

TITLE: Recording and Distribution of VA Central IRB Meeting Minutes**1.0 PURPOSE**

This Standard Operating Procedure (SOP) sets forth the policies and procedures for the recording and distribution of the VA Central IRB meeting minutes. It includes guidance on the actual taking of the minutes, documentation requirements, format, review timelines, and the distribution of the approved minutes.

2.0 REVISION HISTORY

Date of Initial Approval	July 1, 2008
Revision Dates	November 2, 2009 March 26, 2010 September 14, 2010 February 14, 2011 August 10, 2011 December 9, 2011

3.0 SCOPE

3.1 This SOP applies to the VA Central IRB administrative staff and the VA Central IRB members.

3.2 This SOP also applies to those personnel in positions who routinely receive a copy of the completed, approved minutes as part of their duties, to include designated personnel at local sites.

4.0 POLICY

4.1 It is the policy of the VA Central IRB that its meeting minutes meet all VA and federal guidelines in regard to documentation requirements. The VA Central IRB administrative staff and the VA Central IRB Board members ensure that all such documentation requirements are met during the preparation, review, and approval of the minutes. They will also ensure that the minutes are complete and accurate as to the discussions that took place during the meeting and the actions taken.

4.2 It is the policy of the VA Central IRB that there will be no audio or video recordings taken of the proceedings of convened meetings of the VA Central IRB.

4.3 It is also the policy of the VA Central IRB to protect the copies of the meeting minutes as VA sensitive information. The VA Central IRB staff ensures

that the minutes are stored and distributed in accordance with VA information security and other requirements for the protection of sensitive data.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 The VA Central IRB Coordinators are responsible for taking sufficient notes during the course of a meeting in order to prepare a set of official, written meeting minutes that meet all required documentation requirements. The VA Central IRB Coordinator designated for taking the meeting minutes for a particular meeting is also responsible for completing a draft of the minutes within approximately ten working days of the day the meeting was held.

6.2 The VA Central IRB Administrator is responsible for taking complementary notes during the course of a meeting and for reviewing the draft minutes to ensure that they are complete, accurate, and meet all documentation requirements before forwarding the draft to the VA Central IRB Co-Chairs. The VA Central IRB Administrator is also responsible for ensuring that a complete and edited draft of the minutes is available for review no later than three weeks after the meeting date.

6.3 The VA Central IRB Co-Chairs are responsible for reviewing the draft set of minutes and making any changes, corrections, deletions, or additions as needed. The Co-Chairs are also responsible for signing the official record copy of the minutes after they have been approved at the next convened meeting of the VA Central IRB. If one of the Co-Chairs is not available for signature, the minutes may be released and distributed upon signature of the other Co-Chair and will not be further signed after release and distribution.

6.4 All VA Central IRB members are responsible for reviewing the draft minutes prior to the next fully convened meeting of the VA Central IRB and to bring any discrepancies or omissions up at the meeting to consider for correction of the draft prior to the Presiding Co-Chair calling for a vote to approve the minutes.

6.5 All VA Central IRB members and staff, as well as local participating site officials and others who receive copies of the minutes, are responsible for ensuring that VA requirements for the distribution, safeguarding, and storage of VA sensitive data are followed.

7.0 PROCEDURES

7.1 Documenting the Proceedings. The VA Central IRB Coordinators and Administrator must ensure that all pertinent Board discussions are documented accurately and completely.

7.1.1 The VA Central IRB Coordinators will document the proceedings of meetings as they occur using the VA Central IRB Agenda and the Agenda Tools for each project action as a Guide in documenting the proceedings.

7.1.2 The VA Central IRB Coordinator for a specific project must pay particular attention to the required elements for which a determination must be made by the VA Central IRB for each specific project and type of review being conducted at a convened meeting when drafting out the agenda tool.

7.1.3 The VA Central IRB Administrator reviews the agenda tools for each specific project action prior to the meeting to ensure that all required elements that must be discussed are annotated on the tool. The VA Central IRB Administrator also prepares the draft and final agenda, as well as the list of project actions that were reviewed and approved under expedited procedures since the last convened meeting. This list also includes project items reviewed and approved by one of the VA Central IRB Co-Chairs or other designated reviewers, such as minor modifications, minor amendments, serious adverse events, unanticipated problems involving risks to subjects or others, protocol deviations, Local Site Investigator Applications, and routine audit reports as applicable.

