

**From:** David Eaton  
Interim Vice Provost for Research 

**To:** Jeffrey Cheek, Associate Vice Provost for Research Compliance & Operations  
Karen Moe, Asst. Vice Provost for Research; Director, Human Subjects Division  
Zane Brown, Chair, UW IRB Committee A  
Alan Wilensky, Chair, UW IRB Committee B  
Elizabeth Berggren, Chair, UW IRB Committee C  
Jeffrey Purcell, Chair, UW IRB Committee D  
Carl Rimmel, Chair, UW IRB Committee G  
Karen Thomas, Co-Chair, UW IRB Committee J  
Deborah McCutchen, Co-Chair, UW IRB Committee J  
Kathryn Korslund, Chair, UW IRB Committee K

**Date:** December 30, 2010

**Re:** Roles, responsibility, and delegated authority of the Human Subjects Division and the UW Institutional Review Boards

## **1 - Purpose**

The purpose of this memo is to clarify roles and responsibilities within the Office of Research with respect to human subjects research at the University of Washington. By this memo, I also delegate authority for specific human subjects research oversight activities from me as the University of Washington (UW) Vice Provost for Research to other individuals or entities within the Office of Research.

This memo supersedes and replaces the memorandum entitled "Delegation of authority UW IRBs" dated August 17, 2007, from Mary Lidstrom, Vice Provost for Research.

## **2 - Background**

The UW Human Research Protection Program is comprised of many organizational components that work together to oversee UW research involving human subjects. The Human Subjects Division (HSD) and the Institutional Review Boards (IRBs) are two key components. They reside within the Office of Research, under the leadership and authority of the Vice Provost for Research.

The UW is committed to protecting all human subjects who participate in UW research projects, and to being a leader in the research community by consistently demonstrating these core values. As indicated by its Federalwide Assurance, the UW complies with the human subjects regulations known as the Common Rule (45 CFR 46) for all federally-funded research. The UW also complies with all other applicable federal and state regulations pertaining to human subjects

research. These regulations detail the responsibilities of the organization for protecting human subjects. However, since these regulations do not always assign those responsibilities to a specific organizational component, it is incumbent on the University to clarify roles and responsibilities pertinent to its Human Subjects Protection Program. The UW's Vice Provost for Research has the authority to administer and assign these responsibilities. With this memorandum, I hereby delegate the authority and responsibility for the University's implementation and oversight of all applicable federal, state and institutional regulations and guidelines pertaining to the protection of human subjects as described below.

The Vice Provost for Research has previously delegated authority to the Associate Vice Provost for Research Compliance and Operations (AVP-RCO) to serve as the Institutional Official on the Federalwide Assurance with the federal government. The AVP-RCO is responsible for fulfilling all federal obligations and expectations of the Institutional Official for a human subjects research program. The AVP-RCO has the authority and responsibility to appoint chairs and members of the IRBs. In addition, HSD and the IRBs are under the direct supervision of the AVP-RCO.

### **3 – Roles and responsibilities of HSD**

HSD is the central point of contact for researchers, research subjects, regulatory agencies, and other UW offices concerned with human subjects research. HSD is responsible for the administration and support of the IRBs and the IRB's review process, and for ensuring the compliance of that process with all applicable regulations. HSD management and staff are University employees whose positions exist within the standard organizational structure of the University, with all attendant reporting responsibilities, obligations, and accountability. HSD's primary responsibility and accountability is to the University. The HSD Director has overall responsibility for the administration of HSD and the IRBs.

I, as the Interim Vice Provost for Research, delegate to the HSD Director the authority and responsibility for establishing policies and procedures for HSD and the IRBs, within the limits described below. I also delegate to the HSD Director the role and authority for assigning the institutional responsibilities described in federal and state human subjects regulations that are not assigned to other specific entities, offices, or individuals by those regulations or by the Vice Provost for Research.

The HSD Director reports to and is expected to work closely with the AVP-RCO. In addition, the HSD Director is expected to consult with other UW offices, groups, and individuals in developing policies and procedures, and in interpreting regulations and regulatory guidance, as deemed appropriate. Examples of these entities include: the UW Division of the state Attorney General's office; chairs and/or members of the IRBs; HSD management or staff; Human Subjects Advisory Board; and other UW research compliance offices. However, the HSD Director retains the primary authority to establish HSD and IRB policies and procedures, with the required concurrence of the AVP-RCO on policies.

This memorandum is not intended to provide an all-inclusive list of the specific roles and responsibilities of HSD, as delegated to the Director. However, specific examples are listed here in the interest of clarity.

The Director of the Human Subjects Division has the delegated authority and responsibility to perform the following actions (and may also assign these responsibilities to specific HSD staff as approved by the AVP-RCO):

A - Regulations, guidance, policies and procedures

- Interpret regulations and regulatory guidance about human subjects research for HSD, the IRBs, UW researchers, and other UW offices.
- Provide regulatory expertise and guidance to the IRBs.
- Develop, revise, and implement HSD and IRB policies and procedures for all UW human subjects research, regardless of funding source. Policies and procedures must be consistent with applicable federal and state regulations, and with the terms of the UW's Federalwide Assurance. Policies must have the written concurrence of the Institutional Official on the UW's Federalwide Assurance. Though HSD is expected to consult as appropriate with stakeholder groups, the Human Subjects Advisory Board, and others when developing or revising policies and procedures, the Institutional Official's concurrence with policies is the only required approval.
- Promote and expect consistency in interpretation and implementation of policies and procedures by HSD staff and across the IRBs.

