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.