BRIGHAM YOUNG UNIVERSITY

Policies and
Standard Operating Procedures
For the
Institutional Review Board

June 2018

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INTRODUCTION

Regulations require that Institutional Review Boards (IRBs) have written policies and procedures, and that activities at the institution are carried out as described in the written policies and procedures document. These Standard Operating Policies and Procedures (SOP) are written to enable IRBs to maintain a system of compliance. The SOPs of an IRB reflect not only the laws and regulations, but also the underlying ethical principles that are the basis of the IRB's mandate. Finally, these policies also reflect the overarching commitment of Brigham Young University to provide protection for all human subjects involved in research conducted under the direction of its faculty, staff and students.

The ethically responsible investigator is expected to carry the dual burden to advance knowledge that can improve the human condition or generate new knowledge and, at the same time, to recognize the absolute imperative to treat human research subjects with the utmost care and respect.

The purpose of BYU's IRB is, in collaboration with investigators, to facilitate ethical human subjects research. This includes educating the campus community, evaluating research proposals, and monitoring research practice.

These SOPs apply to all operations of the IRB. The SOPs apply to all persons employed by the IRB, all members who serve on it as part of their overall institutional responsibilities, and all others who must subscribe to its decisions and its requirements.

These policies are based on current regulations, ethical principles, and guidelines for the protection of the human subjects of biomedical and behavioral research. The policies and procedures are not an end unto themselves. They are the framework upon which research activities in these facilities are conducted.

LIST OF ABBREVIATIONS

AE	Adverse Event
CFR	Code of Federal Regulations
DHHS	Department of Health and Human Services (or HHS)
FDA	Food and Drug Administration
IBC	Institutional Biosafety Committee
IND	Investigational New Drug
IRB	Institutional Review Board
NIH	National Institutes of Health
OHRP	Office for Human Research Protections (former OPRR)
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

GLOSSARY

1. **CERTIFICATION** — Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

2. **CONFLICT OF INTEREST** — A “Conflict of Interest” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research or a Sponsored Program

3. **DEPARTMENT OR AGENCY HEAD** — Department or agency head means the head of any Federal department or agency and any other officer or employee of any Federal department or agency to whom authority has been delegated.

4. **DEPENDENT** — Dependent is defined as any person who receives more than one-half of his or her annual support from an Investigator, whether or not related to that Investigator.

5. **FAMILY MEMBERS** — Family Members are defined as the Investigator’s spouse and Dependents.

6. **FINANCIAL INTEREST** — “Financial Interest” is defined as anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, salary, commissions, consulting fees, honoraria, equity interests, interests in real or personal property, dividends, royalties, rent, capital gains, intellectual property rights, and forgiveness of debt, other than:

    1. compensation from BYU;
    2. income from seminars, lectures, or other educational activities sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
    3. income from service on advisory committees, or review panels for a public federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or

4. an interest arising solely by means of investment in a mutual, pension, or other institutional investment fund where the Investigator does not exercise control over the management and investments of such fund.

7. **HUMAN SUBJECT** "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(i) data through intervention or interaction with the individual; or

(ii) identifiable private information.

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

"Interaction" includes communication or interpersonal contact between investigator and subject.

"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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

"Identifiable private information" is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

8. **INSTITUTION** Institution means any public or private entity or agency (including federal, state, and other agencies).

9. **IRB** IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

10. **IRB APPROVAL** IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

11. **LEGALLY AUTHORIZED REPRESENTATIVE** Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the

procedure(s) involved in the research.

12. **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.

13. **RESEARCH** Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

14. **SIGNIFICANT FINANCIAL INTEREST**

Significant Financial Interest means one or more of the following Financial Interests of the Investigator (and those of the Investigator's Family Members) that reasonably appear to be related to the Investigator's University Responsibilities:

(1) With regard to any publicly traded entity, it is the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, the value of which exceeds $5,000 from one enterprise or entity;

(2) With regard to any non-publicly traded entity, it is the value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator holds any equity interest;

(3) Intellectual property rights and interests, upon receipt of income related to such rights and interests subject to the de minimis thresholds set forth by the federal regulations and guidance;

(4) Salary, remuneration, or similar payments which exceed, or are expected to exceed, $5,000 within any one-year period, when aggregated for the member and his or her Family Members; or,

(5) Any reimbursed or sponsored travel, related to an Investigator's University Responsibilities subject to the de minimis thresholds set by the federal regulations and guidance; provided, however, that Investigators need not disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an Institution of higher education.

STATEMENT OF AUTHORITY AND PURPOSE

1. Governing Principles

Brigham Young University's Human Research Protection Program (HRPP) and Institutional Review Boards (IRBs) are guided by the ethical principles applied to all research involving humans as subjects, as set forth in the Belmont Report (Appendix A). These principles are defined in the Belmont Report as follows:

- Beneficence -- The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks.

- Autonomy -- Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.

- Justice -- The selection of subjects is equitable and is representative of the group that will benefit from the research.

2. Authority

An Institution's HRPP/IRB is established and empowered under the Institution's executive authorities, and by the Institution's assurance with the Federal Office for Human Research Protections (OHRP). This Institution requires that all research projects involving humans as subjects or human material be reviewed and approved by the IRB prior to initiation of any research related activities, including recruitment and screening activities.

The HRPP/IRB is established to review all BYU human subjects research regardless of the source of funding, if any, and location of the study. All research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, are subject to these policies and procedures if one or more of the following apply:

- The research is sponsored by institutional authorities; and/or
- The research is conducted by or under the direction of any employee, faculty, staff, student or agent of the Institution in connection with his or her institutional responsibilities.

The IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. Specifically:

- The IRB may disapprove, modify or approve studies based upon consideration of human subject protection aspects;
- The IRB reviews, and has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction;
- The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators and auditing the conduct of the study, and observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
- The IRB may suspend or terminate approval of a study; and
- The IRB may place restrictions on a study and the role any investigator in such study.

Regarding externally funded research, if a human subjects research project is part of an application to a sponsoring agency, it must be reviewed and approved prior to the initiation of any human subjects research and/or expenditure of any grant/contract funds.

The IRB also has a relationship to other institutional research review committees. The IRB functions independently of, but in coordination with those other committees. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by institutional officials or other committees. However, those officials or committees may not approve research if it has been disapproved by an IRB.

3. Responsibility

A. IRB Review of Research

All research involving human subjects (as defined below), and all other activities, which even in part involve such research, regardless of sponsorship, must be reviewed and approved by the Institution's IRB(s). No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations as to the definition of “research” or “human subjects,” and their implications for the jurisdiction of the IRB under Institutional policy are determined by the IRB (Appendix C).

The IRB's purpose and responsibility is to protect the rights and welfare of human subjects. The IRB reviews and oversees such research to ensure that it meets well established ethical principles and that it complies with federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection.

The activities that require HRPP/IRB review include any activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual.

B. Failure to Submit a Project for IRB Review

The implications of engaging in human subject research without obtaining HRPP/IRB review/approval are significant. Without such review, no approval will be granted to publish results of such activity, it is also against Institutional policy to use those data to satisfy thesis or dissertation requirements. If the IRB does not approve the research, data collected cannot be used as part of a thesis or dissertation, and/or the results of the research cannot be approved to be published.

SOP: GA 101 Version No: 2 Effective Date: 1/19/18	PROCEDURES MAINTENANCE	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

Following regulations and guidance of OHRP and supported by Institutional policies, ensures that the rights and welfare of human subjects of such research will be overseen and protected in a uniform manner, regardless of changes in personnel. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects.

Standard operating policies and procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research.

Specific Procedures

1.1 Review, Revision, Approval of Policies & Procedures

1.1.1 Changes to regulations, federal guidelines, or research practice as well as the policies and procedures of BRIGHAM YOUNG UNIVERSITY may require a new SOP or a revision to a previously issued SOP.

1.1.2 Approval of new or revised SOPs is required by the Institutional Official**.**

1.2 SOP Dissemination and Training

1.2.1 When new or revised SOPs are approved, they will be disseminated to the appropriate individuals and they will be encouraged to read them.

2. SCOPE

These policies and procedures apply to all IRB members and staff.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.106
21 CFR 56.108, 56.109, 56.113

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: GA 102 Version No: 2 Effective Date: 1/19/18	IRB STAFF AND MEMBERS EDUCATION	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

Education of IRB staff and members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner throughout the Brigham Young University research community.

IRB members, staff and others charged with the responsibility for reviewing, approving, and overseeing human subject research should receive education in the regulations, guidelines, ethics and policies applicable to human subjects research.

Specific Procedures

1.1 Education

1.1.1 Management level staff and members of any IRB who are overseeing research on human subjects, that is managed, funded, or taking place in an entity under the jurisdiction of the Trustees of Brigham Young University will receive initial and ongoing education/training regarding the responsible review and oversight of research and these policies and accompanying procedures.

1.1.2 The IRB Administrator establishes the educational requirements for IRB members and staff who review research involving human subjects at this institution and who perform related administrative duties. Initial and ongoing education is provided by this institution through the OFFICE OF RESEARCH AND CREATIVE ACTIVITIES (ORCA).

1.1.3 Members of the IRB will participate in initial and continuing education in areas germane to their responsibilities.

1.1.4 Chairpersons will receive additional education in areas germane to their additional responsibilities.

1.1.5 IRB staff will receive initial and continuing education/training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOP).

