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Faculty Senate Agenda, March 5, 2007

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FACULTY SENATE MEETING

March 5, 2007, 3:00 p.m.

Merrill-Cazier Library, Room 154

Agenda

- 3:00 Call to Order** John Kras
Approval of Minutes of February 5, 2007
- 3:05 Announcements** John Kras
- 3:10 Consent Agenda**
1. Parking Report Lisa Leishman
2. EPC Business Steven Hanks
- 3:15 Key Issues and Action Items**
PRPC Business Britt Fagerheim
1. Committee on Equity and Diversity
2. EPC-Curriculum Sub-committee Update
- 3:35 Information Items**
1. Human Research Policy..... Jeff Broadbent
2. Comprehensive Campaign PresentationPresident Stan Albrecht
- 3:55 University Business**President Stan Albrecht
- 4:00 New Business**
1. Nominations for President-Elect..... John Kras
2. Regional Campus Representation on Faculty Senate John Kras
3. Discussion of Responsibilities of Faculty Senate Past-President..... John Kras
4. EPC Membership Update Britt Fagerheim
- 4:30 Adjournment**

**FACULTY SENATE
MINUTES
February 5, 2007, 3:00 p.m.
Merrill-Cazier Library, Room 154**

John Kras called the meeting to order at 3:01 p.m.

Approval of Minutes from January 8, 2006

Diane Calloway-Graham motioned to approve the minutes of January 8, 2007. Christopher Terry seconded the motion; motion carried unanimously.

Announcements – John Kras

John Kras encouraged faculty senators to run for president elect. Nominations for this position will be accepted in the March meeting. Candidates must have served a minimum of one year as an elected senate member. If the elected candidate is on his or her last year of senate assignment, that term will be extended to fulfill the new assignment's term requirements. Provost Coward added that this is a serious role and President Albrecht depends on the faculty president to meet with and share ideas.

University Business – Provost Raymond Coward

1. The President was in Salt Lake at the legislature and unable to attend today's meeting. The legislative session is now in its fourth week but issues are still very early on. Provost Coward will be happy to answer specific questions.
2. We finished campus interviews for four candidates for dean of the College of Science. The President has invited back one candidate next week, which will be more of a family-oriented trip. They hope to have an announcement soon.
3. Tomorrow night, the Provost and President are meeting with students regarding Tier II tuition. The Regents makes a formula-driven decision as to what the legislature actually puts into the budget and Tier II is set by individual campuses where we engage with students and find out what they would support.
4. It is early on in the enrollment process, but the numbers look very good at this time. We need to duplicate last year's success for the next three years and we will be in a significantly different position with our dollars.

Consent Agenda Items

1. Bookstore Report
2. EPC Business
3. Committee on Committees Recommends the Appointment of Brett Shelton to the PRPC Committee Replacing Robert King and the Appointment of Hilda Fronske to the Athletic Council

James Barnhill motioned to accept the Consent Agenda. Robert Schmidt seconded the motion; motion carried unanimously.

Information items

1. Comprehensive Campaign Announcement

Kent Clarke with the Advancement office stated that on March 2nd, we will publicly launch USU's first comprehensive campaign. President Albrecht is planning on taking more time at a later date with the Senate explaining more in detail, but Kent wanted to invite and encourage the Senate to include the events of March 2nd as part of their schedule. In conjunction with the annual Founder's Day dinner, there will be an announcement event; invitations will soon go out campus wide. At this event, the goal amount and objectives will be announced. We have already made significant progress towards the goal we have placed.

2. USU Early Retirement Program

Vice President Glenn Ford informed the Senate of the proposed changes to the University's Early Retirement Program. Prior to July 1, 2004, the language talked about early retirement being a privilege and not a right, and that it needed administrative approval. On July 1, 2004, a change was made to call it a benefit. By adding the word 'benefit', we are able to offer it equally to all including those under grants and contracts.

The GASB rules determine guidelines on how to report liability. GASB 47 (current rule) is based on actual enrollment; GASB 45 (new rule) is based on all employees who may **potentially** enroll in the program. The difference is our actuarial liability of \$5 million under GASB 47 and \$93 million under GASB 45. In order for us to maintain the lower liability, we would have to qualify for the GASB 47 rule by July 1, 2007, which would require the removal of the word 'benefit' from our current policy and the inclusion of administrative approval when the request is in the mutual best interest of the employee and the university. This change is consistent with pre-July 2004 language.

Key Issues and Action Items

1. Committee on Equity and Diversity

This was an open discussion on the proposal to create a new Faculty Senate committee to deal with faculty equity and diversity. Will Pependorf motioned to adopt the resolution as a proposal to create a standing committee on equity and diversity by charging PRPC to write this into faculty code. The motion was seconded and carried unanimously.

Jenny Norton stated that the BFW committee had discussed the possibility of this falling under their responsibility. The committee felt they had enough charges and that they would not be able to give this new sub-committee the intensity it deserved. Pat Lambert suggested that someone from BFW sit on this committee for sake of sharing information.

2. Review of Faculty Forum

John Kras stated that the Faculty Forum code calls for senators to meet in November for a forum. However, history has shown that the forum has been open to all faculty to address issues. The options are to follow code and just allow senators or change the code to open the Faculty Forum up to all faculty.

Tom Schroeder moves to open the forum to all faculty and to charge PRPC with preparing the language to reflect this. Pat Lambert seconded the motion; motion carried unanimously. The language will come back from PRPC for two readings, then for a vote.

3. Dean's Tenure and Promotion Committee

Britt Fagerheim reviewed the new code as written by PRPC. Christopher Terry motioned to accept this as code. Tilak Dhiman seconded the motion; motion carried unanimously.

New Business

1. College Caucus

John Kras asked that the colleges caucus between the April 2 Faculty Senate meeting and the April 16 Faculty Senate Executive Committee meeting, as we will be making the new committee assignments. Will Pependorf is working on the preparations for this and will provide the information soon. If an executive committee member's term is up this year, those colleges need to nominate a new representative during those caucuses. The nominated rep needs to have been in place as a senator for one year.

2. Status of Administration as Faculty

Discussed in the last Faculty Senate Executive Committee meeting was a concern about administration hearing certain faculty discussions. On the other hand, administration is important to our process and administrators that are faculty are truly interested from that standpoint. It was pointed out that all meetings are public knowledge and becomes so with minutes. One senator questioned how much influence administration has over decisions and how often faculty 'hold back' when administrators are present. A suggestion is to have the colleges run their caucus and bring issues to the forum – it depersonalizes those concerns and it still brings the issue forward. The administrators then can, and should, be there for solutions. If senators have further ideas they want to share, they were asked to get with their executive committee member in their college or with John Kras.

