HUMAN RESEARCH PROTECTION PROGRAM: GUIDANCE, STANDARDS AND PRACTICES

GRADUATE & RESEARCH AFFAIRS
DIVISION OF RESEARCH AFFAIRS
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1.0 SDSU Institutional Review Board (IRB) General Information

1.1 Institutional Responsibility

San Diego State University 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 Office of Human Research Protections. SDSU’s assurance states requirements and procedures for human subjects protections to ensure that all research conducted within its jurisdiction complies with the Code of Federal Regulations pertaining to human subjects (DHHS Policy - 45 CFR 46; FDA Policy 21 CFR 50 and 56).

1.2 University Administrative Support

Administrative support for the SDSU Human Research Protection Program is provided through Graduate and Research Affairs' Division of Research Affairs. This office is responsible for establishing and maintaining a program in support of ethical and responsible human subjects research conducted under the auspices of SDSU. This is accomplished through initial and ongoing review of human subjects research (Continuing Review Program), Internet access to relevant resources, ongoing education and training, and periodic assessment of resources dedicated in support of these activities.

1.3 IRB Responsibility

The SDSU Institutional Review Board (IRB) implements a review process established within the Code of Federal Regulations (45 CFR 46) to ensure that human subjects research complies with federal regulations, institutional policies and ethical standards. The IRB serves to protect the rights and ensure the safety of people involved as participants in research. The IRB also provides assistance to the investigator in complying with federal and state regulations and institutional standards for human subjects research. The IRB is guided by the ethical principles as set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research also known as the Belmont Report.

1.4 IRB and Institutional Authority

As per 45 CFR 46.109, the IRB may approve research reviewed or may require that modifications to the protocol be made to secure approval to conduct the research. The IRB may also disapprove research. IRB decisions are communicated in writing to the investigator. The IRB may also suspend or terminate approval of research that is not conducted in accordance with the approved protocol or that has been associated with unexpected and/or serious harm to subjects (45 CFR 46.113). Actions taken by the IRB to suspend or terminate approval will be documented electronically and reported to the investigator, institutional official(s) and to the Office for Human Research Protections (OHRP).

Research approved by the IRB may be subject to additional review by the officials of the institution. Authorized institutional officials may approve or disapprove research planned by an employee, student or agent of the University. The institutional officials may not approve research involving human subjects that has not been approved by the IRB (45 CFR 46.112).

1.5 IRB Jurisdiction

The IRB reviews research when procedures are proposed to obtain information about a living individual through the use of a survey, interview, observation, experimentation, or the analysis of human tissues, records, samples or other data previously collected from human subjects. All research involving human
subjects must be reviewed and approved by the Institutional Review Board (IRB) in advance of study initiation (45 CFR 46.109).

IRB review must occur when SDSU is engaged in human subjects research (http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm). For example, SDSU would be engaged in research when:

SDSU or SDSU Research Foundation employees or agents, in connection with his/her institutional responsibilities, intervene or interact with human subjects for purposes of research or obtain individually identifiable private information about human subjects for purposes of research; or

SDSU or SDSU Research Foundation receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

Research that involves the use of SDSU's non-public information to identify or contact human research subjects or prospective subjects or utilizes any SDSU property or facilities in connection with human subjects research.

1.6 IRB Membership

1.6.1 IRB Composition

The IRB is composed of members representing the University faculty, staff and local community. 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. The members represent a variety of disciplines representative of the research reviewed.

1.6.2 Selection/Appointments

The IRB Chair or Director of Research Affairs will confirm that IRB membership is in compliance with regulations (46.107). If an additional member(s) is needed, several methods are used to identify candidates. The existing members may be asked to provide recommendations to the Chair. Department Chairs may be contacted to suggest faculty who are available and interested. Faculty who are active in the research community may be contacted directly to discuss service to the committee. The Chair and the Director of Research Affairs forward recommendations to the Vice President for Research. IRB members are appointed annually for a renewable one-year term by the Vice President for Research in accordance with federal requirements (45 CFR 46.107). Reappointment may occur on an annual basis provided the member demonstrates knowledge of regulations, an understanding of the application of ethical principles, and has available time to devote to associated responsibilities.

1.6.3 Alternate Member

An alternate member may be appointed to the IRB to serve in the absence of a member. The alternate is selected based on the expertise and perspective he/she can bring to the review process. The diversity in an individual's academic and/or professional training as well as experience will contribute to selection of an alternate member. The alternate member may be a scientist, nonscientist, or community member (45 CFR 46.107).

1.7 IRB Member Responsibilities
1.7.1 Member Training

IRB members participate in initial and continuing education by reviewing relevant materials on issues, regulations and guidance concerning human subjects protections (45 CFR 46.107). Successful completion of the SDSU Human Subjects Tutorial and Assessment is a mechanism for the SDSU research community, including IRB members, to demonstrate a basic understanding of both federal and SDSU-specific ethical principles and regulatory compliance practices. In addition to the Human Subjects tutorial, IRB members are familiar with the Human Research Protection Program Guidance Manual (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm), Code of Federal Regulations (45 CFR 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm), the Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm), Office for Human Research Protections - Policy and Guidance (http://www.hhs.gov/ohrp/policy/), and the U.S. Food and Drug Administration (FDA) INFORMATION SHEETS Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update (http://www.fda.gov/oc/ohrt/irbs/default.htm). IRB members are also periodically notified of events such as lectures, workshops and conferences related to human research protections occurring nationally and locally. IRB members are strongly encouraged to attend relevant lectures, conferences and associated events.

1.7.2 Reviewer Expertise (Research Involving Children, Prisoners, etc.)

The IRB membership includes those familiar with the type of research routinely conducted in the social and behavioral sciences. It is required that at least one member of the IRB is a licensed physician to assist with the review of clinical trials and studies that may involve more than minimal risk of physical injury. The IRB recognizes that additional expertise may be necessary when reviewing a protocol (45 CFR 46.107). The IRB may request consultation from subject matter expert when issues relevant to a protocol require outside expertise. Subject matter experts are not IRB members are may not vote on a motion.

1.7.3 Primary Reviewer Process

The primary reviewer is responsible for presenting an in-depth review of a protocol and identifies strengths and weaknesses that may influence approval. A committee member is identified as a primary reviewer based on his or her expertise in the discipline. Assignment as a primary reviewer is indicated on the meeting agenda. The primary reviewer process is used for initial and continuing review as well as proposed protocol modifications that are not eligible for expedited review.

1.7.4 Materials Reviewed by the IRB

1.7.4.1 Primary Reviewer

Using the Virtual IRB system developed at SDSU (vIRB), the primary reviewer reviews the entire application including the protocol, consent documents, grant application (if funded by the Department of Health and Human Services), recruitment materials and other supporting documents faculty sponsor's assurance [students. For clinical trials, the primary reviewer will also review the investigator's brochure.

For continuing review, the primary reviewer reviews the request for continuation of approval along with the consent form(s) and an abstract of the study. The Report of Progress includes the number of subjects intended for study, the number of subjects accrued, a summary of any significant adverse events or unanticipated problems, a summary of protocol revisions approved by the IRB since the last review, current literature that may influence the conduct of the study and an update of financial interests (if applicable). The primary reviewer may also access the protocol prior to the convened meeting to review...
background material. Materials describing any proposed protocol modifications are also accessible to the primary reviewer as a standard practice.

1.7.4.2 IRB Members

For new protocols, each IRB member may access the entire application using vIRB. The application includes the protocol, consent documents, recruitment materials and other supporting documents, faculty sponsor's assurance [students], the investigator’s brochure or the grant proposal(if applicable). Each member may enter comments specific to a protocol within the vIRB system. Each member also documents any conflict of interest related to a specific research protocol (e.g., the IRB member is a co-investigator on the study under review) and will not participate in the review if a conflicting interest is disclosed.

For continuing review, all members may access the request for continuation of approval along with the consent form(s) and an abstract of the study. Additionally, IRB members may access modification requests and adverse event reports.

1.8 Subcommittee Procedures

A subcommittee of the IRB is defined as one or more experienced IRB members designated by the IRB Chair or HRPP Coordinator to act on behalf of the committee when action by the full board is not required (45 CFR 46.110). Subcommittee procedures are used to review studies or reports that may receive expedited or exempt review, that is, studies that involve no more than minimal risk and comply with either the exempt (45 CFR 46.101) or expedited categories (45 CFR 46.110).

1.9 Quorum and Voting Requirements (46.107 and 46.108)

To convene a meeting of the IRB, a majority of the voting members of the IRB must be present. The committee may not convene without a member whose primary concerns are nonscientific. If the quorum fails during the meeting (early departures, loss of nonscientist, excused for conflict) the meeting will be terminated until the quorum can be restored. Any action taken without a quorum present is considered invalid.

An alternate member may be assigned to replace a member who is not able to attend the convened meeting. The alternate may vote only when in attendance to replace a voting member. Individuals designated as non-voting members may contribute to discussion; however, may not serve as a primary reviewer, propose a motion or vote on a motion. In order for a motion to pass, it must receive the approval of a majority of voting members present at the meeting.

1.11 IRB Member Conflict of Interest

Regulations stipulate that an IRB member may not participate in the initial or continuing review of a project in which the member has a conflicting interest except in response to information requested by the committee (45 CFR 46.107e). If a member has a conflict of interest (personal, professional or financial), he/she will leave the meeting room while discussion and voting occurs. Attendance during the meeting is documented in the meeting minutes. If the quorum should fail due to the absence of the member in conflict, the IRB Chair will determine whether the member may remain present and abstain from the vote in order to retain the quorum.

1.12 Education Requirement
SDSU requires that all investigators engaged in human subjects research successfully complete the SDSU human subjects tutorial available at: http://www-rohan.sdsu.edu/~gra/login.php. This requirement is designed to encourage understanding of values toward responsible conduct in research involving human subjects. The tutorial covers basic ethical principles and practices that should be applied whenever human subjects are involved in research studies. The content is based on the Code of Federal Regulations that pertain to human subjects (45 CFR 46), Ethical Principles and Guidelines for the Protection of Human Subjects - known as The Belmont Report, and SDSU's Federalwide Assurance. By successfully completing the tutorial, the investigator demonstrates the knowledge of human subjects protections necessary to satisfy this requirement.

2.0 When is a Review Required?

An IRB review is required when a study meets the criteria as defined by the federal regulations as human subjects research.