1.1.6 IRB members and staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions. Brigham Young University will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

1.2 Documentation

Education/training shall be documented and added to the records of the IRB as described in these policies and procedures.

2. SCOPE

These policies and procedures apply to all IRB members and staff.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107
OHRP IRB Guidebook
21 CFR 56.107

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: GA 103 Version No: 2 Effective Date: 1/19/18	MANAGEMENT OF IRB PERSONNEL	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

IRB staff provides consistency, expertise, and administrative support to the IRB, and serves as a daily link between the IRB and the research community. Thus, the IRB staff is one of the vital components in the effective operation of BRIGHAM YOUNG UNIVERSITY's human subjects' protection program. Therefore, the highest level of professionalism and integrity on the part of IRB staff is expected.

Specific Procedures

1.1 Job Descriptions and Performance Evaluations

Members of the IRB staff should have a description of the responsibilities expected of their positions. The performance of IRB staff will be reviewed according to current Brigham Young University policy.

1.2 Staff Positions

Staffing levels and function allocation will be determined according to Brigham Young University policy, management assessment of support requirements and budget constraints.

1.3 Hiring and Terminating IRB Staff

The human resource policies of BRIGHAM YOUNG UNIVERSITY determine the policies for recruiting and hiring staff.

1.4 Delegation of Authority or Responsibility

Delegation of specific functions, authorities, or responsibilities by the Chairperson to a staff member must be documented in writing.

1.5 Documentation

The policies of BRIGHAM YOUNG UNIVERSITY's Department of Human Resources determine the means of identifying, documenting and retaining formal staff interactions (such as performance reviews, termination procedures).

2. SCOPE

These policies and procedures apply to all IRB staff.

3. APPLICABLE REGULATIONS AND GUIDELINES

None

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: GA 104 Version No: 2 Effective Date: 1/19/18	CONFLICT OF INTEREST: IRB MEMBER AND INVESTIGATOR	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest (COI) should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

Specific Procedures for Member Conflict of Interest

1.1 Definition of a COI for IRB Members

A conflict of interest is defined as a close personal or professional association with the submitting Investigator(s); direct participation in the research (e.g., protocol development, Principal or Sub-investigator); or any significant financial interest related to the research in the sponsoring company as defined in the Research Conflict of Interest Policy as (example, $5,000 or 5% ownership).

Questions regarding COIs may be referred to the IRB Administrator or IRB Chair.

1.2 Disclosure and Documentation of Financial Interest and COI

No regular or alternate member of the IRB or consultant may participate in the review of any research project in which the member has a conflict of interest, except to provide information as requested.

It is the responsibility of each voting member or alternate member of the IRB to disclose any COI in a study submitted to the IRB and recuse himself or herself from deliberations and voting.

The procedures for recusal of IRB members, including the Chairperson, from deliberating/voting on all protocols for which there is a potential or actual financial conflict of interest are detailed in SOP FO 303, IRB Meeting Administration.

1.3 Education and Training in COI

IRB members and staff are required to participate in education and training activities related to conflict of interest issues including those required by their institution.

Specific Procedures for Investigator Conflict of Interest

All PIs and key personnel applying to conduct human subjects research must disclose on each IRB application any potential conflicts of interest involving outside significant financial interest (see Definitions) and

- any proprietary interest related to the research, including but not limited to a patent, trademark, copyright, or licensing agreement;
- any arrangement, ownership interest, or compensation that could be affected by the outcome of the research; and

The IRB will evaluate the disclosure for any considerations relating to the protection of human subjects. If there is a significant financial interest that the IRB believes relates to the study, the IRB will require the investigator to disclose the interest(s) to potential subjects by including appropriate language in the informed consent statement. In addition, the IRB may take any of the following actions:

A. Require an independent investigator to obtain consent;

B. Require an independent investigator to conduct the study;

C. Require independent safety monitoring;

D. Require frequent renewal; and/or

E. Any other restrictive action deemed appropriate based on the nature of the conflict.

The IRB has final authority to decide whether the interest and management, if any, allow the research to be approved.

2. SCOPE

These policies and procedures apply to all IRB members, faculty, staff and students of the BRIGHAM YOUNG UNIVERSITY.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 46.103, 107

21 CFR 56.107

21 CFR 54 (as reference)

42 CFR 50

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: GA 105 Version No: 2 Effective Date: 1/19/18	SIGNATORY AUTHORITY	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

The CHAIRPERSON OR IRB ADMINISTRATOR is authorized by the Institutional Official to sign any and all documents in connection with the review and approval of research projects involving the use of humans as subjects, which have been reviewed and approved pursuant to Brigham Young University policies and procedures. In the absence of the IRB Administrator or Chairperson, the ORCA Director may sign a review or approval of research letter. In all cases individuals must sign their own name and no other.

Specific Procedures

1.1 Authorization for Signatory Authority

Authorization to sign documents not described in this procedure may be made in writing from the Institutional Official.

1.2 Correspondence with External Agencies

Any letters, memos or emails sent to agencies of the federal government, funding agencies (whether private or public) or their agents will be signed by the Institutional Official.

2. SCOPE

These policies and procedures apply to all IRB staff.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: GA 106 Version No: 1 Effective Date: 1/19/18	PI ELIGIBILITY	Supercedes Document Dated: N/A

1. OBJECTIVE

It is the policy of BYU that only individuals meeting the eligibility requirements of a principal investigator defined in this policy may be listed as such on applications for human subjects research.

Specific Procedures

Each human subject research submission must have a designated principal investigator (PI).

The PI generally is a tenured or tenure-track faculty member of the University but may be any full-time academic appointee or staff who is personally and professionally qualified to conduct the project as determined by the dean or director of the submitting unit. Approval of the proposal by the submitting unit or dean's office constitutes the unit's approval of the employee as PI.

Full-time faculty members (regardless of academic rank) and full-time staff are eligible to serve as PI. Other persons (such as visiting faculty) are eligible to serve as PI upon approval by the dean and IRB Office. In such cases, a Memorandum of Understanding must be signed and on file with the IRB Office.

Due to lines of institutional responsibility and accountability, neither post-doctorates nor students, either graduate or undergraduate, may serve as PI. A faculty mentor must be identified as the PI with the student or post-doctorate identified as Co-Investigator. The faculty member shares PI responsibilities with post-doctorate or student.

2. SCOPE

The policies and procedures apply to all human subjects research involving post-doctorates or students.

3. APPLICABLE REGULATIONS AND GUIDELINES

BYU Policy

SOP: OR 201 Version No: 2 Effective Date: 1/19/18	Composition of the IRB	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

The IRB shall ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB should also promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, the IRB shall consist of at least five regular, voting members. Qualified persons from appropriate professions shall be considered for membership. IRB membership shall not consist entirely of men or of women.

The institution will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

Specific Procedures

1.1 Membership Selection Criteria

The members of the IRB shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with this institution beyond IRB membership, either personally or through a family member.

1.2 Composition of the Board

Regular members: The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include:

A. Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which Brigham Young University will draw its research subjects.

B. Scientific members: The IRB includes individuals with appropriate education and experience in social, physical biomedical, or biological sciences. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 CFR 56.107(f).

C. Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in scientific areas.

E. Chairperson: The IRB Chairperson should be a highly respected individual, from within Brigham Young University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The Chairperson must have continuing status at the University in order to serve.

Brigham Young University may invite a graduate student to serve as a representative for the student body.

2. SCOPE

These policies and procedures apply to the membership of the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: OR 202 Version No: 2 Effective Date: 1/19/18	MANAGEMENT OF THE IRB	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

The management of the membership of the IRB and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the IRB Administrator.

Specific Procedures

1.1 Term

Members will be appointed to the IRB for a term of *three* years. The Chairperson will be appointed for a term of *five* years. Graduate Student member will serve on the IRB for a term of *one* year. Reappointment for additional terms may occur, by mutual agreement of the Institutional Official, the IRB Chairperson, the IRB Administrator, and the Member.

1.2 Appointments

The Institutional Official in consultation with the IRB Chairperson and IRB Administrator has the authority to appoint members to the IRB. Members will be solicited from Brigham Young University and greater Utah communities.

1.3 Resignations and Removals

A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. A member may be removed by the Institutional Official. The Chair can be removed with a majority of the IRB members voting against him/her or removal by the Institutional Official.

1.4 Compensation

Participation by Brigham Young University faculty, staff, or students is considered a component of their job responsibilities as established by their supervisors. Regular members who are not affiliated with Brigham Young University may receive compensation for their service.

1.5 Liability Insurance

Regular and alternate members have liability insurance coverage as part of their IRB membership in their capacity as agents of Brigham Young University.

2. SCOPE

These procedures apply to the IRB membership.

3. APPLICABLE REGULATIONS AND GUIDELINES

None

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: OR 203 Version No: 2 Effective Date: 1/19/18	DUTIES OF IRB MEMBERS	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of BYU research. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human subjects protection, biomedical and behavioral research ethics, and the policies of BRIGHAM YOUNG UNIVERSITY germane to human subjects protection.

Specific Procedures

1.1 Duty to Brigham Young University

The IRB is appointed as the Institutional Committee. As such, the IRB members serve BRIGHAM YOUNG UNIVERSITY as a whole, rather than a particular department. Therefore, members must not allow their own interest or that of their department to supersede their duty to protect the rights and welfare of research subjects.

