Title: HRRC Meeting Minutes

SOP # HRP-043  Revision # 2  Effective Date 03/10/2015

Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC

Approved: Richard Larson, MD PhD Vice Chancellor for Research

Date: 3/4/15

Date: 3/10/15

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 approved by the HRRC Chair and accepted by the convened HRRC.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Changes to allow for approval of minutes by the HRRC Chair and acceptance by the convened HRRC.
2.2 Removed VA requirements no longer in VA Handbook.

3 POLICY
3.1 Minutes are to comply with regulatory and guidance requirements.
3.2 Minutes are to record separate deliberations for each action.
3.3 Minutes are officially approved by the HRRC Chair and accepted by the convened HRRC.
3.4 HRRC members may make corrections to minutes
3.5 Minutes may not be altered by anyone including a higher authority once accepted by the convened HRRC.

4 RESPONSIBILITIES
4.1 HRPO staff members carry out these procedures.

5 PROCEDURE
5.1 Execute the “Convene Meeting” activity.
5.2 Under “Attendance Table” record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table.”)
5.2.1 Name.
5.2.2 Status: E.g., chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, Veterans Administration (VA) representative, or alternate member.
5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
5.2.4 Whether the member was present by teleconference.
5.3 Record the total number of members on “DATABASE: HRRC Roster (HRP-601).” Exclude alternate members in this count.

5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 HRRC members on the “DATABASE: HRRC Roster (HRP-601),” then 10/2 = 5 and the next whole number is 6. If there 11 HRRC members on the “DATABASE: IRB/HRRC Roster (HRP-601),” then 11/2=5.5 and the next whole number is 6.

5.5 Record the meeting start time.

5.6 Record a summary of each business item that was discussed.

5.7 For each protocol reviewed record:

5.7.1 Type(s) of review: Initial review, continuing review, review of modifications to previously approved research, or review of Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB/HRRC Approval, Termination of IRB/HRRC Approval.

5.7.2 Protocol Title

5.7.3 Investigator name.

5.7.4 HRRC identification number

5.7.5 Funding Agency (indicate “none” if none)

5.7.6 Grant Title (indicate “none” if none)

5.7.7 Grant ID (indicate “none” if none)

5.7.8 IND or IDE (indicate “none” if none)

5.7.9 Documents reviewed

5.7.10 Summary of the study: Provide a brief summary of the submission and issues useful to understand the agenda item

5.7.11 Consultant report: Summarize the key information provided by the consultant. Delete if there was no consultant.

5.7.12 Criteria for approval. Document each item as determined by the committee. Ensure that any corresponding checklists are completed and included in the HRRC record for the submission.

5.7.13 Level of risk determined by the convened HRRC: Minimal Risk or Greater than Minimal Risk.

5.7.14 Period of Approval: Document the approval period as determined by the committee.

5.7.15 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this.

5.7.16 Staff Information: Confirmation that the HRPO staff member has all necessary information to complete the minutes and post-review activities.

5.7.17 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of HRRC members who were absent or recused. Do not count votes of consultants. If both a regular HRRC member and the alternate HRRC member are present at the meeting record the vote of just one.

5.7.17.1 For: Voting for the motion.

5.7.17.2 Against: Voting against the motion.

5.7.17.3 Abstain: Present for the vote, but not voting “For” or “Against.”

5.7.17.4 Absent: Listed under "Members Present" but not present for the discussion and vote on this protocol for reasons other than a
Conflicts of Interest: List the names of absent members in the vote. For example: "For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0"

5.7.17.5 Recused: Listed under "Members Present" but not present for the discussion and vote on this protocol for because of a Conflict of Interest. List the names of recused members in the vote. For example: "For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George Incia) Substitutions: 0"

5.7.17.6 Substitutions: Listed under "Members Present" When regular members and their alternate(s) are listed under "Members Present" and an alternate member substitutes for the regular member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: "For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India)"

5.7.18 Controverted issues and their resolution. Summarize the issues where HRRC members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was none. If no controverted issues, indicate "None."

5.7.19 Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete.

5.7.20 Modifications required to secure approval: If this is the motion, complete the table with the required changes and corresponding reasons. Otherwise, delete.

5.7.21 Deferral/disapproval reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.

5.7.22 Suspension/termination reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.

5.7.23 Tabbed reason: If the protocol was tabbed, provide the reasons. Otherwise, delete.

5.7.24 For Veterans Administration (VA) research complete the "Additional Veterans Administration (VA) Requirements" table, otherwise delete.

5.8 Record the meeting end time.

5.9 Within 2 business days revise minutes for accuracy and provide them to the HRRC Chair for review and approval.

5.10 Once approved by the HRRC Chair they are uploaded to Click and added to the agenda for the next convened meeting for acceptance by the members.

5.11 Attach the following documents to the approved minutes:

5.11.1 List of exemptions granted.

5.11.2 List of protocols granted approval using the expedited procedure.

6 MATERIALS

6.1 TEMPLATE MINUTES (HRP-501) or equivalent

7 REFERENCES

7.1 21 CFR §56.115(a)(2)

7.2 45 CFR §46.115(a)(2)