ROSEMAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Institutional Review Board

Policy Manual

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INTRODUCTION

The Roseman University of Health Sciences (Roseman or the University) Institutional Review Board (IRB) is established under the authority of the Vice-President for Research who reports to the President of the University.

This Policy Manual describes the responsibilities and roles of the IRB to protect the rights and welfare of human research subjects. The procedures of the IRB to discharge this duty are based on the federal regulations of the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) which are referenced in Appendix 1.

The Policy Manual applies to all types of research involving human subjects conducted under the auspices of the University.

Selected definitions are presented within the body of the Policy Manual. Additional definitions are presented in Appendix 2**.**

PRINCIPLES

The primary responsibility of the Roseman Institutional Review Board (IRB) is to safeguard the rights and welfare of human subjects who participate in research conducted under the auspices of the University and to ensure that subjects are aware of the rights and protections available to them.

These safeguards derive from the following ethical principles, which are articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

> Respect for persons: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.
>
> Beneficence: the obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.
>
> Justice: fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

1 FEDERAL REGULATIONS

Seventeen federal agencies have regulations governing the conduct of research in human subjects: however, no US federal law requires all research involving human subjects to be reviewed in a uniform manner. This Policy Manual includes the requirements of two agencies:

The Food and Drug Administration (FDA) regulates human subject research involving drugs, medical devices and biologic products. These regulations are promulgated under Title 21 (Food and Drugs) of the Code of Federal Regulations (CFR). The FDA requires IRB review of any research involving a drug, biologic, or medical device regulated by the FDA regardless of the source of funding. FDA typically audits IRB activities once every four (4) years but also may conduct an audit due to provocation.

The Office for Human Research Protections (OHRP) monitors compliance with Department of Health and Human Services (HHS) regulations that relate to standards of research involving human subjects. These regulations are promulgated under Title 45 (Public Welfare) Part 46 (Protection of Human Subjects) of the Code of Federal Regulations (CFR). OHRP requires an institution to establish an IRB if the research involves use of federal funds. OHRP typically does not audit IRB activities without provocation such as a concern about noncompliance or complaints from a research subject.

The various parts of Title 21 and Title 45 that pertain to IRB functions are listed in Appendix 1.

1.1 Compliance with HHS and FDA Regulations

If the research is subject to regulation by both HHS and FDA regulations, the investigator or sponsor investigator must comply with both regulations.

1.2 States of Nevada and Utah

The IRB also must meet the requirements of state law(s) which may differ from federal regulations. The Roseman attorney will be consulted as needed to ensure compliance with the review of human subject research requirements of Nevada and Utah state laws.

2 SCOPE OF AUTHORITY

An IRB has regulatory authority to review research involving human subjects, defined in Appendix 2, but has no authority to review activities that are legitimately classified as something other than human subject research.

2.1 Reviews Conducted by the IRB

- All proposed protocols prior to the initiation of the study.
- Proposed change(s) of an approved protocol.
- Continuing review of the research.
- Methods proposed to contact potential subjects.
- Materials to recruit subjects.
- Ensuring that the information given in the informed consent is in accordance with appropriate laws, regulations, and standards.
- Ensuring that either the informed consent or the waiver of informed consent is documented in accordance with appropriate laws, regulations, and standards.
- Risk information including, but not limited to, adverse events reported for drugs, biologics, and medical devices.
- Short form and written summary of information to be given in the short form informed consent process and consent cover letter.

2.2 Other Actions of the IRB

- Determine what activities constitute human subject research
- Approve, conditionally approve, or deny approval of a protocol.
- Ensure that the informed consent documents and procedures comply with federal regulations.
- Determine if a waiver of the informed consent requirement is granted.
- Determine the interval(s) for continuing review of approved protocols.
- Require Annual Check-In/Continuing Review/Project Closure reports from investigators.
- Determine which protocols require verification of information provided by the investigator.
- Apply restrictions to the conduct of a study.
- Suspend or terminate approved protocols due to issues such as protocol violation(s) or increased subject risk.
- Provide guidance to investigators and others regarding the IRB submission and review process.
- Inform the Vice-President for Research of potential problems which may have negative impact on the University.

3 IRB ORGANIZATION

3.1 Chair

The chair serves a one year term with the option to renew.

3.1.1 Qualifications

Required

- Full-time Roseman University Faculty
  - One year of Roseman IRB experience
- Preferred
  - 1+ years as IRB Voting Member
  - Vice Chair experience
  - Intent to serve at least 3 terms as Chair

3.1.2 Duties of the Chair include but are not limited to:

- Ensure that IRB functions comply with applicable regulations of the Department of Health and Human Services (HHS), the Federal Food and Drug Administration (FDA) plus state law.
- Conduct IRB meetings in consultation with the IRB Office to establish the agenda of each meeting.
- Review proposed protocols in compliance with procedures described in this Policy Manual.
- Complete required CITI training.
- Ensure a prompt IRB review of adverse event reports, unanticipated problems, and other information of special concern, which occur during the conduct of a protocol.
- Consult the Roseman attorney through the Vice President for Research's office to:
  - Ensure compliance with federal regulations and state law(s) and
  - Prevent or resolve other legal issues.
- Promptly inform the Vice-President of Research of any potential issue(s) for which the IRB desires to obtain input from the University administration or attorney.

3.2 Vice-Chair

The Vice-Chair will perform the duties of the Chair during his/her absence. The Vice-Chair serves a one-year term with the option to renew.