1.2 Specific Duties

1.2.1 Regular Members:

- Nonaffiliated member(s): Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- Non-scientific members: Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.
- Scientific members: Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.
- Graduate Student member: Graduate Student member is expected to provide input and be willing to discuss issues and research
- Chairperson: In addition to the above responsibilities (germane to the member's capacity), the Chairperson chairs the meetings of the IRB. The Chairperson performs or delegates to an appropriate voting IRB member

expedited review when appropriate. He/she is empowered to suspend the conduct of an approved study deemed to place individuals at unacceptable risk, pending IRB review. The Chairperson is also empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an investigator is not following the IRB's requirements.

A. The Chairperson may appoint a Co-chairperson to assist or act on behalf of the Chairperson in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis. The Chairperson also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Such documentation must be in writing and maintained by the IRB Administrator.
B. The Chairperson represents the IRB in discussions of IRB decisions with other members of the University.
C. The Chairperson directs the proceedings and the discussion of the full-committee meeting. This includes keeping the discussion focused on important IRB issues and seeing that the full-committee meeting process is both effective and efficient.
D. The Chairperson has an in-depth understanding of the ethical issues, state law, institutional policy, and federal research regulations that are applicable to the studies being reviewed. The Chairperson is not expected to be the only authority on compliance issues. The IRB Administrator or other committee members also take responsibility for compliance verification.
E. The Chairperson assists the IRB administration in drafting letters from the full-committee meeting to investigators regarding IRB decisions. The Chairperson reviews and makes decisions about responses to conditions for IRB approval of research in a timely fashion.

The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

1.2.2 Reviewers:
In addition to the duties described in section 1.3.1, each regular member may be expected to act as a Reviewer for studies at convened meetings. Each member presents his or her findings resulting from review of the application materials and participates in the IRB discussion of the study.

2. SCOPE

These policies and procedures apply to all IRB Members.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107, 46.108, 46.109

OHRP IRB Guidebook

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

1. OBJECTIVE

IRB members rely on the documentation submitted by Investigators for initial and continuing review. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets the IRB's criteria for approval.

A submitted protocol will be scheduled for IRB review when it has been determined that the information and materials submitted present an adequate description of the proposed research.

Specific Procedures

1.1 Submission Requirements for Initial Review

1.1.1 Required: Investigators applying for initial approval of a proposed research protocol must submit:

- Complete IRB Application
- Questionnaires & assessment instruments
- Proposed informed consent document
- Proposed subject instructions
- Any other supporting material, such as examples of recruitment advertising, etc.

1.2 Submission Requirements During Approval Periods

1.2.1 During the approval period, Investigators must submit documentation to inform the IRB about changes in the status of the study including, but not necessarily limited to:

- Any protocol changes not previously approved by the IRB
- Deviations from the protocol (protocol violations)
- Reports of serious or unexpected adverse events
- Changes to the status of Principal or Sub-investigators

1.2.2 Progress Report and/or Request to Renew IRB Approval

Within sixty days prior to IRB approval expiration date, Investigators requesting renewal of an approved research project must submit:

- Annual Review of Approved Research form.
- All the required materials that are indicated on the form are also required prior to review.

1.3 Action Taken If Documentation is Not Adequate or Additional Information is

Required

If the IRB or IRB staff determines that the submitted documents are not adequate, Investigators will be required to submit additional information. No incomplete submission will be reviewed by the IRB.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108, 46.111, 46.115

21 CFR 56.108 (a)(4), 312, 812

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: FO 302 Version No: 3 Effective Date: 2/6/18	RESEARCH EXEMPTIONS	Supercedes Document Dated: 1/19/18

1. OBJECTIVE

Research activities in which the only involvement of human subjects will be in one or more specific categories, which are listed in section 1.1 of these Procedures, may be exempt from Federal review. Exempt status proposals are reviewed by the IRB Administrator. Determination of exemption must be based on regulatory and institutional criteria.

Specific Procedures

Human subjects research activities must be reviewed to determine whether the research meets one or more of the exemption categories described below and whether the research complies with applicable ethical standards. Federally-funded research determined to be exempt is not subject to 45 CFR 46 unless otherwise specified.

Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must submit an application to the BYU IRB office for final determination of exemption.

Research qualifies as exempt only if it falls into one or more of the exempt categories described below and meets these additional requirements:

- The research must present no more than minimal risk to subjects.
- The research is consistent with the ethical principles reflected in the Belmont Report, which include:
    - **Respect for Persons (Autonomy).** Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
    - **Beneficence.** Individuals should not be harmed and the research should maximize possible benefits and minimize possible harms.
    - **Justice.** Selection of participants should be equitable and the benefits and risks of research should be distributed fairly.
- As appropriate, there are adequate provisions to maintain the privacy interests of participants and the confidentiality of data.

1.1 Exempt Research Activities

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review:

A. Category 1

45 CFR 46.101 (b)(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

B. Category 2

45 CFR 46.101 (b)(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

C. Category 3

45 CFR 46.101 (b)(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. Category 4

45 CFR 46.101 (b)(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

E. Category 5

45 CFR 46.101 (b)(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

F. Category 6

45 CFR 46.101 (b)(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research involving prisoners
The exemption categories listed above do not apply to research involving prisoners.

Research involving children
Exemption Category 2, 45 CFR 46.101(b)(2), does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Research subject to FDA regulations
The IRB will not consider any research exempt that involves a test article regulated by the FDA, unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(6) and 21 CFR 56.104(d).

Research subject to HIPAA regulations
A determination that a study is exempt does not remove relevant HIPAA considerations. If HIPAA applies to an exempt study, authorization or a waiver of authorization must be obtained.

Continuing Review
Studies confirmed as meeting the criteria for exemption are not subject to continuing review. BYU, nonetheless, remains responsible for exercising proper oversight for research conducted under its auspices. To exercise this oversight, the IRB office will annually send a notice to all PIs to confirm:

- That the research is on-going. If it is not, the PI will be asked to close out the study.
- That the PI is aware of her/his responsibilities under the BYU IRB exemption determination.

2. SCOPE

These policies and procedures apply to Investigator claims for exemption from Federal review.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101

21 CFR 56. 104, 105

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs

1. OBJECTIVE

All studies that do not meet the criteria for exemption or expedited review will be reviewed by the IRB at convened meetings at which a quorum is present. Each IRB will meet *monthly*, or at some other frequency determined by the IRB Chairperson and the IRB Administrator.

Specific Procedures

1.1 Quorum

1.1.1 A quorum is defined as one half of the number of regular members plus one.

1.1.2 A quorum consists of regular and/or their alternate members and includes: at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.

1.1.3 An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.

1.1.4 A special consultant(s) will not be used to establish a quorum.

1.2 Meeting Materials Sent Prior to IRB Meetings

All IRB members will be sent study documentation required for review sufficiently in advance of the meeting to allow time for adequate review. These include:

1.2.1 Agenda: a meeting agenda will be prepared by the IRB Secretary and distributed to IRB members prior to each meeting. The meeting agenda will remind members to declare any potential COI they may have with research that is about to be reviewed at the outset of each meeting. The IRB minutes should also specifically reflect such recusals as they occur during meetings.

1.2.2 Reviewer materials

A. All IRB members

- Full Investigator's protocol
- Proposed informed consent document(s) and/or script as appropriate
- Copies of surveys, questionnaires, or electronic media.
- Copies of letters of assurance or cooperation with research sites

- Advertising intended to be seen or heard by potential subjects, including email solicitations.
- Grant Application: The IRB Administrator or a designated reviewer will review the grant application, if any, to ensure that the research described in the IRB proposal is consistent with the grant application. The grant application does not need to be reviewed by every IRB member. A copy of the grant application or proposal should be retained in the IRB/ ORCA Office and made available to any IRB member who may wish to review it. The IRB may require the Investigator(s) to: (i) summarize, and cross-reference to the application, specific information contained in the grant application; (ii) identify any IRB-approved protocols that describe the proposed research; and (iii) either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.

1.3 Minutes

The Federal regulations for the protection of human subjects [45 CFR 46.115(a)(2)] require that "Minutes of IRB meetings… shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution."

1.3.1 Recording: The IRB Secretary or designee will take minutes of each meeting. Minutes will be written in sufficient detail to show the following:

- Meeting attendance; including status of each attendee (regular member, consultant, etc.), and conflicts of interest, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research and protocol specific determinations.
- Summary of the discussion of controverted issues and resolution;
- Voting results, including number for, against and members who recused themselves.

1.3.2 Approval: Draft minutes will be distributed to members at the next IRB meeting for review and approval.

- Corrections requested by the IRB will be made by the IRB Secretary or designee and the minutes in printed form are made available upon request. The IRB Administrator will maintain copies of the minutes.

A majority of members must vote in favor of an action for that category of action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest will recuse

themselves from the discussion and voting and such will be noted in the minutes.

1.4 Telephone Use

1.4.1 Convened meeting using speaker phone:

Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a electronic communication. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the material the other members have reviewed.

1.4.2 Meetings Conducted Via Conference Calls:

On occasion, meetings may be convened via a conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "polling" (where members are contacted individually) will not be accepted as a conference call.

Members not present at the convened meeting, nor participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

1.5 Voting

Members of the IRB vote upon the recommendations made by the reviewers according to the criteria for approval, protocol specific determinations and frequency of review for each protocol.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.108, 46.109, 46.115

21 CFR 56.108, 56.109

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: FO 304 Version No: 2 Effective Date: 1/19/18	ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

Specific Procedures

1.1 Exemptions

The IRB Administrator will oversee claims for exemption submitted by Investigators in consultation with the IRB Chairperson trained to review exempt protocols. Such claims of exemption will be logged and filed.