Adjournment

The meeting was adjourned at 4:08 p.m.

Minutes Submitted by: Andi McCabe, Faculty Senate Executive Secretary, 797-1166

***Utah State University
Parking and Transportation
Annual Report 2006***

I. SIGNIFICANT ACCOMPLISHMENTS

Constructed a New 613-Stall Parking Structure

The primary focus for the Parking and Transportation Department in 2005-06 was the construction of our new 613-stall parking structure built in conjunction with the new Living/Learning Community for Housing. Joe Izatt, Operations Supervisor, represented Parking for this project, attended weekly meetings and kept the administration informed as necessary. The project's completion has been delayed several times but once fully operational, the structure will greatly enhance the campus community.

Conducted Peer Review

Representatives from Washington State University's Parking Department and Auxiliary Division visited USU in the spring to assess our overall parking operation and make recommendations concerning financial issues, parking assignments and processes, marketing and masterplanning. During their visit, the representatives toured campus facilities, interviewed parking management and staff and conducted focus groups with various stakeholders. They then provided a comprehensive report wherein specific recommendations were made to improve the efficiency of our operation. Several recommendations have already been implemented and others are being considered. This was a valuable experience for our department, and we look forward to the continued execution of their recommendations.

Managed Parking for Athletic Events

Parking for athletic events was previously coordinated and regulated by the USU Track Team. Athletics approached Parking and Transportation Services and requested that our office consider managing athletic event parking. After several discussions and negotiations, Parking began to manage athletic events at the beginning of football season, 2005. This agreement created a win-win solution because Athletics was able to get out of the "parking business" in a better effort to focus on their operations and Parking experienced increased revenue. In addition, since we've regulated the parking lots, few complaints have been received.

Designated Department Representatives

Our office is constantly identifying ways to better coordinate our operations with the campus community. One way to do this was to designate representatives from each administrative department and college with whom our office could communicate when issues arose that directly affected their department/college. A liaison social was held where we had an opportunity to meet the department representatives and better inform them about our operation. We will now communicate with these individuals when parking issues arise and have asked them to keep us informed when parking issues affect employees within their division.

Organized a Customer Appreciation Day

In order to express appreciation to our customers, we coordinated a Customer Appreciation Day. The celebration took place on April 26, 2006 and included prizes, games, food and fun. A marketing campaign was conducted prior to the event to encourage customers to attend. Prizes included terrace parking validations, ice cream coupons and even parking permits. The highlight of the event was "Dunk

the Director” where customers threw three balls in an attempt to dunk Lisa Leishman, Parking Director or Steve Mecham, Chief of Police. Approximately 100 people attended the event and all who were there seemed to have a good time.

II. AGGIE SHUTTLE

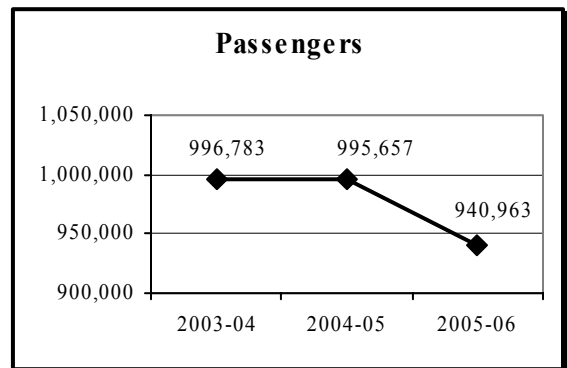
The Aggie Shuttle continues to be the most popular transportation alternative at Utah State University. Seven buses served the campus during peak hours on four different routes.

- The Stadium Express transported passengers from the Stadium Park & Ride area to the Nelson Fieldhouse near the Student Center. It operated from 7:00 a.m. to 6:00 p.m.
- The Campus Loop/Housing Express served the Residence Halls on the perimeter of campus and transported students parking in the “terraced” lots by the bull statue to the central campus area. It operated from 7:00 a.m. to 5:00 p.m.
- The 8th East Express transported passengers from the Agriculture System Technology and Education (ASTE) building, and the apartment complexes along 800 East to the Nelson Fieldhouse near the Student Center. It operated from 7:00 am. to 5:00 pm.
- The South Campus Express transported passengers from the Stadium to the Merrill Library. It also stopped along 600 East and 500 North to accommodate those catching the bus below Old Main Hill. It operated on a 15 minute timed route from 7:00 a.m. to 3:00 p.m.
- The Evening Route combined the Stadium Express and the Campus Loop/Housing Express and operated from 5:00 to 7:00 p.m.

Aggie Shuttle ridership in 2006, as compared to the previous two years, is as follows:

Aggie Shuttle Ridership

3 year-to-date high	996,783 (2003-04)
current value	940,963 ▼
3 year-to-date low	940,963 (2005-06)



The Aggie Shuttle is proud to have the largest university compressed natural gas (CNG) shuttle system in the state of Utah as well as the Intermountain West. CNG is a cleaner burning fuel, which offers far less emissions and is more environmentally friendly than diesel. With the recent purchase of five new buses, our fleet is fully operated by CNG. Since CNG fuel emits fewer particulates into the air and is much better for the environment, USU is able to contribute to the reduction of pollutants.

III. PARKING PERMITS

The USU Parking Office sells a variety of permits to the university community and visitors.

Student Parking Permits:

Students living off campus who wish to park their vehicle on campus have two permit options:

- A) B Permit - allows students to park in designated B areas and any Economy area.

B) Economy Permit - allows students to park in designated Economy areas, which are primarily on the periphery of campus.

Students living in campus Resident Halls are required to purchase a permit to park in the area adjacent to their respective residences.