3.2.1 Qualifications

Required

- Full-time Roseman University Faculty

Preferred

- 1+ years as IRB Voting Member

3.3 IRB Office

Duties of the IRB Office include:

- Maintain an active IRB membership roster.
- Maintain and track the appointment letters of all IRB members.
- Responsible for the conduct and documentation for training of IRB members to ensure their competency to perform IRB functions.
- Ensure that IRB members receive a copy of the Policy Manual plus comprehensive reference materials necessary to review research protocols from an ethical and regulatory perspective.
- Track the status of each submitted protocol.
- Consult with the Chair to establish the meeting agenda.
- Consult with the Chair to make exempt determinations.
- Consult with the Chair to identify IRB members who can review protocols that meet the criteria for expedited review.
- Distribute the submitted protocol and related documents to IRB members seven (7) working days prior to each scheduled meeting.
- Post the meeting schedule
- Issue minutes of each meeting within ten (10) working days after a scheduled or ad hoc meeting. In the event of an unanticipated absence in excess of 30 calendar days, the IRB chair is responsible for issuance of the minutes within the 30 calendar days.
- Verify that the investigator has made all IRB-requested revisions to a protocol or consent document.
- Publish board action documents to PIs through the appropriate electronic submission platform.
- Distribute quarterly and yearly IRB reports to all IRB members and other University officials as necessary.
- Roseman will provide support staff, office and meeting space, storage cabinet and other equipment, plus copying of documents to support IRB functions.

3.4 Voting Members

All voting members are appointed by the Vice-President for Research or designee with recommendation from the IRB Chair.

The membership of the IRB will be diverse, will not be of one profession, and will not be of one campus.

The IRB will contain at least five voting members including:

- One scientific member.
- One nonscientific member who will have as his/her primary focus a nonscientific area.
- One member who is not affiliated with the University and who is not part of the immediate family of a person who is affiliated with Roseman.

3.5 Alternate Voting Members

Alternate members are appointed by the Vice-President for Research or designee. When an alternate substitutes for a voting IRB member, the alternate member has voting rights and is counted in the quorum.

3.6 Terms of Voting and Alternate Members

Voting and alternate IRB members will have 3-year terms with an option to renew. Efforts will be made to appoint new members each year as needed.

3.7 IRB Member Training Requirements

All IRB members must complete the required training. New IRB members must complete the required training within 60 calendar days. The IRB office is responsible for initial and follow-up training of IRB members plus documentation of such training.

3.8 Consultants

The chair of the Roseman IRB may invite consultants to participate in review and deliberations of specific protocols if s/he believes additional expertise would assist in reviewing a particular protocol. A consultant cannot be counted in a quorum and cannot vote. Consultants may be compensated for service provided to the IRB.

3.9 Legal Liability

IRB members and members of the University administration are not immune from legal liability. Examples of liability vulnerability include allegations of:

- Harm caused by IRB approval of an unsafe study design and inadequate consent documents (ex: incomplete, difficult to understand).
- Inadequate action to safeguard subjects after review of adverse event reports or unexpected problems associated with the study.
- Failure to withdraw approval of an ongoing protocol which presents an unacceptable risk to human subjects.

The Roseman attorney will represent IRB members as s/he would for Roseman employees while acting within the scope of their IRB responsibilities.

3.10 Removal

In consultation with the IRB Chair, the Vice President for Research may remove a member from the IRB. If the member feels that the removal is unjustified, the member may discuss the issue with the Vice President for Research. If s/he is unable to resolve the issue, the member may appeal the decision to the President. The decision of the President shall be final.

3.11 Compensation

Monetary compensation will not be provided to IRB members or alternate voting members.

4 IRB OPERATION

4.1 Meetings

4.1.1 Scheduled Meetings

The IRB will meet at least once per academic year. Additional meetings will be scheduled as required by the number of protocols submitted for review or other business items. The Chair or designee will determine the agenda and meeting date(s).

4.1.2 Ad Hoc Meetings

Ad hoc meetings will occur as needed to address topics of special concern such as adverse event reports and unanticipated problems or other issues of special concern associated with the research.

Except when invited by the Chair, scheduled and ad hoc meetings of the IRB are closed to non-members of the IRB.

4.2 Conflict of Interest

An IRB member will not participate in discussion and may not vote on any protocol in which s/he has a conflicting interest (i.e., s/he is the Principal Investigator (PI), co-Principal Investigator, has some financial interest, or other possible reasons of conflicting interest). The recusal will be included in the minutes.

An investigator will not be invited to participate in deliberations or decisions involving any protocol during a scheduled or ad hoc meeting of the IRB. In addition, the appointment of persons to the IRB will not be influenced by comments or information provided by any investigator.

4.3 Quorum

A quorum is defined as majority of the IRB voting members present, including at least one member whose primary concerns are in nonscientific areas. The majority will be calculated by using the "half-plus-one" technique. Attendance is defined as participating in the meeting in person, by phone, by videoconference, or by other technological measures that enable the member to reasonably interact with other members of the Board during the meeting in a timely manner. If a quorum is not achieved the IRB will not review research and/or make policy decisions. If a voting member is unable to attend a meeting, any individual designated as an ‘Alternate Member’ may substitute for that member and vote. If a member is unable to attend a meeting, a member may provide written comments to be reviewed during a meeting. However, this member will not be included in the quorum and may not vote.

4.4 Voting Protocol

A quorum must be maintained throughout the meeting. If quorum is lost during a meeting, then the IRB may not vote on proposed research. Only voting members attending the meeting can vote on issues on the meeting's agenda. The "half plus one" majority affirmative vote requirement is calculated by the formula: # of votes in favor of the submission / total number of members attending the meeting. If the calculation is at least one more than half of the total numbers of members attending the meeting, the vote is affirmative. Therefore, votes in opposition and votes to abstain are included in the denominator. The minutes should identify any member who has a conflicting interest in a research study, and as such, is excluded (recused) from participation in the IRB's review of that particular research including the reason for the recusal. Members who are recused from voting on a specific study because of conflicting interests may not be counted toward the quorum. That is, their recusal may not be recorded as an abstention. Therefore, since abstentions from a vote will be counted in the denominator, an IRB member abstaining from a vote may wish to exercise the option of declining to attend an entire IRB meeting to allow an alternate member to attend the meeting. The IRB Chair and Vice Chair, like any voting member of the Board, have the right to vote on all IRB submissions and/or policy decisions. Voting will be by using an electronic polling system, when possible. If there are technical difficulties, the Chair or designee will conduct the vote by a show of hands or a written ballot (whichever is more convenient).

4.5 Minutes

The IRB Office will issue minutes no later than ten (10) working days after a scheduled or ad hoc meeting. The minutes will include the following information:

- Votes pertaining to research protocols in the following format:
- "Total Votes"; number of votes "For;" number of votes "Opposed;" number of votes "Abstained."
- Actions taken on protocol-related topics plus other topics.
- Date, time and place of the meeting.