1.2 Incomplete Submissions

Incomplete applications will not be accepted for review until the Investigator has provided all necessary materials as determined by the IRB Administrator or designee. The IRB Administrator will notify the submitting Investigator to obtain any outstanding documentation or additional information before the application is scheduled for review.

1.3 Scheduling for Review

Complete applications that appear to meet qualifications for expedited review will be submitted to the Chairperson or his/her designee. If a submission meets expedited review requirements, the review will be performed as described in SOP RR 401 (Expedited Review). All other applications will be placed on the agenda for the earliest meeting possible for review by the full IRB as described in SOP FO 303 (IRB Meeting Administration).

1.4 Distribution to Members Prior to IRB Meetings

Copies of application materials will be distributed to all IRB members, generally ten (10) days prior to the meeting. Each regular member of the IRB, and any alternate members attending the meeting in place of a regular member, will receive a copy of the material. Consultants will only receive copies of material that pertain to their requested input.

The originals of submission materials will be retained in the IRB Office and available for the IRB meeting.

1.5 Confidentiality

All material received by the IRB will be considered confidential and will be distributed only to meeting participants (regular members, alternate members and special consultants) for the purpose of review. All application materials will be stored in an IRB study file with access limited to the IRB members and staff and other authorized officials.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109

21 CFR 56.109

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

1. OBJECTIVE

The IRB's files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.

Records must be accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.

Required documents must be submitted to the appropriate funding entity as required.

Specific Procedures

1.1 Document Retention

The IRB Office must retain all records regarding an application (regardless of whether it is approved) for at least three (3) years. For all applications that are approved and the research initiated, the IRB Office must retain all records regarding that research for at least three (3) years after completion of the research.

1.1.1 Study-related documents:

Adequate documentation of each IRB's activities will be prepared, maintained and retained in a secure location. Retained documents include:

- Copies of all original research protocols reviewed, approved consent documents, and reports of adverse events occurring to subjects and reported deviations from the protocol.
- Agendas and minutes of all IRB meetings.
- Copies of all continuing review activities.
- Copies of all correspondence between the IRB and the Investigators.
- Statements of significant new findings provided to subjects.
- Reports of any complaints received from subjects.

1.2 IRB Administration Documents

The IRB Office must maintain and retain all records regarding IRB administrative activities that affect review activities for least three (3) years.

The IRB Office must retain all records regarding protocols that are approved and the research initiated for at least three (3) years after completion of the research.

1.2.1 Rosters of regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations; and any employment or other relationship between each member and the IRB and/or the Brigham Young University (e.g., full-time employee, part-time employee, paid or unpaid consultant).

Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.

Current and obsolete membership rosters will remain in the IRB Office and then archived according to Brigham Young University policy.

The roster of IRB members must be submitted to OHRP. Any changes in IRB membership must be reported to OHRP.

1.2.2 Maintain current and obsolete copies of the Standard Operating Policies and Procedures.

1.2.3 Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson must be documented in writing and filed in the IRB Office.

1.3 Destruction of Copies

All material received by the IRB, which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the meeting and destroyed by a method deemed appropriate by the Institutional Official.

1.4 Archiving and Destruction

After 3 years, all documents and materials germane to IRB determinations will be archived according to institutional policy. Archiving policies of the Brigham Young University will determine when such archived records may be destroyed.

2. SCOPE

The policies and procedures apply to all controlled documents used in the submission, initial review, and continuing review of research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

21 CFR 56.115

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

1. OBJECTIVE

An expedited review procedure consists of a review of research involving human subjects by the Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRB.

Specific Procedures

1.1 Definition of Minimal Risk

Minimal risk is defined as "...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…."

The IRB may use an expedited review procedure to review either or both of the following:

- Some or all of the research which involves only procedures listed in one or more of the categories below and found by the reviewer(s) to involve no more than minimal risk;
- Minor changes in previously-approved research during the IRB-approval period;

Expedited research categories

- **Category 1**: Clinical studies of drugs and medical devices only when either condition below is met:
    - Research on drugs for which an investigational new drug application (21 CFR 312) is not required. Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review;
    - Research on medical devices for which (1) an investigational device exemption application (21 CFR 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- **Category 2**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    - From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in

an 8 week period and collection may not occur more frequently than 2 times per week; or

- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- **Category 3**: Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
  - Hair and nail clippings in a nondisfiguring manner;
  - Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - Permanent teeth if routine patient care indicates a need for extraction;
  - Excreta and external secretions (including sweat);
  - Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  - Placenta removed at delivery;
  - Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or
  - Sputum collected after saline mist nebulization.

- **Category 4**: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared / approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). **Examples**:
  - Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - Weighing or testing sensory acuity;
  - Magnetic resonance imaging;
  - Electrocardiography; electroencephalography, thermography detection of naturally occurring radioactivity, electroretinography,

ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
    - Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight and health of the individual.

- **Category 5**: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101(b)(4)]. This listing refers only to research that is not exempt.

- **Category 6**: Collection of data from voice, video, digital, or image recordings made for research purposes. If the data collected is considered individually identifiable health information, the data must be protected from inappropriate use and disclosure.

- **Category 7**: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.101(b)(2) and (b)(3)). This listing refers only to research that is not exempt.

- **Category 8**: Continuing review (i.e. renewal) of research previously approved by the convened IRB as follows:
    - Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    - Where no subjects have been enrolled and no additional risks have been identified; or
    - Where the remaining research activities are limited to data analysis.

- **Category 9**: Continuing review (i.e. renewal) of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1.2 Cautions

1.2.1 The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

1.2.2 The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Furthermore, the expedited review procedure may not be used for classified research involving human subjects.

1.3 Authority of the IRB Chairperson

The IRB Chairperson (or designated reviewer) may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the full IRB.

1.4 Notification of the IRB

When the expedited review procedure is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting.

1.5 Documentation

If the study qualifies for expedited review, the IRB Chairperson or designee will document his/her determination of risk.

The minutes will include documentation of the studies that were reviewed via expedited review. Records are available for member review to answer any concerns.

1.6 Additional Items That May be Reviewed by the Chairperson or Designee

1.6.1 Conditional approval pending minor revisions: Revisions to consent documents and other documentation submitted as a result of full IRB review and as a condition to final approval may be reviewed by the IRB Chairperson or his/her designee. Final approval will be issued providing the revisions or documentation do not indicate or result in a **significant** change to the study or change **in** the risk/benefit ratio.

1.6.1 Other Reviews

- The IRB Chairperson may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Any protocol revision that entails more

than a minimal risk to the subjects must be reviewed by the full IRB at a convened meeting.

- Revisions to informed consent documents: Minor changes to informed consent documents that do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures may be reviewed and approved by the Chairperson/designee.
- Serious adverse event and safety reports: The Chairperson will review all reports concerning adverse events. If the Chairperson feels that action is needed to protect the safety of research subjects due to the nature or frequency of reported adverse events, he/she may take such action to the full IRB or designated subcommittee, which will review the adverse events and study in question to determine action, if any, by the IRB. The IRB Chairperson acting for the IRB will review summaries of safety reports and serious adverse events as soon as possible.
- Advertisements: The IRB Chairperson, or his/her designee may approve new or revised recruitment advertisements or scripts.

1.6.2 Translations:

- Translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB(s) that qualifies for expedited review.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102(i), 46.110

21 CFR 56.110

OHRP IRB Guidebook

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: RR 402 Version No: 2 Effective Date: 1/19/18	INITIAL REVIEW - CRITERIA FOR IRB APPROVAL	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

All research proposals that intend to enroll human subjects must meet certain criteria before study related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to BRIGHAM YOUNG UNIVERSITY's system may apply and must be met as well.

Specific Procedures

1.1 Minimal Criteria for Approval of Research

In order for a research project to be approved, the IRB must find that:

A. Risks to subjects are minimized:

- By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

- In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

C. Selection of subjects is equitable.

- In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.

E. Informed consent will be appropriately documented as required by local, state and federal regulations.

F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

H. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.

I. Studies are reviewed at periods appropriate to the degree of risk research subject are exposed to due to their participation in the study, but at least annually.

1.2 Other Criteria

The IRB may require verification of information submitted by an investigator. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

The criteria used to determine whether third-party verification is required may include:

- Investigators that conduct studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Investigators that conduct studies that involve large numbers of subjects, and
- Investigators selected at the discretion of the IRB.

Projects that need third party verification from sources other than the Investigator that no material changes have occurred since previous IRB review is determined, will have such assessment performed as necessary.

1.3 Reliance on Other IRBs for Review and Approval of Research Conducted at BRIGHAM YOUNG UNIVERSITY.

Under authority granted by the Board of Trustees of Brigham Young University, the AAVP may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Multiple Project Assurance/Federal-wide Assurance agreements (MPA/FWA).

2. SCOPE

These policies and procedures apply to all IRB staff and members and to research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

21 CFR 56.108, 56.111

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: RR 403 Version No: 2 Effective Date: 1/19/18	EVENTS REQUIRING INVESTIGATORS TO REPORT TO THE IRB	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

No Investigator has a right to conduct research within this institution. Rather, it is a privilege granted by society as a whole and the Trustees of BRIGHAM YOUNG UNIVERSITY in particular.