7.2 Minimum Documentation Requirements. The VA Central IRB Coordinator and Administrator ensure that the following minimum documentation requirements are met for each meeting:

7.2.1 The VA Central IRB Coordinator ensures that the following minimum requirements are appropriately documented and completed prior to the meeting being adjourned:

7.2.1.1 The date and time the meeting starts and ends.

7.2.1.2 The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.

7.2.1.3 Attendance at the meeting to include members who are participating through video or teleconferencing. A statement is documented in the minutes that the members participating via video or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions. The presence of Alternates will be noted. If an Alternate is attending for the Primary Representative, this will be indicated.

7.2.1.4 When a VA Central IRB member has a real or potential conflict of interest relative to the particular project under consideration, there must be a statement that the member was not present during the deliberations or voting on the project and the member must not be reflected in the number of total members that were present to vote on that action.

7.2.1.5 Actions taken by the IRB, including those involving new projects, continuing reviews, amendments, adverse events, and project deviations, must be documented. There will be a separate recording in the minutes for each action item deliberated. At a minimum, the following must be documented as applicable depending upon the project actions reviewed and the action taken at the convened meeting:

7.2.1.5.1 A written summary of the discussion of controverted issues and their resolution is required for all actions.

7.2.1.5.2 The basis for requiring changes in or disapproving research and documentation of resolution of these issues when resolution occurs is required for all actions unless no change is recommended.

7.2.1.5.3 The determination of the level of risk and the rationale for the determination is required for new studies and continuing review actions, as well as for other actions as applicable.

7.2.1.5.4 The vote on actions including the number of members voting for or against a motion for action and the number abstaining for all actions.

7.2.1.5.5 Whether participant's medical records need to be flagged to protect the participant's safety by indicating participation in a particular research project for new studies and as applicable if the IRB determines that this is an issue.

7.2.1.5.6 The continuing review approval period for new studies and continuing reviews and as applicable for other actions if the IRB determines the continuing review period is affected by the action.

7.2.2 If the VA Central IRB Coordinator or Administrator is uncertain about a particular discussion item and what to document, they should not hesitate to ask for clarification prior to the IRB moving on to a new discussion item.

7.3. Additional Documentation Requirements: In addition to the above required documentation elements, the following additional elements must be documented if applicable to the particular protocol being discussed. They will be

added to the agenda tool as needed to ensure consideration by the IRB members and complete, accurate documentation of the VA Central IRB determinations:

7.3.1 Protocol-specific documentation of the following required findings for each project discussed when the VA Central IRB either approved a consent procedure that does not include or that alters some or all of the required elements of informed consent or when the IRB waived the requirement to obtain an informed consent:

- The research involves no more than minimal risks to the participant
- The waiver or alteration will not adversely affect the rights and welfare of the participants
- The research could not be practicably carried out without the waiver or alteration
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

7.3.2 Protocol-specific determinations regarding waiver of the documentation of informed consent must be documented in the minutes to include:

- Study specific information to show that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm from a breach of confidentiality, **OR**
- Study specific information to show that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

If the investigator is requesting a waiver of the requirement to maintain a master list of subjects in addition to the request for a waiver of documentation of informed consent, this must be discussed and documented separately.

7.3.3 Protocol-specific determinations concerning the review of studies in which vulnerable populations will be involved. This includes the review of additional safeguards to protect vulnerable populations and findings related to the use of surrogate consent.

7.3.3.1 The required determinations for each of the below vulnerable populations as referenced in the applicable VA Central IRB Form 110 Vulnerable Population Supplement will be referenced.

- Pregnant women
- Prisoners
- Individuals with impaired decision making capacity

7.3.3.2 For studies involving the use of children, all determinations as required by VA Central IRB SOP 106, Research Involving Vulnerable Populations and Other Special Categories of Participants, will be documented.

