

April 7, 2010

HWS IRB POLICY DOCUMENT

**PART A: IRB Roles and Responsibilities
At Hobart and William Smith Colleges**

Provost:

- Holds institutional responsibility to ensure that HWS complies with Title 45 of the *Code of Federal Regulations*, Part 46 (45 CFR 46), which implements amendments to the Public Health Service Act (PL 99-158) requiring all institutions engaged in research involving human subjects to establish an IRB.

IRB Administrator:

- On behalf of Provost, ensures compliance with the terms of Hobart and William Smith Federalwide Assurance;
- Has sound knowledge and understanding of the Federal Guidelines relating to the Protection of Human Subjects;
- Has completed mandatory OHRP training associated with the federal assurance process;
- Ensures that all materials needed for IRB review are appropriately logged and available to IRB members in a timely manner;
- Prior to sending applications to IRB members, conducts an initial screen of all submitted materials to ensure completeness and use of appropriate form. Contacts applicants as needed to make necessary changes.
- Communicates pertinent information and IRB actions in a timely manner to IRB members, the IRB Chair, and investigators;
- Ensures that IRB documentation, both current and archival, is fully and accurately maintained in the Provost's Office in accordance with HWS policy, IRB policy, and federal regulation;
- Ensures that the IRB website is accurate and that it contains the most current version of forms, policies, and procedures;
- Communicates the IRB's role and schedule to HWS community semi-annually.

IRB Chair:

- Has sound knowledge and understanding of the Federal Guidelines relating to the Protection of Human Subjects;
- Sets the agenda for IRB meetings in consultation with committee members
- Convenes and conducts IRB meetings as scheduled;
- Ensures that submitted research is reviewed efficiently and consistent with federal regulations;
- Reviews and approves applications for expedited review, continuations, and amendments consistent with federal regulation and HWS policy.

(*Roles and Responsibilities Endorsed by the IRB on May 11, 2009)

PART B: HWS IRB Policies

- **Definition of Quorum** (8/7/06)

The HWS IRB defines a quorum as five members, the minimum number required by Federal Regulation (CFR, Title 45, Part 46).

For review of federally funded research projects, a quorum exists when a majority (5) of members are present, including at least one member whose primary concerns are in non-scientific areas.

For non-federally funded research, the IRB may consider a proposal by e-mail if an in-person quorum cannot be obtained and there is urgent reason to do so. E-mail consideration of a proposal requires that no member of the committee objects to such a procedure (i.e., want an in-person meeting). Approval of a proposal considered by e-mail requires the unanimous consent of at least a quorum of the IRB.

- **Changes in Scope from Original Proposal** (10/2/06)

A researcher is obligated to notify the Chair of the IRB of any change in project scope from that originally approved by the IRB. The Chair will then determine whether or not the proposed change requires a new submission to the IRB and notify the researcher of that decision.

- **Process for Proposal Revisions** (11/2/06)

When corrections or modifications are needed, the IRB committee will determine whether such revisions require full IRB review, Chair review, or Coordinator notation.

- **Observation of Online Public Behavior** (11/13/06)

Data collected using publicly available on-line sources (e.g., chat rooms) can be used in research projects and the researcher does not need to submit an application to the IRB as long as: 1) there is no interaction between the researcher and the subject, and 2) the subjects cannot be identified by the researcher.

- **Active and Passive Parental Consent for Research with Minors** (9/15/08)

In principle, the IRB allows the use of passive parental consent for research with minors on condition that the researcher obtain written permission to employ passive consent from the head of the relevant school or school district. (Note: the researcher is not required to provide a copy of the letter to the IRB.)

Researchers are advised, however, that this policy does not guarantee that passive consent is acceptable in every instance, only that the IRB is willing to consider its use on a case-by-case basis.

- **Oral History Research** (9/15/08)

Research based on oral history requires submission of an application to the IRB.

- **Research on Protected Categories—Policy on HWS Students** (9/15/08)

HWS students under age 18 can participate in research without parental consent, when their participation is inadvertent. In other words, if the purpose of the study is to examine perspectives of 17-year olds, then even HWS students would need parental consent. But a broad study of HWS students (who are by far all 18 and older) that inadvertently captures some 17 year olds is acceptable. Additionally, non-minor individuals from other protected classes can participate if their protected status is irrelevant to the purposes of the research and the research poses no additional risks to the subjects. Any research that targets minors or other protected categories required parental consent (for minors) and a full review (for all protected categories).

- **Continuation of IRB-Approved Research Beyond Four Years** (9/29/08)

If more than four years have elapsed from the end date of the original approved proposal, the IRB, Chair will re-evaluate that proposal when a continuation request is submitted to ensure that the research is still consistent with both Federal regulations and current IRB policy. In the event that the Chair identifies any inconsistency, he will bring that issue to the full IRB for resolution.

- **News Reporter Activities Conducted by HWS Students** (10/20/08)

News reporter activities conducted by HWS students do not require IRB approval.

- **Chair Prerogative Regarding Form B or Form D** (no specific reference in Minutes)

If the Chair has questions or issues regarding information contained in Form B or Form D, s/he can bring the application to the IRB for full review, rather than rejecting the applications outright.

- **Institutional Research** (11/10/08)

In general, the IRB does not consider institutional research subject to IRB review. In making a specific determination, the IRB will be guided by Federal policy as specified in [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101\(b\)\(1\)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101(b)(1)).

- **Minor Editorial Changes** (7/29/09)

With the consent of the researcher, the IRB Coordinator may make minor necessary editorial changes on a proposal; the Coordinator will date and initial any such change.

- **Change in Principal Investigator** (7/29/09)

If a new Principal Investigator takes over previously IRB-approved on-going research, s/he is not required to submit an entirely new Form A application but rather should submit a Form A-Continuation indicating the change in personnel.

- **PI Submits Form D, Subsequently Wishes to Publish** (no reference in Minutes)

Course-based research approved under a Form D exemption normally cannot be published or presented elsewhere. If a researcher does want to publish or present data collected under a Form D exemption, unless each participant has signed a release, the researcher may do so only if: 1) participants were not told that the data would not be published or presented, 2) publishing or presenting the data poses no additional risk to participants, and 3) permission to publish or present the data is obtained by submission of a new Form A to the IRB.

- **Delegation of Chair Responsibilities** (8/24/09)

In those instances in which the Chair has a conflict of interest in a proposal, s/he must recuse himself from all action and discussion involving the proposal, and delegate such responsibilities to another member of the IRB.

When the Chair determines that the IRB workload is excessive, s/he can delegate review of Form B and Form D applications to other members of the IRB.

- **External Researchers** (no specific reference in Minutes)

In addition to obtaining approval from the IRB, external researchers also need to obtain written approval from either the Vice President of Student Affairs (if the research is on HWS students) or the Provost (if the research is on HWS faculty or staff).

- **Conduct of Meetings** (1/20/10)

The IRB will conduct its meetings based on Robert's Rules of Order.

MPB
2/3/10/ Finalized April 7, 2010