Description of the HRPP

The HRPP at Utah State University protects the rights and welfare of human research participants who are included in the university’s research activities. For purposes of the HRPP, and as anticipated in USU’s Federal-wide Assurance, the institution is considered to be engaged in research whenever one of its employees or agents 1) intervenes or interacts with living individuals for research purposes; or (ii) obtains individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

An individual is considered to be an agent of USU if the individual is performing institutionally designated activities or exercising institutionally delegated authority or responsibility. This would include, among others, students or volunteers when interacting with human participants for classroom activities that qualify as human research; employees when conducting research with participants or when using or controlling human participant records; and any individual conducting research with participants at USU-controlled facilities or for whom USU has responsibility. Examples of individuals who would not be considered agents would be employees when conducting human research while on sabbatical through a separate institution; or employees when conducting research for another entity while acting in a consulting role that is not assigned by USU. However, if data derived from consulting work could reasonably be expected to be used later for university related purposes, the employee would be considered an agent.

The HRPP fosters:

- Awareness of and respect for the rights and welfare of human research participants in USU’s research activities,
- Compliance with federal and state regulations by USU’s investigators and employees,
- Alignment of USU’s research activities with ethical principles and federal guidelines,
- Effectiveness in the operations of the Institutional Review Board(s) (IRB) as it carries out its responsibilities for reviewing human research activities, verifying its conformance to federal statutes, and protecting research participants, and
- Continuous improvement of the Program’s efforts to provide education and outreach, track and monitor USU’s human research activities, and assess the institution’s efforts to protect human research participants.

The Office of Compliance Assistance (OCA) is overseen by the Vice President for Research. The OCA, together with the university’s independent IRB, coordinates the campus-wide activities of the HRPP and implements USU policies, procedures and practices associated with the HRPP, including Section 306.9,
“Use of Human Participants in Research” of USU Policy #306, Research; USU Policy #308, Human Participants in Research; the IRB Standard Operating Procedures and the Investigator’s Handbook.

The HRPP is one of several activities supported by the OCA, which has responsibility for the compliant implementation of activities throughout the research organizations of the University. The Federal Compliance Manager (FCM) acts as director of the OCA, and is responsible for oversight of USU’s research policies and procedures. One important element of USU’s compliance effort is the Integrative Compliance Committee, which meets bi-monthly and is chaired by the FCM. The meeting is attended by representatives of USU ethics review committees, Environmental Health and Safety, the Controller’s Office, the Sponsored Programs Office and the offices of the Vice President for Research, the Vice President for Business and Finance, Internal Audit Services, and the Provost.

Both the OCA and the IRB operate under the office of the Vice President for Research, who is the signatory official for USU’s Federal Wide Assurance #00003308. Oversight of the OCA and IRB has been delegated to the Associate Vice-President for Research (HRPP Organizational Chart). Through the OCA, policies and procedures are implemented that guide the operations of the HRPP and the IRB, and that provide a strong ethical foundation for the University’s work with and outreach to research sponsors, investigators and human research participants.

While the policy framework for human protections is implemented across the institution through the OCA, the IRB operates independently in carrying out its duty to review human research protocols and protect human research participants. The OCA has the additional duties of monitoring the IRB’s activities and acting in a support role to the IRB. This role is fulfilled by the Federal Compliance Manager participating on the IRB in an ex officio, non-voting capacity. In addition, the IRB may call upon university’s general counsel, a representative of the Attorney General’s Office for the State of Utah, and other senior officials at USU in carrying out its charge.

The OCA and IRB have access to adequate resources to provide for the effective oversight of USU’s human research activities. The workload of USU’s IRB(s) is assessed regularly to assure that human research activities receive adequate review and monitoring. The Office of the Vice President for Research has established a cooperative program with the OCA and the IRB to provide for the care, safety and welfare of human participants. The OCA has specific responsibility for educational outreach and program coordination with sponsors of human research activities and USU’s human research participants. Through the IRB Office and the OCA, the Program provides ready access to sponsors and participants of the policies and procedures of the university concerning human protections, thus raising awareness of the ethical principles upon which these policies and procedures are based. The OCA and IRB also provide assistance to university employees, research participants and the public in understanding USU’s policy and procedures framework and implementing USU’s human research activities. Training of IRB members, investigators and staff involved in human research activities is tracked by the IRB, and the Collaborative Institutional Training Initiative (CITI) training modules are used for this purpose.
Obtaining scientific review for proposed studies is a responsibility of each study’s principal investigator. It is accomplished through reviews by sponsoring agencies, reviews by thesis committees (for student-conducted research), reviews by departments or colleges, or reviews by members of the IRB (when no other appropriate review body is available).

**Human Research Conducted at USU**

The following types of studies comprise the human research conducted at USU:

<table>
<thead>
<tr>
<th>Type of Research</th>
<th>Number of Investigators</th>
<th>Number of Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational research involving children</td>
<td>34</td>
<td>74</td>
</tr>
<tr>
<td>Other educational research</td>
<td>74</td>
<td>102</td>
</tr>
<tr>
<td>Psychological research</td>
<td>23</td>
<td>61</td>
</tr>
<tr>
<td>Other social science/behavioral research</td>
<td>100</td>
<td>172</td>
</tr>
<tr>
<td>Product Development</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

(Figures drawn from active protocols for FY 2007-2008)

USU’s research is carried out primarily at the main campus in Logan, Utah, though faculty and students at distance education sites throughout the state are also supported by the HRPP in conducting human research. All human research is reviewed by USU’s single IRB, unless USU has entered into an authorization agreement with a separate institution that has an FWA, and whose IRB is judged by USU’s IRB chair to be qualified to review the research.

USU’s human research projects are sponsored primarily by federal and state agencies or by USU. The majority of projects funded by USU represent student training exercises in connection with course work and graduate theses. Only about 7% of USU’s human research is supported by industry or foundations. Of the federally funded research grants that include a component of human research, the National Science Foundation oversees about 30%, the Department of Health and Human Services oversees about 20%, and the Department of Education oversees slightly more than 6%. The remaining federally funded research is split between the Department of Agriculture, the Department of Justice, and numerous others. The FDA provides funding support for no research at USU.

USU’s research is conducted under 45 CFR 46 (The Common Rule); 20 CFR 31 (FERPA, the PPRA); 42 CFR 50 (Scientific Misconduct under DHHS), 45 CFR 689 (Research Misconduct under NSF), PL 104-65 (lobbying); 45 CFR 160 & 164 (HIPAA, Privacy Rule); The America COMPETES Act; 42 CFR 72 & 73 (Select Agent Rule); and 15 CFR 730, et seq (Export Controls under Department of Commerce). In addition it is
subject to contract and cost accounting principles as contained in Office of Management and Budget Circulars A-21 and A-110. USU does not currently conduct research that is subject to 21 CFR 50, 51 (human research under FDA).

State laws that impact USU research include the UCA 63-2 (Government Records Access and Management Act (GRAMA)); UCA 53A-13-301, 302 (FERPA, but somewhat equivalent to federal PPRA); UCA 15-2 (Legal Capacity of Children); UCA 75-5, Part 2 (Guardians of Minors) & 3 (Guardians of Incapacitated Persons); and UCA 63-30 (Governmental Immunities Act).