B – Human subject safety and welfare

- Suspend, on an emergency basis, IRB approval of some or all parts of a human subjects research activity as necessary to protect the safety and welfare of human subjects and when there is insufficient time to bring the situation to the overseeing IRB.
- Require actions or changes in connection with minor non-compliance.

C – Determinations

- Determine whether specific activities are research and/or involve human subjects as defined by appropriate federal and state regulations and guidance.
- Determine whether specific human subjects research activities qualify for exemption from appropriate federal regulations, using the criteria described in federal regulations and guidance.
- Determine whether the UW is engaged in specific research activities, as defined by federal regulations and guidance about engagement.
- Determine whether specific activities or events represent researcher non-compliance, serious non-compliance, continuing non-compliance, unanticipated problems, or adverse events, using definitions established as HSD policy.

D - Communication and coordination

- On behalf of the UW and the UW IRBs, communicate and coordinate with regulatory entities (including other UW offices and IRB offices at other institutions) that regulate or have oversight of activities that may involve human subjects research.
- On behalf of the UW and the UW IRBs, communicate with research sponsors, after appropriate concurrence from and coordination with the UW Office of Sponsored Programs.

#### E - Administration of the IRB review process

- Nominate new IRB members and chairs to the AVP-RCO.
- Establish the operational procedures of IRB meetings.
- Create and revise of the forms used to provide the IRBs with materials for review.
- Screen materials submitted to the IRB for accuracy, clarity, and completeness; require revisions or additions as necessary to make the materials ready for IRB review.
- Schedule IRB review work (subject to the limitation that the IRBs retain the “at will” authority to review information about situations that it believes may pose a risk to subjects or others).
- Administratively close activities that are pending IRB approval, when the researcher has not responded within a specified period of time.
- Administratively close (terminate) research activities whose IRB approval has been lapsed for more than a specified period of time, when the researcher has not responded to repeated requests for information or specific actions.
- Investigate (or delegate the investigation of) complaints, possible non-compliance, and research problems (including but not limited to adverse events and effects) by communicating with researchers and other appropriate individuals or entities. This is distinct from the role of the IRBs, which have the regulatory authority and responsibility to determine which projects require verification from sources other than the investigators that no material changes have occurred since previous IRB review, but not to perform investigations or audits. HSD and the AVP-RCO retain the authority to determine how to fulfill the IRB’s request or requirement for verification or additional information when doing so involves site visits, investigations, or audits.

HSD does not have the authority to (1) approve research that has not been approved by the IRB; (2) disapprove, suspend, or terminate research except as described above; or (3) direct an IRB to vote for a specific option when the IRB is making a decision or determination, though HSD may inform the IRB about relevant information including past IRB decisions or determinations in similar situations.

#### **4 - Roles and responsibilities of the IRBs**

The UW IRBs are University committees that have the authority, roles, and responsibilities described in federal and state human subjects regulations for such institutional research review boards. Except where indicated in those regulations, they do not operate autonomously from the University. With this memorandum, I delegate additional authority and responsibility to the IRBs for the following specific corrective and/or enforcement actions with respect to all University human subjects research, regardless of funding, location, applicable federal regulations, and IRB approval status:

- Suspend some or all parts of a human subjects research activity
- Terminate IRB approval for some or all parts of a research activity that was previously approved by the IRB
- Require modification of some or all parts of a human subjects research activity
- Require additional information from researchers
- Require researcher training and education
- Change the frequency of continuing review

- Require the researcher to provide information to subjects or others, in coordination with other applicable laws, regulations, and UW policies
- Require re-consenting of human subjects
- Require reports after specific milestones
- Require HSD to report a problem or concern to funding agencies/sponsors, other UW offices, co-investigators, collaborators, and/or collaborating institutions
- Require verification of information from sources other than the researcher, subject to the limitation that HSD and/or the AVP-RCO retain the authority to determine how to fulfill the IRB's request or requirement for verification or additional information when doing so involves site visits, investigations, or audits.
- Require additional monitoring of research procedures or outcomes
- Require that subject identifiers (or the link between data and identifiers) be destroyed if those identifiers were collected or relevant research procedures were performed without prior IRB approval.

The UW IRBs do not have authority for the following actions: (1) require that data not be published or presented; (2) require that data not be used for a thesis or dissertation; or (3) require that data be destroyed. Such authority remains with the relevant UW institutional office or authority. However, the IRB may require the HSD Director to take its recommendation for one or more of the above actions to the appropriate UW institutional office or authority, for a timely review and decision.

By the authority delegated to the Vice Provost for Research and by that defined under the University's Federalwide Assurance for its Human Research Protection Program, I declare these actions to be University policy effective as of the date of this memorandum.

cc: Wendy Brown, HSD Assistant Director of Quality & Compliance  
 Sharon Smith Elsayed, HSD Assistant Director of Education & Communication  
 Shannon Sowards, HSD Assistant Director of Operations