April 24, 2006

Dear Colleagues,

Stanford University’s Human Research Protection Program is now fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). That signifies that we meet their national standards to protect human research participants. As part of meeting their standards, we must provide additional oversight in two areas.

1) Investigator Sponsored Trials (ISTS)
When physicians hold their own Investigational New Drug (IND) number or Investigational Device Exemption (IDE) number, they are responsible for fulfilling all regulatory functions usually performed by sponsors, including reporting requirements. SPCTRM will be working with investigators and their research team members, so that they are aware of their obligations. After SPCTRM has completed their education, the Research Compliance Office staff will contact investigators to schedule an audit. The list of sponsor obligations is found in http://humansubjects.stanford.edu/research/documents/SponsorRequirements.doc

2) Consent Observation
A Stanford IRB can request observation of a research participant being consented in certain selected instances. The Research Compliance Office will observe and report findings back to the IRB. Protocols selected for observation will include those that involve:
- High risks to participants
- Particularly complicated procedures or interventions
- Potentially vulnerable populations (e.g., ICU patients, children)
- Study staff with minimal experience in administering consent to potential study participants, or
- Other situations where the IRB has concerns that consent process might not be proceeding well.

The consent observation procedure is found at http://humansubjects.stanford.edu/research/documents/ObservationConsentingProcess.pdf

In addition, SPCTRM and the Stanford University Internal Audit Department will coordinate the timing of the education sessions and future audits related to budget, billing and regulatory practices.

Please let us know if you have suggestions about how we can best implement these AAHRPP requirements. You may also contact Kathy McClelland, Research Compliance Director (723-4697) with questions and comments.

Thank you for your help with this important matter.

Arthur Bienenstock
Vice Provost and Dean of Research

Ann M. Arvin
Associate Dean of Research