See also the Minutes of Institutional Review board (IRB) Meetings guidance for institutions and IRBs

4.6 Records Retention

All records must be retained by the IRB for at least three (3) years after the completion of the research. Applicable IRB records include, but are not limited to:

- Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the protocols, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects
- Minutes of IRB meetings
- Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members
- Written procedures for the IRB
- Statements of significant new findings provided to subjects
- The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.
- Justification for Exempt determinations
- Assessment of submitted proposals as Not Research or Not Human Subjects Research.
- Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of the Federal Regulations.

5 IRB PROTOCOL REVIEW

5.1 Principal Investigator Responsibilities

Through the act of submitting a protocol to the IRB, and being named as the principal investigator (PI) of that study, the PI is agreeing to assume the overall responsibility for the study conduct. By doing so, the PI agrees to:

- Personally conduct or supervise the research
- Ensure that each individual to whom a task is delegated, is qualified by virtue of education, training, and experience (e.g., hospital certification, human subjects research training, state license) to perform each of their delegated tasks
- Protect the rights, safety and welfare of the participants who will be under their care. To do this they are agreeing that the research:
  - Is conducted in accordance with all federal regulatory requirements, state law, and Roseman policies (including IRB Policy Manual)
  - Is conducted in accordance with the IRB approved protocol
  - Is conducted in a manner that ensures the accuracy, security and integrity of the research data and the subsequent analysis of that data.
- Abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
- Comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

5.1.1 Additional Expectations of Clinical Investigators

Adhere to the applicable policies in the Code of Federal Regulations and abide by the Clinical Investigator regulations and responsibilities outlined therein.

5.2 Investigator Training Requirements

Roseman University IRB expects all Roseman-affiliated investigators conducting human subject research to take human subjects research training from the Collaborative Institutional Training Initiative (CITI), for which Roseman University has a university-wide license. The investigators must complete either Biomedical Research or Social & Behavioral research or both training modules depending on the research. Investigators involved in clinical trials, regardless of funding source, must take the appropriate Good Clinical Practice CITI training module. Investigators of protocols funded by the National Institutes of Health (NIH) or National Science Foundation (NSF) must also take the appropriate Responsible Conduct of Research CITI training module. Investigators not affiliated with Roseman University must either submit their training required by their institution along with their institutional policy to demonstrate that they meet their institution's policy or take Roseman University's required CITI training. The IRB retains the authority to require additional training, as needed.

5.3 Submission of New Protocol

Each investigator must register with the electronic submission platformprior to the submission of a new protocol. New protocols are to be submitted using IRBManager. IRBManager is a web-based platform for the electronic submission and review of protocols, automatic notifications, protocol sharing and collaboration, integrated training and credential management, as well as important audit capabilities including electronic revision histories, electronic signatures, and event tracking. The protocols must be submitted using the Initial Submissionform available in the electronic submission platform.

5.4 Levels of IRB Review

All research protocols involving human subjects must be submitted to the IRB to determine if the protocol is exempt from IRB review or shall undergo either an expedited or full committee review. The IRB will use the exempt (45 CFR §46.104) and expedited (45 CFR §46.110) categories defined in the federal regulations.

5.4.1 Exempt Review

Under the HHS regulations (45 CFR §46.104), some research is exempt from having to meet the requirements for approval set forth in the regulations. These exemptions do not apply to research that is classified as greater than minimal risk or involving vulnerable populations. Research activities in which the only involvement of human subjects will be in one or more of the following categories can be classified as exempt:

- Research conducted in established or commonly accepted educational settings
- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior
- Research involving benign behavioral interventions
- Secondary research for which consent is not required
- Research and demonstration projects to examine public benefit or service programs
- Taste and food quality evaluation and consumer acceptance studies
- Storage or maintenance for secondary research for which broad consent is required
- Secondary research for which broad consent is required

The above categories have further conditions that must be met to be designated as exempt. Please refer to 45 CFR §46.104 for complete details outlining qualifications for exempt determination.

These studies will undergo exempt review and may be given an exempt determination, rather than IRB approval. Exempt review, as defined by federal regulations, may be performed by the IRB Office in conjunction with the IRB Chair, or designee. At any time, the IRB Office or Chair may request consultation, additional reviewers, or may refer the item to the full IRB.

5.4.2 Expedited Review

The Secretary of HHS has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure authorized by 45 CFR §46.110 and 21 CFR §56.110. In order to qualify for review via expedited procedures, the research must not be greater than minimal risk and fall into at least one of the nine expedited categories defined by the federal regulations, which are as follows:

- Clinical studies of drugs and medical devices
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Prospective collection of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Research involving materials that have been collected, or will be collected solely for non-research purposes
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Continuing review of research previously approved by the convened IRB
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption

The above categories have further conditions that need to be met to qualify for expedited review. Please refer to OHRP Expedited Review Categories for complete details outlining qualifications for expedited determination.

Expedited review, as defined by federal regulations, may be performed by the IRB Chair, Vice Chair, and/or by an IRB member(s) designated by the IRB Chair. At any time, the expedited reviewer may request consultation, additional reviewers, or may refer the item to the full IRB.

5.4.3 Full Board Review

Protocols that do not meet the criteria for exempt determination or criteria for expedited review, will be reviewed by the convened IRB. FDA regulations do not provide an exempt category for drugs regulated by FDA.

5.4.3.1 Criteria of Protocol Review

See 45 CFR §46.111 criteria for IRB approval of research for protocols that fall under DHSS regulations.

See 21 CFR §56.111 criteria for IRB approval of research for protocols that fall under FDA regulations. A physician member of the IRB will review all protocols involving drugs, biologics, and devices regulated by FDA.

The regulatory criteria include:

- Risk to human subjects is minimized (refer to Appendix 2 - definitions).
- Risk is reasonable in relation to anticipated benefit(s).
- Selection of subjects, including vulnerable populations, is equitable.
- Informed consent procedures are adequate and documented.
- Procedures are adequate to monitor patient safety, confidentiality and privacy.
- Procedures are adequate to protect the privacy of subjects and maintain confidentiality of the data.
- Procedures are adequate to protect the rights and welfare of vulnerable populations.