2.1 Definitions

In determining whether a project requires review by the IRB, the first step is to determine if the project is research and, if research, to then identify whether the people involved are human subjects. The IRB only reviews activities that involve the participation of human subjects in research. The definitions used by the IRB in determining the need for review follow:

2.1.1 Research

The Department of Health and Human Services (DHHS) Code of Federal Regulations (45 CFR 46.102d) has defined research as, "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 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).

2.1.2 Human Subject

A human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction, or (2) identifiable private information (45 CFR 46.102f)."

2.1.3 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) or 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).

For additional human subjects research definitions, please visit the Office for Human Research Protections (OHRP) website: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

2.2 When is IRB Review Required?
IRB review is required when SDSU is engaged in human subjects research (http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm). This occurs when an agent or employee:

“Intervenes with a living individual for research purposes (e.g., to draw/collect blood or other biological samples, dispense drugs, administer treatments, use physical sensors, test sensory acuity, collect information by survey, interview or oral history).

Manipulates an individual's environment for research purposes (control environmental light, sound, temperature, social interactions).

Interacts with an individual for research purposes (obtain consent, conduct interviews, screen potential subjects). Please note: Employees who make information available about a study and/or obtain permission from an individual to release contact information to an investigator but do not consent individuals nor act on behalf of the investigator are not engaged in research.

Releases individually identifiable private information or allows an investigator to obtain an individual’s private information without the individuals written consent (release of patient’s name to investigators for recruitment, allowing access to an individuals academic or medical record).

Obtains, receives or possesses private information that is individually identifiable (with or without a coding system) for research purposes.

Obtains, receives or possesses individually identifiable private information for use in maintaining a statistical center for a multi-site research program.

Receives a direct HHS award to conduct human subjects research that will be carried out by a subcontractor or collaborator.”

2.3 Additional Information on When IRB Review is Necessary

2.3.1 SDSU Sponsored Research

Regardless of where the research activity will occur, the SDSU IRB is required to review all research involving human subjects that is sponsored by SDSU, the SDSU Research Foundation or its ancillaries.

2.3.2 SDSU Involvement

All research projects that involve human subjects conducted by or under the direction of any employee, student, or agent of SDSU or SDSU Research Foundation in connection with his or her institutional responsibilities or that utilizes any property or facility of this institution, whether funded or not funded, are subject to the federal regulations governing such research (see 45 CFR 46 and The Belmont Report), and to the policies and procedures outlined in the University's Federalwide Assurance. IRB review and approval must occur in advance of study initiation.

2.3.3 Collaborative Research

Research conducted in collaboration with other universities, research institutions, or hospitals must be reviewed and approved by the SDSU IRB when the research is conducted by or under the direction of an SDSU employee, student or agent. Studies in which the duties of the principal investigator are formally contracted to a non-SDSU performance site must obtain approval from an IRB designated for that institution in addition to review requirements imposed by the SDSU IRB.
2.3.4 Consultant

The IRB is required to review all research conducted by or under the direction of an agent of SDSU unless the investigator is hired on his/her own time, does not utilize SDSU resources, and will not reference SDSU in documents or publications associated with any reported outcomes.

2.3.5 Students Enrolled in a Joint Doctoral Program

The IRB is required to review all research conducted by or under the direction of an SDSU employee, student or agent performing research related activities as part of their responsibilities at this institution. The requirement to obtain approval from the SDSU IRB is in addition to review requirements imposed by the other institution with which the investigator is affiliated. This requirement will apply primarily to students who are fulfilling degree requirements for a doctoral degree and who are enrolled in two academic institutions.

2.3.6 Research in Foreign Countries

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. Any proposed variations to ethical practices endorsed by the institution and federal regulations (recruitment procedures, consent process, confidentiality practices) that result from cultural, political or social issues unique to the country in which the research will occur must be supported by the investigator.

2.3.7 Pilot Studies

Studies that meet the definition of research that involve human subjects must receive IRB review and approval prior to initiation (see section 2.1 for definitions). Pilot or feasibility studies may include as few as one person, however, the same federal, state and institutional requirements to protect human subjects in research apply regardless of the number of subjects involved.

2.3.8 Nonaffiliated Investigator

Persons not affiliated with SDSU who plan to conduct research that involves the use of SDSU facilities must obtain clearance from the Associate Vice President of Business Enterprises prior to conducting the study and possess documentation indicating IRB approval. The SDSU IRB may also review the study to ensure ethical practices are implemented when conducting the research.

2.3.9 Access of SDSU Non-public Information

Research that involves the use of SDSU non-public information to identify or contact human research subjects or prospective subjects must be approved by the IRB in advance of initiating the research.

2.4 When is IRB Review Not Required?

SDSU is not engaged in research when an employee or agent of the university:

- Consults on research but at no time obtains, receives, or possesses identifiable private information (e.g., a consultant analyzes data that cannot be linked to individual subjects, either directly or indirectly through coding systems, by any member of the research team).

- Performs commercial services for the investigators (or performs other genuinely non-collaborative services meriting neither professional recognition nor publication privileges), and adheres to commonly
recognized professional standards for maintaining privacy and confidentiality (e.g., an appropriately qualified laboratory performs analyses of blood samples for investigators solely on a commercial basis).

Releases anonymous (no codes, links or identifiers) individual information or specimens to an investigator.

Releases identifiable private information to a state or local health department for public health purposes (no research component to the activity).

Releases private identifiable information to an investigator when written permission of the subject has been obtained and is documented.

Accesses information that is readily available to the public.

2.5 Additional Situations when IRB Review May Not be Necessary

IRB review may not be required in the following situations because the project does not meet the criteria for SDSU engagement in research:

2.5.1 Program Evaluation, Needs Assessment and Quality Control

Studies conducted for the purpose of program evaluation, needs assessment, or quality control in which findings are solely intended for use in internal program planning and development and are not designed to contribute to generalizable knowledge (e.g., peer-reviewed publication or presentation) are not subject to IRB review.

2.5.2 Consultation

IRB review is not required when an employee or agent of the university:

- consults on research but does not receive or possess identifiable and private information about persons participating in the study.

- is engaged in research as a consultant through a non-institutional contract. Research activities will occur outside of his/her SDSU employment and he/she will not reference SDSU in documents or publications associated with any reported outcomes.

2.5.3 Research Methods Courses/Class Assignments

The primary purpose of providing training in research methods is for the student to become more knowledgeable about the research process. Instructors may assign a project, in conjunction with the course, in which students design a study, recruit participants, collect and analyze data and report their findings in the form of a final paper. Since the intent of the project/assignment is to train students, the assignment is not considered research as defined within the federal regulations and is not subject to IRB review. The course instructor is responsible for including information about ethical research practices and providing direct supervision of each project. Projects conducted for this purpose should not exceed minimal risk, or target special populations or include sensitive subject matter.

If the assignment results in findings that the student may want to present or publish, it is recommended that the study be replicated and conducted under an IRB-approved protocol. The IRB does not have the authority to approve research retroactively.
2.5.4 Research Not Involving Human Subjects

Although an activity may be considered research (…systematic investigation designed to contribute to generalizable knowledge…), it may not involve human subjects (…a living individual about whom information is obtained through intervention or interaction). Persons involved in a research activity are not considered to be human subjects when the following apply:

The information collected is not about the individual. That is, the person interviewed/surveyed is asked to provide information specific to his/her expertise or profession as opposed to personal information about him/herself (opinions, thoughts, or perceptions). For example, a welder asked to describe the composite of shielding gas, shielding gas flow rate, and formation of the weld bead is not disclosing information about him/herself and, as such, is not a research subject. Likewise, an entomologist who describes the varieties of pesticide used to control a specific pest and to identify the types of pesticides that are used most frequently is contributing his/her expertise rather than information about him/herself.

The person is asked to wear a devise to measure something external to the person (air quality, environmental toxins). No data are collected about the person.

3.0 Review Process and Procedures

The Institutional Review Board (IRB) reviews research involving human subjects to assure that the protocol meets with federal, state and institutional regulations. Activity involving human subjects (identification of prospective subjects, recruitment, etc.) may not be initiated until the study has been reviewed and approved by the IRB.

3.1 vIRB: Web-based Application Submission / Communication with Investigators

SDSU’s virtual IRB (vIRB) is a web-based application system used to create, modify or renew an IRB protocol. The investigator may log onto their vIRB account through the SDSU Web Portal for real-time updates of protocol status (link to: www.sdsu.edu/webportal). When a new protocol is received at the IRB office, the investigator receives an electronic message with the assigned protocol number used to track protocol review status. Once the protocol has been reviewed, the investigator receives notification of the review outcome by electronic correspondence. Once the investigator has received notification that the protocol is approved, research may begin. If a conditional approval is granted, the investigator may log onto their vIRB account to review the protocol sections that require a response. The investigator may respond to the conditions by editing the conditional section and/or uploading revised consent or supporting documents as requested. Next the investigator must formally resubmit the protocol within the “Submit this protocol” module found in the vIRB Protocol Main Menu. Upon IRB review and approval of the response, the investigator will receive correspondence indicating Committee approval. Adverse event reports or other relevant reports are also submitted using the web-based application system. Approximately six weeks prior to the protocol expiration date, the IRB office will advise the investigator to complete a progress report, which must be reviewed and approved by the IRB prior to the protocol expiration date. It is the investigator’s responsibility to submit this report.

3.2 Determining Risk Level

Risk is evaluated by the IRB based on the type, probability, duration and severity of the risk that may or will occur during the research. Once these elements of risk have been evaluated, the anticipated benefits of the study are assessed to determine if the risk to benefit ratio is favorable. Next, the IRB will determine whether the study meets the criteria for or exceeds the parameters identified in the federal definition of “minimal risk.” “Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in
the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(i)). The IRB evaluates risk and whether the proposed research exceeds minimal risk on a case-by-case basis with consideration to the procedures proposed and subject population to be involved in the research.

3.3 Review Classification

There are three classifications for review of human subjects research, exempt, expedited and full committee. Exempt and expedited reviews are also called administrative reviews. All projects submitted for review must include a protocol, informed consent statement and appropriate supporting documents. The division of Research Affairs, in consultation with the IRB, assigns new protocols to these classifications based on federal criteria, e.g. level of risk, how human subjects are involved in the research and the study procedures. Research that is considered minimal risk and that meets federal criteria for an exempt or expedited review (e.g., use of existing data; some survey or interview procedures) may be eligible for review through administrative procedures (exempt) or by subcommittee (expedited) (45 CFR 46.101 & 45 CFR 46.110). All nonexempt research is reviewed through IRB subcommittee (expedited) or by convened committee. Studies receiving an exempt or expedited review are reviewed on a first come first serve basis. Review notification is available to investigators approximately three weeks following application submission for research that is classified as exempt or expedited.