7.3.3.3 For other populations that may be susceptible to undue influence or coercion, the minutes will contain references to the discussion by the VA Central IRB that additional safeguards provided in the study to safeguard participants from undue influence or coercion are adequate and appropriate. These populations include the economically and/or educationally disadvantaged, the terminally ill, illiterate and/or non-English speaking subjects, VA employees and students, as well as participants for whom the investigator is also one of their health care providers.

7.3.4 If the project involves the use of an FDA-regulated product, the presence of a physician is documented as part of the attendance requirements. If the project involves the use of an investigational device, the basis for rating the device a non-significant risk or a significant risk device must be stated.

7.3.5 Documentation indicating approval of a waiver or alteration of the HIPAA authorization must include the following:

- The use or disclosure involved no more than a minimal risk to an individual participant's privacy based on an adequate plan to protect the identifiers from improper use and disclosure; the identifiers will be destroyed at the earliest opportunity consistent with the research unless there is a health or research justification for retaining them or such retention is otherwise mandated by applicable VA or other federal requirements; and written assurance that the requested information will not be reused or disclosed to any other person or entity unless already permitted or required.
- The research could not be practicably conducted without the waiver or alteration
- The research could not be practicably conducted without access to and use of the requested information.
- A brief description of the Protected Health Information (PHI) for which the IRB has determined use or disclosure to be necessary in accordance with the completed VA Central IRB Form 103, Request for Waiver of HIPAA Authorization

7.3.6 Documentation is required in the minutes for projects that involve any of the following:

7.3.6.1 For projects that collect human biological specimens, as well as linked clinical data as part of the research, the minutes must reflect

that the specimens will be maintained in a VA-approved tissue bank. This should be added as an item on the agenda tool to ensure appropriate documentation.

7.3.6.2 For projects proposing to use non-Veterans, the determination by the IRB that there were insufficient Veterans or that there is a compelling argument to use non-Veterans must be documented.

7.3.6.3 For studies that have significant new findings, the determinations of the IRB concerning any actions that need to be taken as a result of the review of these findings must be documented.

7.3.7 For projects undergoing initial or continuing review at a convened meeting of the VA Central IRB, there must be a statement that all required IRB approval criteria has been met if the study is approved or given a pending approval status. In addition, if an informed consent document is part of the study, a discussion concerning the elements of informed consent must also be documented. This can include required minor modifications to the informed consent document.

7.3.8. For projects that underwent initial or continuing review since the last meeting using the expedited review procedure and are being reported to the VA Central IRB members at the meeting for which the minutes are being prepared, the specific category qualifying the review to be expedited is documented. This will be annotated on the list of project actions approved under expedited review procedures that is part of the final agenda for the meeting.

7.3.9 For projects that received exemption determinations since the last meeting and are being reported to the VA Central IRB members at the meeting for which the minutes are being prepared, the exemption category under which the approval was granted is listed.

7.3.10 The meeting minutes must document the review of any serious adverse events, protocol deviations, complaints, or unanticipated problems involving risks that were reported since the previous meeting and reviewed at the convened meeting. If a protocol is suspended or terminated, the reasons are detailed in the minutes.

7.3.11 If SSNs are going to be used by the study team, to include scrambled SSNS and only the last 4 numbers of the SSNs, there must be a discussion documented regarding the investigator's justification for using them if and if the protections in place for safeguarding them are adequate.

7.3.12 The list of projects that were approved under the expedited review process since the last meeting, the list of projects exempted from review since the last meeting, and the list of serious adverse events reviewed by one of the Co-Chairs or assigned reviewers and determined to not be related to the

research will be attached to the minutes of the meeting. Other items that are also to be included on this list as applicable are the review by the Co-Chair or applicable Reviewer of minor modifications, minor amendments, protocol deviations, Local Site Investigator Applications, and audit reports submitted by Research Compliance Officers separately from continuing review but that did not require review by the convened IRB.

7.4 Preparation of the Meeting Minutes: After a convened meeting, the VA Central IRB Coordinator assigned to prepare the minutes will consult with the other VA Central IRB Coordinators and the VA Central IRB Administrator regarding any questions pertaining to the notes taken.