5.4.3.2 Outcomes of Full Board Review of Protocols

The IRB will communicate in writing to the Principal Investigator to indicate the IRB decision regarding the protocol and the informed consent, if applicable, within fifteen (15) working days of the review. If the sponsor would like documentation of the IRB decision, we can provide a copy if a written request is sent to irb@roseman.edu.

There are four (4) possible outcomes:
Approve: an approved protocol requires no further information or action from the investigator prior to initiating the study. The chair will specify:

- The risk determination(s)
- The interval during which the approval remains valid
- The schedule for periodic review by the IRB

Conditionally approve: a conditionally approved protocol requires revision(s) specified by the IRB and may not begin until these revisions have been approved by the IRB. The IRB will also specify if the revised protocol may be reviewed by the expedited review process (refer to Appendix 2 for definitions) or requires full board review. The Principal Investigator must submit a complete, revised protocol. This IRB decision may not be changed by any review conducted by members of the sponsoring entity.
Require modifications: a protocol that requires modifications will have the revision(s) specified by the IRB. The IRB will review the revisions at the next applicable Full Board meeting.
Deny: an investigator may not initiate a research protocol that has been denied approval. The PI may appeal the decision and request a meeting of the IRB to consider the appeal. This IRB decision may not be changed by any review conducted by members of the sponsoring institution.

5.5 Appeal of an IRB Decision

If the Principal Investigator (PI) disputes the IRB decision, s/he may request additional review via an email to the IRB at irb@roseman.edu within sixty (60) calendar days of the IRB decision. The Chair will decide if the appeal is to be considered at its next scheduled meeting or ad hoc meeting. The PI must provide the IRB with written arguments and supporting materials, by submitting an Appeal Request, two weeks in advance of a regularly scheduled meeting and as determined by the chair for an ad hoc meeting. The PI, or designate, may be invited to appear before the IRB to discuss the issue(s). Attendance to the IRB meeting is by invitation only.

The convened IRB's decision will be one of the following:

- Approve
- Conditionally approve
- Deny approval of the protocol

This decision of the IRB is final; there is no further appeal.

5.6 Post-Submission Procedures

After a protocol is submitted, the PI may receive an email requesting clarifications and/or changes to the protocol. After the aforementioned email is distributed, the Principal Investigator has ninety (90) calendar days to submit the requested revisions in the electronic submission platform or the investigator can request one thirty (30)calendar day extension. One extension request will be granted, if requested in writing by the Principal Investigator to the IRB at irb@roseman.edu. If no revisions are submitted in a new package in IRBNet or no extension is requested prior to the deadline, the protocol will be subjected to administrative closure.

Once the requested modifications are made, the IRB will review the protocol and notify the PI of the final IRB decision.

6 POST-APPROVAL PROCEDURES

6.1 Tracking of Approved Protocols

All protocols are reviewed at least once annually. Investigators will receive automatic notices of project expiration to their email. Investigators receive a thirty (30), fifteen (15), and one (1) day notice as well as a final notice on the date of expiration.

- The PI can submit a Closure Form, if the study is completed.
- If the PI would like to continue conducting minimal risk research (exempt or expedited), before the expiration date, s/he must submit the Annual Check-In Form. The Annual Check-In Form includes the current status of research, total number of subjects accrued, comprehensive analysis of all adverse effects, complications or reactions, summary of requested modification or approved modification of the research plan and/or informed consent. The IRB Office can approve the Annual Check-In and continuation of the protocol.
- If the PI would like to continue conducting more than minimal risk research associated with the protocol, before the expiration date, s/he must submit the Continuing Review Form. The Continuing Review form includes the current status of research, total number of subjects accrued, comprehensive analysis of all adverse effects, complications or reactions, summary of requested modification or approved modification of the research plan and/or informed consent. This protocol will need to go before the full convened Board for Continuing Review, unless the research has progressed to the point that it involves only one or both of the following: (1) Data analysis, including analysis of identifiable private information and identifiable biospecimens, or (2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
- If the protocol reaches the expiration date without an Annual Check-In Form, Continuing Review Form, or Closure Form submitted, all research activities for the protocol must cease on the date of expiration. If the PI would like to continue research for the expired protocol after the expiration date, PIs must submit a new Initial Submission Form and receive IRB approval to continue with research activities for the protocol.

Some projects require review more often than annually and/or verification from sources other than the investigators that no material changes have occurred since previous IRB review in order to ensure the continued protection of the rights and welfare of the research subjects. In determining the frequency and requirements of review, the IRB will consider the nature of the study, the degree of risk involved and the vulnerability of the study subject population, along with any other factors deemed relevant by the IRB. The IRB will communicate the protocols review frequency and requirements to the investigator via the electronic submission platform and record the decision in the minutes.

6.2 Ad Hoc Review of Approved Protocols

Ad hoc reviews will be conducted by the IRB Office, within two (2) working days, upon receipt of individual or multiple adverse event reports, unexpected problems which may increase risk to patients and/or reduce any expected benefit(s) or other topics of concern. At this time the IRB Chair will inform the appropriate institution officials regarding the reported events or unexpected problems and may convene a full board meeting depending on the level of risk to determine the course of action.

6.3 Modifications of Approved Protocols

The Principal Investigator may implement a protocol modification without IRB approval only to mitigate an immediate hazard to subjects. These changes must be reported to the IRB Office as soon as possible, but no later than five (5) working days after the modifications. Other modifications of an approved protocol may not be implemented prior to IRB approval.

The PI, or designee, shall submit aModification Requestas soon as possible after determining the need to revise an approved protocol. The request should summarize the proposed modification and provide any new versions of the supporting documents.

6.3.1 Protocols Determined to be Minimal Risk or Less

6.3.1.1 Personnel/Administrative Modification

Addition or removal of key study personnel as well as minor changes that do not affect study participants will be processed by the IRB Office.