3.3.1 Exempt Review

The majority of studies that involve data collection from adults using a survey or interview format are exempt unless the questions deal with a sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol. Surveys and interviews of children are not exempt unless the research meets the criteria of category one described in 45 CFR 46.101 (research conducted in commonly accepted educational settings). Research involving pregnant women and/or fetuses, prisoners, or the institutionalized mentally disabled cannot be exempt.

If the adult subject's identity is not recorded (anonymous) and/or the interview/survey questions are considered non-sensitive, then the research will probably be classified as exempt. If the subject's response to the questions would pose a risk to that person if disclosed, then the research would require an expedited or full committee review (depending on the level of risk) rather than an exempt review.

For all research, the investigator is required to provide adequate information about the research to potential subjects so that an informed decision can be made regarding participation. For research classified as exempt, the investigator can deliver this information verbally or both verbally and in writing depending on the nature of the study. The procedures used to obtain informed consent are included in the protocol review.

The following criteria are used to determine if research is exempt (45 CFR 46.101):

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if
(i) the human subjects are elected or appointed public officials or candidates for public office, or
(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

(5) Research and demonstration projects which are conducted by or subject to the approval of the federal department or agency heads, and which are designed to study, evaluate or otherwise examine:
(i) public benefit or service programs,
(ii) procedures for obtaining benefits or services under those programs,
(iii) possible changes in or alternatives to those programs or procedures,
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(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.

Additional Information:
Categories 2 and 3 are not exempt if the research deals with a sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol.
Surveys and interviews of children are not exempt.
Observation of children is exempt if the investigator does not participate in the activities being observed.

3.3.3 Expedited Review

The IRB Chair or one or more experienced IRB members designated by the IRB Chair may serve as a subcommittee to review research that qualifies for an expedited review using criteria listed in 46.110 below*. When conducting an expedited review, the designated reviewer(s) has the authority to act on behalf of the IRB with the exception of disapproving the research. During the initial review process, questions may arise that require the investigator to provide additional information or clarification about the protocol. Questions developed during the initial review are communicated to the investigator electronically within three weeks of application submission. The investigator is given a 90-day timeframe during which the protocol file will be held in a “pending status” and he/she may respond to the stipulations posed by the IRB reviewer(s). Upon receipt and acceptance of the investigator’s response by the IRB subcommittee approval to conduct the research is communicated to the investigator in writing. If the investigator does not respond to the stipulations for project approval within the 90-day time frame, the protocol is identified as inactive. IRB members are informed of initial and continuing review and protocol modifications reviewed using expedited procedures at the appropriate convened committee meeting.

*The following criteria are used to determine if the research is eligible for an expedited review (45 CFR 46.110):

(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.

(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, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples: (a) hair and nail clippings in a nondisfiguring 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 solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(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.

1. The expedited review procedure consists of a review of the research protocol, consent process and supporting documents by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2. Children are defined in the HHS regulations as "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 will be conducted." 45CFR 46.402(a).

3.3.4 Convened Committee Review

Research not eligible for an exempt or expedited must be reviewed by the convened IRB membership at monthly meetings. All protocols received by the posted deadline for a given month will be reviewed. A committee member is assigned the task of primary reviewer and presenter. Following presentation and discussion, the committee will vote on a motion to either: 1) approve the protocol; 2) request revisions to the protocol to secure approval; 3) request additional information before completing the review; or 4) disapprove the protocol.

3.3.5 Review Time Period
Completion of the initial review takes approximately three to four weeks depending on the volume of submissions received. Administrative reviews are conducted in the order received. Results of Administrative reviews are usually available in 3 to 4 weeks.

The investigator will be notified of the outcome of convened committee reviews approximately one week following the monthly meeting date.

3.4 Approval Criteria

For approval of a research protocol, the following federal requirements must be satisfied (45 CFR 46.111):

Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

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.

Selection of subjects is equitable.

Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, the cognitively impaired, or economically or educationally disadvantaged) additional safeguards are necessary to protect the rights and welfare of these subjects.

3.5 Delay of Approval

The most common reason for delay of approval is an incomplete application or an inadequate consent form. To avoid unnecessary delay, investigators should follow the IRB application instructions carefully so that the protocol, supporting documents and consent process are appropriately addressed. Questions about the application process should be discussed with an IRB analyst prior to submission of the protocol application.

3.6 Funded Research

For funded research, the protocol application must include the narrative section of the grant proposal (45 CFR 46.103f specific to DHHS requirement). In addition, the title of the IRB application must be consistent with the grant that the protocol represents. If an award is received, the SDSU Research Foundation will not release funds until IRB approval is secured. The SDSU Research Foundation has access to information regarding IRB review status for research receiving intra- and extramural funding.

3.7 Approval in Principle

If the research lacks definite plans for involvement of human subjects, an Approval in Principle may be appropriate (45 CFR 46.118). This process allows for the investigator to disclose plans to conduct research with an understanding that human subjects involvement in the research cannot occur until the
IRB approval is secured. Approval in Principle is appropriate when the research plan has not been completely developed or material development will occur prior to any involvement with subjects.

45 CFR 46.118: Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution’s responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. No human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

3.8 Review Decisions

As per 45 CFR 46.109, “An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities.” The review outcomes for research submitted for IRB review including: Approved, Revisions Required to Secure Approval, Insufficient Information and Approval Denied.

3.8.1 Research Approved

If the research is approved, an auto-generated electronic letter from the IRB stating the approval date and terms of approval will be sent to the investigator. In addition, a master of the IRB-approved and stamped informed consent document is uploaded to the protocol. If the investigator is requesting monetary support to conduct the research, the SDSU Research Foundation is notified of the review outcome.

3.8.2 Revisions Required to Secure Approval

A conditional approval or approval with stipulations is awarded if there are correctable problems found in the protocol. In this situation, correspondence is sent to the investigator detailing questions or information for the investigator to address. The IRB comments pertain to specific sections of the protocol which are then labeled “conditional” in the vIRB. To address these stipulations, the investigator provides a response within the appropriate section and/or uploads the revised consent or supporting documents and then formally re-submits the protocol for review within the “Submit this Protocol” module located in the vIRB Protocol Main Menu. Research may not commence until the stipulations have been addressed and accepted by an IRB representative. The investigator is provided with a 90-day time period within which the stipulated conditions must be addressed. Depending on the nature of the protocol revisions needed to secure approval, the investigator's response may be reviewed by the convened committee or by a subcommittee.

3.8.3 Insufficient Information to Complete Review

If a review cannot be completed due to pertinent information missing from the protocol, the investigator is informed of the information needed by the IRB to complete the review. Research activity may not commence until the investigator has provided the information and the IRB has reviewed and accepted the response. The investigator may edit the protocol application and then formally resubmit the protocol for review within the vIRB Protocol Main Menu.

3.8.4 Disapproval (45 CFR 46.109)
If the research is disapproved, the investigator may not conduct the research. The IRB will provide the investigator with the reason for its decision. The investigator may resubmit a protocol to the IRB for review if the reasons given for disapproval can be corrected and addressed.

3.9 Approval Period (45 CFR 46.109(c))

IRB approval is valid for up to one year from the date of initial review (45 CFR 46.109). The length and terms of approval are determined by the IRB based on project complexity and type of risk associated with participation. Protocols that are verified as exempt may be active for up to 5 years provided no changes are made to the protocol.

Investigators are responsible for knowing and monitoring the valid dates of approval for their projects. Failure to renew projects by the expiration date will result in denial of use of any data collected after expiration.

3.10 Appeal of IRB Decision

If the investigator is not satisfied with the decision of the IRB, or with the process by which a decision is rendered, the decision may be appealed. To initiate the appeal, the investigator submits a statement to the IRB noting areas of contention. If the issue is not resolved through the IRB, the appeal is forwarded to the Vice President for Research (or designee), Graduate and Research Affairs - Division of Research Affairs.

4.0 Protocol Development

4.1 Where to Begin?

This guidance is for use by investigators to develop an IRB-protocol for their research.

Prior to developing a protocol, it is recommended that the investigator review “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” also known as The Belmont Report (link to: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm), become familiar with the federal regulations for the protection of human subjects (45 CFR 46) and complete the SDSU Human Subjects in Research Tutorial (http://www-rohan.sdsu.edu/~gra/login.php).

To enter the web based IRB application and begin writing a protocol: Login to the WebPortal using your RedID and password; click “Activate Research Role;” then click “Launch IRB.”

4.2 Protocol Guidance

The Institutional Review Board reviews the study protocol to determine study benefit, associated risks and risk management procedures. The protocol is the most important section of the IRB application as it outlines the specific procedures that will be followed during the course of the study. One of the most common reasons for delay of IRB approval is an incomplete protocol. The protocol should be responsive to the information requested in each section of the protocol outline and written in layman terms.

4.3 Study Abstract

The IRB uses the study abstract to gain a general understanding of the scope of the research and to confirm the type of review classification that is appropriate (e.g., exempt, expedited, or convened
committee). The abstract should articulate why the study is being conducted, how it will be carried out, how the results will be interpreted and how risks will be managed. Specifically, the abstract is a one-paragraph summary of the protocol that includes a brief description of the study purpose/objective, methods, subjects, planned analyses, potential benefits, potential risks, and risk management procedures.

4.4 Statement of Purpose and Background

The IRB will assess the risks and benefits of the proposed research. Part of the risk and benefit analysis includes review of a summary of the literature and other background information (e.g., pre-clinical/animal data if relevant or other facts) in order to justify approval of the proposed human subjects research study.

Within this section of the protocol, the investigator provides relevant background information and literature reviewed to support the proposed research. Discussion includes study relevance, potential for contribution to the discipline and justification for involving humans in the research. If relevant, a summary of pre-clinical/animal data that have been obtained through other research is included. The investigator provides a list of references at the end of the protocol application.

4.5 Subjects

The IRB evaluates subject selection to ensure that the burdens of research participation are distributed equitably across groups of people. A description of subject characteristics is included in this section of the protocol. Additionally, information about recruitment procedures are evaluated along with procedures to protect subject privacy during the recruitment phase.

4.6 Subject Characteristics

Within this section, the investigator defines the group of subjects that are appropriate for use in the research study and provides a description of subject characteristics (e.g., type of population, number of subjects, gender, age range, etc.). The application prompts the investigator to indicate the specific type of subject group(s) to be included in the research. The investigator provides additional information to justify inclusion of special populations in the research where ability to acquire informed consent may be limited.

