



SAN DIEGO STATE
UNIVERSITY

HUMAN RESEARCH PROTECTION PROGRAM:
STANDARDS AND PRACTICES

GRADUATE & RESEARCH AFFAIRS
DIVISION OF RESEARCH AFFAIRS

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I. INTRODUCTION

The San Diego State University (SDSU) Human Research Protection Program (HRPP) Standards and Practices is a reference for IRB members, Research Affairs Analysts, faculty, students and others associated with the HRPP program. This guidebook for standards and practices details the policies and procedures based on regulations governing human subject research. The HRPP Program and the IRB shall adhere to the standards and practices outlined in this guidebook. Other guidance not included in this document is available on the SDSU HRPP website. The website may be accessed at:

http://research.sdsu.edu/research_affairs/human_subjects

II. DEFINITIONS

Children

Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research is conducted (45CFR 46.402(a))

Clinical TrialA Clinical Trial: is 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.

We generally expect that this definition will be applied harmoniously with the definition of clinical trial recently promulgated in the [ClinicalTrials.gov](https://www.fda.gov/oc/clinical-trials) final rule. The definition that appears in the final rule will only be relevant to the requirement for posting of consent forms for clinical trials conducted or supported by Federal departments or agencies (Sec. __.116(h)). It should be appropriate for that relatively narrow regulatory purpose.

Criminal Justice Activities

Activities conducted as part of the legitimate goals of the criminal justice systems (e.g. the collection of human biospecimens at crime scenes relating to victims, suspects, and offenders. Criminal Justice activities DO NOT include social and behavioral studies of the causes of criminal behavior. Studies of the causes of criminal behavior constitute research.

Generalizable Knowledge

The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution (e.g. publication, including thesis or dissertation, presentation or use outside the specific instructional setting.) The exception to the parameters defined occurs when a report of findings is issued to an agency that has contracted with the university to acquire programmatic information (e.g. needs assessment, program evaluation, quality control).

Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(f)).

Interaction

Communication or interpersonal contact between an investigator and subject.

Intervention

The performance of physical procedures to collect data or manipulations of the subject or the subject's environment for research purposes.

IRB approval

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.

Identifiable Biospecimen

A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

Identifiable Private Information

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

Legally Authorized Representative (LAR)

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.

Minimal Risk

The probability and magnitude of harm or discomfort *anticipated in the research* are not greater in and of themselves than those experienced in daily life or during the performance of routine physical or psychological examinations or tests.

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 the information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. medical record). When private information, access or obtained in the context of a research study, is individually identifiable, directly or indirectly, the research is considered human subjects' research.

Research

A systematic investigation, including research development, testing and evaluation, designed and intended to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)." The Office of Human Research Protection (OHRP) deems the following activities NOT to be research: oral history, journalism, biography, literary criticism, legal research, historical scholarship including the collection and testing of information that focuses directly on specific individuals about whom the information is collected. Furthermore, public health surveillance activities including the collection and testing of information or bio specimens conducted, supported, required or authorized by a public health authority. Finally, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions.

Additionally, research does not include public health surveillance activities. For example, safety and injury surveillance, surveillance that allows public health authorities to identify unexpected changes in the incidence of disease in a defined geographic region where public health concerns are raised, surveillance activities designed to enable a public health authority to locate the range and source of disease outbreak. Public health surveillance differs from epidemiologic research in the context under which the investigation is conducted. . While public health surveillance does not constitute research under the common rule, subsequent research using the information collected would come under the definition of research. Further, exploratory studies designed to better understand the factors for chronic disease still constitute research

Surrogate Consent

The use of a Legally Authorized Representative (LAR) with reasonable knowledge of the research participant who shall include any persons described under California law (Health & Safety Code 24178): 1) The person's agent per an advanced healthcare directive, 2) The conservator or guardian of the person having authority to make healthcare decisions for the person, 3) The spouse of the person, 4) An individual as defined in Section 297 of the Family Code, 5) An adult son or daughter of the person, 6) A custodial parent of the person, 7) Any adult brother or sister of the person, 8) Any adult grandchild of the person, and 9) Any available adult relative with the closest degree of kinship to the person.

II. ETHICAL FRAMEWORK

A. Purpose of the IRB

The SDSU IRB's primary responsibility is to protect and ensure that the rights and welfare of human subjects participating in research under the auspices of SDSU or their agents. Toward this aim, the IRB is charged with ensuring that human subjects' research is conducted ethically and in compliance with federal regulations, state or local laws including tribal laws passed by the official governing body of an American Indian (AI), or Native Alaskan (NA) tribe, and local and university policies and procedures. This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects.

B. The Belmont Report

The Belmont Report contains three basic ethical principles central to human subjects' research that guides the Human Research Protection Program (HRPP) and the IRB in assuring protection of the rights and welfare of research subjects. These three principles are respect for persons, beneficence and justice.

1. Obtaining informed consent, protecting the privacy and confidentiality, and enacting additional protections for vulnerable study populations are methods of demonstrating respect for persons.
2. Beneficence requires that the possible benefits of the research be maximized while the possible risks be minimized for the human subjects.
3. To demonstrate the ethical principle of justice, investigators must endeavor to be equitable in the selection of research subjects. This requires equitable distribution of the burden of participation and the benefit of the research. Investigators may not exclude potential participants from populations who may benefit from the outcomes of the research unless there is robust scientific or ethical justification for their exclusion.

IV. SHARED RESPONSIBILITIES OF THE INSTITUTION IN PROTECTING HUMAN SUBJECTS

A. Institutional Responsibility

San Diego State University (SDSU) assumes responsibility for the protection of the rights and welfare of human subjects in compliance with federal regulations as documented within SDSU's Assurance issued by the U.S. Department of Health and Human Services (DHHS). SDSU's assurance includes requirements and procedures for human subjects protections to ensure that all research conducted within its jurisdiction complies with the Code of Federal Regulations (CFR) pertaining to human subjects (DHHS Policy - 45 CFR 46; FDA Policy 21 CFR 50 and 56).

B. University Administrative Support

Graduate and Research Affairs Division of Research Affairs (DRA) provides administrative support for the SDSU Human Research Protection Program. The DRA is responsible for establishing and maintaining a program in support of ethical and responsible human subject's research conducted under the auspices of SDSU. To meet this responsibility, the Institutional Review Board (IRB) conducts initial and continuing reviews of human subjects' research. The HRPP provides links to relevant resources via the HRPP webpage and the IRB SharePoint sites, and provides resources for ongoing education and training in support of these responsibilities and activities.

C. Institutional Review Board (IRB)

The SDSU IRB is accountable for the review of human subjects research to ensure it meets applicable federal regulatory requirements at 45 CFR 46, 21 CFR 50 and 56 and all state or local laws including tribal laws passed by the official governing body of an American Indian (AI), or Native Alaskan (NA) tribe, , institutional policies and the ethical principles within the *Ethical Principles and Guidelines for the*

Protection of Human Subjects of Research also known as the Belmont Report. The IRB serves to safeguard the rights and welfare of human subjects enrolled in research studies where SDSU is engaged in human subjects' research activities. The SDSU IRB may be the designated IRB for review of research as part of an IRB Authorization Agreement (IAA) signed by the signatory officials for both the reviewing and the relying IRB. Conversely, the SDSU may rely on another IRB for review when an IAA signed by signatory officials from both the reviewing and relying IRB is in force. The reviewing IRB is responsible for regulatory compliance.

V. IRB MEMBERSHIP

A. IRB Composition

IRB membership includes at least five members from faculty, staff, students, and the local community from varying backgrounds. The varied membership includes those familiar with the methodologies commonly employed in research at SDSU, at least one licensed physician to assist in the review of clinical trials, and at least one member who is a prisoner representative who has the appropriate background and experience to support the rights and welfare of incarcerated research participants. Furthermore, membership includes at least one individual whose primary concerns are in nonscientific areas and at least one member not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution.

B. IRB Member Appointments

With regard to IRB appointments and membership, The Director of Research Affairs or designee will confirm compliance with federal regulations. Current IRB members may provide recommendations for membership to the Director of Research Affairs or designee. The Director of Research Affairs may contact SDSU Departments for recommendations of faculty for IRB membership. Faculty who are active in the research community may contact the HRPP directly to discuss service to the IRB. The Director of Research Affairs forwards IRB membership recommendations to the Vice President for Research for consideration.

Once IRB members are appointed, the Director of Research Affairs sends a letter outlining the terms of service to the IRB member. The Vice President for Research appoints members annually. The term of service for IRB members is one year. IRB membership may be renewed for IRB members who demonstrate knowledge of federal regulations, state and local regulations and policies, and an understanding of the application of the ethical principles outlined in the Belmont Report. Members must also demonstrate that they have time to devote to the responsibilities associated with IRB membership through regular attendance at IRB meetings. .,

C. Alternate IRB Members

Alternate members are appointed to the IRB to serve in the absence of a regular voting member. Selection of alternative members is based on the expertise and perspective s/he can bring to the

review process, the diversity in an individual's academic and/or professional training and their experience. The alternate member may be a scientist, nonscientist, or community member.

D. Consultants

The IRB recognizes that additional expertise may be necessary for review of an IRB proposal. The IRB may request consultation from subject matter expert when issues relevant to a proposal requires outside expertise. Consultants are not IRB members, do not count towards quorum, and may not vote.