6.3.1.2 Minor Modifications

A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study, does not substantially change the specific aims or design of the study, and does not change significantly the composition of the subject pool. Examples include minor changes of administrative procedures or the text of documents. Must be reviewed by the Chair or Vice Chair.

6.3.1.3 Significant Modifications

A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples include, but are not limited to, any revision of the consent form, protocol methodology, procedures for collecting data, and subject pool. All proposed revisions are reviewed by the Chair, who will determine if the request is to undergo an expedited or full board review.

6.3.2 Protocols Determined to be More than Minimal Risk

Full board review is required for modifications of protocols deemed greater than minimal risk.

The outcomes of the modification request will be similar to any new protocol submission based on the level of risk.

6.4 Suspension or Termination of an Ongoing Study

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's approval or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval must be voted on by the convened IRB, and shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. At this time the IRB Office also will inform FDA and all participating investigators of the decision to terminate an ongoing study involving FDA-regulated drugs, biologics or devices.

7 INFORMED CONSENT

The purpose of informed consent is to provide a potential subject or his/her legally authorized representative with sufficient information to make an informed decision to participate or not participate in the research study. See also HHS Informed Consent FAQs.

The IRB ensures that the protocol provides procedures that will promptly inform each subject of the details of the investigation plus information in the informed consent document. In the event the subject is incapacitated, this information is to be provided to the representative or a family member.

The IRB also considers whether the consent documents:

- Are clearly written and understandable to the intended subject population.
- Include language that is not excessively technical, scientific, or technical.
- Medical terms are clearly defined.

The above three characteristics must be evaluated by at least one non-scientific member of the IRB for each protocol that has an informed consent.

7.1 Full Informed Consent

45 CFR 46.116 details the required elements of written informed consent, which include but are not limited to the purpose of the research, inclusion/exclusion criteria, study procedures, benefits and risks, confidentiality, compensation, funding source, as well as the affirmation that participation in the research protocol is voluntary. This should be signed by the study participant or legally authorized representative. The Full Informed Consent document will be stamped when the protocol is approved. Investigators are required to use only the current, stamped IRB-approved consent form when obtaining informed consent. The Informed Consent Template can be found on the electronic submission platform.

7.2 Short Form

In lieu of the written form described above, federal regulations permit use of a short form written consent document that states that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. For further short form consent stipulations, please reference 45 CFR §46.117.

7.3 Consent Cover Letter

If the research involves using a survey, and there is minimal risk to participants, a consent cover letter will be sufficient to gain study participants' informed consent to participate. It should include all the elements needed in an informed consent document, but no signature is required. For Internet surveys, this letter must be the opening page of the survey. The IRB retains the authority to determine the level of risk to participants and can ask for a Full Informed Consent if deemed necessary.

7.4 Waiver

The IRB may waive the requirement for an investigator to obtain consent or a signed consent form if the criteria as specified in 45 CFR §46.116, 45 CFR § 46.117, 21 CFR 50.23, or 21 CFR 50.24, whichever is applicable, are met. These criteria will be utilized regardless of funding source.

If the Principal Investigator believes a research project meets the above criteria, s/he must will apply for a Waiver of Documentation of Consent or a Waiver of Consent in the Initial Submission form. The IRB will review requests and justifications presented for the applicable waiver criteria.In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The IRB retains the authority to determine the level of risk to participants and can ask for a Full Informed Consent if deemed necessary.

Research on life-threatening conditions: 21 CFR 50.23 and 21 CFR 50.24 also provide the option to waive the consent requirement in research on life-threatening conditions for which available treatment options are unproven or unsatisfactory in situations in which it is not possible to obtain informed consent.

8 DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL DEVICES

8.1 Classification of Investigational Medical Device Protocols

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. The Investigational Device Exemptions (IDE) regulation (21 CFR 812) describes three types of device studies: significant risk (SR), nonsignificant risk (NSR), and exempt studies.

8.1.1 Significant Risk (SR)

SR device is an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
- Is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

8.1.2 Non-Significant Risk (NSR)

NSR device is an investigational device that does not meet the definition for an SR device study.

8.1.3 Exempt

In accordance with 21 CFR 812.2(b), sponsors and investigators of certain studies are exempt from the requirements of 21 CFR Part 812, with the exception of §812.119 (disqualification of a clinical investigator). These may include:

- Consumer preference testing
- Testing of a device modification
- Testing of two or more devices in commercial distribution if the testing does not collect safety or effectiveness data, or put subjects at risk.
- Studies of an already cleared medical device in which the device is used or investigated in accordance with the indications in the cleared labeling are exempt from Part 812.5
- Studies of a PMA approved device are exempt from the IDE requirements if the device is being studied for the indications in the approved labeling.
- Diagnostic device studies (e.g., in vitro diagnostic studies)

8.2 Approval Process for Investigational Medical Devices

When a study involves an investigational medical device, the PI or his/her designee must include the sponsor's initial risk assessment (SR or NSR) and the rationale used in making the risk determinationin the Initial Submission form..

The IRB may request that the PI consult with the FDA for its opinion, as appropriate. However, only written documentation from the FDA will be considered by the IRB in making a determination.

In reviewing the protocol, the IRB makes its own determination of the SR or NSR categories. The IRB reviews reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria, monitoring procedures, and any other information that the IRB deems necessary to make its decision.

If the IRB determines that a protocol submitted involves a SR device and the PI has not received IDE approval, the IRB will request that the PI receives FDA approval of an IDE submission before undergoing further IRB review

If the IRB determines that a protocol submitted involves a SR device that has been deemed NSR by the sponsor, the IRB notifies the PI who notifies the sponsor. The sponsor notifies FDA that an SR determination has been made. The study can be conducted as an SR investigation following FDA approval of an IDE application.

If the FDA determines that a study involves the use of a SR device, an IDE and IRB approval must be obtained before the study begins and studies must be conducted in accordance with IDE requirements.

If an IRB finds that an investigational medical device study poses a NSR, the sponsor does not need to submit an IDE to FDA before starting the study. If the IRB determines that the proposed study is an NSR study, the IRB may proceed to review the study under 21 CFR 56.109 and 21 CFR 56.111.