4.7 For studies involving Special Populations or Vulnerable Subjects

Special populations or vulnerable subjects include children, pregnant women, prisoners, those who may be physically or cognitively challenged, those who may be economically or socially disadvantaged, subordinate individuals (e.g., students and employees), and fetuses. 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 includes 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.

4.7.1 Children

The Code of Federal Regulations (45 CFR 46.401 Subpart D - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd) describes additional protections for children involved as subjects in research. 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 (link to state law on emancipation. 

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

The research does not involve more than minimal risk (i.e., does not expose the child to greater risk than encountered in daily life).

The research involves greater than minimal risk, however the individual subject may receive direct benefit from participating in the research.

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.

The research, while otherwise not approvable presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

4.7.1.1 Involving Children in Research at School

Minor 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 nonparticipants, procedures used to pull out children/subjects during class time, etc.).

4.7.1.2 Wards

The Code of Federal Regulations (46.409- http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.409(a)) provides guidance for children who are wards of the state, an agency, institution or entity can be included in research if:

The research is related to their status as wards

The research is conducted in settings in which the majority of children involved as subjects are not wards. such as schools, camps, hospitals or institutions.

4.7.2 Fetuses, Pregnant Women, and Human In Vitro Fertilization

The Code of Federal Regulations (45 CFR 46.401 Subpart B - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb) provides additional safeguards for research that involves fetuses, pregnant women, and human in vitro fertilization. Pregnant women or fetuses may be involved in research if all of the following conditions are met (45 CFR46.204):

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

(b) The risk to the fetus is 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;
(c) Any risk is the least possible for achieving the objectives of the research;

(d) 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;

(e) 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.

(f) 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;

(g) 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;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) 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

(j) 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. For more guidance on research involving fetuses and human in vitro fertilization please review the Office for Human Research Protections (OHRP) IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_chapter6.htm#g2. For more information on inclusion of pregnant women in research, please go to: http://www.hhs.gov/ohrp/irb/irb_chapter6.htm#g3.

4.7.3 Cognitively Impaired (45 CFR 46.111(b))

Cognitively impaired individuals must be able to make an informed choice to participate in the research. The protocol will include a description of how the potential subject is evaluated to determine capacity to consent along with details of the consent process used to ensure that the prospective subject understands the information presented about the study. The investigator may consider including questions at the end of each section of the consent document to use in assessing participant comprehension of the consent content. This mechanism allows for the investigator to clarify the participant's understanding of specific aspects of the study as the consent process occurs. For example, the study description component of the consent process may be followed with questions such as: “Do you understand what will happen during the testing phase?” “Do you know how many times you will come to the clinic?” If the individual is not legally able to consent for him/herself, the person who is legally authorized to speak on behalf of the individual is responsible for determining whether the proposed study is appropriate.

4.7.4 Prisoners

The Code of Federal Regulations 45 CFR 46.401 Subpart C (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc) allows the IRB to review and approve research that includes prisoners when the following conditions are met:
• The study does not place the subject at more than minimal risk.
• The investigation pertains to; possible causes, effects and processes of incarceration and of criminal behavior or the investigation pertains to prisons as institutional structures or of prisoners as incarcerated individuals.
• 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.

4.7.5 Women and Minorities

Federal guidelines require that NIH-funded studies incorporate a research design that is sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups to examine differential effects of research procedures on such groups. For more information on this topic, please go to: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

4.7.6 College Students

The IRB tries to assess situational coercion and assist investigators to reduce the pressure that a student may experience when recruited to participate in research. The IRB encourages 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, investigator's 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 (e.g., summarize a journal article, attend a research lecture, and assist with data collection).

4.7.7 Employees

The IRB considers 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.

4.8 Selection Criteria

The IRB reviews the criteria for subject selection to determine whether selection practices are equitable and justified. The research protocol should include rationale to support the selection criteria and a description of how the inclusion/exclusion criteria will be assessed and by whom (qualifications and credentials of the individual making the assessment are appropriate to include).

4.9 Screening Procedures

The IRB reviews procedures to protect subject privacy and confidentiality during the screening process. This includes evaluating the informed consent process for the screening component and procedures to determine eligibility. It may be necessary to evaluate individuals for eligibility before they are formally enrolled into the study. The study protocol should include how screening will take place (e.g. interview, survey, records review) and how consent will be obtained, and how data collected during screening will be handled if the person is found to be ineligible (e.g., used as research data or destroyed). If individuals will disclose private information, the IRB reviews the procedures used to obtain consent from the person in advance of implementing screening procedures. If the protocol identifies specific inclusion and
exclusion requirements to determine subject eligibility (e.g., age, physical or psychological condition), the IRB will review a screening checklist in which specific inclusion and exclusion criteria are listed and defined. The IRB will review the procedures used to document appropriate screening of subjects. For example, it is recommended that a screening checklist is completed for each subject enrolled and that a checklist is maintained in the study master file or in individual subject files.

4.10 Recruitment

The IRB requires a description of how and by whom potential subjects will be identified and recruited. If records are accessed to identify potential subjects, the IRB reviews a description of procedures used to ensure that records are only accessed by those with consent from the individual.

4.10.1 Advertisement/Announcements/Flyers/Scripts

Advertising a research study for the purpose of recruiting participants is part of the informed consent process. Printed or electronic media intended for use in subject recruitment are reviewed by the IRB to ensure that the procedures proposed for informing 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 and presentation of information the prospective subject needs to determine their eligibility and interest. This includes the review of content, language, and design. Information should not be misleading to subjects, as such, the use of words that appear neutral as opposed to sensational are encouraged. Attention should be paid to the use of appropriate graphics, font size and format/design, and to accurate spelling and punctuation. The following information should be included in recruitment materials:

1. name and contact information of the principal investigator and/or research facility;
2. concise description of the study purpose;
3. a description of the task(s) a subject will be asked to complete
4. 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 should 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.

4.10.2 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 names of individuals are released from private sources to an investigator are generally not endorsed by the IRB. Recruitment procedures should allow for the individual to consent to the release of information in advance of being contacted directly by an investigator.

Established Legal/Ethical Protections:

The IRB advises against the release of identifiable private information from a source to an unaffiliated investigator without the permission of the potential subject where legal and ethical guidelines prohibit the source from doing so.
An example of when this may occur is when an investigator is attempting to identify prospective subjects according to specific eligibility criteria for recruitment to a study by accessing private files through a hospital or medical clinic.

To obtain permission to access private and identifiable information about a prospective subject, the investigator will need to propose procedures to obtain consent from the individual(s) involved. This may be in the form of a release form used by the source to document permission to release information to the investigator. The consent statement should describe the information is requested, how it will be used and to whom it will be given. IRB review and acceptance of this consent document is required in advance of its use.

No Established Legal/Ethical Protections.

The IRB does not endorse the release of information about an individual in cases where the individual may normally consider the information to be private regardless of whether or not this information is protected by law or the ethics of a specific profession.

The IRB advises against procedures that involve a person or organization providing information about another individual/potential subject without his/her permission for the purpose of recruitment.

The IRB recommends procedures that allow for an organization or an enrolled subject to provide information about the study to a prospective subject (flyer, postcard or other announcement) that allows for the prospective subject to initiate contact if he/she would like additional information about the study.

Please note: Research that involves the collection or study of existing data, documents, records or specimens where the sources are recorded in a manner that subjects cannot be identified, directly or through identifiers linked to the subject may meet the criteria for exempt review.

4.10.3 Recruitment Incentives – Finder’s Fees and Bonus Payments

Any remuneration (in cash or in kind) for patient referral is considered unethical and is not permitted 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.

Please visit the American Medical Association web site for more information on this topic available: http://www.ama-assn.org/ama1/pub/upload/mm/369/65b.pdf.

4.11 Informed Consent Process

“Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. This assurance protects all parties - both the subject, whose autonomy is respected, and the investigator, who otherwise faces legal hazards. The "proxy consent" of someone other than the subject is not the same as the subject's own consent, although it may
be an acceptable substitute when a subject is unable to give informed consent.” (OHRP IRB Guidebook, Available: http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e2).

Within the section pertaining to informed consent, the IRB will review the procedures that will be followed during the informed consent process. The IRB will review the process used to introduce the informed consent document and procedures used by the investigator to ensure full disclosure of the research (i.e., purpose of the study, study description, risks, benefits, confidentiality, investigator's telephone number to call for questions, etc.). The IRB will also review procedures developed by the investigator that will enhance the potential subject's understanding of the research (e.g., use of audio/visual materials or reiterating complex information in lay terminology). It is important to include a description of the person who will make initial contact with the potential subject to demonstrate that this individual is knowledgeable about the study, can present the information to potential participants and will promote voluntary participation. The IRB will also consider how and where the research will be introduced to the individual to assess whether the timing and setting of the informed consent process is conducive to objective decision making. If minor children are involved in the study, the IRB will review the process used to obtain parental consent as well as assent from the minor child. The IRB will review the consent document(s) for use in obtaining and documenting consent from study participants. Consent forms must adequately describe the study using language appropriate for the target audience. If relevant, the investigator will be asked to translate consent documents into the subject's primary language after the English version of the consent form has received IRB approval.

### 4.11.1 Waiver of Consent Requirements

If waiver of consent, alteration of consent content or waiver of consent documentation is requested, the IRB must review justification to support the request. As per 45 CFR 46.116 (d), the IRB may waive the requirement to obtain informed consent or approve a consent procedure which alters some of the consent content if the IRB finds and documents that:

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 the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

### 4.11.2 Waiver of Consent Documentation

The IRB may waive requirements to document voluntary participation via a signed consent form if:

- the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern (45 CFR 46.117 (c) (1)).
- the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (45 CFR 46.117 (c) (2)).

If waiver of consent is requested, the protocol must include justification to support the request. The IRB rarely approves waiver of informed consent.

### 4.11.3 Assent from Children (45 CFR 46.408)

Assent is demonstrated by a child’s agreement to participate in research. In California, a child is a person who is under the age of 18 years (unless legally emancipated). It is required that the investigator makes adequate provisions to solicit assent from children unless the IRB waives this requirement.
The IRB will review a description of the process and procedures for obtaining assent from the child. Determining whether the child is able to assent depends upon the child's age and maturity. If the child is considered to be capable of providing assent, whether or not assent is documented is also determined by the IRB. Generally, children are able to read and write to some extent by age 7. As such, documenting assent by having the child sign an assent form is usually a procedure that is incorporated for children age 7 – 17.