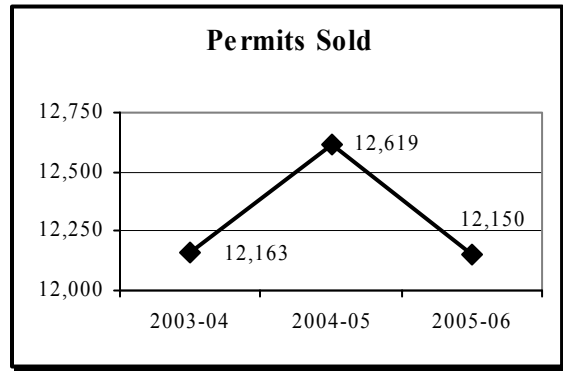
Faculty/Staff Parking Permits:

Any new faculty/staff member who wishes to park his/her vehicle on campus has the opportunity of purchasing either an A4 or Economy permit. Faculty/staff parking assignments are also made for specific parking areas in closer proximity to employment locations. Faculty/staff members must contact the Parking Office to be placed on a waiting list for these specific areas.

Following is a comparison of permits sold for the past three years:

Permits Sold

3 year-to-date high	12,619 (2004-05)
current value	12,150 ▼
3 year-to-date low	12,150 (2005-06)

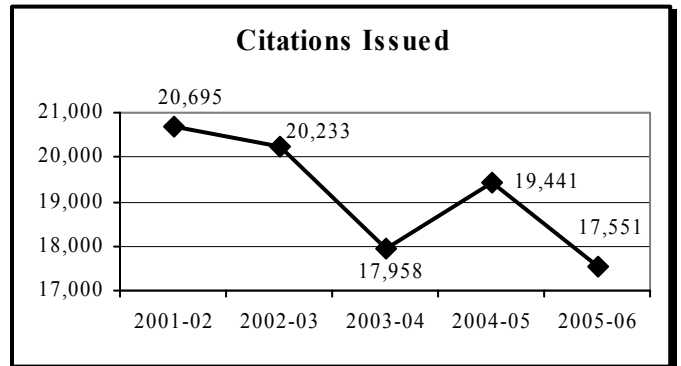


IV. PARKING ENFORCEMENT

During the academic year, the department employed twelve part-time Parking Service Officers. One of their many responsibilities was to enforce the department’s established rules and regulations. Parking enforcement is performed on a regular basis in order to place a value on parking permit purchases, increase the safety of the campus community, and to ensure appropriate access to campus. We plan to continue to issue citations to ensure orderly parking and safe traffic flow on campus.

Citations Issued

5 year-to-date high	20,695 (2001-02)
current value	17,551 ▼
5 year-to-date low	17,551 (2005-06)



V. APPEALS

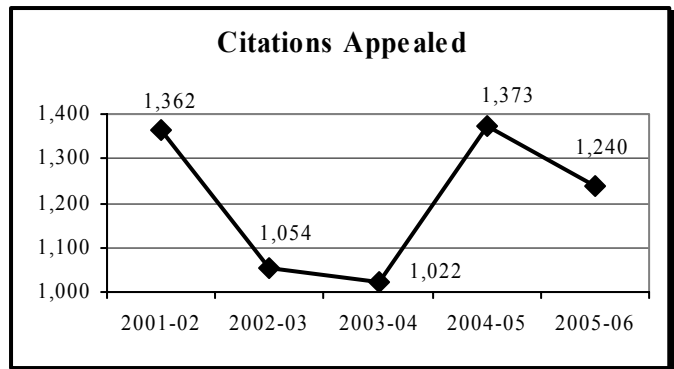
If an individual receives a citation and believes he/she has grounds for an appeal, the citation may be appealed within 14 calendar days from the date of issuance by appearing at the Parking Office or submitting an on-line internet appeals form. The Appeals Officer reviews the appeal and makes one of the following decisions:

- **Reduce the fine.**
- **Grant the appeal and waive the fine.**
- **Deny the appeal, leaving the fine at the appropriate amount.**

Following is a comparison of appeals submitted for the past five years.

Citations Appealed

5 year-to-date high	1,373 (2004-05)
current value	1,240 ▼
5 year-to-date low	1,022 (2003-04)



If an individual does not agree with the decision of the Appeals Officer, he/she may appeal to the Director of Parking and Transportation. Of the 29 citations that were appealed to the Director, ten were excused, eight were reduced, nine were denied and two did not appear for their appointment.

If the person does not agree with the Director's decision, he/she submits an appeal to the Appeals Committee. This Committee consists of a chair, a faculty/staff member and a student. The Committee is the final decision making body for appeals. No citations were appealed to the Appeals Committee in 2005-2006.

The department feels that the University's citation appeals process is extremely effective and fair. Only 7.07% of the citations that were written in 2005-2006, were appealed.

**Report from the Educational Policies Committee
February 15, 2007**

The Educational Policies Committee met on February 1, 2007. Minutes of these meetings are posted on the Educational Policies Committee Web Page, and are available for review by the members of the Faculty Senate and other interested parties.

The Educational Policies Committee, after careful review, recommends approval of the request from the College of Agriculture to change the name of the Western Region SARE Program to the Western Region SARE Center.

402.3 MEMBERSHIP; ALTERNATES; TERM; VACANCIES

3.1 Membership

The Senate shall be composed of the following members: (1) Fifty-five faculty members elected by and from faculty members eligible to vote in Senate elections (see policy 401.6.3(2)(d)); (2) the President and the Provost of the University or their designees; (3) eight appointees of the President of the University who shall be vice presidents and/or deans, six of whom must hold faculty appointments and must be designated annually preceding elections to the Senate; (4) the ~~three~~ **four** chairs of the Academic Freedom and Tenure Committee, the Budget and Faculty Welfare Committee, ~~and~~ the Professional Responsibilities and Procedures Committee, **and the Faculty Diversity, Development and Equity Committee**, if they are not one of the faculty members elected to the Senate; and (5) three students, who shall include the Associated Students of Utah State University (ASUSU) President or a designee, the ASUSU Vice President for Academic Affairs or a designee, and the Graduate Student Senate (GSS) President or a designee.

...

402.12 SENATE STANDING COMMITTEES

....

12.8 Faculty Diversity, Development, and Equity Committee

The duties of the Faculty Diversity, Development, and Equity Committee are to (1) collect data and identify and promote best practices for faculty development, mentoring, and work environment to facilitate **the success of diverse faculty** at all career levels; (2) evaluate and advocate processes for faculty recruitment, promotion, and retention that promote diversity, **fair pay standards**, and work/life balance for the faculty; (3) **evaluate** the status of faculty development, mentoring, diversity, and equity; and (4) report to the faculty senate on the activities and findings of the committee and make recommendations for implementation.