E. Conflict of Interest

The IRB Chairperson or members may have a conflict of interest if they are an investigator on a study, or have a financial or other interest for a proposal under review. In cases where a conflict of interest exists, the IRB member will recuse themselves from the IRB deliberations and vote for the study in which they have a conflict. The IRB records any conflicts of interest in the IRB minutes and vote.

F. IRB Member Training

IRB members participate in initial and continuing education. This is accomplished via CITI Training in the Protection of Human Subjects, the review of the Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research, the Common Rule and (<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>), and the U.S. Food and Drug Administration (FDA) INFORMATION SHEETS Guidance for Institutional Review Boards and Clinical Investigators, (<http://www.fda.gov/oc/ohrt/irbs/default.htm>). Relevant materials on issues, regulations, and guidance are also presented at IRB meetings. The SDSU Human Research Protection Program Standards and Practices Manual is a resource for IRB members who review and ratify the manual.

VI. RECORD KEEPING AND DOCUMENTATION

A. IRB Membership Roster

The HRPP Office located within the Department of Research Affairs maintains the current IRB membership roster and report any changes to OHRP. The IRB roster contains the following information:

1. Name
2. Title
3. Voting status
4. Affiliation
5. Department
6. Degree(s)
7. Contact information
8. Representative capacity

9. Appointment Date
10. Term expiration date

B. Documentation of Expedited Reviews

The outcome of the expedited reviews is documented in correspondence to the Principal Investigator and on IRB meeting agendas.

C. IRB Minutes

The Research Affairs [IRB] Analysts take IRB minutes. The minutes include the following:

1. Attendance by name
2. Call to order, documenting that the required quorum was present, including a scientific member, a non-scientific member and a prisoner representative as required
3. Approval of prior IRB meeting minutes
4. Business items
5. Actions taken by the IRB for initial and continuing review of research including the vote, approval period and risk determination
6. The basis for requiring changes in or disapproving research
7. A summary of any controverted issues and their resolution
8. The determination of the frequency of continuing review based upon degree of risk

D. Attendance at IRB Meetings in the IRB Minutes

IRB minutes list the attendance as follows:

1. Names of members present including their membership and voting status. For members attending via telephone conference, the method or their attendance is recorded in the minutes.
2. Names of any guests present

E. Quorum Requirements

The IRB observes the following rules:

1. A quorum consists of a majority of IRB members (or their designated alternate). Quorum includes at least one scientific member, one non-scientific member, and at least one prisoner representative, as required.
2. Approval of research is by a majority vote of the quorum present.
3. Members recusing themselves due to a conflict of interest count toward quorum.
4. The following individuals do not count as quorum and will not vote: any individual not listed on the IRB membership roster, any ad hoc reviewer or consultant, any guests present at the meeting
5. When an IRB member and their alternate are both present at a meeting, only one may vote.

F. In the event of loss of quorum during a meeting, no discussion of, or action requiring a vote may continue until quorum is restored.

G. Documentation of Votes by the Convened IRB

Votes and deliberations on each action reviewed at a convened IRB meeting, include the number of members voting “for”, “against”, and number of those who are abstaining, or who are recused from the vote are documented in the IRB minutes.

H. IRB Deferral Documentation

When the IRB does not take action on an agenda item, the deferral and the reason for the deferral is documented in the IRB minutes. The review of the item is placed on the agenda for the next scheduled IRB meeting as appropriate unless noted otherwise.

I. Basis for Requiring Changes In or Disapproving Research

The minutes of the IRB meeting includes the basis for requiring changes in or disapproving research. Additionally, the IRB includes in its written notification to the investigator, a statement of the reasons for its decision and give the investigator an opportunity to respond in person, in writing or both.

J. IRB Correspondence

Study records include accurate records of communications to and from the IRB. The HRPP maintains all study-related IRB correspondence in the appropriate study file located in the HRPP office and/or the electronic IRB system.

The IRB notifies Principal Investigators (PIs) in writing of all IRB decision regarding each proposal including the regulatory criteria upon which IRB decisions are based. The PI is responsible for assuring the conduct of the research study complies with IRB approval.

K. Responses to IRB Correspondence

For any proposal reviewed at a convened IRB meeting, the primary reviewer for a proposal reviews any IRB-required response to modifications from a PI. For expedited reviews, a reviewer designated by the IRB Chairperson may review an IRB-required response for modifications. , When the IRB tables the review of a proposal, the PI response to the IRB is reviewed by the primary reviewer(s) at a fully convened IRB meeting.

L. Time Allowed for Submission of Modifications to Secure Initial IRB Approval

In cases where a research study is approved pending minor clarification and/or modification at the time of initial review, the IRB grants PIs 90 days to submit a response to the IRB. If a PI does not submit a response to the IRB within the 90-day timeframe, the IRB administratively withdraws the proposal from IRB consideration. If the PI wishes to obtain IRB approval for an administratively withdrawn proposal, a new IRB submission is required.

The IRB considers exceptions to this policy on a case-by-case basis, in extraordinary circumstances such as T delays in funding or sponsor-required changes to the proposal.

VII. EXEMPTION FROM IRB OVERSIGHT/REVIEW

Research studies meeting the definition of research involving human subjects, must undergo review and exempt determination by the IRB Chairperson or designee before the proposed research can commence. **Study team members may not make the determination of exempt status for the proposed research.**

A research study involving human subjects may be exempt from IRB oversight if it meets the following regulatory criteria found at 45 CFR 46.104. The exceptions are as follows:

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B.(additional protections for pregnant women/human fetuses/neonates)* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C.(additional protections for prisoners/detainees)* The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D (additional protections for minors).* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d)(1) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(d)(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(d)(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(d)(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(d)(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(d)(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.

(d)(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(d)(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

The HRPP notifies PIs of exempt determinations in writing. In the event that a study does not meet the criteria for exemption, the proposal is reviewed under expedited or full board procedures. In this case, additional information, or documentation may be required from the PI. The HRPP notifies the IRB is of exempt determinations via the IRB agenda.

If the PI proposes an amendment to the IRB for a study previously determined to be exempt from IRB oversight, the PI must submit an amendment to the IRB for review by the IRB Chairperson, or reviewer designated by the IRB Chairperson. The amendment is reviewed and if it does not change the exempt status of the study, a Research Affairs [IRB] Analyst will generate an Exempt Verification letter. If the amendment changes the status and the study no longer meets exemption criteria, the IRB reviews the research as non-exempt research either under expedited or full board procedures. This may require additional information or documentation from the PI.

VIII. ROUTINE IRB REVIEW

The IRB shall review and has the authority to approve, require modification to, or disapprove research.

A. Initial Review

The IRB reviews all research proposals for research that engages SDSU in human subjects' research. PI's must obtain final, unconditional approval prior to the commencement of any human subjects' research activities including the recruitment or consenting of research participants. For studies conducted by SDSU graduate students, a Faculty Advisor for the student will be a co-Principal Investigator (Co-PI) for the study. As Co-PI, the Faculty Advisor (FA) is ultimately responsible for the conduct of the study. The FA and must supervise and advise the student during the design and conduct of the research study. For studies requiring review at a convened IRB meeting, the primary reviewer(s) will: 1) review and lead the discussion on the proposal, 2) provide an assessment of the soundness and safety of the protocol, and 3) make any recommendations regarding the protocol and any study documentation. The HRPP may ask the PI will be to provide a telephone number where the PI can be reached to answer any questions that arise during the IRB's discussion of the proposed study under review.

The IRB will make the following determinations required by 45 CFR 46.111(a):

(1) Risks to subjects are minimized: By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies 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 (*e.g.*, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) 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. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) 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, §46.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

To facilitate an evaluation of the criteria for approval, the IRB reviewers may employ a Reviewer Checklist supplied by the HRPP office; however, the completion of the checklist is not compulsory.

In addition, at the time of initial review at a convened IRB meeting, the IRB determines the frequency of continuing review for the research study, however, continuing review may not be less than once every 365 days. However, the IRB may determine that a study requires IRB review more than once per year. The IRB may also determine that the IRB review a study after the study team enrolls *x* number of participants.

B. Continuing Review

Continuing reviews are only required for studies initially reviewed at a fully convened IRB meeting. The IRB will conduct substantive and meaningful continuing review of studies meeting based on regulatory criteria of research at intervals appropriate to the degree of risk, but not less than once per year.

The IRB notifies Principal Investigators in writing of the approval date and expiration date (as applicable) at the time of initial review approval. In order to allow for adequate time for submission and review of continuing review materials and applicable documents, the HRPP office sends a courtesy notice 45 and 30 days prior to expiration of IRB approval. It is the PIs responsibility to maintain current IRB approval regardless of whether or not they receive the courtesy notice for continuing review.

In conducting continuing review of research, the IRB will review:

1. The number of subjects planned for inclusion in the study
2. The number of subjects studied to date
3. The number of subjects the PI still plans to recruit
4. The number of subjects who have refused to participate
5. A summary of the complications or adverse events to the subjects
6. A summary of the modifications made to the protocol within the last approval period
7. A summary of the changes in literature which would affect the study

A research study conditionally approved at continuing review may not accrue new participants after the research study's expiration date, until the PI meets the conditions determined by the IRB and final IRB approval is conferred.