Written documentation is not required for children when (45CFR46.408):

- A child is under the age of 7
- It is determined that is incapable of being reasonably consulted
- “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 through a verbal interaction and the IRB will review a script of what will be said during the verbal consent process. Information presented to the child should be age appropriate and include an introduction and basic information about what he/she will be asked to do if they participate.

4.11.4 Parental Permission (45 CFR 46.408)

If a child will be involved as a study participant, the IRB will review procedures used to obtain and document permission from the parent or guardian. The parental permission/consent process, including documentation, will include all information normally required for informed consent.

The IRB may waive the requirement for parental permission, 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 reasonable requirement to protect the subjects (for example, neglected or abused children). Parental permission 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.(46.408 (c)).

4.11.5 Non English Speaking Subjects

If non-English speaking persons will be recruited, the IRB will review a description of the qualifications of the person who will conduct the translated consent process (verbal and written). The IRB will review the English version of the consent document before approving the translated version. After the English version has been approved by the IRB, the investigator will forward a copy of the translated document to obtain the IRB stamp of approval.

4.12 Potential Problems

Within this section of the protocol, the investigator is asked to address potential problems involving subject identification, recruitment or data collection that may negatively affect the ability to conduct this study and discuss how these problems will be managed.

4.13 Research Design and Methods

The IRB evaluates the research design to weigh the potential benefits of the study in relation to the potential risks. The IRB protocol must include adequate information about the research design for the IRB
to make an informed judgment that the design will result in meaningful and valid data. The IRB will review a description of the research design, the scientific rationale underlying the proposed research and the statistical basis for the structure of the investigation. The IRB will also review the specific aims of the research, the hypotheses to be tested, the questions to answer and the type of data to be gathered and tested.

The OPRR IRB Guidebook (1993) states, “The value of research depends upon the integrity of the study results. One of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare by improving health care. But if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study.”

If the IRB determines that the experimental designs or statistical methods are inappropriate, the investigator will be asked to make revisions so that review of the protocol may continue. Some common issues to consider include the appropriate number of subjects, the power of the study (effect size estimates), the type of statistical procedure (e.g., parametric versus nonparametric), and the type of study.

4.13.1 Subject Involvement

The IRB will review the tasks that subjects will be asked to complete as study participants. Specifically, the protocol should describe what subjects will do while involved and the amount of time that participation in each aspect of the study will take. The protocol should also discuss any investigational, experimental, or special procedures that will involve the subject (medical devices, electrical equipment, etc.). If the research involves exercise testing, blood draws or DEXA scans, the protocol must include approved procedures identified within the Exercise Protocols section of this guidance.

4.13.2 Tests, Questionnaires, and Interview Guides

Keeping in mind the methodological distinctions between qualitative and quantitative research, the IRB reviews all research instruments such as surveys, interviews or questionnaires planned for use in data collection. As such, the investigator is asked to include all interview schedules and survey instruments with the completed protocol application. The investigator may submit draft versions of study instruments for review; however, the IRB must review the final instruments (quantitative study) prior to approving the use of those instruments for data collection. Investigators conducting a qualitative study, where the development of interview questions or research instruments is dependant on the unique contexts of the study, are asked to submit draft copies of the research instruments (surveys, interview protocols, probe questions etc.) for initial review and approval. Any substantive changes to the interview or probing questions must be reported to the IRB as a protocol modification so that assessment of risk associated with participation may be evaluated.

4.13.3 Deception or Incomplete Disclosure

Deception involves not fully informing subjects of the real purpose of the study or providing false information about the study to subjects. This may be appropriate and justifiable in some circumstances, particularly in social and behavioral research, but is also questionable from an ethical standpoint since informed consent is compromised. If the protocol involves deception, the IRB will review a complete description of how deception will be used. The IRB will need justification for the inclusion of deception and possible alternatives to the use of deception. In studies involving deception, the protocol should include procedures to debrief subjects following participation. The debriefing statement should be presented both orally and in writing and include a description of the deception involved and an explanation about the true purpose of the research. In addition, this statement should inform subjects of their right to withdraw their data from the study, if they feel upset or uncomfortable with the deception involved, and still receive any
incentives offered to participants. Studies involving deception are reviewed by the full committee and not eligible for exempt or expedited classification.

4.13.4 Study Location

The IRB will determine the appropriateness of the location and the setting where subjects will participate in this research. The protocol 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. Performance Sites: If the research is supported by federal funds and persons not affiliated with SDSU will conduct the study, it is necessary for the investigator to document that the facility has an assurance with OHRP and that a local IRB has reviewed the study for conduct at the performance site.

4.14 Potential Benefits

The IRB uses information about anticipated benefits expected to result from the study in conjunction with potential risks associated with participation to determine whether or not the study should occur. Anticipated benefits may be to the subject, the population from which the subject was drawn, scientific knowledge or society. Therefore, the investigator must provide the IRB with a clear description of the anticipated benefits that will be derived from this study.

4.15 Risks

Research subjects may be exposed to risks as a result of participation in a study. When recruiting participants for research, information about the types of risks associated with study participation must be presented to each prospective subject. The protocol and the consent form must include a description of any foreseeable risks or discomforts to the subjects (45 CFR 46.116 (2)). An investigator should not state that there are no risks associated with his/her study. An investigator must provide a description of any risks or discomforts the subjects might encounter as a result of participation, as well as a description of provisions he/she has made to address these risks or discomforts. The Office Human Research Protections (OHRP) has provided the following descriptions of types of risks that may be associated with research participation.

- Physical harm is often associated with research involving medical procedures; however, it can also be related to research testing aspects of physical fitness or public health concerns. Minor pain and discomfort, as well as drug side effects or injury resulting from an invasive procedure should be considered when evaluating exposure to physical harm. The physical risk may be minor and transient; however, some procedures may result in adverse events that may be considered serious and possibly permanent. Psychological harm may occur when subjects are asked to disclose or think about personal feelings and/or behaviors or are involved in an experiment that involves a manipulation of the environment or deception. The subject may experience changes in awareness, thought processes and emotion as a result. Social or Economic harm is associated with research where sensitive information about the subject (e.g., alcohol and other drug abuse, mental illness, illegal activities, etc.) is obtained. A breach in the confidentiality of this information may lead to the individual being labeled in a way that could affect their reputation, insurance eligibility, or employment. In addition to the type of risk to which the participant may be exposed, the IRB will review the probability, duration and severity of the risk involved depending on the nature of the study.

4.15.1 Data Safety Monitoring Board (DSMB)

"Monitoring of the research by the investigator is important because preliminary data may signal the need to change the research design, change the information presented to subjects, or even to terminate the project before the scheduled end date." (OPRR IRB Guidebook, Available: http://hhs.gov/ohrp/irb/irb_chapter3.htm - e5). When applicable, the IRB will review the process used to
monitor data collected to ensure the safety of subjects (e.g., clinical trial studies) (45 CFR 46.111(a)(6)). Note that all Phase III randomized clinical trials supported or performed by the National Cancer Institute (NCI) require monitoring by a DSMB. For more information on DSMBs, please visit the NCI website at: http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm.

4.15.2 Assessment of Risk

The IRB will review information provided by the investigator to evaluate the type, probability, duration and severity of risk that will or may occur during research participation. The IRB will also assess whether the risks and inconveniences associated with the research are reasonable in relation to the anticipated benefits to the subjects and in relation to the knowledge that may reasonably be expected to result from this research. The risks associated with the study must be outweighed by benefits in order for the IRB to approve a study.

4.16 Confidentiality Procedures

To maintain confidentiality of research data, the investigator should protect information obtained from the subject to avoid the unintentional access by others (45 CFR 46.111(a)(7)). A federal Certificate of Confidentiality may be issued to protect sensitive data from being subpoenaed by a court of law. The IRB may determine that documentation of informed consent be waived if this process increases the risk of a breach of confidentiality. Subjects should be provided with information about the procedures used to protect confidentiality.

Guidelines for developing procedures to address confidentiality include:

Limit the personal information recorded to that which is essential to the research;

Store personally identifiable data securely and limit access to the principal investigator and authorized staff;

Code data as early in the research as possible and dispose of the code linking the data to individual subjects when data have been processed;

Do not disclose personally identifiable data to anyone other than the research team without the written consent of the subjects or their legal representative. (Exceptions may be made in case of emergency need for intervention or as required by regulatory agencies).

If the data are considered to be sensitive (e.g., sexual preference or practices, use of alcohol or other drugs, illegal conduct, psychological or mental health records, etc.) and place the subject at legal risk, more elaborate measures to protect confidentiality may need to be implemented. In some cases, it may be appropriate to apply for a federal Certificate of Confidentiality. For more information about the purpose and use of a federal Certificate of Confidentiality, please visit the NIH Office of Extramural Research website: http://grants1.nih.gov/grants/policy/coc/.

4.16.1 Anonymity and Confidentiality

The terms anonymity and confidentiality are often used interchangeably, however these two terms do not share the same meaning. Anonymity means that the identity of the subject is never recorded or associated with the data collected. Maintaining confidentiality involves recording but concealing the subject’s identity or codes linked to the individual’s identity. The IRB will review the procedures used to maintain either anonymous or confidential data. If the subject’s identity will be recorded or a code will be created which is linked to the subject’s identity, the IRB will review the rationale for doing so. If it is necessary to track information over time, the investigator should consider using a coding strategy that is not linked to the subject’s identity.
4.16.2 Reportable Disclosures

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.

4.16.3 Coding Data for Tracking Purposes

In survey research, an investigator may wish to code data to track respondents. This may occur when the investigator wishes to recontact non-respondents or to analyze information about non-respondents to describe the study sample or to link data obtained from the same respondents on different measures. The IRB considers these tactics appropriate as long as during the informed consent process individuals are told how their identity will be recorded and/or that they may be recontacted. If coding will be used, the IRB will review a description of the coding scheme to determine that adequate provisions have been considered regarding maintaining the confidentiality of information collected. If the individual's identity is linked to the code, the IRB will review how this information will be used once data collection is complete.

4.16.4 Image and Voice Recording

If a study involves the use of the audio or video recordings, the IRB will review where the subject’s image or voice will be presented and to whom. The subject should be informed about how images may be used within the consent document. If the investigator would like permission to present the recorded image for purpose other than the specific research for which the subject is consenting, an addendum to the consent is used to obtain this authorization. A sample Videotape Release Form can be found on the Research Affairs website at: http://gra.sdsu.edu/research.forms. Note: studies that will include image or voice recording receive an Expedited or Full Committee review depending on the level of risk.

