Town Hall Meeting

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

AUGUST 26, 2022
10:00 - 11:00 AM

We'll start shortly...
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 Visit

- Association for the Accreditation of Human Research Protection Programs (AAHRPP) will visit Stanford virtually on **October 21 and 22, 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.
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 (Human Subject Stem Cell Research (SCRO)).

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

- For questions, contact Kathy McClelland (kathymcc@stanford.edu), Director of the RCO.

- Session will be hosted at our Town Hall, September 30th, 2022.
Research Office Oversight:
SAD-R

Dr. Ruth O’Hara,
Senior Associate Dean for Research
Lowell W. and Josephine Q. Berry Professor
of Psychiatry and Behavioral Sciences,
Stanford University School of Medicine

sadrmedicine@stanford.edu
**Significant Research Resources in SoM to Support Your Research**

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Significant Research Resources in SoM to Support Your Research

- Biobank
  Director Justin Vincent-Tompkins
  http://med.stanford.edu/sbc/biobank.html

- Clinical Translational Unit
  Director Raj Prasad
  https://med.stanford.edu/ctrunit.html

- Clinical Research Quality
  Director Jennifer Brown
  https://med.stanford.edu/spectrum/study-team-resources/clinical-research-quality-crq.html

- SoM Research Development Office
  Director Sandra Holden
  https://med.stanford.edu/srdo/contacts.html

- Quantitative Sciences Unit/BERD
  Director Manisha Desai
  https://med.stanford.edu/qsu.html
Faculty Director: Associate Dean, Jon Bernstein, M.D.

- Conflict of Interest Review Program Staff Contacts:
  - Barbara Flynn at bflynn@stanford.edu or 723-7226
  - Shannon Shankle at sds@stanford.edu or 723-0969

- Relevant Websites:
  - https://doresearch.stanford.edu/research-scholarship/conflicts-interest
Translational Workforce Development (TWD)

Essentials of Clinical Research (10 two-hour sessions held annually in winter quarter)
This course provides an overview of basic principles of clinical research design, including biostatistics; study design and interpretation of diagnostic and predictive test studies; and required and desired elements of clinical trial protocols. Participants will be introduced to the regulatory aspects of clinical research conduct and oversight, Good Clinical Practice (GCP) principles, and ethical dimensions of clinical research.

Intensive Course in Clinical Research (ICCR) (held annually in September)
A one-week immersion course in study design for novice clinical investigators, senior residents, fellows, and junior faculty at Stanford pursuing a career in clinical and translational research.

Research Career Accelerator Program (meets monthly)
A monthly seminar series designed for Stanford junior faculty, fellows, and postdocs who are recipients of individual career development awards (CDAs) from the government (e.g., K awards) or from professional societies. ReCAP provides an opportunity for CDA awardees to interact with their peers in the School of Medicine community and to learn from senior faculty how best to position themselves for future success.

Clinical Research Operations Program (on-going)
Offers 4 to 5 classes a month specific to clinical research involving human subjects. The goal of the program is to raise the quality of clinical research across Stanford and to enhance the career growth of clinical research personnel.

More information
Email: researchoffice_training@lists.stanford.edu
Website: https://med.stanford.edu/spectrum/education-and-training.html
Office of Clinical Research Quality

Regulatory Support

- Developing standard operating procedures, clinical trial policies, and best practices within the School of Medicine.
- Conducting quality audits, both routine and upon request
- Assisting with corrective and preventive action when needed
- Education and training via Spectrum's programs for researchers, faculty, trainees, and staff on Good Clinical Practice and Clinical Research Operations; and ad hoc upon request
- Tracking and trending clinical trial compliance from a variety of internal and external sources
  - IND/IDE support
  - CT.gov support
  - Investigator and coordinator training
  - Audit preparation and support
  - [https://med.stanford.edu/spectrum/study-team-resources/clinical-research-quality-crq.html](https://med.stanford.edu/spectrum/study-team-resources/clinical-research-quality-crq.html)
  - clinicalresearchquality@stanford.edu
When in Doubt?
Do not know where to start?
You are stuck or delayed?

PLEASE REACH OUT! DO NOT WAIT!

roh@stanford.edu
ANNOUNCEMENTS
CALL FOR ABSTRACTS
Stanford Maternal & Child Health Research Institute Symposium

Abstracts Due: September 5, 2022
Symposium with Moderated Poster Session: October 20, 2022

Share your latest research developments in maternal or child health, learn from experts in the field, and connect with your colleagues at the 2022 MCHRI Symposium!

Visit the Abstracts and Poster Submission Symposium Website for more details
https://stan.md/3wtXpUX
2nd Annual Precision Mental Health and Wellness Symposium

The future of personalized neuroscience and mental health

Wednesday, September 28
9 am – 5 pm

Registration now open!

Opening Plenary Speaker:
Joshua A. Gordon, M.D., Ph.D.

Opening Plenary | Q&A

Keynote Speaker:
Ruth O’Hara, Ph.D.
Cognition, emotion and risk factors across the lifespan

Keynote Speaker:
Boris Heifets, M.D., Ph.D.
Rapid acting mental health therapeutics

Keynote Speaker:
Zhenan Bao, Ph.D.
Next-generation wearable developments for wellness and precision mental health

Keynote Speaker:
Olu Ajilore, M.D., Ph.D.
Neural and digital signatures of affective disorder

Plenary Speaker:
Karl Deisseroth, M.D., Ph.D.
Translational neuroscience of drug-altered states

Plenary Speaker:
Alan Schatzberg, M.D.
Innovative therapeutics for mood disorders