45 CFR 46.110(c); 21 CFR 56.110(c)