The membership, election, and appointment of members; term of members; officers; and meetings and quorum of the Diversity and Equity Committee shall be parallel to those of the Academic Freedom and Tenure Committee, as stated in policy 402.12.3(2) through 12.3(5).

12.89 Executive Committee of the Faculty Forum

12.910 Senate Handbook Committee

Comment [USU1]: Reflect the activities outlined in (1).

Comment [USU2]: Our understanding is that the committee will focus on diversity but the language was initially more broad.

Deleted: **success**

Comment [USU3]: The definition of equity, as we interpreted it for this context, relates specifically to the issue of fair pay standards.

Comment [USU4]: Monitor is too strong, raises specter of oversight, charging committee to do something for which they don't necessarily have resources. Also puts members in position of administration.

Deleted: **equity**,

Deleted: **monitor**

402.12 SENATE STANDING COMMITTEES

EPC recommendations

12.6 Educational Policies Committee

(5) Curriculum Subcommittee.

The Curriculum Subcommittee will formulate recommendations on curricular matters, such as course changes, and forward the same to the Educational Policies Committee.

This subcommittee shall consist of ~~a representative from each college;~~ one faculty representative from the libraries; two students, one from ASUSU and one from the GSS; a faculty representative from the Graduate Council; the Chair of the General Education Subcommittee; and a faculty representative (vice provost or designee) from Regional Campuses and Distance Education. ~~three faculty members appointed from the elected membership of the Educational Policies Committee, one faculty representative from the Libraries, and two students, one from the ASUSU and one from the GSS.~~ It is the responsibility of the voting members to represent their unit to the subcommittee and to represent the subcommittee to their unit. This includes informing their unit of deadlines, procedures, and upcoming actions. ~~The terms of Educational Policies Committee members on the subcommittee will correspond to their terms on the Educational Policies Committee.~~ The term of office for student members shall be one year and shall coincide with the term of ASUSU and GSS officers. The subcommittee shall elect a chair annually.

Comment [USU1]: Reflects current practice, since not all colleges have curriculum committees

Deleted: the eight chairs of each of the college curriculum committees

The Curriculum Subcommittee shall include at least three members from the elected membership of the Education Policies Committee (EPC). If the Curriculum Subcommittee (as constituted above) has fewer than three members from EPC, the EPC may appoint additional members to the Curriculum Subcommittee from its elected membership.

Deleted: to correct this deficiency.

“Human Participants in Research” Policy

Presented by the Vice President for Research

Background:

Policy # 306 “Research” was approved at USU in 2004 as the first of a series of four policies intended to strengthen USU’s research compliance infrastructure. Policy # 308, Human Participants in Research, is the second of this series, and policies to address Animal Welfare and an Institutional Conflicts of Interest policy are nearing completion. The research policy (# 306) refers to these new policies as pending and cannot be considered complete without their inclusion. ***This policy (# 308) does not materially change the way the Institutional Review Board (IRB) carries out its review and approval process.*** It is fully consistent with the IRB’s existing Standard Operating Procedures and its Investigator Handbook. In fact, preparation of the policy prompted some streamlining of existing IRB procedures, and the policy reinforces these improvements.

Rationale for implementation:

1. ***The policy will formalize and strengthen USU’s commitment to the protection of human participants in research.*** The university’s contract with faculty and employees is its policy. If a requirement is not in the policy, enforcement can become a challenge.
2. ***Implementation of this policy is required for USU to achieve accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).*** A site visit from this accrediting body is expected this year.
3. ***The Human Research Protection Program statement clarifies USU’s institutional approach to protecting participants in our human research activities.*** This is particularly important for federal regulatory requirements, because the courts hold the institution responsible for compliance, not the institution’s employees individually.
4. ***Implementation of this policy reduces the risk of federal intervention,*** including audits and increased regulatory actions.

Policy development

- The policy was developed by borrowing concepts and language from several models provided by leading research institutions.
- Additional materials from AAHRPP, including policy tip sheets, were reviewed and incorporated in the policy.
- The policy has been reviewed by the Research Council, deans and faculty of research-intensive colleges, the internal accreditation task force, the IRB, a group of researchers specifically solicited by OCA to comment on a recent draft of the policy, and the VP council.

HUMAN RESEARCH PROTECTION PROGRAM UTAH STATE UNIVERSITY

The Human Research Protection Program (the Program) at Utah State University protects the rights and welfare of human research participants who are included in the university's research activities. The Program 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 research activities, verifying its conformance to federal statutes, and protecting research participants
- 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 Program, under the direction of the Office of Compliance Assistance (OCA), has primary responsibility, in concert with the university's independent IRB(s), for implementation of Section 306.9, "Use of Human Participants in Research", of USU Policy #306, *Research*, and for USU Policy #308, *Human Participants in Research*.

Coordination with USU's Ethics Review Program

The Program is one of several activities overseen by the OCA, which has responsibility for the ethical review and compliant implementation of activities throughout the academic and research organizations of the University.

Responsible Officer and Institutional Assurance

Organizational responsibility for the Program resides with the Vice President for Research, who is the signatory official for USU's Federal Wide Assurance #00003308. Oversight of the OCA has been delegated to the Associate Vice-President for Research. Through the OCA, policies and procedures are implemented that guide the operations of the Program 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 underpinning is implemented across the institution through the OCA, the IRB operates independently under the direction of the Vice President for Research in carrying out its duty to review human research protocols and protect human research participants. The OCA has the additional duty of monitoring the IRB's activities. This role is fulfilled by the Federal Compliance Manager (who directs the OCA) participating on the IRB in an *ex officio* capacity.

Operation of the Office of Compliance Assistance

The OCA has access to adequate resources to provide for the effective oversight of USU's human research activities. These activities focus on social and behavioral research, educational research, and product research and development. The workload of USU's IRB(s) is assessed regularly to assure that human research activities receive adequate review and monitoring. In addition, the Office of the Vice President for Research, with assistance from the OCA, provides oversight of 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 OCA, the Program provides ready access to 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 Program also provides assistance to university employees, participants and the public in understanding and implementing USU's human research activities. Training of investigators and staff involved in human research activities is tracked by the IRB, and the Collaborative IRB Training Initiative (CITI) training modules are used for this purpose.