IRB approval may be withdrawn at any time if warranted by the conduct of the research. The regulations authorize the IRB to establish procedures for the concurrent monitoring of research activities involving human subjects. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research involving human subjects must be reviewed no less than once per year.

IRB approval for the conduct of a study may be withdrawn if the risks to the subjects are determined to be unreasonably high, for example, more than an expected number of adverse events, unexpected serious adverse events; or evidence that the Investigator is not conducting the investigation in compliance with IRB or Institutional guidelines. Such findings may result in more frequent review of the study to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or the study terminated. As appropriate, continuing review may include:

- Review of Serious and Unexpected Adverse Events
- Amendments
- Review of Significant New Findings
- Reports from Employees, Staff and Faculty
- Noncompliance
- Site Visits and Third-Party Verification

Specific Procedures

1.1 Serious and Unexpected Adverse Events

Subject safety is of the greatest importance for both the individual subject and the goals of the clinical study. If the event is serious and unexpected, prompt reporting to the Sponsor and to the IRB is mandatory. Reports will be reviewed by the IRB Chairperson or designee. If the Chairperson determines that action may be needed to protect the safety of research subjects due to the nature or frequency of reported adverse events, he/she may take such action and/or the full IRB or designated subcommittee will review the adverse events and study in question to determine action, if any, by the IRB. The IRB, or

designated subcommittee will review summaries of all safety reports and serious adverse events as soon as possible at a convened meeting.

1.2 Amendments

Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

Investigators or Sponsors must submit requests for changes to the IRB in writing. Upon receipt of the protocol change, the Chairperson or his or her designee, with assistance of the IRB Administrator, will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the IRB. Minor changes, involving no more than minimal risk to the subject, will be reviewed by the expedited review procedure (SOP RR 401-Expedited Review).

1.3 Significant New Findings

During the course of a study, the IRB may review reports generated from adverse event reports, current literature, and other sources to ascertain the status of the study and assess whether or not the risk/benefit balance is still acceptable. The IRB will determine whether or not new information needs to be conveyed to subjects, or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy.

1.4 Reports of Concerns

It is the responsibility of the IRB staff and members to act on information or reports received from any source that indicate a study being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of research subjects.

1.5 Ensuring Prompt Reporting of Any Serious or Continuing Noncompliance with Applicable Regulations or the Requirements or Determinations of the IRB

All credible reports of inappropriate involvement of human subjects in research must be investigated by the IRB Chairperson/IRB Administrator and referred to the IRB. The results of the investigation will be reported to the appropriate BRIGHAM YOUNG UNIVERSITY official(s). Regulatory authorities or Sponsors may also be notified. Such reports of noncompliance may come from any source including IRB members, Investigators, subjects, institutional personnel, the media, anonymous sources or the public.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm

to subjects. All such suspension and or terminations will be reported to the OHRP and FDA as appropriate.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.109, 46.112, 46.115

21 CFR 812.64

21 CFR 56.108, 56.109, 56.113

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: RR 404 Version No: 3 Effective Date: 2/6/18	CONTINUING REVIEW – CRITERIA FOR RENEWAL	Supercedes Document Dated: 1/19/18

1. OBJECTIVE

The IRB conducts continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year.

Specific Procedures

Studies Confirmed as Exempt

- Studies confirmed as meeting the criteria for exemption are not subject to continuing review. BYU, nonetheless, remains responsible for exercising proper oversight for research conducted under its auspices. To exercise this oversight, the IRB office will annually send a notice to all PIs to confirm:
- That the research is on-going. If it is not, the PI will be asked to close out the study
- That the PI is aware of her/his responsibilities under the BYI IRB approval

Studies Approved by Expedited Review or Convened IRB

1.1 Interval for Review for Purposes of Renewal

The IRB must conduct continuing review of protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk, which is determined at the initial review, but not less than once per year. “Not less than once per year" means that the research must be reviewed on or before the one-year anniversary of the previous IRB review date, even though the research activity may not have begun until sometime after the IRB gave its approval.

Investigators or qualified designees are required to submit a periodic report prior to the expiration of the study or as specified by the IRB, but at least annually. The report should normally be filed 60 days before the study approval period ends.

1.2 Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If Continuing Review Report forms and other requested progress reports are not received as scheduled, the Investigator must suspend the study and study enrollment.

However, if the Investigator is in communication with the IRB, the Continuing Review Report or other report is forthcoming, and in the opinion of the IRB, subjects participating is such a study would suffer a hardship if medical care were discontinued, appropriate medical care may continue beyond the

expiration date for a reasonable amount of time. However, new subjects cannot be enrolled. The IRB will address on a case-by-case basis those rare instances where failure to enroll new subjects would seriously jeopardize the safety or well-being of an individual.

1.3 Criteria for Renewal

Continuing review must be substantive and meaningful. When considering whether or not to renew a study, the IRB revisits the same criteria used to grant initial approval. Therefore, the IRB (or the reviewers for protocols reviewed under an expedited procedure) must determine that:

- The risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
- The selection of subjects continues to be reasonable in relation to anticipated benefits;
- Informed consent continues to be appropriately documented;
- Additionally, there are:
    - Provisions for safety monitoring of the data,
    - Protections to ensure the privacy of subjects and confidentiality of data, and
    - Appropriate safeguards for vulnerable populations.

Because it may be only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio, the IRB can then determine whether or not the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination.

In order to determine the status of the study, the following will be revisited:

1.3.1 Consent document: Each member of the IRB shall review the currently approved consent document and ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject in an updated consent document.

1.3.2 Current approved protocol including any amendments to protocol since initial review: A copy of the protocol will be sent to the reviewer of the continuing review. Amendments to a research protocol should be submitted as generated during the course of the study. They also may be submitted at the time of continuing review. A separate cover letter describing the change and all appropriate documentation (approved consent form) must accompany the continuing review application.

1.3.3 Progress report: All IRB members shall receive a progress report prepared and submitted by the Investigator along with the number of

subjects entered to date and since the last review. The progress report shall summarize adverse event experiences, amendments, changes in training of personnel and new COI disclosure as applicable, and provide a reassessment of the risk-to-benefit ratio.

1.4 Possible Outcomes of Continuing Review

As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. The IRB may need to impose special precautions or relax special requirements it had previously imposed on the research protocol.

1.5 Expedited Review for Renewal

A protocol that was originally reviewed using the expedited review procedure may receive its continuing review on an expedited basis. Additionally, a standard-review protocol that meets the continuing review requirements under Expedited Review Category 8 or 9 may undergo expedited review (e.g. no subjects have been enrolled, remaining activities limited to data analysis; see SOP RR 401, Expedited Review for all requirements).

When conducting research under an expedited review procedure, the IRB Chairperson or designated IRB member conducts the review on behalf of the full IRB using the same criteria for renewal as stated in section 1.3 of this Procedure. If the reviewer feels that there has been a change to the risks or benefits, he or she may refer the study to the full IRB for review.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109, 46.111

21 CFR 56.108,111

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: RR 405 Version No: 2 Effective Date: 1/19/18	CATEGORIES OF ACTION	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or to specify modifications required to secure IRB approval of the research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with the IRB's conflict of interest policies. When reviewed via expedited review, the Chairperson or designee can take any of the following actions except to disapprove a study.

Specific Procedures

1.1 Determinations

The IRB may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

A. Approval: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or Chairperson or designee and, if appropriate, expire within one (1) year of the meeting date, but not later than the day preceding the date of review.

Approvals are always considered conditional. The conditions for continued approval, and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

B. Withheld Approval: Minor modification of, or addition to, a protocol or accompanying document(s) is required. Changes will be voted upon during the IRB's meeting, as well as the terms of approval. The Investigator will be informed in writing of the required changes and requested information and must provide the IRB with the changes or information.

The IRB Chairperson or his/her designee has the authority to review the information via expedited review unless the IRB requires that the material or information be reviewed by the full IRB, the reviewer or another individual delegated by the IRB to review the response. Upon satisfactory review, approval will be issued as of the date that the requested information or materials are approved. However, the expiration date of IRB approval will be based on the anniversary date of the initial IRB review. Subjects must not be recruited into the study until final approval has been issued.

C. Tabled: Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator.

D. Disapproval: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108, 46.109

21 CFR 56.109, 56.111, 56.113

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: RR 406 Version No: 1 Effective Date: 1/19/18	SUBJECT COMPENSATION	Supercedes Document Dated: N/A

1. OBJECTIVE

Research subjects may be offered compensation to offset the time and inconvenience involved in participating in research. Within bounds, it may also serve as an incentive for participation. It is not, however, to be considered a benefit of participation in the research.

There are no specific regulations on compensation other than it may not constitute undue influence or coercion. Investigators and IRB are both responsible to ensure that any compensation provided to subjects is fully disclosed and does not constitute either undue influence or coercion.

Specific Procedures

How subjects may be compensated may take different forms, both monetary and non-monetary. Examples include but are not limited to

- Monetary: cash, gift cards, coupons
- Non-monetary: gift, course credit, extra credit

Compensation may, further, be provided to a subject either directly and indirectly or by means of a drawing.

Both the investigator and the IRB should carefully consider the timing of the compensation. If the research involves a single interaction between the investigator and the subject, compensation should be provided immediately following said interaction or as soon as appropriate thereafter. For research that involves multiple interactions or procedures, providing the compensation at the end of the research may pressure the subject to not withdraw as it is their right – and thus constitute undue influence or coercion. In such cases, compensation should be prorated through the course of the study and provided proportionately throughout the course of the research.