The IRB may approve or disapprove the proposed research based on local context and its responsibilities to protect human subjects in research even when approval of the device has been granted by the FDA.

The decision of the IRB (both risk assessment and approval) will be documented in the decision letter in IRBNet.

8.3 Monitoring of Unanticipated Adverse Events Involving Medical Devices

Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, or any other unanticipated serious problem associated with the device that relates to the rights, safety or welfare of subjects.

Caused or contributed to a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- Failure
- Malfunction
- Improper or inadequate design
- Manufacturer
- Labeling
- User error

Federal regulations require the sponsor (or sponsor-investigator) to notify the FDA plus all participating investigators and IRBs of the following information:

- Cases in which a device may have caused or contributed to an unanticipated adverse event.
- Withdrawal of a protocol approval by the FDA or any IRB.
- Use of a device without obtaining an informed consent.
- Any deviation from the investigational plan to protect the life and well-being of subject in an emergency.

8.3.1 Protocol Required Actions

Protocols submitted to the IRB must convey the following required actions of investigators, sponsors plus data and safety monitoring boards.

8.3.1.1 Investigator

Within five (5) working days of being aware of any deviation from the approved protocol to protect the life or physical well-being of a subject in an emergency the investigator will notify the sponsor and the reviewing IRB.

Within five (5) working days of using a device without obtaining informed consent, the investigator will inform sponsor and the reviewing IRB.

Within ten (10) working days of being aware that any unanticipated adverse device effect occurred during an investigation, the investigator will inform the sponsor and the reviewing IRB.

No less often than annually, the investigator will submit progress reports of the investigation to the sponsor and the reviewing IRB.

Within three (3) months after termination or completion of an investigation, the investigator will provide a final report to the sponsor and the reviewing IRB.

8.3.1.2 Sponsor

Within five (5) working days of being informed that the FDA or another IRB withdrew approval of the protocol, the sponsor will inform all participating investigators and all reviewing IRBs.

Within ten (10) working days of being aware that an unanticipated adverse effect occurred during an investigation, the investigator will inform all participating investigators and all reviewing IRBs.

8.4 Monitoring of Risks Involving Drugs, Biological Products and Medical Devices

As a condition of approval, the IRB requires that a proposed protocol contain definitions and procedures to ensure prompt reporting by the investigator and sponsor of the following risk information to the IRB and/or the FDA plus the appropriate agency head of the HHS:

- adverse events
- protocol violations
- protocol revisions
- possible loss of privacy or confidentiality
- suspension or termination of IRB approval by FDA or other IRB

8.5 Monitoring of Adverse Events Involving Drugs and Biological Products

The IRB may obtain risk information that is distributed from multiple sources. Federal regulations require the sponsor to notify promptly the FDA and all participating investigators of serious adverse events that are unexpected and may be associated with use of the drug or biologic. Although not required by regulations, sponsors also typically instruct investigators to simultaneously notify IRBs at participating sites. The form to report adverse events and unanticipated problems can be found on the electronic submission platform.

8.5.1 Serious adverse event (SAE)

Any experience that is:

- Fatal.
- Life-threatening.
- Permanently disabling.
- Requires inpatient hospitalization.
- A congenital anomaly, cancer or overdose.

8.5.2 Unexpected adverse event

Any adverse experience that is:

- Not identified in nature, severity, or frequency in the current investigator brochure.
- or, if an investigator brochure is not required, that is not identified in nature, severity or frequency in the risk information described in the general investigational research plan or elsewhere in the current application.
- Associated with use of the drug there is a reasonable possibility that the adverse event may have been caused by the drug or biologic.

8.5.3 Protocol Required Actions

Protocols submitted to the IRB must convey the following required actions of investigators, sponsors plus data and safety monitoring boards.

8.5.3.1 Investigator

Within two (2) full working days of being aware that a human subject experienced a serious adverse event (SAE) as described below, the investigator will inform the study sponsor and the Roseman IRB by phone, facsimile or email. This information also will be submitted on the SAE report form(s) provided in the study protocol.

8.5.3.2 Sponsor

The sponsor (and sponsor-investigator) must promptly inform the FDA and all participating investigators of serious adverse event that are unexpected and possibly associated with use the drug or biologic.

For drugs studied under an investigational new drug (IND) application, the sponsor must inform FDA of death and life-threatening events within seven (7) calendar days of receipt and other SAEs within fifteen (15) calendar days of receipt.

For FDA-approved drugs not studied under an IND), the sponsor must inform FDA of other (not life-threatening or fatal) serious adverse events that are unexpected and may be associated with use of the investigational drug or biologic within fifteen (15) calendar days of receipt.

The protocol will specify that the sponsor must also send a copy of the report to the IRB. The sponsor must also inform the IRB of serious adverse events obtained from multi-center sites.

8.6 Data and Safety Monitoring Board (DSMB)

The IRB may receive a summary of individual adverse event cases or an analysis of cases conducted by a Data and Safety Monitoring Board which is typically funded by the sponsor. The DSMB report is typically received from the sponsor rather than directly from the DSMB.

8.7 Outcomes of IRB Review of Risk Information

Within three (3) working days of receipt, the chair or designate will conduct an ad hoc meeting of IRB quorum to review SAE reports. This meeting will include both a physician and non-scientific member. The possible outcomes of IRB review are:

- Continued approval of the protocol without change.
- Request the sponsor to submit an analysis of the reported case(s) in light of similar adverse event reports.
- Revise the consent document and re-consent the study participants.
- Withdraw (rescind) approval of the protocol.

In each instance, the IRB will send an email within five (5) working days to inform the investigator and sponsor of the IRB's decision(s).

9 SPECIAL CASES OF RESEARCH

The special cases of research discussed below will only be acted upon as described if the Institutional Review Board (IRB) determines that Roseman University is engaged in research. In general, this Institution is considered engaged in Human Research when this Institution's employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about or identifiable biospecimens from the subjects of the research; or (3) the informed consent of human subjects for the research. Roseman will utilize the Office for Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research to make this determination.