For studies that undergo expedited review, continuing reviews are eliminated unless the reviewer explicitly justifies why continuing review would enhance the protection of research participants.

Additionally, continuing reviews are not required for any studies that have progressed to the point that the study only data analysis of identifiable private information or bio specimens, or accessing follow-up clinical data from procedures the participants would undergo as part of clinical care.

For studies reviewed and approved prior to July 19, 2018, the IRB may convert the study to the revised continuing review requirements, and studies which were previously determined to be minimal risk and would meet the criteria at 45 CFR 46.110(9) may no longer require continuing review. The IRB will document the conversion of these studies in the review comments and IRB minutes.

C. Notification for Continuing Review

For studies requiring Continuing Review, the HRPP Office sends a first notification to the PI approximately 45 days before the current expiration date of approval to remind the PI to submit a Continuing Review Report. If a Continuing Review submission is not received after the first notice, a second notice is sent 30 days prior to the approval expiration date. If the PI

does not submit a Continuing Review Report prior to the expiration date of approval, the HRPP Office sends an Expiration notice via InfoEd to the PI instructing them that all research activities must stop. The notice instructs the PI to submit a Continuing Review Report within 30 days of the approval expiration date. . If the IRB does not receive a Continuing Review Report within 30 days of approval expiration, the study is closed and the PI must submit a new IRB submission for the study.

D. Ongoing Review

1. Review of Amendments in IRB Approved Research and Consent Documents

The IRB must conduct a review of all proposed changes to IRB approved research studies, including minor modifications to any previously approved study documents. The IRB must approve any changes before the implementation of the proposed changes, *except when necessary to eliminate apparent immediate hazards to subjects*. In the latter case, PI must submit the changes to the IRB for review promptly after the change.

2. Absence of a Principal Investigator

When a PI will be absent for a prolonged period of time (e.g. more than one month) and will be unable to oversee the research where participants are continuing to be followed as part of the research, the PI must notify the IRB prior to their departure, except in the case of unforeseeable absence due to an emergency.

The PI must submit an amendment to appoint a new PI during their absence for review and approval prior to their absence. Before approval, the individual(s) must be a qualified SDSU faculty member and must complete all required education consistent with HRPP policies.

IX. EXPEDITED IRB REVIEW OF RESEARCH

The IRB determines the eligibility for expedited review using the criteria found at 45 CFR 46.110. The criteria is listed below in italics.

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. 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.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) 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.

(D) The expedited review procedure may not be used for classified research involving human subjects. Classified research is research that is conducted by the federal government.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 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.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant 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

(b) from other adults and children², 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(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: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected non-research [or IRB approved research] purposes. (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.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(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.)

(8) Continuing review of research previously approved by the convened IRB as follows: (a) 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 (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

(9) Continuing review 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.

The IRB Chairperson or a reviewer designated by the IRB Chairperson conducts an expedited review. When conducting an expedited review, the IRB Chairperson or designated reviewer(s) has/have the authority to act on behalf of the IRB, but may not disapprove the research.

X.CONVENED IRB MEETINGS

Unless research falls into one or more categories appropriate for expedited review, the IRB will conduct initial and continuing reviews of all non-exempt research at a convened IRB meeting at which a quorum is present, including at least one member whose interest is primarily scientific, one members whose interest is non-scientific and if required a prisoner representative.

A. IRB Meeting Schedule

The HRPP Office posts the current IRB meeting schedule, including the deadlines for submission at http://research.sdsu.edu/research_affairs/human_subjects. The HRPP Office sends the IRB members the meeting agenda, minutes from the previous IRB meeting, and all applicable review materials at least one (1) week prior to convened meetings to allow sufficient time for review of agenda items.

B. IRB Meeting Procedures

The IRB Chairperson calls the meeting to order once a quorum is established. The IRB reviews and discusses the minutes from the prior IRB meeting, and determines if any revisions to the minutes are necessary. After the discussion, the IRB Chairperson calls for a vote on the IRB minutes.

The IRB reviews and discusses each agenda item requiring action by the IRB after a presentation of the agenda item by the primary reviewer(s). For each agenda item, the reviewer(s) for the agenda item make a recommendation to approve, conditionally approve pending minor modification(s) and/or clarification(s), table the review, or disapprove. An IRB member seconds the motion and the IRB Chairperson - calls for a vote.

Review and determination of approval for a protocol may be deferred if necessary if, for example, the absence of representational expertise or if quorum is lost.

If the IRB is unable to review all of the agenda items within the time allotted for the meeting, or if enough or quorum is lost, the meeting will be reconvened as soon as possible. If it is not possible to reconvene the meeting prior to the next regularly scheduled IRB meeting, the agenda items will be added to the next scheduled meeting.

For new agenda items, if a PI has supplied their telephone contact information, and they are available during the meeting time, the PI may attend the meeting in person or via teleconference during the meeting to answer any of the IRB's questions regarding their research study. Principal Investigators may not be present in person or via teleconference for any of the IRB deliberations or vote for their research study.

The Research Affairs [IRB] Analysts take minutes at each IRB meeting.

C. Actions Taken by the Convened IRB

The minutes will include all applicable actions listed below and the votes by the convened IRB.

1. **Approved:** The IRB approves a study when the IRB determines that all of the approval criteria at 45 CFR 46.111 are met and that no clarification or modification to the proposal or study documentation is required..
2. **Conditional approval:** The IRB conditionally approves a study when the IRB is able to make the required determinations at 45 CFR 46.111, and that only minor modifications are needed to the proposal and study documentation. Once the PI makes the modifications required by the IRB, the revised submission is sent to the primary reviewer(s), or a reviewer designated by the IRB Chairperson for verification that the requested changes have been made in order to secure final unconditional approval.
3. **Tabled:** A review of a study submission is tabled when the IRB finds that the submission lacks sufficient information to proceed with its review or that substantive clarification and/or modification is needed before a the IRB can make a risk benefit determination. The IRB must review a PI's response to the IRB for a tabled review at a fully convened IRB meeting,
4. **Disapproved:** The IRB determines the criteria for IRB approval of the research at 45 CFR 46.111 are not met and the research cannot be conducted.
5. **Acknowledged:** Acknowledged is used when one of the actions above does not apply (e.g. when information is shared with the IRB which does not require an IRB vote).

D. Use of Subcommittees to Support IRB Activities

The IRB Chairperson may appoint a subcommittee on an ad hoc basis to perform non-review functions for the IRB as needed.

E. Use of Primary Reviewers

1. Assignment of Primary Reviewers

The Senior Research Affairs [IRB] Analyst, in conjunction with the IRB Chairperson or the Director of Research Affairs, as necessary, will assign two primary reviewers for each initial or continuing review agenda item. .The assignments are based on the expertise of the IRB member. Amendments and Adverse Events may be assigned one IRB reviewer.

2. Responsibility of Primary Reviewers

1. Primary reviewers are responsible for thoroughly familiarizing themselves with all details of agenda items to which they are assigned.
2. They will conduct an in-depth review of the protocol, consent form and any related study documentation
3. The primary reviewer will lead the IRB discussion of the research at the convened IRB meeting, voice any concerns regarding the research, and identify any clarifications or modifications needed from the PI to secure IRB approval.

3. Absentee Reviewer

If a reviewer will be absent from the meeting, the other reviewer assigned will confer with the absent reviewer prior to the meeting and present the absent reviewers evaluation. If it is not

possible, for the two reviewers to confer prior to the meeting, the lead IRB Analyst, assigns another IRB member to the review the protocol if there is ample time to conduct a meaningful, in-depth review prior to the meeting. If this is not possible, the IRB may be required to defer the review of the protocol.

F. Materials for IRB Review

All IRB members and consultants, when applicable, are with sufficient information to ensure thorough review of each research proposal or amendment to an existing, previously approved proposal. All IRB members have the opportunity to discuss each research proposal reviewed during a convened meeting. Consultants may not vote on the review of an agenda item as they are not IRB members.

1. Initial Review Materials

- a. The HRPP Initial Review Application
- b. Consent form(s), as applicable
- c. Assent form(s), as applicable
- d. Any recruitment materials/fliers, as applicable
- e. Any questionnaire(s)/survey(-ies)/Data collection sheet(s), as applicable
- f. Any Eligibility screening checklist(s), as applicable

All of the review materials listed above applies to all initial reviews conducted at a fully convened IRB meeting or by expedited procedures the materials listed are also reviewed when making an exempt determination.

2. Continuing Review Materials

- a. The HRPP Initial Review Application
- b. The Informed Consent form, as applicable.
- c. The Assent form(s), as applicable
- d. Any other study instruments or recruitment documents, as applicable
- e. Any amendments made to the study since initial review approval
- f. Any unanticipated problems reported since initial review approval

All of the review materials listed above applies to all continuing reviews conducted at a fully convened IRB meeting or by expedited procedure.

3. Ongoing Review Materials

All IRB members and reviewers will have access to all relevant documents submitted for ongoing review (e.g. Amendments, Adverse Events or other reportable events), as well as any previously reviewed and approved documents necessary to determine that regulatory criteria for approval have been met.