7.4.1 The VA Central IRB Coordinator prepares a complete working draft of the minutes and forwards it to the VA Central IRB Administrator approximately 10 work days after the meeting took place. The draft will be completed according to the attached template and as outlined in the agenda. However, the template is a sample only of the suggested order of the agenda and the organizational layout to be followed in creating the agenda and minutes. The actual minutes will reflect the proceedings of the meeting as they occurred, which may include changes in the order or content of the agenda. Upon completion of the draft, it will be forwarded to the VA Central IRB Administrator for review.

7.4.2 The VA Central IRB Administrator makes any changes, additions, or deletions and then forwards the completed draft to the VA Central IRB Co-Chair and adds the review of the draft minutes to the agenda of the next convened IRB meeting.

7.4.3 The Co-Chairs may elect to review and make changes to the draft prior to the convened meeting or wait until the convened meeting to indicate the changes. If a Co-Chair makes any changes prior to the meeting, these will be made to the minutes and a new draft provided to the members for review prior to the meeting if time permits.

7.4.4 Minutes cannot be altered by anyone, including a higher authority once approved by the members at a subsequent IRB meeting.

7.5 Approval and Distribution of the Minutes. The minutes are approved and distributed as follows:

7.5.1 At the next regularly scheduled convened meeting of the VA Central IRB, the members make any further suggestions for corrections, additions, or deletions and the Presiding Co-Chair then calls for a vote. Upon approval of the minutes, any approved changes are made and the minutes then signed by one or both of the Co-Chairs.

7.5.2 After signature by the Co-Chairs, the minutes are distributed as follows:

- One hard copy is kept in the VA Central IRB files Meeting Minutes Notebook. Minutes are filed by Month and Year.
- A copy is scanned and added to the VA Central IRB Shared drive
- A copy is made available to of all meeting minutes to all Local VA Central IRB Site Liaisons through the VA Central IRB Local Site Liaison folder on the VA Central IRB secure SharePoint site. VA Central IRB Local Site Liaisons are sent an e-mail informing them whenever a new set of meeting minutes has been loaded. VA Central IRB Liaisons are responsible for ensuring the minutes are reviewed at their local facility per local R&D SOPs.

7.6 Access to Meeting Minutes Records. Copies of particular VA Central IRB meeting minutes or access to the entire meeting minutes file may be made available as follows:

- FOIA requests received for copies of VA Central IRB meeting minutes are forwarded to the VHA FOIA Officer who makes a determination of what can be released. Minutes are redacted as instructed by the VHA FOIA Officer prior to any release.
- Access to the minutes is made available to any government entity or accreditation organization that is performing an inspection, investigation, or quality assurance review as part of its official duties.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 164, Department of Health and Human Services, Security and Privacy

8.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.5 21 CFR 812, U.S. Food and Drug Administration, Investigational Device Exemptions

8.6 VHA Directive 2000-043, Banking of Human Research Subjects Specimens

8.7 VA Office of Research Oversight (ORO) Human Research Protection Program (HRPP) Checklist

Attachment
Sample Minutes Template

I have reviewed and approved the content of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 12/9/11

**VA CENTRAL INSTITUTIONAL REVIEW BOARD
MEETING MINUTES
[Date]**

CALL TO ORDER

1. The meeting was called to order by Co-Chair [Name of Presiding Co-Chair, date and time, and location.]

ATTENDANCE

2. The following members were present in person:

<u>Voting Members</u>	<u>Status</u>
------------------------------	----------------------

Make a special note if a member is serving in a representative capacity for a vulnerable population.

First Name, Last Name, Credentials Scientist/Nonscientist

<u>Non-voting Members</u>	<u>Status</u>
----------------------------------	----------------------

First Name, Last Name, Credentials Representative Capacity

Make a note who is an Alternate and indicate if they are serving in the Representative Capacity for the Primary member.

The following members **attended via teleconference or videoconference**. All members participating via teleconference or videoconference received all pertinent materials in sufficient time to review them prior to the meeting and were able to actively and equally participate in the discussion of all project actions reviewed.