4.16.5 Record Storage and Access

In an effort to further protect subject privacy, the IRB will review where and for how long research records will be stored and who will have access to the study data (hard copy or electronic files) once data have been collected and filed. Subjects should also be made aware of where and for how long research records should be kept, therefore, this information should also be included in the consent form. The IRB will also review procedures used to dispense of research records, samples/specimens upon completion of the research activity.

4.16.6 Release of Test Results

Data collected for research purposes may also be relevant to the participant’s physician or other professional. In some cases, it may also be appropriate to disclose test results to the participant. This may depend on the investigator’s training in accurately interpreting the results of a test that has been used for research purposes and the implications of imparting this information to the subject (e.g. access to healthcare or mental health counseling services). The protocol should address the collection of data that may also have clinical relevance and describe whether this information will be disclosed to the participant and/or to a clinical professional that is chosen by the participant.

4.16.7 Transportation of Data
If data are collected at an off-site location, the protocol should include procedures to ensure that data will be transported in a manner that minimizes risks associated with the inadvertent loss or theft of data. For example, when transporting study materials by car (samples, completed surveys, etc.), materials should be removed from the car as soon as possible. If data are to be sent to an independent facility such as a laboratory or other research center for data processing, every effort should be made to strip identifiable information from the data to avoid disclosure of private information to others outside of the research team.

4.16.8 Certificate of Confidentiality

If the research includes disclosure of potentially sensitive or illegal information, additional measures to protect the participant's privacy and confidentiality may be needed. A federal Certificate of Confidentiality provides additional protection for the subject in that the data would be protected from subpoena by a court of law. To initiate the process to obtain a Certificate of Confidentiality for this study, contact:

Olga Boikess, National Institute of Mental Health, 6001 Executive Boulevard, Room 8253, MSC 9653, Bethesda, MD 20892-9653, Email: oboikess@mail.nih.gov. Upon receipt of the Certificate, forward a copy to the IRB. Visit the NIH Office of Extramural Research website at http://grants1.nih.gov/grants/policy/coc/ for more information.

4.17 Costs

“Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective subjects during the consent process.” (OPRR IRB Guidebook, Available: http://hhs.gov/ohrp/irb/irb_chapter3.htm#e5). If the study exceeds minimal risk, the consent form and the protocol should state how costs pertaining to any injury incurred due to study participation will be covered and by whom. A study that exceeds minimal risk means that the probability or magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102).

4.18 Compensation and Incentives

To assist in subject recruitment, an incentive may be offered. The IRB considers the appropriateness of study compensation/incentives when reviewing protocols. 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. The purpose of the incentive is to encourage participation. By awarding the incentive only when a task is completed, it may create an undue influence that does not allow for the participant to discontinue if uncomfortable. The amount and type of incentive should not coerce or unduly influence the prospective subject into participating. Receipt of the incentive should not be contingent on study completion. Potential participants should understand what incentives will be offered before agreeing to participate in the study. The terms of the incentive should be described during the consent process and within the consent form. Incentives may also be described on recruitment materials, but should not be sensationalized or exaggerated.

4.18.1 Prorating

The IRB encourages the use of a prorated incentive payment system when appropriate. This allows for 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.
4.18.2 Coercion/Undue Influence

Voluntary participation is achieved when the possibility of coercion or undue influence is minimized. An incentive payment or compensation for participation may compromise a persons ability to volunteer. The IRB reviews the type and amount of incentive offered to determine if it is appropriate given the potential for risk or significant discomfort that research participants may experience. There are other situations that also present the potential for coercion or undue influence that the IRB will evaluate to enhance the likelihood that the person is able to volunteer and not feel pressured to participate in the research. The recruitment and consent process are also reviewed to ensure that participants are freely volunteering to participate in the study.

4.18.3 Lottery

A lottery incentive involves conducting a random drawing in which one or more individuals receive an incentive. If a lottery incentive will be used, the consent form will include an estimated timeline for when the information about the drawing will occur, how the person will be notified, how many prizes will be offered and the chances for winning one of the prizes (e.g., You have a one in five chance of winning a prize in the drawing.). This will allow the participant to understand their chances of receiving an incentive for participation.

4.18.4 Amount

The IRB will consider the value of the incentive in order to determine its appropriateness and to minimize the potential for coercion.

4.18.5 Payment Type

If an incentive is offered to research subjects, the IRB will determine whether the amount and form of payment are appropriate. Monetary incentives are typically in the form of cash, check/money order, gift card or redeemable coupon. Non-monetary incentives may also be offered.

4.18.6 Verification of Incentive Receipt

Payment verification is generally required for monetary incentives. To protect the privacy of research participants, investigators must not disclose personally identifiable data to anyone outside the research team without the written consent of the subjects or their legal representative. This information includes subject name, social security number, or other identifying information. For record keeping purposes, the research team will need to document funds were used to pay incentives to research participants. If the incentives total $600.00 or more in a calendar year, the name and social security number and total amount paid in the year will be needed for tax purposes. For lesser amounts, codes may be used in place of identifying information to certify how cash advances were distributed. This list of code numbers and corresponding payments may be sent to the SDSU Research Foundation for verification of incentive payment.

4.19 Investigator Experience
The IRB considers the investigator's experience in the area of research to be undertaken to ensure that the research will be carried out appropriately. The IRB will review a brief summary of the investigator's relevant research experience/training. If the investigator is a student, the IRB will also review the qualifications and experience of the faculty member responsible for the research. In addition, a student may include in his/her research experience any classes that addresses human subjects issues, such as research methods. As all student initiated research involving human subjects, whether dissertation, thesis or other research projects, must be supervised by an authorized faculty member, the IRB requires that all students submit a Faculty Sponsor Assurance Form with his/her protocol submission. This form can be accessed at: http://gra.sdsu.edu/research.important forms. Both faculty and student investigators must complete the SDSU human subjects training tutorial available online: http://www-rohan.sdsu.edu/~gra/login.php.

4.20 Conflict of Interest

The IRB considers the investigator's financial interests and potential for conflict of interest when evaluating the protection of human subjects. If a financial interest is reported that may be associated with the research, the IRB will assess the investigator's objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. The SDSU Conflict of Interest committee may also review disclosures where a financial interest is reported. The IRB will review 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 upload the Financial Interest Disclosure form to the IRB application.

4.20.1 Identification and Management of Potential Conflict

If a financial interest is reported that can be managed, the Conflict of Interest Committee will determine a management plan appropriate for the study.

4.20.2 Disclosure within Consent Form

If the investigator has disclosed a financial interest in the research, the consent form may include a description of the financial interest as well as how the interest has been managed to avoid the possibility of a conflict in the conduct of the research.

4.21 Special Considerations

Investigators that include certain procedures in the research, for example exercise testing, genetic testing, testing of non-FDA approved substances, studies conducted over the Internet and studies involving women of child-bearing potential, are asked to provide additional information in the IRB protocol. The following paragraphs (4.21.1.1 through 4.21.1.8) include procedures or special considerations specific to conducting exercise testing at San Diego State University.

4.21.1 Exercise Testing

Tests routinely conducted in exercise research protocols are 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\textsubscript{2max}), endurance test protocols, hydrostatic weighing, venipuncture, bone mineral density (DXA scan), lactate threshold, or exercise in the heat must incorporate the appropriate exercise testing protocol within their research protocol reviewed by the IRB.
The exercise protocols are included below in sections 4.21.1.1 to 4.21.1.7. The investigator is required to verify compliance with the IRB approved exercise protocol that is planned for use in a research study upon submission of the IRB application.

The exercise protocols also provide text to include within the informed consent document about the test procedures, associated risks and risk management strategies. This content may be edited if several tests are planned for use that, for example, have similar risks and/or risk management procedures.

4.21.1.1 Exercise Protocol: Maximal Aerobic Power (VO$_{2\text{max}}$)

Appropriate Applications
The testing of maximal aerobic power through direct measurement of maximal oxygen consumption (VO$_{2\text{max}}$) is considered the best measure of cardiovascular fitness. VO$_{2\text{max}}$ has been assessed in a wide range of subjects, from children to the elderly, both fit and unfit, including cardiac patients. It is often used in studies to determine the effects of exercise training on fitness, both from short-term training, e.g., several weeks to longitudinal studies of a year or longer.

For older subjects (i.e., men $\geq 45$ years; women $\geq 55$ years), a standard three-channel ECG will be used where adequate monitoring and recording of the heart activity can be attained.* The use of ECG with other individuals will be restricted to studies that require quantification and qualification of heart rate, including any abnormal beats. For the majority of testing conditions requiring an ECG, a single lead will be used for monitoring and recording the ECG.

*Exception: ECG monitoring is not necessary for male and female endurance athletes up to age 59 years who are currently (within at least the past 12 months) training at maximal or near-maximal intensity, and who have no major cardiovascular risk factors.

Risk Stratification [ACSM Guidelines for Exercise Testing & Exercise Prescription, 2006, pg 27]

**Low risk**
1. Men $<$45, women $< 55$ years of age who are asymptomatic (as screened by the PAR-Q) and who self-report no more than one of the following risk factors for cardiovascular disease (CVD): current cigarette smoker; hypertension (SBP $>$140 mm Hg or DBP $>$90 mm Hg); obesity (BMI $>$30); sedentary; diabetes (Type 1 or 2); hypercholesterolemia; family history of CVD (cardiac death or event before age 55 years in father or other male first-degree relative, or before age 65 years in mother or other female first-degree relative. In addition, to be considered low risk, individuals must not be taking any medications prescribed to lower blood pressure or reduce serum cholesterol.

2. Endurance athletes $<$60 years of age (male and female). Must be currently (and for a minimum of the past 12 months) training and competing in endurance events, e.g., running, cycling, swimming, etc., including maximal or near-maximal bouts of exercise, AND have no known risk factors listed in #1 above (other than age).

**Moderate risk**
Men $\geq 45$ and women $\geq 55$ years of age (except athletes listed in #2 above), or any individual who has two or more risk factors mentioned above.

**High risk**
1. Individuals with known cardiovascular or pulmonary disease, or one or more signs/symptoms as screened with the PAR-Q.

**Exception:**
Persons with asymptomatic coronary heart disease with good exercise capacity (greater than or equal to 8 METS), good left ventricular ejection fraction (greater than 50%, and no evidence of ischemia may be considered at moderate risk, according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR) guidelines. Persons with a previous diagnosis, signs or symptoms of cardiac disease will be required to see their cardiologist yearly and receive a letter of clearance, and return a completed and signed copy of Form A, which is a document produced by the AACPR (see attached).
Form A asks the participant's cardiologist to determine the participant's risk according to the AACPR. If an individual meets the above criteria AND has written consent of their cardiologist, he/she may be categorized as **moderate**, rather than **high risk**.