All information regarding compensation must be provided to the subject through the informed consent document and process including but not limited to:

- Amount of compensation
- Timing of compensation
- If a drawing, description of the drawing process and odds of winning compensation

2. SCOPE

The policies and procedures apply to all human subjects research providing compensation to subjects conducted by BYU investigators

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

4. REFERENCES TO OTHER APPLICABLE SOPs

SOP: SC 501 Version No: 2 Effective Date: 1/19/18	VULNERABLE POPULATIONS	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

Not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Some persons are in need of extensive protection, even to the point of excluding them from activities that may harm them. Other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. Indeed, some types of research may, in and of themselves, create a vulnerable group – that is, the subjects lose their autonomy or are exposed to unknown risks. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

Potentially vulnerable groups may include:

- Prisoners
- Children
- Pregnant women and fetuses
- Other vulnerable groups

Specific Procedures

1.1 Prisoners

1.1.1 If an investigator indicates in the study submission that prisoners will participate in the research, or that subjects may reasonably be expected to be incarcerated at some time point during the study, the following additional requirements will apply to IRB review of the project:

A. Local regulations: In addition to meeting federal regulations, the project must comply with local and state requirements for inclusion of prisoners as subjects.

B. IRB composition: A majority of IRB members will have no association with the prison(s) involved; and at least one member shall be a prisoner advocate with appropriate background and experience to serve in that capacity.

C. Additional duties where prisoners are involved: The IRB may review research involving prisoners only if it finds that the following conditions are met:

- The research falls into one of the following categories:

i. The research under review involves solely research on the practices both innovative and accepted, which has the intent and reasonable probability of improving the health and well being of the subjects. In cases where prisoners may not benefit from the research because they are assigned to a control group in a manner consistent with the protocol approved by IRB, the FDA has published notice in the Federal Register of its intent to approve such research.

ii. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials on hepatitis) provided that the Secretary, HHS, or designee has published notice in the Federal Register of its intent to approve such research.

- Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.
- The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.
- Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Unless the Investigator provides the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of eligible prisoners for the research project.
- Any information given to subjects is presented in language that is appropriate for the subject population.
- Adequate assurance exists that parole board(s) will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the clinical investigation will have no effect on his/her parole.
- Where there is need for follow-up examination or care of subjects after the end of their participation in the research, adequate provision has been made for such examination or care, taking into account the varying lengths of prisoner sentences, and for informing subjects of this fact.

1.1.2 When Subjects Become Prisoners During a Research Protocol

This policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the protocol, *e.g.,* after the research has commenced. This is necessary because it is unlikely that

review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the subject.

- If a subject becomes a prisoner after enrollment in research, the Principal Investigator is responsible for reporting this situation in writing to the IRB immediately.
- At the earliest opportunity after receiving the Investigator's notice or otherwise becoming aware of the prisoner status of a subject, the IRB should review the protocol again with a prisoner representative as a member of the IRB. The IRB should take special consideration of the conditions of being a prisoner.
- Upon this review, the IRB can either (a) approve the involvement of the prisoner-subject in the research in accordance with this policy or (b) determine that this subject must be withdrawn from the research.
- Additionally, the IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the subject's participation by the Investigator without regard to the subject's consent.

1.2 Children

Research in children requires that the IRB carefully consider consent, beneficence, and justice.

The determination of risk (possible harms) and possible benefit to the child is at the core of the concept of beneficence when considering research in a pediatric population.

Therefore, the IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has the authority to approve the study.

1.2.1 Determination of risk:

When reviewing research conducted on children, risk is defined in terms of minimal and greater than minimal risk, and may only be approved by the IRB as follows:

Risk determination	Benefit assessment	IRB action
Minimal	With or without direct benefit	Approvable
Greater than minimal risk*	Potential benefit to child	Approvable
Greater than minimal risk	No direct benefit to individual offers general knowledge about the child's condition or disorder	Approvable case-by-case*
Greater than minimal risk	No direct benefit to child offers potential to, "understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects"	Not approvable**

* Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances.

**Approval to proceed with this category of research must be made by the Secretary of the HHS with input from selected experts, and following opportunity for public review and comment.

1.2.2 Children may be subjects of research only if informed consent is obtained from the parents or legal guardian. Children over the age of 7 must agree to participate in the research and provide written assent and separate assent forms should be provided based on reasonable age ranges for comprehension i.e., 7-10, 11-15, 16-18 years of age.

1.3 Pregnant Women and Fetuses

1.3.1 Pregnant women or fetuses prior to delivery may be involved in research if all of the following conditions are met:

A. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

B. The risk to the fetus is not greater than minimal, or any risk to the fetus, which is greater than minimal, is caused solely by interventions

or procedures that hold out the prospect of direct benefit for the woman or the fetus;

C. Any risk is the least possible for achieving the objectives of the research;

D. The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46, unless altered or waived in accord with Sec. 46.101(i) or Sec. 46.116(c) or (d);

E. The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;

F. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D;

1.3.2 Research involving, after delivery, the placenta, the dead fetus, or fetal material.

- Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
- If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent regulations apply.

1.4 Other Vulnerable Groups

Although federal regulations list vulnerable groups, other vulnerable groups may include mentally impaired persons, employees of the Sponsor or Investigator, terminally ill patients, and the very elderly. The IRB will determine special protections for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies and state and federal law.

Cognitively Impaired Subjects:

Studies involving subjects who are decisionally-impaired may take place over extended periods. The IRB should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB should consider whether, and when, it should require a reassessment of decision-making capacity.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
45 CFR 46.111, 46.116
45 CFR 46: Subparts B, C, D
21 CFR 56.111
OHRP IRB Guidebook

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: SC 502 Version No: 1 Effective Date: 1/19/18	DECEPTION AND INCOMPLETE DISCLOSURE IN RESEARCH	Supercedes Document Dated: N/A

1. OBJECTIVE

Deception and incomplete disclosure can be valuable research methodologies. In social and behavioral research especially, deception and/or incomplete disclosure are often necessary to avoid study bias or test a hypothesis that requires subjects' misdirection; however, their use presents special challenges to ensure that research is conducted ethically.

The use of deception and/or incomplete disclosure can interfere with the ability of subjects to make fully informed decisions about whether or not to participate in research, and thus research employing these methods requires special consideration by the IRB. In addition to determining if study procedures interfere with subjects' ability to provide informed consent, and if there is sufficient justification for the use of such measures, the IRB will also evaluate if a debriefing process is necessary, and if so, if it has been adequately developed.

Specific Procedures

Definitions

Deception involves an investigator providing false information to subjects or intentionally misleading them about some aspect of the research.

Incomplete disclosure occurs when an investigator intentionally withholds material information about the specific purpose or nature of the research.

For research involving deception or incomplete disclosure

- The study must not present more than minimal risk to the subjects.
- The investigator must demonstrate that the deception/incomplete disclosure is necessary to meet the aims of the research.
- When practical and deemed appropriate, during the informed consent process, subjects should be told that some information is being withheld and will be provided at a specified time.
- Unless impractical or inappropriate, investigators should debrief subjects regarding the deception and/or incomplete disclosure. The debriefing should occur as early as possible, without interfering with the research. The debriefing should take place as early as possible, preferably at the conclusion of the subject's participation but no later than the conclusion of the research.
- The research must meet the criteria for a modification of the required elements of informed consent.

2. SCOPE

The policies and procedures apply to all human subjects research involving deception or incomplete disclosure conducted by BYU investigators.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

4. REFERENCES TO OTHER APPLICABLE SOPs

SOP: CO 601 Version No: 2 Effective Date: 1/19/18	IRB COMMUNICATION	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

It is important that staff, subjects, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, department heads, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The investigator and his/her research staff interact with subjects; therefore it is vital that open and frequent communication with the investigative team be maintained.

Specific Procedures

1.1 Investigator Notifications

1.1.1 Initial submission: The Investigator will be notified in writing of the IRB's decision as soon as possible after the meeting. If the approval is pending upon receipt and review of requested materials or responses from the Investigator or Sponsor, the IRB must receive the response within 30 days of the date of notification; however, this period may be extended if the Investigator/Sponsor communicates a need for an extension.

1.1.2 Renewals and revisions: Investigators will be notified in writing as soon as possible as to action taken by the IRB for any continuing reviews or revisions.

1.1.3 Notification of final approval: Investigators will be notified in writing of the final approval. The IRB-approved consent form will be dated with the period of approval and submitted to the Investigator with the final approval letter. Standard conditions for continued approval include, but are not necessarily limited to:

- Informed consent is obtained and documented.
- The IRB is notified of serious adverse events.
- Changes to the protocol, and deviations from the protocol are reported.
- Continuing review reports are submitted to the IRB.
- Documentation of FDA approval prior to study initiation.

1.1.4 Disapproval: Correspondence will provide the reason(s) for disapproval and instructions to the Investigator for appeal of this decision.

1.2 Investigator Appeal of IRB Action

An investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing and submitted to

the IRB Administrator. Investigators may also appeal an IRB decision to disapprove a study. Any such appeal may be in writing or in person and must be reviewed by the full IRB at a convened meeting. If the appeal is denied and the study disapproved, the Investigator's institution cannot override the IRB's decision.