G. Individual IRB Consultations

Individuals who have questions regarding IRB practices and standards (e.g. whether or not their study involves human subjects) should direct their questions in writing to the Research Affairs [IRB] Analysts via the main HRPP Office email at irb@sdsu.edu. *Investigators should not contact the IRB members directly with questions related to IRB standards and practices.*

Requests for personal consultation received by an IRB member should be forwarded to the Research Affairs [IRB] Analysts via irb@sdsu.edu.

XI. APPEAL OF IRB DETERMINATIONS

The IRB will provide the PI a written statement of its reasons for disapproving or requiring modifications in proposed research and will give the PI an opportunity to respond.

An investigator may request an appeal of an IRB decision in the following circumstances:

1. A suspension or termination of a previously approved protocol;
2. When the investigator believes the IRB's decision was based on inadequate or inaccurate information or is out of compliance with University policy, state law, or federal regulations;
3. When sanctions are imposed by the IRB;
4. When the investigator disagrees with the process by which a decision was rendered.

Investigators should send their written appeal directly to the IRB via the HRPP Office (irb@sdsu.edu) describing the specific reasons for their request. HRPP Staff will arrange a meeting between the investigator and all relevant IRB members to discuss the issues in an attempt to arrive at a resolution.

If this process does not result in a resolution, the appeal may be forwarded to the Vice President for Research (VPR) or designee. The VPR may, upon review of the appeal, initiate an inquiry into the process and/or data used by the IRB to arrive at its decision, and render an opinion or make a recommendation. The VPR may opt to convene an ad hoc committee to facilitate this review. However, *the decision by an IRB to disapprove a research project cannot be reversed by other officials at the institution. Final recommendations for approval remain the purview of the IRB.*

XII. DETERMINATION OF CONTINUING REVIEW DATE

A. Determination of Continuing Review Date for Studies Reviewed at a Convened Meeting

Per federal regulations, the IRB approval period may not be longer than one (1) year from the date of approval for studies initially reviewed at a convened IRB meeting. If at a fully convened meeting, the IRB approves a study and no modifications are required to secure approval, the effective date of approval is the date of the meeting. If the IRB approves a study pending minor clarification or modification, the effective date of IRB approval is the date at which the IRB determines the study team has made all required changes and issues an approval.

B. Expiration of IRB Approval

For studies requiring continuing review, the regulations at 45 CFR 46 make no provision for any grace period to extend the conduct of research beyond the expiration date of IRB approval. When a continuing review of a project does not occur prior to the end of the approval period specified by the IRB, IRB approval expires. This occurs when an investigator fails to provide a Continuing Review Report to the IRB, or the IRB has not conducted a continuing review and re-approved the research by the expiration date of approval. If the IRB approval for a study has expired, all research activities involving human subjects including the recruitment of participants, the collection of data, or the analysis of data must stop, unless it is determined to be in the best interest of the previously enrolled participants to continue (e.g. when the research interventions hold out the prospect of direct benefit to the participants or when withholding study interventions poses increased risk to the participants.)

The Principal Investigator determines whether or not it is in the best interests of the previously enrolled participants to continue after expiration of approval, but the investigator must submit a report to the IRB to obtain confirmation that the IRB agrees with this determination. The confirmation may be made by the IRB Chairperson, an IRB member designated by the IRB Chairperson, or at a convened IRB meeting. If the IRB determines that it is not in the best interest of the previously enrolled participants to continue participation, the PI must stop all research intervention, interaction or data analysis.

If the PI wants to continue a project that has had expiration in IRB approval, the PI should complete and submit a Continuing Review Report for review and approval. In order to retain the anniversary date for the, the IRB will approve the project for a period of less than one (1) year.

An expiration of IRB approval is not considered to be a suspension or termination of IRB approval; therefore, expirations of IRB approval do not need to be reported to the Office of Human Research Protection (OHRP) as indicated at 45 CFR 46.103(a) and 46.103(b)(5).

Investigators are responsible for knowing the dates of approval for their projects and maintaining current IRB approval.

D. Criteria for Requiring Review More Often than Annually

The IRB may determine a human subjects' research study requires review more frequently than once per year. This may be determined at any time for any reason, including the level of risk, the nature of any adverse events, any amendments to the study, and the study population.

The IRB may consider the following factors in determining the criteria for which studies require review more frequently than once per year:

1. Probability and magnitude or anticipated risks to subjects.
2. Likely medical condition of the proposed participants

3. Experience and qualifications of the PI
4. Nature and frequency of adverse events observed in similar research at this institution
5. Vulnerability of the population under study
6. Any other factors the IRB deems relevant

When specifying an approval period of less than one year the IRB may define the approval period as a time interval or a maximum number of participants. For example, the IRB may require review after six (6) months or after 10 participants. The approval period is documented in the IRB minutes.

XIII. CONTACT WITH POTENTIAL SUBJECTS

The IRB requires a description of how and by whom potential subjects will be identified and recruited. When records, such as medical records are reviewed to identify potential study participants, , the IRB reviews a description of procedures used to ensure that records are only accessed by those with consent from the individual, or that comply with FERPA or HIPAA.

A. Advertisement/Announcements/Flyers/Scripts

Printed or electronic media intended for use in subject recruitment is reviewed by the IRB to ensure that the procedures proposed for recruiting potential subjects are not coercive and do not state or imply an outcome or other benefit beyond what is outlined in the consent documents and the protocol.

Recruitment advertisements, such as flyers, postcards, brochures, newspaper advertisements, press releases, or postings on the internet are reviewed for the accuracy, consistency with the research plan, and presentation of information the prospective subject needs to determine their eligibility and interest. This will include the review of content, language, and design to ensure information does not mislead potential subjects. The following information is required to be included in recruitment materials:

1. Name and contact information of the principal investigator and/or research facility;
2. A concise description of the study purpose;
3. A description of the task(s) a subject will be asked to complete
4. The eligibility criteria for subject participation;
5. Time or other commitment required of the subjects; and
6. Location of the research and person to contact for further information.

Please note: In medical studies, advertisement materials must make no claims, either explicitly or implicitly, that the research activity is safe, effective, equivalent, or superior to any other current practice.

Reference to incentives offered may include that subjects will be paid but should not emphasize the payment or the amount to be paid (e.g. by the use of larger, bolded, italicized fonts).

B. Legitimate Access to Records

A primary concern of the IRB specific to subject recruitment involves protecting the privacy and confidentiality of prospective subjects. Recruitment procedures in which private sources release names of individuals to an investigator are generally not endorsed by the IRB. Recruitment procedures should allow the individual to consent to the release of information in advance of contact by an investigator.

C. Recruitment Incentives –Finder’s Fees and Bonus Payments

The IRB considers any remuneration (in cash or in kind) for patient referral unethical as it may compromise the provider-patient relationship. The policy set forth by the American Medical Association Code of Ethics states: “Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical.” Referral incentives may include, but are not limited to monetary compensation, stock options, material goods or other incentives such as food or entertainment. In addition, bonus payments to the investigator, study coordinator or provider for the purpose of encouraging recruitment of subjects to the study may compromise the judgment of the research team and is not acceptable.

The IRB does not endorse practices that involve remuneration of any kind to a provider for patient referrals or bonus payments to members of the research team for purposes of subject recruitment.

XIV. REPORTS OF PROBLEMS IN RESEARCH

A. Adverse Event and Unanticipated Problems Reporting

1. Reportable Events/Problems
 - a. All unanticipated problems involving risk
 - b. Unanticipated Serious Adverse Events

The PI must report serious adverse events to the IRB immediately at least within 48 hours of the event.

Serious adverse events are defined as(i) events that have resulted in death; (ii) are life threatening; (iii) require inpatient hospitalization; (iv) result in persistent or significant disability/incapacity, (v) result in a congenital anomaly/birth defect; or (vi) any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

All other problems (listed below) must be reported to the SDSU IRB **within 5 days**.

- c. Any apparent serious and/or continuing non-compliance.
- d. Protocol deviations

- e. Any unauthorized use, disclosure, removal, theft, or loss of PHI or individually identifiable private information.

Examples of losses under item (e) above include but may not be limited to:

- a. Signed consent forms, data collection forms or case report forms containing PHI
- b. The loss or theft of a laptop, flash drive, smart phone or tablet containing private identifiable information.

B. How to Submit a Report of a Problem in Research

Principal Investigators must report Unanticipated Problems, Adverse Events, or other reportable events that occur on their studies to the IRB via InfoEd. . For more information contact the HRPP office at 619-594-6622 or at irb@sdsu.edu

All other Reports of Potential Non-compliance or complaints may be reported by telephone, in person, or online. For more information see: http://research.sdsu.edu/research_affairs

Important: San Diego State University prohibits any retaliatory action against individuals who, in good faith, makes a call or written report regarding compliance, or cooperates with an investigation or corrective action.

Review of a Report of a Problem in Research

The IRB reviews the report to determine if the adverse event or problem is serious, unanticipated and related to the research. The IRB Chairperson will also determine if immediate action is warranted.

C. Convened IRB Review of a Report

When the IRB Chairperson or IRB member designated by the IRB Chairperson determines an unanticipated problem is serious, unanticipated and related, the report is at next IRB meeting. In cases where the Unanticipated Problem is an instance of non-compliance, the IRB Chairperson (or designee) will determine if the non-compliance is serious and continuing. Instances of serious and continuing non-compliance is reviewed at the next fully convened IRB meeting. If at the fully convened IRB meeting, the IRB determines the unanticipated problem is serious, unanticipated and related, or that an instance of non-compliance is serious and continuing a report of the problem is submitted to OHRP in compliance with reporting requirements.

