

AAHRPP Site Review Feedback

IRB member continuing education

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AAHRPP

- 5 year accreditation
- Initial 2008
- Reaccreditation 2011

The screenshot shows the AAHRPP website homepage. At the top left is the AAHRPP logo with the text "Association for the Accreditation of Human Research Protection Programs, Inc.®". To the right of the logo are several small national flags. Further right are links for "Forms", "Newsletter", "Contact Us", and a yellow "LOGIN" button. Below the logo is a dark blue navigation bar with the words "Learn >", "Apply >", "Connect >", and "Grow >" in white. A search bar is located on the right side of this bar. The main content area has a light blue background with a large heading "The Value of Accreditation". Below this heading is a paragraph of text and a yellow "Get Started >" button. To the right of the main heading is a white box titled "Tip Sheets" containing a yellow arrow icon and the text "Tip Sheet 26 Reviewing Research Involving Adult Participants with Diminished Functional Abilities", with a "View more >" link below it. Below the main content area is a white horizontal bar with two small circles. The bottom section of the page is divided into four columns: "Advance Newsletter" with links for "Advance March 2016 Edition: Preparing for Single IRB Review?" and "Advance Fall Edition 2015: Responding on Reaccreditation and AAHRPP's 'Contracts' Standard, Simplified and Clarified"; "What's New" with links for "AAHRPP Client Survey Results", "AAHRPP Accredits Eight More Research Organizations: Six in U.S., One Each in China, Saudi Arabia", "News Release: AAHRPP Accredits Three More Research Organizations", and "AAHRPP Translates Standards into Simplified Chinese"; "FEATURED Accreditation Guidance" with the text "As your Organization begins to consider applying for accreditation, take a look at the documents listed below for an overview of the procedures involved and the standards Organizations meet:" and two yellow arrow icons pointing to "Evaluation Instrument for Accreditation" and "AAHRPP Accreditation"; and "CASE STUDY From De Minimis to Gold Standard" with the text "Lehigh Valley Health Network routinely oversees approximately 400 research protocols." and a "Read More >" link.

Why accreditation?

Large investment by institution

- Goals
 - Implement best practices
 - Staff/faculty development
 - Culture of improvement
 - Risk mitigation
 - Reputational benefits
 - Competitive advantage

Standard I-4: The Organization responds to the concerns of research participants.

Element I.4.B.

No one evaluated and made improvements, as needed, to Thomas Jefferson University's outreach activities.

- Meet with campus representatives.
 - Inventory existing outreach.
 - Assess current goals .
 - Assess measures for evaluating effectiveness
 - Establish mechanism by which OHR will be notified of changes in outreach activities of other university offices.
 - Monitor by QI
 - Teach IRB members

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

Element II.1.B.

Although IRB Chairs, IRB Vice-Chairs, IRB members, and IRB staff were periodically evaluated, no one provided individual feedback.

Current process of evaluation of IRB members
will now include feedback to members

Standard II-2: The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.D.

When the convened IRBs requested substantive clarifications or modifications that were directly relevant to the determinations required by the IRBs, the protocol was not returned to the convened IRBs and was approved by the expedited procedure.

Revised policies

- Guidance for IRB Voting Criteria
- GA 113 – Section 4.1: Referral to OP 206 for voting options.
- OP 206 – Section 4.6.2: Voting options updated.
- RR 402 – Section 5: Referral to OP 206 for voting options.
- RR 404 – Section 3: Referral to OP 206 for voting options. Clarification of when expedited procedure may not be used.
- RR 408 – Sections 4.4 and 4.5: Referral to OP 206 for voting options. Clarification that expedited reviewer may not disapprove research.
- Minutes Template – Checkboxes for the voting options have been added to the 3 full review sections.

QI to measure adherence

Communicate to research community

Standard II-5: The IRB or EC maintains documentation of its activities.

Element II.5.B.

IRB minutes did not document all required information. IRB minutes did not reflect discussion of controverted issues by IRB members.

We are implementing the following plan to redress this issue:

1. Written notes taken will be reviewed by Chair, who will distill to brief statements describing each controverted issue.
2. Minutes template is revised to include section for controverted issues.
3. OHR staff and IRB Chair have been educated.
4. Adherence to the new procedure will be assessed on an ongoing basis by the QI team.

Next Steps

*Additional
documentation
requested*



- Dates of IRB education
- Details of feedback procedure
 - Already started with chairs
- How and when are we communicating with research community
- When will QI start
 - Already started