584.1 PURPOSE

The purpose of this policy is to govern the involvement of human participants in the conduct of research at Utah State University. 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.

584.2 DEFINITIONS

2.1 Research

For the purposes of this policy, research is defined in harmony with 45 Code of Federal Regulations (CFR) 46 as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

For the purpose of this policy, a systematic investigation is defined as a process that involves the formulation of a hypothesis or research question and the collection and/or analysis of data that will lead to a conclusion that either supports or disproves the hypothesis or that answers the research question. 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.

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: 

2.2 Human Participant

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 CFR 46.

2.3 Human Research

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: 

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 be 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.

2.4 Investigator

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.

Principal Investigator (PI) is an investigator who is an employee of the University and is authorized by his/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.
2.5 Intervention

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.

2.6 Interaction

Interaction includes communication or interpersonal contact between investigator and participant.

2.7 Vulnerable Populations

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.

1. 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]).
2. A child’s guardian, according to U.S. Department of Health and Human Services (DHHS) regulations, is an individual authorized to consent on behalf of the child to general medical care.
3. A guardian of an incapacitated adult shall be a person who has qualified as such pursuant to testamentary or court appointment.

2.8 Private Information

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 (e.g., 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.

2.9 Minimal Risk

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.
2.10 Conflict of Interest

An individual 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 307 Conflicts of Interest.

An Institutional Conflict of Interest (ICOI) exists whenever the financial or other interests of the University, or of an Institutional Leader acting within his or her authority on behalf of the university, conflict with - or have the potential to conflict with - obligations to University research participants or others.

Unaddressed ICOI can give rise to bias entering into the decision making of the university, which could raise questions regarding the integrity of the research.

Examples of such biases might be:
- Special handling of issues addressed by University departments or oversight committees, such as the Institutional Review Board (IRB).
- Management decisions that:
  - Affect data ownership or sequestration of data.
  - Restrict publication or dissemination of research results.
  - Restrict intellectual property rights.
  - Influence research agendas within the University.

For purposes of the Human Research Protection Program, Institutional Leaders are those senior leaders who are in a position to directly influence salaries, appointments, resource allocation or oversight of human participant research. This will include the president, vice presidents, associate vice presidents, deans, administrative directors, center directors and department heads. Members of the USU Board of Trustees have their own disclosure requirements, and USU shall coordinate with the Board of Trustees to identify any financial interests they may hold that would be considered to create an Institutional Conflict of Interest.

2.11 Confidentiality

Confidentiality is the withholding of certain information as specified under an agreement between USU and another individual or entity (e.g., 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).

584.3 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. No other official of the University may approve human research that has not 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:

1. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report).*
4. 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.”

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 USU review bodies – including the Sponsored Programs Office, the Conflicts of Interest Committee, the RGS Division of Research Integrity and Compliance, 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:

1. Approve, require modification to secure approval, or disapprove all human research activities overseen or conducted at USU;
2. 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;
3. Observe, or have a third party observe, the consent process;
4. Observe, or have a third party observe, the conduct of the research.
5. Authorize a separate IRB or other review body that has a current Federal-Wide Assurance to provide oversight of a multi-site or specialized study under an authorization agreement, as allowed by federal statute.

584.4 PROCEDURES

4.1 Principles

Principles that IRB members consider during their reviews are set forth in the IRB Review Checklist document (available at: http://rgs.usu.edu/irb/resources/forms-for-reference-only) current at the time of application. These principles include:

1. Minimizing the risks to participants.
2. Balancing of risks with the potential benefits from the study.
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.

4. Providing adequate detail about the study in language that is understood by the participant so the participant can make an informed decision.

5. Maintaining participants’ privacy and confidentiality.

6. Informing participants that their participation is voluntary and that they are free to withdraw from the study at any time without consequence.

4.2 Protocols

Protocols submitted to the IRB are categorized as follows:

(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.

Certain human research may be exempt from review under certain circumstances, in accordance with 45 CFR 46.101(b), subsections a-f. These may include the following: certain educational settings; certain tests, surveys, certain interviews and public behavior observations; certain existing data, documents, records, and specimens; certain public benefit or service programs and certain food taste/acceptance studies.

These exemptions must be arrived at by analyzing the decision charts referred to at HHS.gov under Policies and noted as “Checklists & Decision Trees” located currently at http://www.hhs.gov/ohrp/policy/checklists/index.html.

(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 a limited number of experienced board members who possess 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) 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.

4.3 Protocols submitted to the IRB for review

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)

(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.