Ethical Principles in Human Research

During the Second World War experimentation with human participants was carried out in Nazi Germany. The atrocities represented by that "research" were the subject of trials held in Nuremberg, Germany following the war, and resulted in the Nuremberg Code, the first statement of ethical principles as they related to human research. Though the Nuremberg Code did not carry the weight of law, it became the basis for establishing the principles that humans participating in research do so voluntarily, and that the benefits of research must outweigh the risks.

During those same years and continuing until the early 1970s experimentation was being carried out in Tuskegee, Alabama on African-American men who had become infected with syphilis. Though penicillin became widely available in the late 1940s, it was not administered to the research participants in Tuskegee. When the Tuskegee Study came to light, Congress quickly passed the National Research Act of 1974 and called together a national commission to consider how to avoid irresponsible research in the future. The commission met in Belmont, and their report has come to be called the Belmont Report. The principles set forth in the Belmont Report continue to guide human research practices in the United States. They are:

- Respect for Individuals
- Beneficence
- Justice

These guiding principles are indirectly codified in U.S. law as 45 Code of Federal Regulations (CFR) 46, referred to as the Common Rule. Under the Common Rule, all

research involving human participants must be reviewed and monitored by an Institutional Review Board (IRB). The Common Rule is strictly adhered to at USU, and is the basis of USU's Policy #308, *Human Participants in Research*.

Reviewing and Conducting Human Research under USU Policy

USU has promulgated three primary guidance documents for the operation of the Program and the Institutional Review Board(s): Policy #308, *Human Participants in Research*, the IRB Standard Operating Procedures, and the Investigator's Handbook. These documents are available to the public and the University community at <http://www.usu.edu/research/irb>. These documents set forth IRB and institutional operational procedures including:

- Determining when studies meet the regulatory definitions of human research;
- Determining when studies are exempt from applicable federal, state, and local regulations, and from certain of USU's policies and procedures;
- Addressing protection for human participants involved in exempted research;
- Providing guidance about regulatory compliance, and resolving differences between federal regulations and Utah law;
- Identifying, minimizing or eliminating individual conflicts of interest held by investigators (see USU Policy # 307, *Conflicts of Interest*);
- Coordinating with the Office of Compliance Assistance to identify, minimize or eliminate institutional conflicts of interest;
- Addressing allegations and findings of non-compliance with the Program's requirements and with federal and state statutes;
- Addressing unanticipated problems involving risks to human research participants;
- Measuring and improving the HRPP's effectiveness, quality and compliance with the federal and state laws and with organizational policies and procedures;
- Soliciting concerns and suggestions from Investigators, administrators and others for improvement of USU's Human Research Protection Program, and its IRB review process.

Training of USU Personnel Involved in Human Research

The IRB Standard Operating Procedures require that, prior to submitting any research protocol involving human participants for IRB review, an investigator must be certified by the IRB by completing on-line training available through CITI. Further, all personnel who will be involved in conducting the research must be so certified before the study begins. This training is also provided as a component of USU's Research Integrity course, which is available to provide instruction on the Responsible Conduct of Research to all NIH trainees employed at USU, as well as to other research-oriented students.

In addition, training is provided to members of the Program and the IRB(s) at USU on an ongoing basis to ensure that they are knowledgeable in USU's policies, procedures and applicable federal and local laws. Members of the IRB are also encouraged to participate

in training sessions sponsored by professional organizations like the Applied Research Ethics National Association (ARENA) and governmental agencies, such as the Office for Human Research Protections (OHRP).

Use of Investigational or Unlicensed Test Articles

At this time, USU does not participate in trials or testing of investigational drugs or biomedical devices involving human participants. It is the policy of the university not to allow use of investigational or unlicensed test articles (as defined in 21 CFR 56.102 (1)) in its research programs.



POLICY MANUAL

GENERAL

Number 30X

Subject: Human Participants in Research

Effective Date:

Date of Last Revision:

30X.1 INTRODUCTION AND DEFINITIONS

- 1.1 The purpose of this policy is to govern the involvement of Human Participants in the conduct of Research at USU. The University is committed to safeguarding the rights and welfare of human participants, and complies with the regulations of the U.S. federal government and the State of Utah.
- 1.2 For the purposes of this policy, Research is defined in harmony with 45 CFR 46 as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to Generalizable Knowledge.
 - 1.2.1 For the purpose of this policy, Generalizable Knowledge is any result of Research that is intended to be extended (or generalized) beyond the population or program being investigated. Such extension shall include public disclosure of such results either in public settings, through publication of a thesis or dissertation, or through other dissemination or publication.
 - 1.2.2 The USU Institutional Review Board (IRB) shall have the sole responsibility, through interaction with the Principal Investigator and review as set forth in this policy, to determine whether an investigation to be conducted constitutes Research in accordance with 45 CFR 46, as illustrated in Decision Chart #1, published as guidance by the Office of Human Research Protections (OHRP), available at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

1.3 A Human Participant (“Participant”) in Research is a living individual, about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual; or
2. Identifiable private information.

The terms “Human Participant” and “Participant” are equivalent to the terms “Human Subject” and “Subject” as used in the “Common Rule”, 45 Code of Federal Regulations (CFR) 46.

1.4 Human Research, or Research involving Human Participants is any Research, as defined above, that involves Human Participants in accordance with 45 CFR 46 and as illustrated in Decision Chart #1, published as guidance by the OHRP, available at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>.

1.4.1 The USU IRB shall have the sole responsibility of determining whether an investigation constitutes Human Research, under the above definition.

The following activities, which may found to be exempt from Common Rule (45 CFR 46) requirements, shall nonetheless be included among those to be submitted for IRB review: quality improvement programs and program evaluations carried out for other than exclusive use by the organization sponsoring the evaluation, classroom exercises that are associated with research methodologies courses, public health activities and innovative health care.

1.5 Investigator is a person or entity affiliated with USU, whether as an employee, student or otherwise, whose role statement, job description, employment assignment and/or function within the University is, either in whole or in part, to carry out Research. Such Investigators shall include, but not be limited to, USU faculty, professional researchers, research assistants, laboratory and clinical staff, and others as may be designated by the Vice President for Research.

1.5.1 Principal Investigator is an Investigator who is an employee of the university and is authorized by his or her unit and college, or by the Vice President for Research, to take responsibility for Research involving Human Participants. This individual shall have primary responsibility for submitting Research protocols and carrying out Research programs that protect the health and well-being of Human Participants, as set forth in this policy.

1.6 Intervention includes both physical procedures, by which data are gathered (for example, venipuncture), and manipulations of the Participant or the Participant's environment that are performed for research purposes.