1.3 Noncompliance

Investigator noncompliance may often be the result of communication difficulties, therefore the IRB will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study, especially if the rights and welfare of subjects may be jeopardized.

However, if it appears that an investigator is intentionally in noncompliance, the IRB, through the IRB Chairperson will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Copies of such correspondence shall also be sent, as circumstances merit, to the individual's Chair, Dean, and the AAVP over Research.

Should noncompliance continue, appropriate action will be determined at a convened meeting. Action by the IRB can include but is not limited to:

- Halting the research until the Investigator is in compliance. If the research is halted, OHRP will be notified if the research is funded by a government agency, and FDA will be notified if the research involves an FDA regulated product or agent.
- Requiring the Investigator to complete a training program.
- Barring the Investigator from conducting further research.
- Any other action deemed appropriate by the IRB.

When unapproved research is discovered, the IRB and the institution will act promptly to halt the research, ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the Investigator's fitness to conduct future human subject research.

Serious or continuing noncompliance with federal policies on the protection of human subjects or the policies, procedures or determinations of the IRB must be reported promptly to the AAVP over Research as well as the appropriate department or agency head for funded proposals, to OHRP and/or FDA as appropriate.

The IRB's responsibility is to protect the rights and welfare of research subjects, which could be placed at risk if there is misconduct on the part of an investigator or any member of the investigative team. It is, therefore, the duty of the IRB to be receptive to and act on good faith allegations of misconduct. Allegations of misconduct in science should be referred to the AAVP over Research for handling under BRIGHAM YOUNG UNIVERSITY policies.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109, 46.113

21 CFR 56.109, 56.113

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: CO 602 Version No: 2 Effective Date: 1/19/18	COMMUNICATION TO OTHER ENTITIES	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

The IRB is required by federal regulation and institutional policy to communicate certain actions to entities that may have an interest in the status of the research being conducted.

Specific Procedures

1.1 Communications to Others

The purpose of this PROCEDURE is to ensure prompt reporting to appropriate Institutional Officials, funding sources, agency heads, regulatory agencies and any other appropriate entity of:

- Any unanticipated problems involving risks to human subjects or others
- Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB
- Any suspension or termination of IRB approval

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46. 113
21 CFR 50.24, 56.113, 812.66

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: IC 701 Version No: 2 Effective Date: 2/6/18	INFORMED CONSENT	Supercedes Document Dated: 1/19/18

1. OBJECTIVE

The informed consent document and process is central to the responsible conduct of human subjects research. This policy identifies the key components of the informed consent document and process.

Specific Procedures

Researchers may not involve human beings as subjects in research unless the researcher has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR). Exception to this policy requires that the IRB grant a waiver or modification of the informed consent requirement.

- A researcher shall seek informed consent from the prospective subject or LAR only under circumstances that provide sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the prospective subject or LAR (whether orally or in writing) shall be in language understandable to the subject or LAR.
- The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision, and an opportunity to discuss that information.
- Informed consent, as a whole, must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.
- **For consent forms longer than 3 pages,** informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research, and must be organized and presented in a way that facilitates comprehension. Research which is regulated by the FDA (i.e. subject to 21 CFR 50 and 21 CFR 56), and not conducted, supported, or otherwise subject to regulation by another Federal department or agency, is encouraged but not required to include the concise and focused presentation in the consent process.
- Informed consent (whether oral or written) may not include any exculpatory language through which the subject or LAR is made to waive or appear to waive any of the subject's legal rights, or that releases or appears to release the researcher, the sponsor, the institution, or its agents from liability for negligence.

Elements of informed consent

Unless altered or waived by the IRB, the following information shall be provided to each subject or LAR:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subjects.
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, including a statement that notes the possibility that specific regulatory authorities (e.g., HHS, FDA, ED, DoD, DOJ as applicable) may inspect the records;
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Language limiting the subject's right to withdraw from the study is not permitted; and
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another researcher for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
    - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Unless altered or waived by the IRB, one or more of the following additional elements shall also be provided to each subject or the LAR, when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that

are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's or the LAR's consent;
- For studies involving payment for subject participation, a payment statement explaining details and any conditions of payment;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

The following information must be provided when applicable:

- When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), a statement notifying the subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act;
- If a researcher has a financial interest related to a research study, a statement regarding the financial interest and its management;
- If NIH-funded or a Certificate of Confidentiality has been granted, statement regarding Certificate of Confidentiality protections;
- If the research involves genetic information, statement describing the Genetic Information Nondiscrimination Act (GINA); or
- If the radiation/radioactive materials are used for research purposes, radiation risk language.
- For studies conducted or supported by the U.S. Public Health Service (PHS) involving HIV testing, PHS requires that subjects whose test results are associated with personal identifiers be informed of their own test results and provided the opportunity to receive appropriate counseling unless the situation calls for an exception under special circumstances.

The IRB may require that additional information be given to subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

Waiver or alteration of consent

The IRB may waive the requirements to obtain informed consent, or approve a consent procedure that omits some, or alters some or all, of the elements of informed consent if the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the requested waiver or alteration; and
- Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

For research involving public benefit and service programs conducted by or subject to the approval of state or local officials, the IRB may waive the requirement to obtain informed consent, or approve a consent procedure that omits some, or alters some or all, of the elements of informed consent if the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine:
    - public benefit of service programs;
    - procedures for obtaining benefits or services under those programs;
    - possible changes in or alternatives to those programs or procedures; or
    - possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

Documentation of informed consent

Unless the IRB grants a waiver of documentation of informed consent as described below, informed consent will be documented by the use of an IRB-approved, written consent form, signed and dated by the prospective subject or prospective subjects' LAR at the time of consent. A copy shall be given to the person signing the form.

The consent document should be a written informed consent form that meets the requirements of this policy. The researcher shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's LAR.

Unless waived, informed consent should be documented as follows:

- Subjects who are willing to participate in research must sign a copy of the IRB-approved and electronically stamped informed consent statement prior to participating in research procedures.
    - Signature may be provided via physical, “wet” signature, a physical or digital copy of a wet signature, or verified electronic signature via encrypted digital signature, observed electronic signature, electronic signature pad, voice print, digital fingerprint, or signature made with a fingerprint on a touchscreen.
    - If the consent conversation is not conducted face-to-face, the subject may electronically submit or mail a signed copy of the informed consent document to the research site (preferably to the interviewer and/or researcher). Unless the IRB approves otherwise, the study team must receive a copy of the signed document prior to beginning research procedures.
    - If the subject is physically unable to provide a signature, they should make a mark on the informed consent document and the study team should document the circumstances. If the subject is unable to make a mark, an impartial witness should witness the documentation process and sign the consent document.
- The subject (or LAR) must enter the date of signature on the consent document to permit verification that consent was actually obtained before the subject began participation in the study. The subject’s research record and/or medical records should document that the consent process occurred prior to participation in the research.
- The person conducting the consent interview must also sign and date the informed consent document as the “person obtaining consent”. The signature of the PI is not required on the consent document, unless he/she is the person conducting the consent interview.
- If the subject wishes to take the consent document home in order to review it and/or further consider participation in the research study before signing, the person obtaining consent may sign the consent document when the consent is presented to the subject. The subject may sign the consent document at a later time after making a decision to participate.

The IRB may waive the requirement for the researcher to obtain a signed informed consent form for some or all subjects if it finds either of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

For FDA-regulated research, the IRB may waive the requirement that the subject or the subject's LAR sign a written consent form only if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In cases in which the documentation requirement is waived, the IRB may require the researcher to provide subjects or LARs with a written statement regarding the research.

IRB review and approval

The informed consent process shall be described in the BYU IRB Questionnaires and an informed consent document provided for the IRB's review and approval, when appropriate. The IRB will review the information and ensure that all requirements consistent with this policy are met. To ensure that subjects' consent is voluntary, the IRB will consider whether any undue pressures, including excessive payment, will be brought to bear on potential subjects. Such pressure may be subtle as, for example, when a teacher asks his/her own students to become subjects of his/her research. Upon approval, the consent statement will be electronically stamped.

Informed consent process

The PI is ultimately responsible for ensuring consent is obtained but may delegate this responsibility to members of the study team who are appropriately trained to obtain consent and provide information about the study.

The informed consent process should be conducted via a conversation between the study team and the prospective subject, unless the IRB approves a consent process which does not include a conversation. The informed consent document provides a guide for the informed consent conversation and provides the subject with information which can be referenced later. If the consent conversation cannot be conducted face-to-face, the informed consent process may be conducted over the telephone or via other electronic means. The subject should be provided with a copy of the informed consent document prior to the conversation so they can review during the discussion.

Subjects who can understand and comprehend spoken English but are unable to read the informed consent document for any reason (e.g. illiteracy, blindness or diminished vision, dyslexia, unable to obtain a copy of the consent document for review, etc.) may be enrolled in a study; however, special care must be taken to ensure the individual is able to understand the concepts of the study and evaluate the risks and benefits of being in the study when it is explained orally.

- The study team must present the information orally and document the circumstances.

- An impartial witness must observe the entire consent process and sign the consent document. Although not required, a video recording of the consent interview is recommended.