The Senior Research Affairs [IRB] Analyst will assign a primary reviewer to review and present the event at the meeting. The primary reviewer as well as all IRB members have access to the IRB e-submission system and are expected to review the report in prior to the meeting.

The IRB will consider the following actions:

1. Modification to the protocol
2. Modification of information in provided in the informed consent document and during participant consenting
3. Providing additional information to past study participants
4. Notification of current study participants if the new information might affect their willingness to continue participation
5. Requiring the re-consent of currently enrolled participants
6. Modification to the continuing review schedule
7. Monitoring of the research
8. Monitoring of the consent process
9. Suspension of research
10. Termination of research

D. For Cause Suspension or Termination of IRB Approval of Research

The IRB Chairperson or designee may require an immediate, temporary suspension of enrollment of new participants and/or continued participation of previously enrolled participants, pending convened IRB review of an adverse event, unanticipated problem involving risk or research that is not being conducted in accordance with IRB requirements.

Upon review, if the IRB determines there is an unanticipated problem involving risk, or that there is serious continuing non-compliance, they may vote to suspend or terminate approval of the research.

The IRB will notify the PI in writing of such suspensions or terminations. The correspondence will include a statement for the reasons for suspension or termination. In the event of suspension or termination, the IRB provides the PI with an opportunity to respond to the IRB in person or in writing if they choose to do so.

E. Mandatory Reporting to SDSU Institutional Officials and External Agencies

The IRB reports any suspension or termination of IRB approval to the appropriate institutional officials, the HHS agency that supports the research, and OHRP. The reports will include the reasons for the IRB's action as well as:

1. The name of the institution(s) (e.g., university, hospital, foundation, school, etc.) conducting the research project;
2. The title of the research project and the title of any related grant, contract, or cooperative agreement;
3. The name of the principal investigator for the research project;
4. The number of the research project assigned by the IRB and the number of the applicable HHS award(s) (grant, contract, or cooperative agreement);
5. A detailed description of the reason for the suspension or termination; and

6. The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

When an IRB (a) suspends or terminates its approval during the period for which IRB approval had already been given or (b) disapproves a research project at the time of continuing review, the IRB determines procedures to ensure that the rights and welfare of currently enrolled subjects are protected, subjects are not put at risk, and subjects receive appropriate care, if indicated, during the period of suspension or following the cessation of the research. This is particularly important in the context of clinical trials. For example, the IRB, in consultation with the PI and determines whether it is in the best interests of currently enrolled subjects to (a) continue receiving the interventions that were being administered to subjects under the research project, (b) be transferred to another institution engaged in the research so that participation of the subjects in the research may continue, or (c) be transitioned to care outside of the research context. Continuation of subjects on interventions that administered under the research project may be appropriate at least temporarily, for example, when those interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects. If the IRB decides that already, enrolled subjects should continue to receive the interventions that administered to subjects under the research project, data collection (especially safety information) should also continue for such subjects.

In the case of an adverse event or other research related problem, the IRB will determine whether the investigator has developed appropriate measures to remedy the problem and to avoid the occurrence of a similar problem in the future. If the IRB determines that the adverse event [or other problem] is related to the research and that the problem was unanticipated, the PI will be asked *at a minimum* to modify informed consent procedures so that current participants are notified of the event so that they may determine whether they wish to continue their participation. The investigator may also be required to revise the informed consent process for use with future participants so that all foreseeable risks that are involved in the study are described. In addition, the IRB will determine on a case-by-case basis whether additional substantive changes such as major revisions to the protocol are required.

Federal law may also require the IRB to report the incident to the Office of Human Research Protections (OHRP) (45 CFR 46.103(a)). The IRB will report the incident to OHRP when it has been determined that the adverse event is also considered an unanticipated problem and therefore meets all of the following criteria:

1. The adverse event is unexpected in nature, severity and frequency;
2. The adverse event is related or possibly related to participation in the research; **and**
3. The adverse event suggests that the research places subjects or others at greater risk of physical or psychological harm than was previously known or recognized.

(Modified from OHRP's "Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem" available: <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/>).

Adverse events that do not meet the criteria as described above will not be reported to OHRP; however, the SDSU IRB maintains that authority to require protocol revisions, suspend, or terminate any protocol that is not being conducted in accordance with the SDSU IRB requirements for approved research or that has been associated with unexpected serious harm to subjects. The IRB will promptly notify the investigator if this determination is made.

M. Recognizing a Deviation from an IRB Approved Protocol

The IRB presumes the PI is implementing protocol procedures consistent with IRB approval. However, the IRB recognizes that deviations and exceptions to approved IRB protocols may occur. A protocol deviation occurs when there is inconsistency between the procedures carried out in a study and the procedures stated in the research protocol, or when regulations regarding the manner in which research is being conducted are not being followed. Protocol deviations may directly harm or present the risk of harm to human subjects, or may be administrative in nature, such as those related to data or record keeping. As indicated in section XI, protocol deviations must be reported to the IRB.

XV. REGULATORY CRITERIA APPLIED DURING IRB REVIEW

A. Required Criteria for IRB Approval of Research

The IRB will determine the following during initial and continuing review and approval of research as stated by the DHHS and the FDA regulations. IRB approval of a study means the IRB has determined that all regulatory criteria for approval are met.

1. The IRB must consider the risk level to participants in evaluating proposed research during initial and continuing review. The IRB identifies the risks to the participant. These risks must be clearly stated in the informed consent form. The IRB determines the risk level of the study protocol by evaluating the nature of the risk, including the potential physical, psychological and social/economic harms to the participants. The IRB also evaluates the probability of the risk as well as the procedures in place to mitigate the risk of harm as well as the experience of the investigator. Based on the information in the protocol, informed consent form, and other related study documents the IRB determines if risk level of the study is minimal or greater than minimal risk. The IRB determines the interval for continuing review based on the level of risk for the research study. Further, the IRB assesses the risk/benefit ratio for all human subjects' research studies.

2. Risks are minimized

To approve research, the IRB must determine at the time of initial or continuing review that the risks of the research are minimized using procedures (1) which are consistent with sound research design, and (2) do not expose the study participants to unnecessary risks.

3. Risks Reasonable Relative to Anticipated Benefits

At initial and continuing reviews as well as during the review of proposed amendments or unanticipated problem reports, the IRB must make a determination that the risks of the research are reasonable in relation to any anticipated benefits to participants and/or the importance of the knowledge resulting from the research.

4. Equitable Selection of Participants

During IRB review of the study related documents, the IRB determines that the selection of the participants is equitable with respect to gender, age, economic class etc. The IRB will not approve a study that does not provide adequately for the equitable selection of participants or has not provided appropriate scientific or ethical justification for excluding classes of people who might benefit from the research. To determine equitable selection of participants, the IRB evaluates the purpose of the research; the setting, the ethical justification for including any vulnerable populations as well as the justification for excluding classes of persons who might benefit.

5. Informed Consent Requirements

To approve research, the IRB must determine that legal informed consent is obtained from each prospective participant, the participants legally authorized representative (LAR), or the parent/guardian unless informed consent requirements may be waived or altered. The prospective participant, their LAR, or their parent/guardian must be given the opportunity to consider whether to participate.

6. Documentation of Informed Consent

To approve the research, the IRB must determine that informed consent will be documented in accordance with, the Common Rule, the FDA and other applicable federal, state and local regulations, unless the study meets criteria for waiver of documentation or alteration of informed consent.

7. Review of Data Safety Monitoring Plans and Data Safety Monitoring Boards

As applicable (e.g. clinical trial studies), the IRB reviews and determines that the research plan makes adequate provision for the monitoring of the data to ensure the safety of the participants. Note that all Phase III randomized clinical trials supported or performed by the National Cancer Institute (NCI) require monitoring by a Data Safety Monitoring Board (DSMB).

8. Privacy of Participants and Data Confidentiality and Security

The IRB requires that participant confidentiality is maintained and their privacy protected. The IRB recognizes the importance of protecting participant confidentiality and carefully evaluates each protocol to determine the measures to protect participant privacy.

At the time of initial and continuing review, the IRB ensures the study team protects the privacy and confidentiality of research participants. The IRB evaluates the methods used to obtain private information about potential participants and the use of personally identifiable information (PII) or protected health information (PHI), the methods to protect the privacy and confidentiality and the security and storage of the research data. In some cases, where the funding agency does not

automatically issue a certificate of confidentiality, the IRB may require a Certificate of Confidentiality be obtained to provide additional protection of the research data.

In reviewing privacy and confidentiality protections, the IRB will consider the nature, probability and the magnitude of harm likely to result from a breach of confidentiality.

B. Additional Considerations during IRB Review and Approval of Research

1. Advertisements

The IRB is responsible for ensuring the selection of participants is equitable; therefore, the IRB must approve all final versions of advertisements and participant recruitment materials (e.g. scripts, emails, flyers) prior to posting and/or distribution. *Draft documents will not be reviewed or approved by the IRB.* Recruitment materials must be included with the initial application or amendment (if applicable). The IRB reviews the documents for accuracy and consistency with the protocol. The IRB will also determine whether the materials are coercive or unduly optimistic.

