

Notes from AAHRPP Site Visit

Dec. 16 - 19, 2008

- Active and successful participation of interviewees (*over 90 individuals*)
- Very positive feedback at conclusion of the visit
- Stanford HRPP will work with AAHRPP to address identified areas requiring improvements (*if any*)
- Results of the review will be presented to AAHRPP Council in March 2009, and final Reaccreditation Status will be determined

Areas Received Positive Feedback

- Highly engaged institutional officials
- Process of scientific review - *especially for studies not externally funded*
- Institutional COI policy
- Extent of communication between various entities involved in HRPP
- Knowledge of interviewees (all positions)
- e-Protocol
- Culture of continuous quality improvement
- All HRPP components working together
- Posters *in the conference room*

Areas for Possible Improvements

- Disapproval template letter - Does not contain language stating that an investigator can respond in person or in writing. Note - The process is clearly stated in the HRPP Policy Manual and is carried out in practice.
- Pregnant women's findings - Checklists and minutes do not clearly state why the protocol meets each specific condition of pregnant women's finding. Note - This is not a regulatory requirement.
- In social and behavioral science studies, more flexibility in interpretation of regulations in waiving and altering parts of consent process. Note - Site visitors advised caution be used in applying such flexibility.

January 5, 2009 Stanford received written report from AAHRPP

- One observation noted regarding Stanford's "Disapproval Letter"

The organization's disapproval letter stated that investigators could submit a new application in response to a decision of disapproval by the IRB. This practice was inconsistent with the organization's policies and procedures that stated that an investigator would be given an opportunity to respond to a decision of disapproval in person or in writing.