Physician supervision of maximal exercise tests is based on risk categories.

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>Physician supervision not necessary</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>Physician supervision required</td>
</tr>
<tr>
<td>High Risk</td>
<td>Individuals not tested at SDSU; referred back to their physician for possible follow-up treatment</td>
</tr>
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**Test Description**

**VO$_{2\text{max}}$ assessments** are conducted in the Kasch Exercise Physiology Laboratory (ENS 255), ENS Annex Exercise Physiology Laboratory (ENS 102) at SDSU and in the Fitness Lab at 9245 Sky Park Court.

Each subject will be screened for cardiovascular disease using the Physical Activity Readiness Questionnaire (PAR-Q). Any individual who answers “yes” to any of the PAR-Q questions will be excluded from the test. Subjects who meet specific study criteria and who do not report cardiovascular disease or its symptomology will undergo a maximal graded exercise test on a selected ergometer (treadmill, cycle, rowing machine, hand-crank cycle). Guidelines of the American College of Sports Medicine (ACSM) are adhered to regarding physician supervision of tests (see above).

To determine VO$_{2\text{max}}$, subjects undergo a maximal graded exercise test to voluntary exhaustion. This means that the subject makes the decision when the test is over. On a cycle ergometer, the test is terminated when the subject can no longer turn the cranks at the desired frequency; on the treadmill, the test is terminated when the subject can no longer run at the treadmill speed and stands straddling the treadmill belt while holding on the railing. In addition, the subject is spotted at his/her side to prevent a possible fall. When testing an athlete, in particular, he/she is coached to proceed as long as possible. Untrained individuals, older subjects, and children are encouraged to “give a hard effort,” but not coached to continue to their absolute physical limits. Following a test, the subject goes through a cool-down at a self-selected intensity until recovered.

Test protocols vary somewhat in terms of duration of each stage (1-3 minutes) and increments in intensity, but all begin with a 5-10 minute warm-up followed by a gradual increase in work effort until volitional exhaustion. Typically, a graded exercise test takes 8-12 minutes, excluding warm-up and cool-down. Throughout the test, the subject breathes through a rubber mouthpiece on a two-way re-breathing valve that is connected by low-resistance tubing to a metabolic measurement system. A computer permits analysis of the expired air for oxygen consumption and carbon dioxide production. Heart rates are monitored continuously, usually with a heart rate monitor that obtains a signal from a transmitter strapped around the chest. Older, inactive subjects are also monitored for heart arrhythmias and/or ischemic changes using a standard 3-lead ECG. Blood pressure is also monitored and recorded at each stage with older subjects. Only technicians trained in exercise ECG and blood pressure monitoring are permitted to test older and/or higher-risk subjects.

ECG assessment requires the placement of at least three electrodes, and possibly six, on the skin surface of the subject’s chest. Each electrode surface site is prepared to ensure that the electrode remains on the skin during exercise. The preparation process requires that the technician rub the electrode site with gauze until slightly red and to cleanse the area with alcohol prior to placing individual electrode pads. This process must be performed to remove natural body oil and dead skin that can interfere with the electrical signal and ECG assessment.

As follows ACSM guidelines, general indications that will be used for stopping an exercise test include:

- Onset of angina or angina-like symptoms;
• Significant drop (>20 mm Hg) in systolic blood pressure or a failure of the systolic blood pressure to rise with an increase in exercise intensity;

• Excessive rise in blood pressure: systolic pressure >260 mm Hg or diastolic pressure > 115 mm Hg;

• Signs of poor perfusion: lightheadedness, confusion, ataxia, pallor, cyanosis, nausea, or cold and clammy skin;

• Failure of heart rate to increase with increased exercise intensity;

• Noticeable change in heart rhythm;

• Subject request to stop;

• Physical or verbal manifestations of severe fatigue;

• Failure of the testing equipment.

Training/Supervision Required
Technicians or investigators need to be knowledgeable and trained in two specific areas: 1) administration of graded exercise tests, including ability to conduct pre-test health screenings, and knowledge and recognition of signs and symptoms of cardiovascular disease; and, 2) procedures for conducting metabolic measures. These procedures require academic preparation in exercise science. Graduate students in the SDSU M.S. program in Exercise Physiology take coursework and have lab experiences to prepare them for these assessments. In addition, before they are allowed to collect data they must demonstrate to their faculty supervisor that they are competent in all these procedures.

All staff will be properly trained in application of electrodes and their respective monitoring and recording. Proper skin preparation is essential for good ECG tracings and staff will be trained. Once trained, minimal supervision will be necessary.

Risks
Maximal exercise testing may produce light-headedness, fatigue, nausea, and delayed-onset muscle soreness. These side effects are usually minimal in fit subjects. They are also minimized by having a gradual warm-up as well as cool-down (at least 5 minutes each) and by having the subject refrain from eating for at least 2-3 hours before their test. For treadmill testing, there is also a small risk of falling. This risk is managed by having at least one spotter at the subject’s side.

There is also a risk of a cardiac event, such as a heart attack, cardiac arrest, or dangerous arrhythmia. This risk is less than 1 occurrence in 12,000 tests of healthy subjects, and approximately 1-2 occurrences in 10,000 tests of higher risk and diseased subjects (ACSM Guidelines for Exercise Testing and Prescription, 2006).

There are minimal risks associated with an ECG. The most common is the debriding of the skin in preparation of ECG recording. In order to get a good ECG tracing, the skin must be properly prepared which will cause some reddening of the area where the electrodes are placed on the chest surface.

Risk Management
All test personnel are required to have current CPR certification and to be trained in emergency procedures for the particular lab. An AED (automated emergency defibrillator) is located within 10 ft of the test participant. A telephone is located within 50 feet of the ergometers. Individuals with probable CVD, as screened with the PAR-Q, are not tested at SDSU or at the Sky Park lab. Subjects are warmed up and cooled down gradually, which has been shown to decrease the incidence of cardiac arrhythmias.
during and after stress testing. In instances when ECG is monitored, only the necessary amount of skin preparation will be debrided, which minimizes perceived subject discomfort.

The mouthpiece and valves fall into the semi-critical device category. This device will come into contact with mucus membranes, but will not penetrate body surface. High-level disinfection using liquid glutaraldehyde disinfectants (e.g. Cidex) is acceptable according CDC recommendations. We use EPA-registered sterilants for this purpose in our laboratories.

Older is defined as men over 45 years and women over 55 years of age according to guidelines of the ACSM. Partial CVD risk is determined by the PAR-Q, i.e., subjects are asked about symptomology and whether they are hypertensive. Thus, a subject is screened out of studies if he/she reports symptoms indicative of CVD. However, if a subject reports high blood pressure, depending on the particular study, he/she would not necessarily be excluded from participating. The investigator will take BP of anyone self-reporting hypertension; if BP is >140/90, he/she will be excluded from studies involving high intensity or maximal exercise unless the study is specifically recruiting this population in which case a physician will monitor the exercise test.

ECG monitoring is normally conducted only in studies of older men (>45 yr) and women (>55) with diabetes or hypertension, who, in addition to their age, are at higher than average risk for cardiovascular complications during a maximal exercise test. The attending physician will be responsible for interpreting the ECG. Typically, the physician is accompanied by research assistants or faculty trained to recognize arrhythmias and possible ischemic responses. ECG monitoring is not necessary in studies of low risk individuals.

Exercise ECG will be used to determine possible ischemic responses to exercise, as well as dysrhythmias. Since, under most circumstances, a physician is supervising a maximal test in which ECG is being monitored, the physician will communicate test results to the subject. If an investigator is monitoring ECG without the presence of a physician, a suspected abnormal response will be criteria to terminate a test prematurely (see criteria for test termination on pg 106 of ACSM Guidelines, 2006). If this occurs, the subject will be told that the test was stopped “because your ECG response was not completely normal. I will make a copy of this test for you and I recommend that you show it to your physician. Since I am not a physician, I cannot answer specific questions about your test, therefore, it is best if you call your doctor to discuss this with him/her.”

All female subjects will be asked whether they are more than 3 months pregnant; if so, they will be excluded from maximal exercise testing.

Potential Benefits
Subjects receive a summary of their results. Measuring VO$_{2\text{max}}$ is a frequent request by athletes and coaches for they believe it will aid in planning and monitoring the athletes' training. Labs that conduct such testing often charge $150-300. In instances where an ECG is measured, it will provide the staff a better means of assessing the qualitative (rhythm) and quantitative (rate) heart function during and after exercise.

Consent Form Content (Description of the Study section)
Prior to undergoing a maximal exercise test, we will conduct a brief health screening to determine whether testing would put you at increased risk for an abnormal cardiac event such as a dangerous rhythm disturbance or a heart attack. If you are not at increased risk, you will be asked to report to the lab well rested; we recommend that you do no high-intensity exercise for 48 hours before your scheduled test. Also, please do not eat at least 2-3 hours before your test, but continue to drink water during this time.

For the VO$_{2\text{max}}$ test, you will be fitted with a mouthpiece and nose-clip, so that all of your expired air can be collected and analyzed for the amount of oxygen you consume and carbon dioxide you produce. You will be able to breathe normally through your mouth, but not through your nose. After a 5-10 minute
warm-up, we will increase the work effort every 2-3 minutes until you no longer feel you can continue. Because you will not be able to talk through the mouthpiece, you will communicate with us using hand signals. Every 2-3 minutes during the test, we will ask you to rate your perceived exertion, on a scale of 1-10. This helps us determine when you are getting close to your maximal effort. Note: This last sentence can be deleted for athletes or physically conditioned subjects, as it becomes obvious when they are approaching maximum effort; also, having them attempt to rate their exertion distracts them from focusing on giving a true maximal effort.

(If ECG is to be monitored)
You will have specific sites on the surface of your chest prepared for electrode placement. During the preparation process, the technician will rub several sites with a gauze pad and then cleanse the area with alcohol prior to placing individual electrode pads on the area. This preparation process may be slightly uncomfortable. You will keep these electrodes on your skin until the end of the exercise, or until the technician indicates to you to remove them.

Consent Form Content (Risks and Discomforts section)
You are being asked to perform high-intensity maximal exercise that may lead to physical discomforts (e.g., fatigue and nausea). These risks associate with participating in this study may include muscle cramps, muscle strain and/or joint injury, delayed muscle soreness, lightheadedness, and fatigue. You may feel delayed muscle soreness (24-48 hours) after exercise. There is a risk of a cardiovascular event (approximately 1 in 12,000 people) such as a heart attack or rhythm disturbance, since the exercise will be very high intensity. To manage possible risks, there will be at least one CPR-certified investigator present at the testing, as well as a telephone available should an emergency arise. If at any time during the test you want to stop, you can signal as instructed and we will stop the test. You will feel very tired at the end of the test, but should recover within a few minutes.

