Town Hall Meeting

WITH DR. RUTH O'HARA
SENIOR ASSOCIATE DEAN FOR RESEARCH

SEPTEMBER 30, 2022
10:00 - 11:00 AM

We'll start shortly...
Today’s Panelists

• **Dr. Ruth O’Hara**, Senior Associate Dean for Research – School of Medicine, Professor, Dept of Psychiatry

• **Tani Prestage**, Senior HRPP and IACUP Policy Lead, Offices of the Vice Provost and Dean of Research – Research Compliance
AAHRPP Visit

- Association for the Accreditation of Human Research Protection Programs (AAHRPP) will visit Stanford virtually on **October 20 and 21, 2022**, for Stanford’s reaccreditation.
- Many individuals have been selected by AAHRPP for interviews.
  - Researchers working with Human Subjects: Protocol Directors and Principal Investigators, and Study Coordinators
  - IRB Panel Chairs
  - IRB Panel Members
  - IRB Panel Staff
  - Leaders of Key Human Subjects Programs: e.g., CCTO, SAD-R Office, CRQ Office.
- Stanford’s Research Compliance Office (RCO) is notifying researchers who AAHRPP has identified for interview.
- RCO will hold sessions to prepare for these interviews: More information will be forthcoming on these sessions.
The Stanford University Human Research Protection Program is seeking re-accreditation by AAHRPP – The Association for the Accreditation of Human Research Protection Programs.

Stanford’s Institutional Official
Professor Kam Moler
Vice Provost and Dean of Research

AAHRPP will be virtually visiting our campus over Zoom as part of the re-accreditation process. When: October 20-21, 2022
AAHRPP Virtual Site Visit

• Research Compliance Office will hold sessions to prepare the selected individuals for the interviews.

• Revise your understanding of Human Subjects Regulations.
  – Cohorts under investigation (adult, pediatric, students (SDOC), athletes, etc.).
  – When in doubt obtain a Human Subjects Determination.
  – Even if doing a clinical trial not at Stanford, as a Stanford Faculty member you must have Human Subjects Approval here.
  – Special Categories (Stem Cell Research (SCRO), Animal Research (APLAC)).

• For more information, see: https://researchcompliance.stanford.edu/
  https://researchcompliance.stanford.edu/panels/hs

• For questions, contact Tani Prestage (tani.prestage@stanford.edu).
AAHRPP

Research Office Town Hall
Tani Prestage
Sr. HRPP and IACUP Policy Lead
AAHRPP Accreditation

- Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredits human research protection programs through a set of standards that evaluates HRPP quality and human research protections
- Stanford demonstrates through written policies and discussion with stakeholders about practices a commitment to ethical human research
- Process improves and strengthens systems that protect the rights and welfare of research participants
Human Research Protection Program

• Although the Institutional Review Board (IRB) is a major component in the protection of research participants, it is not the only part of the program

• HRPP is the collective effort by all of the components that participate in the conduct, review, approval, education, quality improvement, and facilitation of human research

• The whole HRPP ensures that Stanford complies with all applicable federal, state, and local regulations and requirements
Re-accreditation Process

- The process is based on comprehensive self-assessment of policies, review of various documents, and interviews
- Virtual site visitors will interview over 50 HRPP personnel
- Anyone who has a role in HRPP may be selected for an interview
- Investigators will be selected over diverse ranges of experience, protocol volume, types of research, and risk levels
- Site visitors will interview other study team members, key HRPP personnel, IRB members and RCO staff.
Interview Expectations

AAHRPP is interested in awareness of and knowledge about key human research concepts and policies, including, but not limited to:

• Regulations such as the Common Rule (45 CFR 46), FDA regulations, the VA, and NIH Conflict of Interest

• Procedures used to implement protection for participants such as elements of informed consent, strategies for minimizing risk, and reporting of unanticipated problems

• HRPP education, training, participant outreach, and monitoring campus-wide

• Awareness of your role within the Human Research Protection Program

• Communication with the RCO/IRB and where to find information
Please cite the CTSA in your work!

• The Center for Translational Sciences Award (CTSA) provides support to many researchers in the School of Medicine.

• Some examples of CTSA-sponsored services:
  – BERD statistical consulting services
  – OnCore participant enrollment tracking
  – Research participation and community engagement programs

• If you have received any of these services, please cite the CTSA in your published works and presentations!

• An example of the citation:
  – This work was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR003142 (PI: O’Hara).