Recruitment materials may not include any of the following:

- a. Statement or implication of a certainty of favorable outcome or other benefits beyond what is outlined in the consent and protocol;
- b. Exculpatory language
- c. Emphasis on payment or amount of incentive to be given by such means as larger font or bold typeface; or
- d. A promise of free treatment when the intent is only to say participants are not charged for participation in the study.
- e. As applicable, FDA-regulated study recruitment materials may not include any claims inconsistent with FDA labeling.

Any information on recruitment materials should be limited to the information the prospective participant needs to make an informed choice regarding whether or not to participate in the research study. The recruitment materials should include:

- a. The name and contact information of the investigator
- b. The location where the research study will be conducted
- c. The purpose of the research
- d. A summary of the eligibility criteria
- e. A description of the benefits and burdens of participation (an example of a burden might be traveling or parking costs)
- f. Time commitment required
- g. A clear statement that this is research and not treatment.

2. Payments to Research Participants

To assist in subject recruitment, an incentive may be offered. During review, the IRB considers the amount and type of incentive. Incentives for participation should not be so large as to coerce or unduly influence the prospective subject with regard to participation. The incentive should be reasonable compared to the burden or inconvenience incurred by study participants. It is important that the incentive be awarded for participation in the study rather than for completing a specific task as

awarding the incentive only when a task is completed, may create an undue influence to encourage continued participation when the participant is uncomfortable with the research. Receipt of the incentive must not be contingent on study completion. Potential participants should understand what incentives will be offered before agreeing to participate in the study. The amount of any incentive should be described during the consent process and be included in the informed consent form.

a. Prorating

The IRB supports the use of a prorated incentive payment system when appropriate. This allows the subject to be paid as the study progresses and does not create the perception of a penalty for discontinuing participation. In some cases, the incentive structure involves graduated payments over the course of the study to encourage continuation without creating an undue influence for participation. The IRB may accept procedures to pay the incentive in one payment at the end of the study when there is a direct benefit to the subject and a complete data set (all sessions, all interviews, all surveys) must be acquired in order to draw any conclusions from the study.

b. Drawings/lotteries

California law prohibits lotteries which are defined as any scheme for the disposition of property by chance among persons who have paid or promised to pay anything of value for the chance of obtaining property the name by which the scheme is known is immaterial.

See:

https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?chapter=9.&part=1.&lawCode=PEN&title=9.

Drawings or lotteries have three elements: (1) a prize, (2) consideration, and (3) distribution of a prize by chance. In the context of research, the prize is the incentive given by chance and participation in the research is the consideration. Drawings or lotteries that are exclusive to research participants are not legal. If the drawing or lottery is open to all regardless of whether or not the individual participates in the research, then the drawing or lottery is legal. Thus research study proposals which will include the disposition of incentives via a drawing or lottery must include a plan for how non-participants will be allowed to enter the drawing/lottery, and the consent form and any recruitment materials must include the following:

- (1) a general timeframe for when the drawing will close
- (2) include an estimated timeline indicating when the drawing will occur
- (3) a description of how the winner will be notified
- (4) the number of prizes to be given
- (5) the chances of being awarded the prize

C. Payment Type

Monetary incentives are typically in the form of cash, check/money order, gift card or redeemable coupon. **IMPORTANT NOTE:** If the amount of the incentive to be paid to participants is \$600.00 or more, either as one-time payment or in aggregate, SDSU must comply with U.S. federal tax law and file a IRS 1099 Misc form for each participant to whom a payment or payments meeting the threshold given above has/have been made. Participants must be told in the informed consent form the limits federal tax law places on confidentiality regarding their participation in research, and that their name, address, social security number, and the amount they were paid will be reported to the IRS. Non-monetary incentives may also be offered.

D. Payment Type for Research under a Department of Defense (DOD) Addendum

The Department of Defense (DOD) prohibits United States military personnel from receiving pay or compensation for research participation during duty hours. During off-duty hours military personnel may be compensated for research participation.

E. Compensation for Injury

Information on compensation for injury must be included in all informed consent forms for studies that the IRB determines are greater than minimal risk. The informed consent form must include contact names and telephone numbers per the requirements in the text of the Informed Consent form template found at:

<https://sdsuedu.sharepoint.com/sites/GRA/res/RA/HRPP/SitePages/Home.aspx>

F. Certificates of Confidentiality

In cases where a research study involves the collection of sensitive, identifiable information, the IRB may determine that a research study warrants special protection to protect participants from the risk of investigative or judicial processes. This special protection is obtained via a Certificate of Confidentiality. The purpose of the CoC is to protect against any involuntary release of sensitive information about individual participants for use in legal proceedings. As of October 1, 2017 National Institute of Health awardees no longer have to apply to the NIH to obtain a CoC. The NIH now issues a CoC for all ongoing or new research funded as of December 13, 2016. The NIH also issues CoCs for research funded by other Health and Human Services (HHS) agencies including the CDC, FDA, HRSA and SAMHSA as well as non-HHS Federal Funders and non-Federal Funders. . Investigators funded by non-NIH HHS agencies should contact the Certificate Coordinator for their funding agency. For those funded by non-HHS Federal Funders or funded by non-Federal Funders should consult the [NIH Certificate of Confidentiality Kiosk online](#).

G. Clinical Trials

H. Compliance with State and Local Law

The principal investigator will follow and adhere to all applicable state and local laws in jurisdictions where research is taking place.

State law and mandated reporting requirements may limit the extent to which the investigator is able to protect the subject's confidentiality. If through interview or measurement, the subject is likely to disclose illegal or dangerous behavior (e.g., if the subject reports any kind of abuse or serious harm to self or others) the investigator must disclose whether and to whom information will be reported. The investigator will include a description of the limits to confidentiality within the consent document.

Research conducted in a foreign country by or under the direction of an SDSU-affiliated investigator must be approved by the IRB and adhere to University and federal/state guidelines. Participants at international sites must be provided protections that are in accord to those given to research subjects in the United States.

I. IRB Consideration of Conflict of Interest

The IRB will consider the investigator's financial interests and potential for conflict of interest when evaluating the protection of human subjects. If a PI reports a financial interest, which may be associated with the research, the IRB assesses the investigator's objectivity in communicating risks, selecting subjects, obtaining informed consent, and collecting, analyzing and reporting data. The SDSU Conflict of Interest committee may also review disclosures where a PI reports a financial interest. The IRB reviews whether the investigator (including the investigator's spouse or dependent child) or any person affiliated with the project has any financial interest, financial relationship, governance or administrative affiliation with any entity that is providing funds for or which has rights to intellectual property resulting from this study. If a financial interest is reported, the investigator must complete and submit the Financial Interest Disclosure form with their IRB application.

J. Principal Investigator Expertise

During review, the IRB will consider the qualifications and resources of the PI and members of the research team.

K. Student Research

For Graduate Students: A SDSU faculty member must be the Faculty Advisor (FA) for all student research involving human subjects, whether dissertation, thesis or other research projects. The FA acts as Co-PI on student research projects. The FA does not need to be affiliated with the student's academic department; however, they do need to be a member of the student's thesis or doctoral committee. The FA must be knowledgeable regarding the regulations governing human subjects' research. As FA, the faculty member is responsible to actively mentor and supervise the student in both the planning and conduct of the study to ensure that the study is likely to achieve the intended purposes and objective of the research. Further, as the FA, the faculty member will be held accountable for compliance with federal, state and local regulations relating to the protection of human subjects. In supervising and mentoring students, faculty is responsible for:

1. Ensuring the student under their supervision has an appropriate understanding of the federal regulations that govern research involving human subjects.

2. Meeting regularly with the student to monitor the study progress and to ensure the study is being conducted per the IRB approved protocol.
3. Oversee the prompt reporting and assist the student in handling research related problems, including significant or untoward adverse event reporting within five (d) days of occurrence. *Note: As FA, the faculty member is ultimately accountable for reporting research related problems as outlined in Section XI.*
4. Fulfill the human subjects' education requirement by completing online human subjects education.
5. Ensuring the student submits a Final Report to the IRB to close the study upon completion of the research and prior to the student's departure from SDSU.

In the event the FA will be away from SDSU for an extended period of time, they will need to submit a modification to change the PI during their absence as outlined in Section VI.D.3.

The student may act as the Principal Investigator for the research study. As such the student is responsible for:

1. Obtaining IRB approval prior to initiating any research activities
2. Ensuring the description of the proposed study in the IRB application is accurate and complete prior to IRB submission
3. Informing the IRB of all proposed changes or additions to the previously approved study before implementation unless there is an immediate risk of harm to the subject. If a change is implemented to protect subjects from harm, informing the IRB as soon as possible after the fact.
4. Submitting a Report of Progress for continuing review by the IRB prior to the approval expiration date
5. Reporting unanticipated problems involving risks to subjects or others and adverse events within five (5) days of becoming aware of the problem or event
6. Immediately informing the IRB if they become aware of any information that may materially alter the risk/benefit ratio of the study
7. Informing the IRB of study closure or termination
8. Fulfilling the Human Subject education requirement by completing online human subjects training
9. Agreeing to meet with their FA on a regular basis for the monitoring of study progress
10. Arranging for the Co-PI to accept responsibility for the research in the event of their absence from SDSU prior to the absence
- 11.