<u>Voting Members</u>	<u>Status</u>
------------------------------	----------------------

<u>Non-voting Members</u>	<u>Status</u>
----------------------------------	----------------------

The following members were excused:

<u>Members</u>	<u>Status and Voting or Non-voting</u>
-----------------------	---

Total Voting Membership: #	Quorum: #
-----------------------------------	------------------

The following staff members from the VA Central IRB Administrative Office were present in person:

Names

Role

CONFLICTS OF INTEREST

3. The Presiding Co-Chair briefed the members on Conflict of Interest (COI) procedures. No members had any conflicts of interest with the business before the VA Central IRB this date **[or state if there were conflicts identified]**.

REVIEW AND APPROVAL OF MINUTES

4. A motion was made and seconded to approve the minutes of **[date]**. **[If the minutes were approved, state specifically any change to the content of the minutes. Changes in formatting or identification of typographical errors can be summarized.]**

TOTAL = #; VOTE: FOR = #, OPPOSED = #, ABSTAINED = #

REPORT ON ITEMS REVIEWED AND APPROVED UNDER EXPEDITED PROCEDURES

5. All members were provided a copy of the listing of Project Actions Reviewed and Approved utilizing Expedited Review Procedures from **[dates]**. *Indicate if there were any comments and if so, what study did they pertain to if any specific study was discussed.* A copy of this listing is attached to these minutes.

INITIAL REVIEW OF PRINCIPAL INVESTIGATOR/STUDY CHAIR APPLICATION(S):

[Document within the minutes as voting members leave and/or return to the meeting. Members with COI who leave the room and cannot be counted towards quorum or vote . For example, VA Central IRB member (provide name) left the room because of COI (describe reason) and did not participate in the vote.]

6. The VA Central IRB reviewed the following new studies: (Repeat, as applicable, the information below for each new study reviewed.)

VA Central IRB Number:

Title:

Principal Investigator/Study Chair:

Items Reviewed:

Reviewer Overview:

VA Central IRB Discussion:

Call-in by Study Team:

VA Central IRB Determinations:

Based on the VA Central IRB's discussion, a motion was made and seconded as follows: **[Determination Made: Table (no action), Defer for Major Modifications, Approve Contingent Upon Required Minor Modifications, Approve Contingent Upon Receipt and Review of Local Site Comments, Approve, Disapprove].** All IRB approval criteria [are met, are not met, or will be met upon submission and approval of required modifications.]

Modifications

If modifications are required, these would be listed in the following format:

Principal Investigator/Study Chair Application and Protocol

Informed Consent

HIPAA (Privacy Officer Representative requirements)

Recruitment Material

[Other categories may be added as applicable to the modifications required.]

The VA Central IRB also made the following additional determinations:

Informed Consent and Waiver Request Determinations

If waiver requests are reviewed document as follows, as applicable, and include protocol-specific determinations for approving the waivers.

The submitted **Request for Waiver or Alteration of the Informed Consent Process** (VA Central IRB Form 112a) for (for recruitment purposes only, for entire project, or if only for one or more specific elements of informed consent) was reviewed. The VA Central IRB determined the research involves no more than minimal tangible or intangible risk to participants; the waiver or alteration will not adversely affect the rights and welfare of the participants, the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the participants will be provided additional pertinent information after participation.

The submitted **Request for Waiver of Documentation of Informed Consent** (VA Central IRB Form 112b) for (all interactions with participants or specific interactions) was reviewed. The VA Central IRB determined the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context or the only record linking the participant and the research would be the consent document and

the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

If the investigator also requested a waiver of the requirement to maintain a master list of subjects in addition to the request for a waiver of documentation of informed consent document as follows:

The VA Central IRB reviewed the investigator's request for a waiver of the requirement to maintain a master list of subjects entered into the study and determined that the waiver was appropriate in order to protect the subject's privacy and the confidentiality of the data.

The submitted **Request for Waiver or Alteration of HIPAA authorization** (VA Central IRB Form 103) for (recruitment purposes only, for entire project, or for specific elements) was reviewed. The VA Central IRB determined the following criteria were met and the use of the PHI as detailed in the VA Central IRB Form 103, Request for Waiver of HIPAA Authorization was adequately justified:

- The use or disclosure of protected health information involves no more than minimal risk to the privacy of the individuals.
- The alteration or waiver will not adversely affect the privacy rights and welfare of the individuals.
- The research cannot be practicably conducted without the alteration or waiver.
- The research cannot be practicably conducted without access to and use of the protected health information.
- The privacy risk to individuals whose protected health information is to be used or disclosed is reasonable in relation to the anticipated benefits, if any, to the individuals and the importance of the knowledge that may reasonably be expected to result from the research.
- There is an adequate plan to protect the identifiers from improper use and disclosure.
- There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by applicable VA or other federal requirements.
- The protected health information will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of the research project.