(2) 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) 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://rgs.usu.edu/irb/resources/informed-consent-samples) and be approved for use in the study by the IRB. It contains the following elements as required under 45 CFR 46.116:

(a) A statement that the study involves research.
(b) A statement of the research to be performed and the purpose of the research.
(c) A description of reasonably foreseeable risks or discomforts.
(d) A description of reasonably foreseeable benefits to participants and others.
(e) Appropriate alternatives to the study that may benefit the participant.
(f) A statement of confidentiality.
(g) Availability of compensation or treatment for injury.
(h) Contact information for:

1. Answers to pertinent questions about the research.
2. Answers to pertinent questions about the research participants’ rights.
3. Reporting of research related injuries or harms.
4. The research team (if not provided above) for questions, concerns, or complaints.
5. Someone independent of the research team for problems, concerns, questions, information or input.

(i) A statement explaining that participation is voluntary and that there is no penalty or loss of benefit to which the participant was entitled if the participant withdraws or refuses to participate.

(j) When appropriate:

(i) The consequences of a participant’s decision to withdraw from the research.
(ii) An approximate number of participants involved in the study.

(k) The informed consent form shall contain adequate information, written in plain language familiar to the participant, so that he/she can make an informed decision regarding participation.

4.4 Protocol Process

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.

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.

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 he/she 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).

4.5 Retention of Records

Records shall be retained by the PI 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.

The IRB shall retain for at least three years after the completion of the research (or for protocols which are cancelled without participant enrollment, for at least a three-year period after cancellation) the following records in accordance with 45 CFR 45 Section 115:

1. Minutes of IRB meetings.
2. Protocols.
4. Department of Health and Human Services-approved sample consent documents and protocols, when they exist.
5. Reports of injuries to participants.
6. Records of continuing review activities including continuing review status reports submitted to the investigator.
7. Other progress reports submitted by investigators.
8. Statements of significant new findings provided to participants.
9. For initial and continuing review of research by expedited procedure;
   a. The specific permissible category.
   b. A description of action taken by the reviewer.
   c. Any findings required under regulations.
10. For exemption determinations, the specific category of exemption.
11. Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
   a. Waiver or alteration of the consent process.
   b. Research involving pregnant women, fetuses, and neonates.
   c. Research involving prisoners.
   d. Research involving children.
12. For each protocol’s initial and continuing review, the frequency for the next continuing review.
13. Copies of all correspondence between the IRB and investigators.
14. A list of IRB members to be maintained on a continuous basis.
15. The standard operating procedures of the IRB to be maintained on a continuous basis.
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).

4.6 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 that training was completed.

4.7 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 individual 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 who 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.

Outside interests of USU or its Institutional Leaders that are related to USU research, and that could give rise to Institutional Conflicts of Interest (ICOI) shall be identified through two mechanisms which shall trigger initiation of an ICOI assessment procedure conducted under RGS Procedure 532:

1. A screening process conducted by the Sponsored Programs Division. All sponsored projects for which there is an external, non-governmental sponsor shall trigger an ICOI assessment.
2. A screening process conducted directly by the IRB. All projects in which a product or service is to be used, but which are not directly sponsored by the outside entity providing the product or service (and therefore not subject to Sponsored Programs review) shall trigger initiation of an ICOI assessment.

The ICOI assessment identifies matches between outside interests identified through the above screening processes with financial interests held by USU or its Institutional Leaders. Each match identified under these assessments shall be provided by the Federal Compliance Manager to the Institutional Conflict of Interest Committee along with any
proposed management plan and/or review of existing internal controls that would provide adequate management of the ICOI. After its review and action the ICOI Committee shall forward to the IRB any approved plan or recommendation. Copies of this document shall also be provided to the department head and dean of the affected unit(s). The IRB shall have final authority to accept and have the management plan implemented, to alter the management plan, or to deny the management plan and reject the study.

The Conflict of Interest Committee, appointed by the University President to oversee the implementation of Policy # 307 "Conflicts of Interest", shall, with the addition of a member deemed independent by the President, be constituted as the Institutional Conflict of Interest Committee, and shall have oversight of the implementation of the ICOI procedures contained herein.

The Conflict of Interest Committee will consist of:

1. the Provost or an authorized designee of the Provost (Committee Chair);
2. a representative from the Office of the Vice President for Research;
3. a representative of the Institutional Review Board;
4. a representative of the Faculty Senate;
5. a representative of the Intellectual Property Services Office; and
6. a member external, unaffiliated to the University.

Others may be added as the President deems appropriate. The Federal Compliance Manager and general counsel serve as ex officio members of the Committee.

The Institutional Conflict of Interest Committee shall meet as required to review all disclosed Institutional Conflicts of Interest related to Human Subjects Research; shall review for approval all Institutional Conflict of Interest management plans; shall recommend elimination of conflicts as it deems necessary; and shall monitor all active management plans.

4.8 Researcher Noncompliance: Allegations, Investigations, and Disposition

The purpose of this section of the policy is to ensure, consistent with Utah State University’s Federal Wide Assurance, that human subjects research is conducted in accordance with applicable regulations, USU Policies governing human subjects research, IRB Standard Operating Procedures (SOPs), and determinations of the USU IRB.