Undergraduate Students: Undergraduate Students may work on a faculty member's approved research study. Undergraduate students are not permitted to be Principal Investigators.

L. Human Subjects Education Verification

The HRPP staff will verify education for the protection of human subjects training is current and complete for all study team members listed on a study protocol as part of an initial review submission, a Continuing Review Report, or Amendment submitted for IRB review. This may entail a request from HRPP staff for copies of training certificates from the principal investigator for study staff. Unconditional IRB approval will not be granted until all study team members engaged in human subjects research (e.g. personnel interacting or intervening, or who have access

to Personal Identifiable Information) have completed human subjects training and their training is current

M. Research Involving Deception

A foundational ethical principal of the Belmont Report, which is the report on which the Common Rule is based, is “Respect for Persons”. The use of deception in research creates an ethical dilemma as legally effective informed consent, allowing prospective participants to be self-determining, cannot be obtained.

The use of deception is sometimes employed in psychological or educational research. Deception in human subjects’ research occurs when participants are not told the true purpose of the research or are given incomplete information regarding the purpose of the research in an effort to avoid participant bias.

If an investigator includes a statement in the consent document indicating that the participant will be unaware or misled regarding the nature or purpose of the research, the study may meet exempt criteria under the 2018 Common Rule.

If an investigator determines that it is not feasible to obtain prospective agreement from the study subject to participate in research that employs the use of deception, the IRB must determine that any deception is justified and necessary to meet the aims of the research. Furthermore, deception may only be permitted where the IRB determines and documents the following: .

1. The research presents no more than minimal risk to the participants.
2. The waiver or alteration does not adversely affect the rights and welfare of the participants.
3. The research could not practicably be carried out without the waiver or alteration.
4. Where appropriate, the subjects have been provided with additional pertinent information after participation.

In studies involving the use of deception, the protocol should include procedures to debrief subjects following participation where appropriate. The debriefing statement should be presented in writing (and orally, when possible) and include a description of the deception involved and an explanation about the true purpose of the research. Additionally, this statement should inform subjects of their right to withdraw their data from the study. In the event the participant withdraws their data from the study, the PI must still provide any incentives offered as remuneration to study participants. Studies involving deception that do not meet exempt criteria must be reviewed at a fully convened IRB meeting.

N. Research Sites

The IRB considers the appropriateness of the research location and setting in determining whether or not the research location will have a negative impact on the rights and welfare of the research participants. The protocol and other supporting documents should address any special considerations associated with recruitment or data collection at the location (e.g., identifying potential subjects, setting appropriate for obtaining informed consent, confidentiality of data and

privacy concerns). Additionally, when questionnaires or surveys will be completed online investigators must provide the IRB with the URL that subjects will use to access the survey.

XVI. INFORMED CONSENT REQUIREMENTS AND DOCUMENTATION

A. Purpose of Informed Consent Process and Documentation

Investigators must obtain legal informed consent from the participant or participant's legally authorized representative (LAR) **before** conducting any eligibility screening or research procedures, unless the IRB waives or alters the informed consent requirements.. **Informed consent is more than just obtaining a signature on the informed consent form. It is an ongoing process** of information exchange between the participant, the principal investigator, and the study team.. Informed consent involves giving the prospective participant sufficient information about the research including the risks and potential benefits to allow them to make an informed, voluntary decision regarding participation.

The consent process begins during participant recruitment and includes any oral instructions and/or explanations, the presentation of the informed consent form and any other pertinent materials approved by the IRB, the opportunity to ask questions and receive answers, and the signing of the informed consent form by the participant or LAR and the Principal Investigator. Throughout the study, the PI and other IRB approved study team members should encourage participants to ask questions at any time during procedures or study visits, or contact the investigator for any questions that arise between study visits.

Informed consent may only be sought under circumstances that provide the participant or LAR with sufficient opportunity and information regarding possible participation. The circumstances include:

1. Assessing the prospective research participant's capacity to consent prior to obtaining signature on the informed consent document, to ensure that s/he is able to understand study procedures and the risks and benefits of participation.
2. Ensuring the information in the informed consent document is written and presented at approximately an 8th grade reading level and in a language that is understandable to the participant or LAR.
3. Excluding any exculpatory language from the informed consent process in which the participant is made to waive, or appear to waive, any of their legal rights, and releases or appears to release SDSU or SDSU employees or agents from liability for negligence.
4. Ensuring participants give consent without coercion or undue influence.

The form must be signed and dated by the participant or the participants LAR as well as the Principal Investigator. The PI must provide the participant or their LAR with a copy of the signed consent form.

The PI may obtain documented consent electronically so long as the informed consent process contains all of the required elements of informed consent (see Required Elements of Informed Consent).

If the study procedures involve audio and/or video recording and the recordings will be released outside of the study team, a signed SDSU Video Release Consent form will be obtained from the participant.

B. Observation of the Informed Consent Process

The IRB has the authority to observe the informed consent process of any currently active research study. Situations where the IRB might consider such an observation might include reports of a complaint or possibility of undue influence or coercion. An IRB member or designee may observe a consent session as an impartial observer.

C. Informed Consent Reading Level

Federal regulations require that informed consent documentation be written at the appropriate reading level of the potential participant population and be obtained in a language that is understandable to the participant or the participant's LAR. General guidance is that the consent form be written at approximately an 8th grade reading level.

In cases where the study team obtains informed consent from non-English speakers, the PI is responsible for working with the IRB to determine that an effective and appropriate method is in place. This may include the use of a reliable, certified translator or a certified translation of the informed consent form.

D. Required Elements of Informed Consent

Federal Regulations mandate the inclusion the following fundamental informed consent elements and additional elements:

1. Name of the Study
2. Name of the PI and Co-PI
3. A concise and focused presentation of the key information that is most likely to assist a prospective participant or their legally authorized representative in understanding the reasons why one might want to participate or the reasons why one might not want to participate.
4. A statement that the study involves research.
5. An explanation of the purpose of the research
6. Expected duration of the subject's participation
7. A description of the research procedures
8. Identification of any procedures which are experimental
9. A description of any reasonably foreseeable risks or discomforts to the participant

10. A description of any benefits to the participant or others which may reasonably be expected from the research
11. Alternatives to participation that may be advantageous to the participant.
12. Extent of privacy and confidentiality.
13. For studies that involve the collection of identifiable private information or identifiable bio-specimens the consent must include one of two statements: (a) a statement that identifiers might be removed from the information or bio-specimen, and that the de-identified information and/or bio-specimen could be used for future research studies or be given to another investigator for future research studies without additional informed consent being obtained **or** (b) a statement that the participants information or bio-specimens collected as part of the research will not be used or distributed for future research studies.
14. For studies which are greater than minimal risk: An explanation as to whether medical treatment is available if injury occurs
15. An explanation of who to contact for answers to pertinent questions regarding the research, participants rights, research related injury, or to voice concern about a specific research project.
16. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefit to which the participant is entitled.

Additional Elements of Informed Consent, as appropriate:

1. A statement that a particular treatment or procedure may involve risk to the participant
2. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard for the subject's consent
3. Significant new findings: the participant must be informed of any significant new findings which may affect the risks or benefits of the research and the participants willingness to continue participation
4. Any additional costs that may result from participation
5. Consequences of a participant's decision to withdraw from the study
6. Procedures for orderly termination of participation by the subject
7. The approximate number of participants to be enrolled
8. The amount and schedule of all payments to the participant
9. Any real or apparent conflict of interest by the investigators

For Broad Consent where identifiable private information and/or bio-specimens will be retained for future research

A description of any reasonable foreseeable risks or discomforts to the participant

A description of any benefits to the participant or others that may reasonably be expected from the research.

A statement that any new findings developed during the course of the research that may related to the willingness of the subject to continue participation will be provided to the subject

A statement whether clinically relevant research results including individual research results will be disclosed to the subject, and if so under what conditions

A statement that the subject's bio-specimens (even after identifiers are removed may be used for commercial profit and whether the subject will share in those commercial profits

For research involving bio-specimens, whether the research will (if known) or might include whole genome sequencing.

A general description of the types of research that might be conducted with the identifiable private information or identifiable bio-specimens.

A description of the identifiable private information or identifiable bio-specimens that might be used in research, whether sharing of identifiable private information or bio-specimens might be used in research, whether the sharing of identifiable private information or identifiable bio-specimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or bio-specimens

A description of the period of time that the identifiable private information or identifiable bio-specimens may be stored and maintained (this could be indefinite), and a description of the period of time that the identifiable private information could be used for research purposes (this could be indefinite).

Unless a subject or their legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using their identifiable private information or identifiable bio-specimen.

Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the participant in all circumstances, a statement that such results will not be disclosed to the participant

An explanation of whom to contact for answers to questions regarding the participant's rights and about storage and use of the participants private identifiable information or identifiable bio-specimens, and whom to contact in the event of research-related harm.