Note: If an informed consent document was reviewed, a statement that all required elements were included should be documented. This can be done during the discussion by the Informed Consent Reviewer or as part of the detailing of the informed consent modifications, if any.

Risk Level (Include protocol-specific determinations as discussed)

The VA Central IRB conducted a risk/benefit analysis and determined the research falls into the category of "not greater than minimal risk" due to the information provided in the submitted materials which described procedures and provisions for which the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

or

The VA Central IRB conducted a risk/benefit analysis and determined the research falls into the category of "greater than minimal risk" due to the information provided in the submitted materials which described the risk as a minor increase over minimal risk and which is justified by the importance of the knowledge that may reasonably be expected to result.

Continuing Review Period

The VA Central IRB recommended a 12-month approval.

or

The VA Central IRB recommended an approval period of (i.e., six months) due to (specify reason such as the degree of risk involved in the research).

Flagging of medical records (Include protocol-specific determination)

The patient's medical record (electronic or paper) must be flagged to protect the participant's safety by indicating the subject's participation in the study, and the source of more information on the study.

FDA-Regulated Studies

Document that a physician is present (can be done as part of the meeting attendance listing via member credentials) and that an IND/IDE has been validated or one is not required.

NSR/SR determination for medical devices (Include protocol-specific reasons for determination)

The VA Central IRB reviewed the submitted information pertaining to the device and its proposed use and determined it to be a non-significant risk device in accordance with Food and Drug Administration regulations.

or

The VA Central IRB reviewed the submitted information pertaining to the device and its proposed use and determined it to be a significant risk device as defined in Food and Drug Administration regulations.

Use of Non-Veterans

The use of non-Veterans as detailed in this study by the investigator is appropriate since *(specify reason)*

Determinations for Vulnerable Populations

For the following vulnerable populations, indicate that the applicable VA Central IRB Form 110 Vulnerable Population Supplement was reviewed and what the protocol-specific determinations that were made regarding the use of the populations:

- Pregnant women
- Prisoners
- Impaired Decision Making Capacity Individuals

For all other vulnerable populations or special categories of participants who may be susceptible to undue influence or coercion, indicate that the determination regarding the use of the population and any additional safeguards.

Significant New Findings

Document if any study had significant new findings and what action, if any, was taken by the VA Central IRB and why.

Vote:

TOTAL = #; VOTE: FOR = #, OPPOSED = #, ABSTAINED = #

[Each project action reviewed will continue to be documented in the above manner and customized depending upon the project type and actions taken. These reviews include but are not limited to the listing that follows.]

RE-REVIEW OF DEFERRED STUDY

REVIEW OR RE-REVIEW OF NEW LOCAL SITE INVESTIGATOR APPLICATIONS

REVIEW OF LOCAL SITE COMMENTS

REVIEW OF REQUESTS FOR CONTINUING REVIEW

REVIEW OF AMENDMENT REQUESTS

REVIEW OF SERIOUS ADVERSE EVENTS OR SERIOUS UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS

REVIEW OF APPARENT SERIOUS NONCOMPLIANCE

Document when VA Central IRB voting members leave the meeting and return. If a member recuses themselves from the discussion of a particular study action, document that the absence was due to the recusal.

TRAINING

7. **[Document any training the members received.]**

ADMINISTRATIVE ISSUES

8. **[Document any administrative issues discussed.]**

ADJOURNMENT

9. There being no further business, the meeting was adjourned at **[time]**. The next meeting is planned for **[date and time]**.

Recorder

Date

Co-Chair

Date

Co-Chair

Date

The minutes were reviewed and approved by the VA Central IRB at the convened meeting on **[date]**.

Attachment
List of Expedited Actions/Items