- 1.7 Interaction includes communication or interpersonal contact between Investigator and Participant.
- 1.8 The IRB gives special consideration to protecting the welfare of particularly vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. A Child is a person under the age of 18 who is not able to legally consent to treatments or procedures involved in the research (see Utah Code Annotated 75-1-201 (29)). A Child's Guardian, according to DHHS regulations, is an individual authorized to consent on behalf of the child to general medical care. A Guardian of an incapacitated adult shall be a person who has qualified as such pursuant to testamentary or court appointment.
- 1.9 Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private Information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for the obtaining of the information to qualify as Research involving Human Participants.
- 1.10 Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the Research are not greater, in and of themselves, than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.
- 1.11 Conflict of Interest is a situation in which a University employee owes a professional obligation to the University, which is or can be compromised by the pursuit of outside interests. Conflicts of Interest are further defined and discussed in USU Policy No. 307, "Conflicts of Interest."
- 1.12 Confidentiality is the withholding of certain information as specified under an agreement between USU and another individual or entity (for example, a collaborating institution) wherein the entities agree to maintain as confidential all Private Information regarding the Research, protocol, investigational process, and information discovered during the investigation. Also, the right of a Human Participant to have Private Information protected from disclosure except as allowed under the Privacy Rule (42 CFR 160, 164)

30X.2 POLICY

USU Investigators must adhere to strict ethical standards when involving Human Participants in their Research. These standards are in place to protect the basic rights of Participants. Any Research that departs from the spirit of these standards violates University policy. All Research performed under the auspices of USU, including collaborative Research conducted with one or more public or private entities, in which

Human Participants are involved must be reviewed and approved by the Institutional Review Board (IRB) appointed by the Vice President for Research, or by such other review body as shall be designated by the IRB. USU, through its Human Research Protection Program, its IRB and other review processes, works together with Investigators, sponsors and Research Participants to uphold ethical standards and practices in its Research.

The IRB review and approval process shall be conducted in accordance with all U.S. federal government and state laws, and all university policies and regulations that govern the use of Human Participants in Research, including the IRB Handbook and the IRB Standard Operating Procedures current at the time of the review. The requirement for IRB review and approval applies to all Human Research involving USU Investigators or Human Participants in all locations, whether funded or not, and whether conducted by faculty, students or other employees. It also applies to persons unaffiliated with the university who wish to investigate Participants who are under the protection of the university, such as students and patients. No such study shall begin before it has been approved by the IRB. Investigators are encouraged to consult with the IRB administrator, or the IRB chair, during preparation of an early draft of proposals to be submitted, at which time concise and current details concerning Human Research can be obtained.

The IRB web site, at <http://www.usu.edu/research/irb> is made available to Principal Investigators, Investigators, Human Participants and others in order to provide ready access to USU's Policies, Standard Operating Procedures, the IRB Handbook and associated information. Interested parties should make use of the information provided electronically, and whenever appropriate they may contact the IRB administrator or chair for additional assistance with the preparation, approval and execution of protocols involving Human Participants.

Investigators are referred to the following documents and regulations, hereby made a part of this policy by reference:

- *Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report)*
- 45 CFR 46 "Protection of Human Subjects," (The "Common Rule")
- 45 CFR 160 and 164A,E "Standards for Privacy of Individually Identifiable Health information," ("The Privacy Rule")
- 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought"
- Department of Health and Human Services guide document: "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection."

If an Investigator is unsure of the interpretation of the federal and state statutes and guidelines as listed, or has other questions regarding the applicability or effect of federal,

state or local laws or regulations, he/she shall contact University Counsel for advice and direction.

The USU IRB is authorized to approve Research protocols involving Human Participants through the Federal-Wide Assurance # 00003308, dated September 6, 2002. This assurance is on file with the Office of Human Research Protections, U.S. Department of Health and Human Services. USU delegates to the IRB the responsibility for reviewing Research protocols primarily for the purpose of ensuring that Human Research is carried out in accordance with ethical principles, as outlined in the Belmont Report, and for protecting the welfare and rights of Human Participants. The IRB shall act independently in this capacity, but shall coordinate its review with other review bodies – including the Sponsored Programs Office, the Conflicts of Interest Committee, The Office of Compliance Assistance and the Office of the Vice President for Research – whose responsibilities under USU policy include review of the scientific and scholarly validity of the proposed research study, and its freedom from bias introduced because of unmanaged conflicts of interest. The IRB is authorized to:

- approve, require modification to secure approval, or disapprove all Human Research activities overseen or conducted at USU;
- suspend or terminate approval of Human Research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
- observe, or have a third party observe, the consent process;
- observe, or have a third party observe, the conduct of the Research.
- Authorize a separate IRB or other review body that has a current FWA to provide oversight of a multi-site or specialized study under an authorization agreement, as allowed by federal statute.

30X.3 PROCEDURES

3.1 Principles that IRB members consider during their reviews are set forth in the *IRB Protocol Review Standards* document (available at: <http://www.usu.edu/research/irb/forms/IRB%20Protocol%20Review%20Standards%203-19-03.pdf>) current at the time of application. These principles include:

- 3.1.1 Minimizing the risks to Participants.
- 3.1.2 Balancing of risks with the potential benefits from the study.
- 3.1.3 Obtaining informed consent from the Participant or permission from a legal guardian before participation. Such consent or permission must be in writing unless waived by the IRB.

- 3.1.4 Providing adequate detail about the study in language that is understood by the Participant so the Participant can make an informed decision
 - 3.1.5 Maintaining Participants' privacy and Confidentiality.
 - 3.1.6 Informing Participants that their participation is voluntary and that they are free to withdraw from the study at any time without consequence.
- 3.2 Protocols submitted to the IRB are categorized as follows:
- 3.2.1 Exempt from further review. Determination of exempt status shall be made in accordance with the Standard Operating Procedures of the IRB, and shall in no case be made by an individual who might have a conflict of interest concerning the study. All Research adjudged to be exempt shall nonetheless be subject to monitoring and continued review by the institution through the IRB so that the health, well-being and privacy of Human Participants involved in such Research are adequately protected. Such review shall require an annual update confirming that the then-current activities qualify for exemption, outlining any changes made in the protocol or indicating that the project has been completed and/or terminated.
 - 3.2.1.1 Certain Human Research shall be exempt from review under the following circumstances, in accordance with 45 CFR 46.101(b), subsections:
 - (1) Educational settings (see Decision Charts 2 & 3. All decision charts referred to in this subsection are available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>). For certain activities, such as classroom activities, the USU IRB provides a Classroom Research Assignment Application, which may be submitted by an investigator to determine whether a classroom activity may be exempt, and for which a full application may not be required. See USU IRB Standard Operating Procedures for further information.
 - (2) Or (3) Tests, Surveys, Interviews, Public Behavior Observations (see Decision Charts 2 & 4.)
 - (4) Existing Data, Documents Records or Specimens (see Decision Charts 2 & 5)
 - (5) Public Benefit or Service Programs (see Decision Charts 2 & 6)
 - (6) Food Taste and Acceptance Studies (see Decision Charts 2 & 7)