Non-compliance is any situation, incident, or process during the conduct of human subjects research that is inconsistent with any of the following: applicable local, state, federal laws, regulations or policies; USU Policies; IRB SOPs; approved IRB protocols; or any directive from the USU IRB. Non-compliance may be minor and/or infrequent, or serious and/or continuing. USU’s IRB works in collaboration with USU’s RIC, University Counsel, and other USU units in receiving allegations of, evaluating, and taking corrective action with respect to non-compliance related to human subjects research. Definitions and terms regarding non-compliance, and processes carried out with regard to non-compliance shall be as set forth in the IRB SOPs, Section II.B.10.
Non-compliant activities may be identified through IRB oversight, self-reporting, or reporting from employees, human participants or others. Allegations of non-compliance may be presented to the IRB Chair or Administrator, the Federal Compliance Manager at the RIC office, USU’s Internal Audit Services (IAS) either through the hotline or with a representative of IAS, or to University Counsel. Any report of alleged non-compliant behavior involving human subjects research shall be reported to the IRB chair at the earliest opportunity. Utah State University does not tolerate retaliation against individuals who come forward in good faith with allegations of non-compliance. In instances where non-compliance is determined, notifications will be made to the appropriate department head(s) and dean(s).

The IRB Chair shall make the initial determination of whether the substance of the non-compliance allegation would constitute non-compliance involving human subjects research. If so the IRB Chair shall follow the steps set forth in IRB SOPs, Section II.B.10, to initiate an investigation into the alleged non-compliance.

The IRB Chair or the Institutional Official may suspend the research pending investigative outcomes and determinations by the convened IRB if there is cause to believe that the allegations may constitute serious or continuing non-compliance, or if the allegations otherwise contain information that would constitute an elevation in the risk to participants.

Investigative findings shall be presented to the IRB at its next convened meeting. The IRB shall review the documentation and evidence as required in the IRB SOPs. If the convened IRB determines that serious or continuing non-compliance has occurred, it shall require a corrective action plan as deemed appropriate for the circumstances. The IRB is authorized to suspend or terminate its approval of human subjects research. Other actions may be required, including but not limited to: more frequent review of approved research presented by the researcher, increased monitoring of the consent process or of the research, informing participants of aspects of the non-compliance that may have increased their risks, or impacted their willingness to participate in the research, or requiring additional training for researchers and research staff involved.

4.9 Unanticipated Problems

Investigators shall follow the procedures contained in the IRB standard operating procedures, Chapter 9.j whenever an unanticipated problem arises having to do with risks to human participants or others. The PI shall have responsibility for identifying and reporting unanticipated risks as set forth in the SOPs, Chapter 4.f, submitting information to the chair of the IRB in sufficient detail for the Chair to draft the report as required in 4.11, below, and otherwise as required by the SOPs. If the 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.

4.10 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.

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 USU Office of Compliance Assistance, Research Integrity Officer, University Counsel, and the appropriate funding agency as set forth in 4.11, below.

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.

When a termination or suspension involves the withdrawal of current participants from a study:

1. Enrolled participants will be notified by the IRB.
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. 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.

4.11 Reports of Unanticipated Problems

Reports of unanticipated problems involving risks to participants or others, terminations, suspensions and serious or continuing non-compliance shall be submitted to federal agencies in compliance with applicable regulations. The Institutional Official shall ensure that all required reportings are completed within 15 business days.

The IRB Chair shall have responsibility for coordinating with the principal investigator, gathering any additional required information and writing the initial report, which shall include:

(1) The nature of the event or problem.
(2) The findings of USU.
(3) The action taken by the IRB and USU.
(4) The reasoning underlying the actions taken.
(5) Any plans or recommendations for a continuing inquiry or investigation.

The IRB chair shall submit the draft report in a timely manner to the RGS Division of Research Integrity and Compliance and the Research Integrity Officer for review.
Research Integrity Officer shall have responsibility for final approval and signature of the report, and for its submission to the appropriate agency. Copies of the reports shall be distributed to the IRB, Office of Human Research Protections (OHRP) when the research is covered by U.S. Department of Health and Human Services regulations, and other federal agencies when research is overseen by those agencies and such agencies required reporting separate from that to OHRP.

584.5 CONTINUOUS IMPROVEMENT OF THE HUMAN RESEARCH PROTECTION PROGRAM

The IRB and the RGS Division of Research Integrity and Compliance 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.

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.

584.6 RECRUITMENT PROHIBITIONS

The following activities shall not be permitted:

1. Payments to professionals in exchange for referrals of potential participants (finder’s fees).
2. Payments designed to accelerate recruitment that are tied to the rate of timing of enrollment (bonus payments).