9.1 Research Conducted by Roseman Faculty/Staff at Other Institutions

If some portion of the research is conducted at another institution, Roseman may be the IRB of record or Roseman may acknowledge the determination from the IRB of record. The Roseman IRB will review documentation presented by the other institution and will seek consultation with the Roseman legal counsel, if necessary. For studies involving federal funds, both institutions must obtain a federal wide assurance (FWA) of protection of human subjects.

If all research activities are planned at another institution (resources, participants such as patients/students/faculty/staff) that does not have an IRB, the Roseman IRB may serve as the IRB of record. The Roseman IRB will review documentation presented by the other institution and will seek consultation with the Roseman legal counsel if necessary.

If a Roseman-affiliated investigator conducts all research activities (data collection, participant recruitment, resource utilization) at another institution and the other institution has given IRB approval of the protocol, an abbreviated Initial Submission form must be submitted by the investigator in the electronic submission platform. Then, the Roseman IRB would establish a reliance agreement to rely on the external IRB.

In the event another institution that does not have an IRB is the recipient of a grant under which Roseman faculty will be conducting research, the Roseman IRB may serve as the IRB for the grantee. The Roseman-affiliated investigator must submit an application in the electronic submission platform to be considered for approval. The investigator should also submit documentation on the agreement with the other institution(s) from the Roseman Grants Office.

9.2 Research Approved by a Central IRB

If a Roseman-affiliated investigator would like to use Roseman resources (such as students/faculty/staff) to be a site for a protocol that requires usage of a central IRB (e.g., clinical trials), the investigator must submit an abbreviated Initial Submission form, along with the necessary supporting materials, in the electronic submission platform. The Roseman IRB will issue a final Acknowledgement of Approval letter once all materials are received. Only after that letter is published, can research activities take place. The IRB office reserves all the rights to determine the level of risk of the study and will communicate with the investigator if the Roseman IRB application needs to be submitted.

9.3 Research Conducted by Roseman Students

Students will not be given access to the electronic submission platform. To better facilitate student learning, students must work with their faculty advisor to develop a protocol. The submissions should be written and submitted by a faculty investigator. That faculty investigator must ensure and document the proper training of student investigators.

9.4 Roseman Students as Study Subjects

Roseman students cannot be required to participate in research to satisfy the requirements of a Roseman course. Coercion, undue influence, and breach of confidentiality are the main concerns that may be associated with inclusion of Roseman students as subjects in research associated with Roseman.

9.5 Review of Research Involving Vulnerable Populations

9.5.1 Children Under 18 Years of Age

As specified in 46 CFR 45 Subpart D - Additional Protections for Children Involved as Subjects in Research, research involving children is classified into the following four categories depending upon the risks and benefits of the proposed research:

- Research not involving greater than minimal risk.
- Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual subjects.
- Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

9.5.2 Other Vulnerable Populations

45 CFR 46 Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research and Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects describe vulnerable research populations. Other vulnerable populations may be mentally disabled (cognitively impaired) persons, economically educationally disadvantaged persons, racial minorities, the very sick, and the institutionalized. These populations may be susceptible to coercion or undue influence to participate in a study.

The IRB will consider if the following types of vulnerability may compromise the ability of an individual to provide informed consent or take other actions of self-protection:

- Cognitive or communicative: unable to comprehend information or express an opinion.
- Institutional: subject to the formal authority of others (ex: prisoners).
- Deferential: subject may be subordinate to another person.

- Medical: research may be perceived as providing the only help for a serious medical condition.
- Economic: health care is only available through participation in research protocol.
- Social: members of a group may be subject to additional risks than other groups.

9.6 Review of Research under the Federalwide Assurance (FWA)

The following additional terms apply when Roseman becomes engaged in human subjects research conducted or supported by an U.S. federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule.

9.6.1 Reporting Events

The IRB Chair, in conjunction with the IRB Office, will report any of the following situations to the IRB, the appropriate institutional officials, the head of any U. S. federal department or agency conducting or supporting the research (or designee), and OHRP:

- Unanticipated problems involving risks to subjects or others.
- Serious or continuing noncompliance with applicable U.S. federal regulations or the requirements or determinations of the IRB.
- Suspension or termination of IRB approval.

9.6.2 Reliance on External IRB

This Institution assures that it will rely upon only Institutional Review Boards (IRBs) registered with OHRP to review the research to which this FWA applies. Whenever the Institution relies upon an IRB operated by another institution or organization for review of research to which the FWA applies, the Institution must ensure that this arrangement is documented by a written agreement between the Institution and the other institution or organization operating the IRB that outlines their relationship and includes a commitment that the IRB will adhere to the requirements of the Institution's FWA. OHRP's sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement must be kept on file at both institutions/organizations and made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

9.6.3 Extending an FWA to Cover Collaborating Investigators

HHS regulations at 45 CFR 46.103(a) require that each institution engaged in HHS-conducted or -supported human subjects research provide written assurance, satisfactory to HHS, that it will comply with the requirements of the HHS regulations for the protection of human subjects, unless the research is exempt under 45 CFR 46.101(b). HHS regulations at 45 CFR 46.103(b) require that each institution engaged in HHS-conducted or -supported human subjects research certify to the HHS funding agency that the research has been approved by an IRB designated in the assurance.

Roseman will use the Individual Investigator Agreement provided by OHRP when extending FWA coverage.

9.6.4 Assurance Identification/IRB Certification

Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

Roseman will use the Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule) form, OMB No. 0990-0263 to certify that all criteria stated above is met.

10 PRIVACY AND CONFIDENTIALITY

The IRB will review the protocol and other relevant documents to determine if procedures are designed to protect privacy and confidentiality in accordance with the Common Rule.

Examples include, but are not limited to, procedures used in face-to-face and telephone interviews, access to records stored in different locations, identification of codes and access to codes.

FDA regulations require the informed consent must describe the extent, if any, to which confidentiality of records which identify the subject will be maintained and notes the possibility that the FDA may inspect the records of a human subject.

APPENDICES

APPENDIX 1

Applicable Regulations of the Food and Drug Administration and the Department of Health and Human Services

The U.S. Federal regulations are organized in the following manner:

The Code of Federal Regulations (CFR) codifies rules published in the Federal Register by the federal government.

