AAHRPP Site Review Feedback

IRB member continuing education
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- 5 year accreditation
- Initial 2008
- Reaccreditation 2011
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