- 3.2.2 Subject to expedited review. If the IRB administrator finds that a protocol involves no more than Minimal Risk, expedited review may be conducted by the IRB administrator and a limited number of board members with expertise in the Research activity being conducted. Selection of IRB members to conduct expedited reviews shall be by the IRB Chair, and expedited reviews shall be performed in accordance with the Standard Operating Procedures of the USU IRB. This process generally requires a period of four to six weeks to complete.
 - 3.2.3 Subject to full review. In cases where more than Minimal Risk is involved, and where expedited review is deemed by the IRB administrator to be insufficient or inappropriate, the protocol is subject to review by the full board. Such reviews typically require a period of four to six weeks to complete.
- 3.3 Protocols submitted to the IRB for review shall be presented by a Principal Investigator, and shall consist of three components. (Forms and information can be found at <http://www.usu.edu/research/irb>):
- 3.3.1 IRB Application Form – Completion of this form will allow the IRB Administrator to quickly place the protocol in the appropriate review category (exempt, expedited, or full board review). These forms have been developed to minimize the response time of the IRB. All sections of the application must be completed in order for the IRB to begin its review. Information should be written in lay language, avoiding jargon and acronyms.
 - 3.3.2 A copy of the grant, thesis or dissertation upon which the project is based. If a project has none of the above documentation, a description of methods and objectives, and a clear, concise description of procedures to be used in the project shall be submitted.
 - 3.3.3 Informed Consent Form - This document must conform to the requirements of the IRB Standard Operating Procedures as reflected in the *Informed Consent Checklist* (available at: <http://www.usu.edu/research/irb/forms/InformedConsentChecklist.doc>) and be approved for use in the study by the IRB. It contains the following elements as required under 45 CFR 46.116:
 - 3.3.3.1 A statement that the study involves Research
 - 3.3.3.2 A statement of the Research to be performed and the purpose of the Research
 - 3.3.3.3 Reasonably foreseeable risks or discomforts
 - 3.3.3.4 Reasonably foreseeable benefits to participants and others

- 3.3.3.5 Appropriate alternatives to the study that may benefit the participant
 - 3.3.3.6 A statement of Confidentiality
 - 3.3.3.7 Availability of compensation or treatment for injury
 - 3.3.3.8 Contact information
 - 3.3.3.9 A statement explaining that participation is voluntary and that there is no penalty for withdrawal.
- 3.3.4 The Informed Consent form shall contain adequate information, written in plain language familiar to the participant, so that s/he can make an informed decision regarding participation.
- 3.4 IRB applications shall be completed on line in accordance with the IRB Standard Operating Procedures. Incomplete packages will be returned to the Investigator without review. The IRB administrator and staff work with Investigators to verify completeness of submissions and identify concerns or needed clarifications. Reviews are then conducted as described above. If full board review is required, the Investigator will provide ample copies of packets for each board member (as directed by the IRB administrator) no later than two weeks before the monthly IRB meeting.
- 3.5 Upon completion of the IRB review, notification of decision regarding the protocol is sent by the IRB administrator to the Investigator. Revisions are sometimes needed, and when the protocol is considered to meet acceptable standards, the Research protocol will be approved for one year (beginning on the date the protocol was approved), or such other term (never greater than one year) as shall be determined by the IRB.
- 3.6 For those protocols that require an extension beyond the one-year limitation of the IRB approval, a Status Report will be mailed to the Investigator by the IRB Office one month before the anniversary approval date. The Investigator will have ten working days from the date of receipt to submit the Status Report form. A memo shall be attached to the Status Report form stating the Investigator's intention to continue the Research and document any modification to the experimental protocol. The memo shall contain a concise overview of the Research to date (i.e., current copy of the informed consent, number of subjects involved, summary of any recent significant findings, adverse events, etc.). If the protocol is acceptable, an approval letter will be sent to the Investigator, extending the project for an additional year. Continuing review may occur more than once a year depending on the level of risk.

The Investigator will maintain a current file for each protocol s/he submits and have a copy of all records relating to the research protocol (IRB application form,

data derived from the study/case report forms/computer data/adverse events, correspondence with the IRB/sponsor/funding sources/FDA/others, sponsor's protocol—if applicable, original Informed Consent and Assent forms).

- 3.6.1 Retention of Records – Records shall be retained by the P.I. for all protocols for three years from the date the study is completed, terminated, or discontinued. Federally-funded Research may require a longer record retention period.
- 3.6.2 The IRB shall retain for at least three years the following records in accordance with 45 CFR 45 Section 115:
 - 3.6.2.1 Minutes of IRB meetings
 - 3.6.2.2 Records of continuing review activities
 - 3.6.2.3 Copies of all correspondence between the IRB and Investigators
 - 3.6.2.4 A list of IRB members
 - 3.6.2.5 The Standard Operating Procedures of the IRB
- 3.6.3 Investigators will notify the IRB office if they either leave the university before the Research is completed, or complete the Research and leave the institution before the end of the three-year record retention date. If the Investigator desires to take copies of the research records to another institution, additional issues may need to be resolved related to the Health Insurance Portability and Accountability Act (HIPAA, 45 CFR 160).
- 3.7 IRB Training in the Protection of Human Participants in Research – USU requires Investigators, co-investigators, and any research personnel who interact with Participants in Research to be trained in the ethical protection of Human Participants. Certification achieved by completion of prescribed training shall be valid for three years from the date when training was completed.
- 3.8 Conflicts of Interest – The IRB Application Form shall include questions designed to identify any potential individual conflicts of interest that may arise in connection with the study. Positive disclosures of conflicting interests shall be referred by the IRB administrator to USU's Federal Compliance Manager so that the conflict of interest can be fully disclosed and managed or eliminated, as required under federal guidelines and in accordance with USU Policy # 307, "Conflicts of Interest.". No Research for which a conflict of interest has been disclosed shall be conducted under an IRB-approved protocol until a Conflict of Interest Management Plan has been approved for the work by the USU Conflict of Interest Committee. In addition, members of the IRB shall be queried at the beginning of each IRB review meeting concerning potential conflicts of interest

they may have in connection with protocols to be reviewed. Members of the IRB that disclose such conflicts may provide information to the Board as requested, but shall recuse themselves from voting for approval or disapproval of the protocol in question.