Title 21 (of 50 titles) involves foods and drugs. (Thus, FDA regulations are contained in Title 21.) Each title is composed of nine (9) volumes which contain a total of 1,300 parts. Each part has a subpart which is further arranged into sections and subsections.

Title / Part / Subpart / Section / Sub-section
An explanation of the following citation: 21 CFR 56.107(a)
Ex: 21 CFR Part 56 (Institutional Review boards)

21 CFR 56. Subpart b (IRB Organization and Personnel)

21 CFR 56.107 (section 107 (IRB membership)

21 CFR 56.107(a) (subsection (a) provides information about IRB Membership – "Each IRB shall have at least five members ."

Thus, information that describes the FDA requirements for how many members are to be included in an IRB is found in 21 CFR 56.107(a).

The following FDA regulations contain information that is relevant to IRB functions:

Title 21 CFR Part 50: Informed Consent

Title 21 CFR Part 56: Institutional Review Boards

The following FDA regulations specify the requirements of sponsors, investigators and sponsor-investigators to report adverse reactions involving drugs and biological products.

Title 21 CFR 314.80: a dverse event reporting involving marketed prescription drugs with an approved New drug application (NDA)

Title 21 CFR 310.305: a dverse event reporting involving marketed prescription drugs without an approved New drug application (NDA)

Title 21 CFR 312.32: adverse event reporting involving marketed or non-marketed drugs or biological products (including vaccines) with an investigational New drug application (IND).

Title 21 CFR 600.80: adverse event reports involving marketed biological products with an approved biological License application (BLA).

Title 21 CFR 1271.350: adverse event reports involving human cells, tissues, and cellular and tissue-based products.

The following FDA regulations specify the requirements of investigators and sponsors to report unanticipated device effects involving investigational drugs prior to FDA approval:

Title 21 CFR 812.150: investigational medical devices.

The following FDA regulation specifies the requirement of the IRB to determine if an investigation involves a significant risk device:

Title 21 CFR 812.66.

The following FDA regulations specify the requirement of manufacturers and user facilities to report adverse events associated with marketed medical devices:

Title 21 CFR 803.50, 21 CFR 803.52, 21 CFR 803.53.

Title 21 CFR 812.2: Safety and effectiveness of medical devices. IRB approval of an investigation. Abbreviated IDE application.

Title 21 CFR 812.40: General responsibilities of sponsors.

Title 21 CFR 812.42: FDA and IRB approval.

Title 21 CFR 812.46: Monitoring investigational medical devices.

Title 21 CFR 812.60: IRB composition, duties, and functions.

Title 21 CFR 812.62: IRB approval.

Title 21 CFR 812.64: IRB's continuing review.

Title 21 CFR 150 Withdraw of IRB approval.

Title 21 CFR 812.100: General responsibilities of investigators.

Title 21 CFR 812.140: IRB records.

Title 21 CFR 814.124: Institutional Review Board requirements.

The following Health and Human Services regulations contain information that is relevant to IRB function:

45 CFR Part 46: Protection of Human Subject

APPENDIX 2

Definitions

Adverse event – an undesirable and unintended, although not necessarily unexpected, result of experimental interventions.

Assent – an affirmative documented agreement to participate in research made by an individual not competent to give legally valid informed consent (e.g., a child or a cognitively impaired adult).

Belmont Report – a statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

Benefit – a benefit is a valued or desired outcome--an advantage. Anticipated benefits may express the probability that subjects and society may benefit from the research procedures. Research may benefit the individual, for example, by alleviating a condition or providing a better understanding of his or her disease. Research that has no therapeutic intent may still benefit society as a whole. If research will not benefit individuals, it is required to provide a reasonable likelihood of resulting in benefits to society, e.g., the advancement of important knowledge.

Clinical Trial - a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Data Safety and Monitoring Board (DSMB) – a committee composed of qualified individuals whose function is to:

- Review various risk information (adverse events, protocol violations, possible loss of privacy or confidentiality) obtained during conduct of a research protocol involving human subjects
- Recommend actions to resolve specific issues associated with risks. The DSMB is typically established by a pharmaceutical company or other commercial entity that sponsors the study.

Exempt – a review of proposed research by the IRB Office in conjunction with the IRB Chair that is minimal risk and qualifies for one of the exempt categories.

Expedited Review – a review of proposed research by the IRB Chair plus at least one additional experienced member designated by the Chair. Federal regulations permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Federalwide Assurance (FWA) – written documentation of an institution's commitment to comply with federal regulations governing human subject research when reviewing federally funded research.

Full Board Review – Review of proposed research at a convened meeting that does not meet the criteria to be designated exempt or the categories for expedited review.

Human Subject – a living individual about whom an investigator conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens.
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable Biospecimen - a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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

Informed Consent – a person's voluntary agreement, based upon an adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence

Legally Authorized Representative - an individual, 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.

Medical Device – any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Ex; surgical lasers, wheelchairs, sutures, intraocular lenses, reagents and test kits for in vitro diagnosis of disease and conditions such as pregnancy.

Minimal Risk – a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical, physiological or psychological examinations or tests.

OHRP – Office of Human Research Protections – an office within the U.S. Department of Health and Human Services.

Private Information - 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).

Research – a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Research includes, surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration and service programs and clinical trials.

Risk – The probability of harm, including: physical (ex., adverse events), psychological (ex., depression, confusion, fear, stress, loss of self-esteem), social or economic (ex.., breaches of confidentiality and privacy in research involving drug or alcohol use, sexual behavior, mental illness, illegal activities, could lead to embarrassment in a social group, prosecution, or loss of employment, insurability concerns). Both the probability and magnitude of possible harm may vary from minimal to significant. Risks include immediate risks of study participation as well as risks of long term effects.

Protocol – The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the experimental procedures, and the proposed methods of analysis that will be performed on the collected.

Sponsor-Initiated Study – a clinical investigation initiated by a person or other entity who does not actually conduct the investigation.

Investigator-Initiated Study - a clinical investigation initiated by an individual who both initiates and actually conducts, alone or with others, the clinical investigation.

Vulnerable Populations – Those who are susceptible to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.