Informed Consent Procedures for Non-English-Speaking Subjects

- Informed consent information provided to subjects or the subjects' LAR must be in a language understandable to the subject or the LAR. As such, the consent conversation and informed consent document should be in a language understandable to the subject (e.g. in the subject's first language or a language in which the subject is fluent).
- If the researcher anticipates that non-English-speaking individuals will likely be enrolled in the study, plans for language-appropriate consent procedures should be considered and described in the IRB submission. If a non-English consent document is provided for IRB review and approval, the IRB will require certification that the translated documents are correct or documentation that the non-English versions have been reviewed by an expert in the required language.

Informed Consent Procedures with Special Populations

Because of the special vulnerability of certain populations of subjects (including children, prisoners, pregnant women, individuals lacking consent capacity, and transnational participants), federal regulations, state and local laws, and institutional policies require additional protections regarding their consent to participate in a research study.

Revisions to the Informed Consent Document

- Revisions to the informed consent document must be reviewed and approved by the IRB prior to implementation.
- Newly enrolled subjects must sign the most recently approved version of the consent document.
- When submitting a revised consent document for IRB review and approval, the study team must notify the IRB whether previously-enrolled subjects will be notified of the new information and, if so, the timing and mechanism of the notification. The IRB will consider the study team's plan for notification and ensure its appropriateness.
- If the study team is aware of new or increased risks that are not reflected in the current IRB-approved consent document, study teams must not enroll new subjects until the revised informed consent document is available.
- If the IRB agrees that previously-enrolled subjects should be re-consented using the new informed consent document, the re-consent process should be documented and a note made in the subject's record when the re-consent process is completed. The original, signed new consent document must be retained in the study records and a copy provided to the subject (or LAR). Any previously signed consent documents should be retained and not discarded.

When a Subject Withdraws from Research

If a subject wishes to discontinue participation in the research, data collected on the subject to the point of the subject's withdrawal from a study remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

If a subject wishes to discontinue participation in the research and the researcher would like to continue to follow the subject's health and collect clinical data from his/her medical records, a separate IRB-approved informed consent containing all required elements must be developed and presented to the subject at the time of his/her withdrawal from the study requesting this follow-up to be done. The subject must give permission (i.e., sign this separate informed consent document) in order for clinical data to be collected. If the subject declines to consent to the follow-up, the researcher must not access the subject's medical record or other confidential records for purposes related to the research, but may consult public records, such as those establishing survival status.

2. SCOPE

The policies and procedures apply to all non-exempt human subjects research conducted by BYU researchers that include informed consent document(s) and process.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116, 46.117
21 CFR 50.25, 50.27, 56.109(b)-(d)
FDA Guidance, IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects (July 2017)
82 Fed. Reg. 7,149, 7,265 (Jan. 19, 2017) (to be codified at § _.116).
83 Fed. Reg. 2,885 (Jan. 22, 2018).

1. OBJECTIVE

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (such as written documentation). The IRB may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria.

Specific Procedures

1.1 IRB Waives One or More Requirements of Informed Consent

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - Public benefit or service programs;
    - Procedures for obtaining benefits or services under those programs;
    - Possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration, as in prospective emergency research conducted under 21 CFR 50.24.

Or that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation;
- The research could not practicably be carried out without the waiver or alteration.

1.2 Request for Waiver or Modification of Consent Form

If Principal Investigator would like to request a waiver of **signed** consent or some of the elements of informed consent, he must fill out the *Request for Waiver or Modification of Consent Form* IC 702-B. The IRB will review the

request based upon the elements set forth in 1.1 then approval or denial will be sent in the *Notice of Approval* letter.

2. SCOPE

These objectives and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116, 46.117

21 CFR 50.23, 50.24, 50.27, 56.109(c), 56.109(d)

FDA Guidance, IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects (July 2017)

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: IC 703 Version No: 2 Effective Date: 1/19/18	ASSENT	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is accomplished by soliciting the informed consent of the prospective research subject. In the case of the cognitively impaired adult or non-autonomous child, applying the principle of respect for persons is problematic. Therefore, consent of either the parent or legally authorized representative is required. However, any individual capable of some degree of understanding (generally, a child of seven or older, or a cognitively impaired adult) should participate in research only if they assent. When assent is required by the IRB, however, the decision of the individual assenting should be binding.

Specific Procedures

1.1 Use of Assent

In instances where the subject is not legally capable of giving informed consent (*e.g.*, minors) or where the subject is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the subject when in the judgment of the IRB, the subject is capable of providing assent.

1.1.1 Assent means a subject's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

1.1.2 In determining whether subjects are capable of assenting, the Investigator and the IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the subjects is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subject and is available only in the context of the research, the assent of the subject is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

1.1.3. When the IRB determines that assent is required; it shall also determine whether and how assent must be documented.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116

45 CFR 46 Subpart D

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: RI 801 Version No: 3 Effective Date:	IRB-REQUIRED INVESTIGATOR ACTIONS	Supercedes Document Dated: 1/19/18

1. OBJECTIVE

Between IRB initial approval of a protocol and the time of continuing review of a study, it is the Investigator's responsibility to keep the IRB informed of unexpected non-serious and serious adverse events and other unexpected findings that could affect the risk/benefit ratio of the research. An investigator is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events. Investigators are also responsible for informing government and other Sponsors of any unanticipated or serious adverse events, as appropriate.

Specific Procedures

1.1 IRB Review of Research

All human subjects research that is conducted by or under the direction of any employee, faculty, staff, student or agent of BRIGHAM YOUNG UNIVERSITY in connection with his or her institutional responsibilities must be reviewed by the IRB.

1.2 Informed Consent

The Investigator must obtain informed consent from subjects prior to their enrollment into the research. The Investigator must use the informed consent document approved by the IRB. Approval and expiration dates are indicated on the first page of the consent document. Consent documents are valid only during the dates indicated on the form; and the Investigator may use the forms only during the period for which they are valid.

1.3 Adverse Event Reporting

The IRB must be informed of any serious, unexpected or alarming adverse events that occur during the approval period. Investigators or Sponsors must also submit Sponsor-generated reports of adverse events occurring at other investigative sites.

1.4 Changes in Approved Research

Changes in approved research, during the period for which approval has already been given, may not be initiated without IRB review (or expedited review, where appropriate) and approval. Investigators must submit requests for changes to the IRB in writing. Upon receipt of the protocol change, the IRB Administrator will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the IRB. Minor changes involving no more than minimal risk to the subject will be reviewed by the expedited review process.

1.5 Periodic Reports

The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. A *Renewal Application of Approved Research* Form will be available to the Investigator for this purpose.

1.6 Student-Conducted Research

The IRB reviews human subjects research under federal regulations. As such, research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. Student-conducted research related to a class project does not generally qualify as research and therefore does not require IRB review. For questions of applicability, contact the IRB Office. Research conducted for master theses and doctoral dissertations do qualify as research – thus, any human subject involvement in theses or dissertations require confirmation of an exemption or IRB approval prior to being initiated. All students or fellows must obtain the participation of a faculty advisor as the primary investigator (PI) on the IRB application.

2. SCOPE

These policies and procedures apply to all investigators at BRIGHAM YOUNG UNIVERSITY.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102(d), 46.109, 46.111

21 CFR 56.102(c), 56.109, 56.111

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: QA 901 Version No: 2 Effective Date: 1/19/18	QA/QC PROGRAM	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

Quality assurance and control of the daily operations of the IRB ensure effective support of the IRB's mandate. Therefore, the QA/QC program consists of three components:

- Training and continuing education of IRB staff
- Interactions with the IRB community outside of BRIGHAM YOUNG UNIVERSITY
- Regular review and assessment of procedures

Specific Procedures

The AAVP has the authority to implement a QA/QC program and to act on identified deficiencies by implementing corrective action via revisions to the Standard Operating Policies and Procedures.

2. SCOPE

These policies and procedures apply to all IRBs at BRIGHAM YOUNG UNIVERSITY.

3. APPLICABLE REGULATIONS AND GUIDELINES

None

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

SOP: QA 902 Version No: 2 Effective Date: 1/19/18	AUDITS BY REGULATORY AGENCIES	Supercedes Document Dated: 6/1/07

1. OBJECTIVE

BRIGHAM YOUNG UNIVERSITY acknowledges that certain regulatory agencies have the authority to audit the operations of IRBs, and supports such audits as part of its continuing effort to maintain high standards for human research protections.

Entities that may audit IRBs include: FDA and OHRP. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

Specific Procedures

1.1 Preparing for an Audit

1.1.1 For external audits involving OHRP or FDA, the following must be notified immediately:

- Associate Academic Vice President (AAVP)
- IRB Chairperson
- The IRB staff designated to participate in the audit are required to follow the steps outlined by this institution for preparing the site for an audit.

1.2 Participating in an Audit

1.2.1 IRB staff are expected to know and follow the procedures outlined by this Institution for the conduct of a regulatory audit.

1.2.2 Prior to being granted access to IRB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents, and no entity other than those listed on the consent forms may have access to any document that includes subject identifiers.

1.2.3 Auditors will be provided with adequate working area to conduct an audit and IRB staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.

1.2.4 Documents may be copied and taken off-site only by individuals authorized in writing by the AAVP to do so.

1.3 Follow-up After an Audit

Reports of the audit, either verbal or written, should be addressed by the IRB ADMINISTRATOR/IRB CHAIRPERSON, (with the assistance and support of BRIGHAM YOUNG UNIVERSITY Administration), as soon as possible after the audit.

2. SCOPE

These policies and procedures apply to all IRBs at BRIGHAM YOUNG UNIVERSITY system.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115

21 CFR 56.115

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.