Resources Supporting the HRPP

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Research Compliance Office
Examples of Different Types of Research

- Cancer Study
- Genetic Testing
- IND Research
- Retrospective Chart Review
- Behavioral Deception Study
- Tissue Sample
- Child cognitive studies
- Device Research
Resources Supporting the HRPP

STANFORD* provides for communication and interaction for its units that might be involved with conduct of human research (AAHRPP Element 1.2.D)

* STANFORD refers to the 5 affiliates, SU, SHC, LPCH, VAPAHC, and PAIRE.
Communication and Interaction

- Stanford University is accredited by AAHRPP
- Follows AAHRPP standards

(The responsibility for) protecting research participants is not limited to the...IRB. Accreditation examines...the organization as a whole...(as) a coherent, effective system to protect research participants

Principle 2, AAHRPP
AAHRPP Requirements

STANDARD I-2:

• (We) assure the availability of resources sufficient to protect the rights and welfare of research participants

Elements established to provide resources for the HRPP that:

• I.2.A. Are **sufficient** for conducting its activities

• I.2.C. Are **necessary for...protection, care** of research participants, and **safety** during the conduct of the research

• I.2.D. provide for **communication and interaction**...involved in the conduct of human research.
Communication

- Radiation Safety
- Biosafety
- Stem Cell Research
- Cancer Center Clinical Trials
- Conflict of Interest
- Security and Controlled Access (deal with pharmacies)
- Office of Technology Licensing
- Research Management Group (part of the Office of Research Administration)
Radiation Safety Committee
ex officio member of Medical IRB’s

Looks at:
• Radioactivity from isotopes or radiochemicals (e.g. P$_{32}$, radioactive iodine)
• Radiation from instruments (e.g. X-ray machines)

- Evaluate the cumulative amount & amount per exposure - dosimetry
- Mainly in nuclear medicine or x-ray protocols
- Limits set for workers, pregnant women, children and adults
Radiation Safety Committee
ex officio member of medical IRB’s

Looks at:

• Radioactivity from isotopes or radiochemicals
  (eg: P\textsubscript{32}, radioactive iodine)
• Radiation from instruments (e.g. Xray machines)

Without this approval, a study will either be
tabled to a future convened meeting, or will be
approved contingent on Radiation Safety
Committee recommendation for approval
Biosafety Panel
ex officio member of Medical IRB’s

- **Biosafe** - creating a safe environment for humans & ensuring no impact to environment.

- **Biohazardous** materials include all infectious organisms that cause disease in humans, or cause significant environmental/ agricultural impact.

- Deal with protocols that have recombinant DNA, transgenic plants or animals, and human gene transfer.
Biosafety, cont.

- Protocols...requiring Biosafety review **must be reviewed and approved** in addition to review by the IRB

- A new protocol generally **will not be presented** at an IRB meeting until the Biosafety Panel has approved it
Stem Cell Research Oversight

SCRO:

- Advises...(on) issues related to research with human stem cells and covered stem cell lines
- Reviews and approves stem cell research
- Drafts policies and procedures
- Effective October ‘09 - Integration of current SCRO panel into Medical Panel 3 to form IRB/SCRO Review Panel
Conflict of Interest Committee

- **COI** – a *divergence* between an individual’s private interests and his/her professional obligations to the university.

- **ICOI** – "Institutional conflict of interest
  
  def:
  
  “a situation in which the financial investments or holdings of SU…or…of institutional leaders might affect/reasonably appear to affect institutional processes for the *design, conduct, reporting, review or oversight of human subjects research*"
The IRB will not approve a protocol until any (and all) disclosed COI has been reviewed and resolved by the COIC.

As appropriate, a plan or strategy to adequately eliminate, mitigate, or manage the conflict can be determined necessary by the COIC.
Financial Considerations RMG, OSR, ICO and OTL

Depending on the funding source, either grant/contract finalization or departmental approval is required before research can begin.

These entities are responsible for providing:

- contract negotiations
- handling industry agreements,
- dealing with material transfer agreements (MTAs)
- intellectual property (IP)
Financial Considerations RMG, OSR, ICO and OTL

**RMG** – Research Management Group
**OSR** – Office of Sponsored Research
**ICO** – Industrial Contracts Office
**OTL** – Office of Technology Licensing
Cancer Center Clinical Trials Office

- **CCTO** is part of the Cancer Center in the School of Medicine
- Provides regulatory, administrative, research, and educational services to investigators conducting clinical trials
  - The SRC (Scientific Review Committee) review is conducted in parallel with IRB review. **Both approvals are required** to conduct HS research
- The Stanford Cancer Center requires that adverse events be **reported** to the Data Safety Monitoring Committee (DSMC).
- The DSMC determines which reported items are sent to IRB