Welcome:
Jeff called the meeting to order at 9:05 a.m.

As a follow-up from the last HSPB meeting, Jeff invited Board members to provide input on what content to place on the HSPB member roster. Members agreed that the roster should list HSPB member name, affiliation, and email.

Action Item: Update HSPB member roster with member name, affiliation, and email and circulate updated roster to members via email.

Approval of minutes from meetings of 1/15/2010 (Jeff Cheek)
The Board accepted the minutes of the 1/15/2010 meeting as submitted.

Major discussion item: Human Subjects Assistance Program (HSAP) (Karen Moe)
Karen provided a status report on the revised UW HSAP. This will be the new name for the UW Human Subject Compensation Plan, when this major revision is implemented.

Current Plan. The current plan has existed since 1972, as a way to compensate human subjects for adverse events experienced as a result of research. UW is one of the few universities in the nation to have such a plan. The plan was developed out of consideration of three factors: ethical principles; risk
management of human subjects research; and encouraging individuals to participate in human subjects research.  It is a University policy, not an insurance plan.

Characteristics of the current plan:
- Applies to all UW research studies regardless of the location except for research initiated and sponsored by industry.
- "No-fault"
- Covers physical harms
- Reimbursement includes up to $10,000 for out-of-pocket expenses related to treatment of a research-related adverse event.
- Write-off of bills for care of the adverse event, if delivered at a UW Medicine facility.

Rationale for major revision. The plan has not been significantly revised since its inception in 1972. Reasons for this major revision include:
- There have been many significant changes in the regulatory and healthcare environment, including the Medicare policy of paying for treatment of adverse events in many clinical trials. The current plan is structured in a way that does not allow the University to take advantage of this opportunity, when appropriate.
- The nature of the University has changed significantly, with numerous new affiliates and other relationships now established. It is important to provide additional clarity about which of these situations are, or are not, addressed by the plan.
- There is a need for additional documentation and communication about the plan, particularly the procedures by which it is implemented.
- There is a need for a review of the existing specific elements of the plan.

Revision process and status. About three years ago, an ad hoc committee was assembled with representation from the Human Subjects Division, Risk Management, UW Medicine, Office of Sponsored Programs, the Attorney General’s office, and researchers. The committee has thoroughly reviewed all aspects of the current plan, and has explored several options for changes. The committee and its executive sponsors recently finalized the revised plan policy and elements, and it is now working on the revised procedures and forms. When that work is completed, the plan will be presented to the Board of Regents for review and approval. The revised plan is likely to be implemented by the end of the calendar year.

The specific changes. The specific revisions to the plan include the following:
- A significantly-improved description of the plan, for use in consent forms.
- A $250,000 limit to the write-off of UW Medicine charges for treatment.
- A requirement to report the adverse event within one year of the end of the treatment, procedure, or event that caused the event.
- Two different versions of the plan: one covers all research-related adverse events (e.g., for healthy volunteers) and the other covers only unexpected research-related adverse events (e.g., for non-healthy volunteers who are participating in a study for which there is good reason to expect each individual subject to benefit from the study).
- Slight expansion of the definition of an adverse event, from “physical harm” to “medical problem”.
- Establishment of a HSAP Steering Committee, for governance and decision-making.
- New procedure for determining whether the HSAP applies to a specific adverse event. This determination is currently made by the researcher. In the revised HSAP, the determination will be made by the HSAP Steering Committee. The Committee will consider the researcher’s assessment, together with the assessment of other appropriate medical consultants, as needed.
- Additional written policy, procedures, tools, for:
  o Identifying which studies are addressed by the revised HSAP
  o Reporting adverse events to the HSAP
  o Evaluating adverse events
  o Reimbursements / charge write-offs
Karen distributed the draft versions of some of the tools. (1) A formal flow chart will be used to identify whether a study is eligible for the HSAP before the study starts. This decision will be incorporated into the IRB initial review process. The decision includes several factors, including the source of funding, which institution administers the funding, and the identification of the research institution on the consent form. (2) Another flow chart describes the process for determining whether the HSAP applies to a specific adverse event in a HSAP-eligible study.

After the procedures and tools are finalized, the next steps will include chartering the Steering Committee, give update to the executive sponsors, and present to the Board of Regents to amend existing standing order of compensation plan. Then HSD and the Steering Committee will develop a communications/education plans for campus, IRB members, and HSD staff.

Studies that already exist will continue to be covered by the current (soon-to-be-former) plan.

**Brief process improvement reports (Karen Moe)**

Karen provided a brief update of current process improvement projects completed in HSD. She will provide a report each meeting of those projects that have completed.

- **A document website for HSPB members located on Catalyst has been created, active as of yesterday.** Karen will send link later today or Monday. The website requires a UW NET to access. Materials related to beta test of application revision have been posted.
- **Seattle Biomedical Research Institute (SBRI) agreement:** UW students doing research with researchers at SBRI no longer need to obtain “dual” IRB review through the UW and through SBRI. Instead, the UW will rely upon SBRI’s review (which is performed by Western IRB). This should enhance UW’s relationship with SBRI in providing great opportunities to students.
- **Material Transfer Agreements (MTAs):** Researchers need to sign an MTA when sending biological specimens off campus. MTAs involving human subjects issues are handled by OSP. There has been some misunderstanding when an MTA is needed relative to when IRB approval will be granted for sending samples out, based in part on some out-dated information in the flow chart on the MTA website. The flow chart is being corrected, to give researchers more accurate information about the now-more-efficient process for executing a MTA.
- **Repositories:** There are several large, old, and very active research repositories on campus that submit one to four modifications to the IRB every week. These modifications are typically based on procedures developed with the repository was first established. Federal guidance and “best practices” developed in the past several years has made many of these procedures out-of-date and most of the modifications unnecessary. HSD has gradually been identifying these repositories and working with repository staff to clarify when they do or don’t need to submit a modification to the IRB. This is significantly reducing the work for the repository staff and for the IRB committee with oversight responsibility for the repository.

**Follow up on previous discussion items (Karen Moe)**

- **Michigan pilot project described at last meeting:** We were considering whether to participate in a pilot project led by the University of Michigan that would take advantage of some seldom-exercised regulatory flexibility for certain frequent types research. At the last meeting, Karen reported that she would solicit HSD staff input on our current ability to take on another project. Since then, she determined that the workload in the relevant staff areas has increased significantly in the past several months and that it is not possible for the staff to take on another project for a while. However, HSD will implement these changes independently of the Michigan-led group after completing some other current projects.
- **IRB application form revision (follow up from previous meeting):** HSD doing a “beta test” of the revised application form, starting this week. The beta test forms are located on Policy Board’s Catalyst site. Members can look at the documents and provide feedback. Karen invited members to let her or Sharon Elsayed know if they know of anyone interested in beta testing.
• **Issues and activities related to genetics research:** HSD still plans to hold a discussion forum for researchers to talk about GWAS studies and DBGap studies and how IRB is treating and reviewing the genetics part of the application. The timeline for creation of the forum is the last half of April.

**Request: desperate need for MDs on IRBs (Karen Moe)**
Karen reiterated that there is a desperate need for MDs to serve as members on the IRB Committees. HSD will reach out to UW Medicine about this in a variety of ways. Anything HSPB members can do to help would be greatly appreciated.

**New business / future agenda items (Board Members)**
Next meeting is scheduled for May 21. Jeff will send request for agenda items per usual.