

Preparations for the AAHRPP Site Visit Suggested Documents to Pull For Initial Accreditation or Rec accreditation

The table below lists examples of documents that may be requested by AAHRPP in preparation for the AAHRPP site visit at a VA Facility. It is designed to be used to assist in preparing for the site visit. This is not an inclusive list. AAHRPP may request documents not appearing on this list specific to the submitted application. All documents appearing on this list may not be requested by AAHRPP. However, do not look further back than 2 years for any requested document. If you cannot locate a requested document within a 2-year timeframe, just note that the document cannot be located within the timeframe. If you have questions concerning your VA Facility's document pull list when you obtain it from AAHRPP, please contact AAHRPP for clarification prior to the site visit.

**VA Facility with a HRPP and its own IRB or
VA Facility using an IRB of an *Academic Affiliate
*Not Planning to Obtain AAHRPP Accreditation**

If the IRB Committee or R&D Committee maintains documents in electronic form, please contact AAHRPP to discuss ways to make records available to the site visitors.

1. The most 3 recent set of minutes for each IRB.
2. The results of the organization's most recent review/evaluation of the following:
 - a. The resources allocated to the human research protection program.
 - b. Whether the number of IRBs was appropriate to the volume and types of research reviewed.
 - c. The membership and composition of the IRB
 - d. Knowledge and skills of individuals involved in the human research protection program.

**VA Facility with a HRPP using an IRB of another VA Facility or an
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If the IRB Committee or R&D Committee maintains documents in electronic form, please contact AAHRPP to discuss ways to make records available to the site visitors.

1. For each investigator/research staff interview, pull the complete IRB protocol file and R&D protocol file listed in the agenda.
2. The results of the organization's most recent review of the following along with a summary of changes made in response to the review:
 - a. The resources allocated to the human research protection program.
 - b. Whether the number of IRBs was appropriate to the volume and types of research reviewed.
 - c. Knowledge and skills of individuals involved in the human research protection program.
 - d. Participant outreach activities.

Preparations for the AAHRPP Site Visit Suggested Documents to Pull For Initial Accreditation or Rec accreditation (Continued)

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- e. Performance of:
 - i. IRB members.
 - ii. IRB chairs.
 - iii. IRB staff.
- f. Participant outreach activities.
- 3. Resume for each IRB member.
- 4. R&D Minutes for the past 12 months.
- 5. Template letters (or examples) used to communicate to investigators:
 - a. Approved research
 - b. Contingently approved research
 - c. Disapproved research
 - d. Tabled research
 - e. Expiration of research due to failure to obtain continuing review
- 6. Provide the complete IRB protocol file for:
 - a. For each investigator and research staff scheduled in the agenda for an interview.
 - b. The 5 most recent protocols initially approved by a convened IRB.
 - c. The 3 most recent protocols initially approved by a convened IRB involving pregnant woman.
 - d. The 3 most recent protocols initially approved by a convened IRB involving participants with diminished capacity to provide consent
 - e. The 5 most recent continuing reviews approved by a convened IRB.
 - f. The 5 most recent modifications to previously approved by the convened IRB.
 - g. The 5 most recent protocols initially approved using the expedited procedure.
 - h. The 3 most recent protocols initially approved using the expedited procedure involving waiver of written documentation

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- 3. R&D Minutes for the past 12 months.
- 4. Protocol files for the most recent 3 non-compliance cases.
- 5. Protocol files for the most recent 3 conflict of interest cases reviewed by a convened IRB including the conflict management plan.
- 6. Protocol files for the most recent 3 unanticipated problems involving risks to participants or others.
- 7. Documentation related to the 3 most recent complaints received by the HRPP, including the protocol file.
- 8. Results of the 3 most recent internal audits of protocols reviewed by the convened IRB, including the protocol file.
- 9. Results of the 3 most recent internal audits of protocols reviewed by the expedited process, including the protocol file.
- 10. Results of the 3 most recent internal audits of protocols determined to be exempt, including the protocol file (if the organization uses the exempt criteria).
- 11. Copies of the 3 most recent audits of protocols performed by the affiliate IRB, if any.
- 12. Copies of the 3 most recent audits of your program by sponsors or CROs.
- 13. Copies of external audits of your program by consultants for the last year.
- 14. Five most recent contracts (do not include subcontracts or federal contracts).

Preparations for the AAHRPP Site Visit Suggested Documents to Pull For Initial Accreditation or Reccreditation (Continued)

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- of consent.
- i. The 3 most recent protocols initially approved using the expedited procedure involving waiver or alteration of the consent process.
- j. The 5 most recent continuing review approvals approved using the expedited procedure.
- k. The 5 most recent modifications approved using the expedited procedure.
- l. The 10 most recent exemption determinations granted.

(Note: The term “complete IRB protocol file” refers to all information required by regulations. If information is stored in multiple files, site visitors should be provided with all files. For example, if correspondence between the investigator and the IRB or information relating to non-compliance is stored in another location, all of these files should be made available to site visitors.)

- 7. Protocol files for 3 most recent protocols reviewed more often than annually.
- 8. Protocol files for the most recent 3 non-compliance cases.
- 9. Protocol files for the most recent 3 [investigator] conflict of interest cases reviewed by the convened IRB including the conflict management plan.
- 10. Protocol files for the most recent 3 unanticipated problems involving risks to participants or others.
- 11. Documentation related to the 3 most recent complaints received by the HRPP, including the protocol file.

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- 15. Five most recent funding agreements (not including contracts, subcontracts or federal grants).
- 16. Additional documents requested by site visitors.

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(Continued)**

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12. Results of the 3 most recent audits of investigators performed by your organization for each of the following:
 - a. Protocols reviewed by the convened IRB
 - b. Protocols reviewed by the expedited process
 - c. Protocols determined to be exempt (if your organization uses the exempt criteria)

These may be random/routine or for cause audits.
Include the protocol file along with the results of the audit.

13. A copy of the most recent internal audit of your IRB records.
14. Copies of the 3 most recent audits of your IRB and IRB records by sponsors or CROs.
15. Copies of audits of your IRB and IRB records by external consultants for the last year, if any.
16. Five most recent contracts or funding agreements (do not include subcontracts or federal contracts).
17. Additional documents requested by site visitors.