- 3.9 Allegations and findings of non-compliance. Incidents of non-compliance shall be handled by the IRB unless the nature or duration of non-compliance indicates the need for institutional intervention.
- 3.9.1 Non-compliant activities may be identified through IRB oversight, self-reporting, or reporting from employees, Human Participants or others. Reports should be made to the chair of the IRB, and any report of non-compliant behavior involving Research under the oversight of the IRB shall be reported to the IRB chair at the earliest opportunity. Sufficient information shall be submitted to identify who exhibited the non-compliant behavior, when it took place, and any other pertinent details to allow for determination of non-compliance.
- 3.9.2 The IRB chair shall make the initial determination if the allegation is non-compliance involving Human Research. If non-compliance is suspected, but does not involve Human Research, the chair shall provide all pertinent information to the Office of Compliance Assistance for further action.
- 3.9.3 Upon making a finding of non-compliance that is neither serious nor continuing, the IRB Chair shall take steps to correct the non-compliant behavior with the investigator. The IRB Chair shall also notify the Department Chair, Dean, the Office of Compliance Assistance (OCA) and the Responsible Institutional Official of the circumstances surrounding the behavior and corrective actions taken.
- 3.9.4 In cases of serious non-compliance (defined as non-compliant activities that could jeopardize the rights or safety of Human Participants) or continuing non-compliance (defined as non-compliant activities that recur either on the same project or by the same investigator after the IRB chair has taken corrective action), the IRB chair shall notify the OCA for further action. The OCA has been established to provide support to the IRB, Investigators, Human Participants, and other individuals and entities with regard to adherence to federal and state statutes, regulations and guidelines. In conjunction with USU's Responsible Institutional Official (RIO) and others, the OCA receives and processes allegations of misconduct and non-compliance arising from Research activities of the university, and facilitates any associated inquiries and investigations. Information about and contacts for the OCA are available at: http://www.usu.edu/aia/academic/c_overview.cfm. Allegations of non-compliance may be presented to the IRB administrator, the Federal Compliance Manager at the OCA, USU's Internal Audit Services (IAS)

either through the hotline or with a representative of IAS, or to University Counsel.

- 3.10 Adverse events and unanticipated problems. Investigators shall follow the procedures contained in the IRB Standard Operating Procedures and IRB Handbook whenever an adverse event or another unanticipated problem arises having to do with risks to Human Participants or others. The P.I. shall have responsibility for identifying and reporting unanticipated risks, submitting information to the chair of the IRB in sufficient detail for the chair to draft the report as required in 3.12, below, and otherwise as required by the SOPs. If the adverse event or unanticipated risk is life-threatening, emergency services shall be summoned and all reasonable steps shall be taken to ensure the safety and well-being of the Participants or any others affected.
- 3.11 Suspensions and Terminations of previously approved Research. The IRB is authorized to suspend (defined as temporarily discontinuing) or terminate (defined as permanently discontinuing) Research in order to protect the rights and welfare of Research Participants and others.
 - 3.11.1 The determination of the appropriate action shall be made by the IRB chair, based on non-compliance with the IRB-approved protocol for the Research, or on the association of the Research with an unexpected serious harm to Participants or others. Determinations shall be ratified by the membership of the IRB, and shall be reported to the OCA, RIO, University Counsel and the appropriate funding agency as set forth in 3.12, below.
 - 3.11.2 Suspensions may be lifted if an investigation determines that the harm was not associated with the Research, or if compliance with the approved protocol is re-established, and is determined to be sufficient to protect the rights and welfare of Human Participants.
 - 3.11.3 When a termination or suspension involves the withdrawal of current Participants from a study:
 - 3.11.3.1 Enrolled participants will be notified by the IRB.
 - 3.11.3.2 Participants to be withdrawn will be informed by the IRB of any unexpected risks to which they may have been subjected, and shall be provided with support in understanding and ameliorating those risks.
 - 3.11.3.3 Participants to be withdrawn will be informed by the IRB of any follow-up that is required or offered, and will be informed that any adverse event or unanticipated problems involving risks to them or others should be reported to the IRB and others as appropriate.

3.12 Reports of unanticipated problems, terminations, suspensions and serious or continuing non-compliance shall be submitted to federal agencies in compliance with applicable regulations.

3.12.1 The IRB chair shall have responsibility for coordinating with the P.I., gathering any additional required information and writing the initial report, which shall include:

3.12.1.1 the nature of the event or problem,

3.12.1.2 the findings of USU,

3.12.1.3 the action taken by the IRB and USU

3.12.1.4 the reasoning underlying the actions taken,

3.12.1.5 any plans or recommendations for a continuing inquiry or investigation.

3.12.2 The chair shall submit the draft report in a timely manner to the OCA and the RIO for review. The RIO shall have responsibility for final approval and signature of the report, and for its submission to the appropriate agency.

3.13 Continuous improvement of the Human Research Protection Program.

3.13.1 The IRB and OCA shall work together to measure and report the performance of the Human Research Protection Program to USU's administration. Annual and unannounced reviews of the IRB's operating and review procedures shall be carried out in order to assess the effectiveness and quality of the processes; and to assure compliance with USU's policies and procedures, and with applicable federal, state and local laws and guidelines.

3.13.2 USU Investigators, other USU employees, Human Participants and sponsors of Research are encouraged to bring forward concerns and suggestions regarding improvement of the Program, including the IRB review process.

402.12.6 Educational Policies Committee

(2) Membership.

The Educational Policies Committee consists of the Provost, one faculty representative from each college, one faculty representative from [Regional Campuses and Distance Education](#), one faculty representative from the Libraries, two student officers from the ASUSU, and one student officer from the GSS. The faculty representatives are elected to the committee in accordance with policy 402.11.2.

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