E. Waiver of Documentation of Informed Consent

The IRB may waive the requirement to obtain written documentation of informed consent. In the event the IRB approves a waiver of documentation of informed consent the IRB will review a written description of the information to be provided to participants. The IRB may also require the investigator to provide the participants with a written statement regarding the research. In approving the waiver the IRB must find and document either of the following:

1. The only record linking the participant and the research would be the signed consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. In this case the participant will be asked whether s/he wants documentation linking them to the research, and the participants wishes will govern.

OR

2. The research involves no more than minimal risk of harm to the participants and involves procedures for which written consent is not normally required outside of the research context.

F. Waiver of Alteration of Informed Consent

Federal regulations permit the IRB to approve a consent procedure that does not include or alters some or all of the required elements of informed consent. To approve such a waiver or alteration, the IRB must find and document of the following conditions are met:

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: (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; and
2. The research could not practicably be carried out without the waiver or alteration.

OR, the IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent, or waive the requirements to obtain informed consent if the IRB finds that ALL of the following are met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without a waiver or alteration;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation (e.g. debriefing)

G. Assent of Minors

In California, a child is an un-emancipated minor under the age of 18 years. Children may not provide consent for participation in research. They may provide assent. The ability for a child to provide assent depends upon the child's age and maturity. Assent is demonstrated by a child's positive agreement to participate in research whether documented or not. The IRB requires that investigators make adequate provision to solicit assent from children. To this end, the IRB will review a description of the process for obtaining assent from a child participant.

If the IRB determines child participants are capable of providing assent, they will determine whether or not assent should be documented. Generally, children are able to read and write to some extent by age 7 and can provide documentation of assent.

Written documentation is not required for children when:

1. A child is under the age of 7

2. It is determined that the minor is incapable of being reasonably consulted
3. The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

When documentation is not required, the IRB requires that the investigator conduct the assent process verbally. The PI should submit a script of the verbal assent process for IRB review and approval. Information presented to the child should be age appropriate and include an introduction and basic information about what s/he will be asked to do if they participate.

IRB decisions regarding obtaining assent form minors will be documented in the IRB minutes.

H. Parental Consent

If a minor will be involved as a study participant, the IRB will review procedures used to obtain and document consent from the parent or guardian. The parental consent process, including documentation, will include all the required elements of informed consent.

The IRB may waive the requirement for parental consent, if it is determined that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a required to protect the subjects (e.g. neglected or abused children). Parental consent can only be waived provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

XVII. REVIEW OF RESEARCH INVOLVING POTENTIALLY VULNERABLE SUBJECTS

Categorically vulnerable populations, as listed in the Federal Regulations Include:

1. Pregnant women, neonates and fetuses;
2. Prisoners
3. Persons lacking decision-making capacity
4. Minors

Other groups which may be vulnerable are those who may be physically or cognitively challenged, those who may be economically or socially disadvantaged and subordinate individuals such as, students and employees. Additional safeguards to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence must be included within the protocol (45 CFR 46.111(7)(b)).

Considerations for vulnerable subjects include evaluating the individual's ability to volunteer or provide informed consent to research participation. There are specific federal regulations (45 CFR 46 Subparts B - D) that apply to conducting research with vulnerable populations which assures that the risks associated with participation are minimal or that the research is of direct benefit to the subjects. Special considerations will be made by the IRB in reviewing protocols that include vulnerable subjects.

A. Pregnant Women, Neonates and Fetuses

The Code of Federal Regulations (45 CFR 46.401 Subpart B - <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr->

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

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

1. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
2. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
3. Individuals engaged in the research will have no part in determining the viability of a neonate.

The IRB will determine that all aspects of the research comply with this subpart. The IRB gives special consideration to subject selection, monitoring and oversight of informed consent, and monitoring the research as needed. .

B. Prisoners

The Code of Federal Regulations 45 CFR 46. Subpart C <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111>

Permitted Research Involving Prisoners (45 CFR 46.306):

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

1. The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under [§46.305](#) of this subpart; and
2. In the judgment of the Secretary the proposed research involves solely the following:
3. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
4. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
5. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
6. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the

Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

In addition to all other responsibilities prescribed for Institutional Review Board under [this part](#), the Board [IRB] shall review research covered by this subpart and approve such research only if it finds that:

1. The research under review represents one of the categories of research permissible under [§46.306\(a\)\(2\)](#);
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board [IRB] justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that parole boards 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 research will have no effect on his or her parole; and
7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

The IRB will carry out such other duties as may be assigned by the Secretary.

The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the IRB under this section have been fulfilled.

Or, the investigation pertains to conditions that affect prisoners as a class of people (e.g., vaccine trials, research on disease that is more prevalent in prisoners than other groups and research on social and psychological problems of prisoners such as alcoholism, drug addiction and sexual assaults) or the study has the likelihood of improving the health or well-being of the prisoner.

C. Cognitively Impaired Participants

Research involving individuals who may have impaired decision-making capacity warrants special attention by the IRB as members of this population may be vulnerable to coercion. Such individuals must be protected from exploitation and harm, while allowing the conduct of essential research on problems which are relevant to this population.

In cases where research involving individuals who have impaired decision-making capacity is approved, surrogate consent from a Legally Authorized Representative (LAR) will need to be obtained for such individuals.

The principal investigator must have adequate procedures in place for assessing and ensuring subjects' capacity, understanding, and informed consent or assent. A description of these procedures must be included in the study protocol.

D. Children

A child is defined by the State of California as a person who is under the age of 18 years and is not legally emancipated.

The IRB may only approve research involving children when all conditions of this subpart are satisfied as follows:

1. The research does not involve more than minimal risk (i.e., does not expose the child to greater risk than encountered in daily life).
2. The research involves greater than minimal risk, however the individual subject may receive direct benefit from participating in the research.
3. The research involves greater than minimal risk and no prospect of direct benefit to the participant; however, the results of the research will contribute to generalizable knowledge about the subject's disorder or condition.
4. The research, while otherwise not approvable presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Children can be involved in research conducted in a school setting when the data collected will be used to assess classroom instructional strategies/techniques, curricula development, or classroom management techniques. The protocol should address whether class time is used or if children are participating outside of structured class time (address nonparticipating students, supervision of non-participants, procedures used to pull out children/subjects during class time, etc.).

Wards of the state, agency, institution or entity can be involved in research if:

1. The research is related to their status as wards, or
2. The research is conducted in settings in which the majority of children involved as subjects are not wards (e.g. schools, camps, hospitals)

E. SDSU Students

The IRB will assess the possibility of situational coercion and pressure that a student may potentially experience when approached by an investigator as a potential research subject. The IRB requires investigators to follow recruitment procedures intended to create the opportunity for students to participate in research while reducing the possibility of unintended coercion. For example, investigators are asked to avoid one-on-one solicitations of students by faculty, graduate assistants or other students. If research participation is a course requirement, an equitable alternative to participation in a study as a method of obtaining course credit should be offered.

F. SDSU Employees

The IRB will consider the potential for coercion or undue influence and issues of confidentiality when employees are recruited as research subjects. Investigators are asked to state how voluntary participation will be ensured if the subjects under study are recruited by the employer or the researcher is sponsored by the employer. Recruitment procedures should allow for employees to participate in the study without jeopardizing their job status, their pay or their relationship with their supervisors.

XVIII. CONSIDERATIONS FOR SPECIFIC TYPES OF RESEARCH

A. Behavioral and Social Science Research

The primary concerns when evaluating behavioral and social science research are the risk of harm to participants with respect to psychological or social harm. Therefore, the IRB will assess the following:

1. The potential for the participants to experience stress, anxiety, guilt or trauma that could result in genuine psychological harm
2. The risks of criminal or civil liability or other risks that could result in serious social harms such as damage to financial standing, employability, insurability, reputation, stigmatization or damage to social or family relationships.
3. If information is to be collected on living individuals other than the consented participants (e.g. other family members), the IRB will consider the risk of harm to those individuals. Information of this nature may be collected in the context of an auto-ethnography or oral history.

To mitigate such risks, the IRB will review the proposal for appropriate preventative protections, debriefings, adequate disclosure of risks, and mechanisms to protect the privacy and confidentiality of participants or others affected by the research.

Finally, the use of confidential information is an essential element of much behavioral and social research. Methods used to identify potential participants or to gather information about participants must not compromise the privacy of the individuals.

When information linked to individuals will be recorded as part of the research design, the IRB will ensure that adequate precautions are taken to safeguard the confidentiality and the privacy of the individuals.

B. Internet Research

Human Subjects research conducted on the internet is subject to IRB review and approval. In reviewing research to be conducted via the internet, the IRB will consider study procedures in place to obtain informed consent and to protect the privacy and confidentiality of the subjects participating.

C. Research Commonly Conducted in the Department of Public Health

Tests routinely conducted in research protocols conducted in the Department of Public Health will be reviewed by the IRB for standardized procedures, appropriate risk management techniques and required training. Investigators who plan to collect data that involve maximal aerobic power (VO_{2max}), endurance test protocols, hydrostatic weighing, venipuncture, bone mineral density (DXA scan), lactate threshold, genetic testing, or exercise in the heat are advised to incorporate the appropriate exercise testing protocol within their research protocol reviewed by the IRB.

Template language for consent forms may be found on the HRPP SharePoint site:

<https://sdsu.edu.sharepoint.com/sites/GRA/res/RA/HRPP/SitePages/Home.aspx>