Compensation for Injury section (If injury is not covered by the study)
If any complications arise, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization because of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. San Diego State University will not pay for any care, lost wages, or provide other financial compensation [include San Diego State University Research Foundation if this research is funded]. However, if you feel you have a claim that you wish to file against the State [or the Research Foundation], please contact Graduate and Research Affairs - Division of Research Administration at (619) 594-6622 to obtain the appropriate claim forms.

Compensation for Injury section (If injury is covered by the study)
If you need any treatment or hospitalization as a result of being in this study, all reasonable and customary medical expenses above what your insurance will cover will be paid by __________________ as long as: you have followed all of the directions of the study investigator, you have notified the investigator immediately of the injury, you have followed medical advice regarding the injury, and you have not deliberately caused the injury.

4.21.1.2 Exercise Protocol: Endurance Tests

Appropriate Applications
Endurance tests may be used to study cardiorespiratory and/or metabolic effects at various intensities of effort. They can also be used to collect data in thermoregulatory and altitude studies and in other studies examining the effects of endurance exercise on blood concentrations of hormones, electrolytes, etc. The exercise intensity used in a protocol is usually determined as a percent of one’s VO\textsubscript{2max}; if so, VO\textsubscript{2max} must be determined before the endurance test can be performed. These two procedures, under almost all circumstances, are not conducted on the same day. According to ACSM guidelines, three categories of intensity are suggested: 1) light/low (<50% VO\textsubscript{2max}); 2) moderate (60-75% VO\textsubscript{2max}); and 3) heavy/high.
(≥80% VO_{2max}). However, individual investigators may propose variations of these guidelines in their own protocols.

Test Description
After selection of the desired intensity, the subject warms up for 5-10 minutes, after which the ergometer is set to the selected intensity. For example, if the investigator selects 70% of VO_{2max} as the intensity for a treadmill study, the speed and grade are adjusted until the subject reaches 70% of his/her VO_{2max}. A variation that is frequently used for cycle ergometry testing is to conduct the endurance test at a given percent of each subject’s peak or maximum power output. For a test, the subject is asked to continue exercising either for a pre-determined time or until volitional exhaustion. Typically, heart rate is also monitored throughout the test using a heart rate monitor that takes its signal from a transmitter strapped around the chest with an elastic band.

Training/Supervision Required
Technicians or investigators need to be knowledgeable and trained in administering exercise tests, including the ability to conduct a pre-test health screening, and knowledge and recognition of possible signs and symptoms of cardiovascular disease. Technicians must also be familiar with the specific ergometer they propose to use in their study. If students are taking metabolic measures, i.e., collecting expired gases and analyzing for O_2 consumption and CO_2 production, they must first demonstrate this competency to the satisfaction of their faculty sponsor. These procedures require academic preparation in exercise science courses. Graduate students in the M.S. program in Exercise Physiology take coursework and have lab experiences to prepare them for these assessments.

Risks
The risk of a cardiac event is lower than it would be for maximal testing, however, the exact risk is not known. Any exercise bout may produce light-headedness, fatigue, possibly nausea, and delayed-onset muscle soreness. These side effects are usually minimal in fit subjects. They are also minimized by having a gradual warm-up as well as cool-down (at least 5 minutes each) and by having the subject refrain from eating for at least 2-3 hours before their test. For treadmill testing, there is also a small risk of falling. This risk is managed by having at least one spotter at the subject’s side.

Risk Management
Lactate threshold assessments are conducted in the Kasch Exercise Physiology Laboratory (ENS 255) and ENS Annex Exercise Physiology Laboratory (ENS 102) at SDSU and in the Fitness Lab at 9245 Sky Park Court. All test personnel are required to have current CPR certification and trained in emergency procedures for the particular lab. A telephone is located within 50 feet of the ergometers. Individuals with probable cardiovascular disease, as screened with the PAR-Q, are not tested at SDSU or at the Sky Park lab.

The mouthpiece and valves fall into the semi-critical device category. This device will come into contact with mucus membranes, but will not penetrate body surface. High-level disinfection using liquid glutaraldehyde disinfectants (e.g. Cidex) is acceptable according CDC recommendations. We use EPA-registered sterilants for this purpose in our laboratory.

Potential Benefits
There may be no direct benefits to subjects. However, depending on the specific protocol, subjects may receive the results of their testing, which could possibly benefit them in their training.

Consent Form Content (Description of the Study section)
Prior to undergoing the exercise protocol, we will conduct a brief health screening to determine whether testing you would put you at risk for an abnormal cardiac event such as a dangerous rhythm disturbance or a heart attack. If you are not at risk, you will be asked to report to the lab well rested; we recommend that you do no high-intensity exercise for 48 hours before your scheduled test. Also, please do not eat at least 2-3 hours before your test, but continue to drink water during this time.
For this endurance test, you will run (walk) on the treadmill (or cycle ergometer) at a workload that is equal to (XX) percent of your VO\textsubscript{2max}. We want you to continue to exercise as long as you can (or for a specified time period).

Consent Form Content (Risks and Risks Management section)
(For needle sticks or venipuncture) Procedures that require blood samples to be collected have the risk of soreness, bruising and/or swelling at the collection site. Prior to each finger stick, the area will be cleaned with an alcohol swab. After the stick, you will be instructed to maintain slight pressure on the area to minimize additional bleeding.

(If high intensity exercise is included) If you are asked to perform high-intensity exercise you may experience physical discomforts that may include muscle cramps, muscle strain and/or joint injury, delayed muscle soreness, lightheadedness, and fatigue. It is likely that you will feel significant delayed muscle soreness (24-48 hours) after. There is also a risk of a cardiovascular event (less than that associated with maximal testing of 1 in 12,000 people) such as a heart attack or rhythm disturbance when participating in high intensity exercise. To manage possible risks, there will be at least one CPR-certified investigator present at the testing, as well as a cellular phone available should an emergency arise.

4.21.1.3 Exercise Protocol: Hydrostatic Weighing

Appropriate Applications
This test is used to determine body density and estimate body composition.

Test Description
This procedure utilizes the difference in densities of the fat and non-fat masses to determine overall body density, which can be used to estimate body fat percent. Briefly, the subject is placed in a water tank and weighed after maximally exhaling. Differences in the dry and underwater weights are used to calculate body density. However, an allowance must be made for residual lung volume—the air that remains in the lungs after a maximal exhalation—as this air increases a subject's buoyancy. Residual lung volume can be either measured or estimated. In our laboratory, residual lung volume is usually indirectly measured using an oxygen-dilution technique (Wilmore et al., 1980). A 5-L Douglas re-breathing bag fitted with a two-way breathing valve is flushed and filled with 100% oxygen. While in a seated position and fitted with the mouthpiece on the Douglas bag and a nose clip, the subject takes several normal breaths of ambient air. Afterwards, the subject performs a maximal inhalation followed by a maximal exhalation and briefly holds his/her breath at the end of the exhalation. At this point, the mouthpiece valve is turned so that the subject begins rebreathing from the 100% oxygen. The subject takes 6-8 deep breaths after which the valve is closed and the subject removed from the Douglas bag. At least two, but sometimes three trials are performed with several minutes between trials.

The most accurate estimate of body composition by hydrostatic weighing requires residual lung volume to be measured. There are, however, situations because of expediency or lack of equipment in which residual lung volume is estimated. One way to estimate residual lung volume is from published tables that are based on age and weight. Another method is to estimate residual volume from the measured vital capacity. In this procedure, a seated subject, while fitted with a nose clip and connected to a spirometer, performs a maximal inhalation followed by a maximal exhalation. Vital capacity is the volume of the maximal exhalation from which residual lung volume is estimated based on gender, as a percentage of the vital capacity.

After having measured or estimated residual lung volume, the subject's dry weight is measured and then, wearing a swimming suit or running shorts, the subject climbs into the underwater weighing tank and sits in a seat that hangs from a force load-cell. The procedure involves the subject performing a maximal exhalation and slowly leaning forward in the chair until the top of his/her head is under water. After the underwater weight stabilizes (5-8 seconds), the subject is instructed, though yelling or pounding on the side of the tank, to return to an upright position. During a weighing, the subject is always free to stand up or return to the upright position. Four to eight trials are usually performed.
The non-skid steps up to the top of the tank where the subject enters are equipped with a handrail, and after climbing the steps, the subject climbs down a ladder into the water. Depth of the water is approximately 54 inches, which is maintained between 30 and 34 °C. While seated, the subject faces a clear plexiglas side to minimize feelings of claustrophobia. After each testing session, the water is drained and the tank allowed to dry.

Training/Supervision Needed
All test personnel are required to have current CPR certification and are trained in emergency procedures for the particular lab. A telephone is located within 30 feet of the underwater weighing tank.

Risks
Other than risks of falling while getting into or out of the underwater weighing tank, there are no physical risks associated with this protocol. Subjects not comfortable in water or in putting their head underwater may experience slight anxiety during the underwater weighing.

Risk Management
Subjects are encouraged to be careful while getting into or out of the underwater weighing tank. For individuals who experience anxiety during the underwater weighing, the test administrator will go more slowly with the subject and encourage him/her to stand up in the water should the anxiety become too strong.

The mouthpiece and valves used for the measure of residual volume fall into the semi-critical device category. This device will come into contact with mucus membranes, but will not penetrate body surface. High-level disinfection using liquid glutaraldehyde disinfectants (e.g. Cidex) is acceptable according CDC recommendations. We use EPA-registered sterilants for this purpose in our laboratory.

Potential Benefits
The subject obtains his/her body composition, which is an important component of overall personal fitness.

Consent Content  (Description of the Study section)
There are two parts to this procedure. First, we will measure your residual volume, which is the amount of air that remains in your lungs after performing a maximal exhalation. Afterwards, we will weigh you underwater. Together, this information will be used to estimate your body fat percentage.

To measure your residual volume, you will perform 2-3 trials of breathing in and out of bag containing 100% oxygen. In a seated position and wearing a nose clip, you'll be connected to a breathing mouthpiece connected to the bag of oxygen. First, you will take several normal breaths from the outside air and then perform a maximal exhalation. At that time, a valve will be turned which will direct your breathing from the bag of oxygen. You'll take 6-8 deep breaths after which you'll be removed from the valve. After a couple of minutes, you will repeat this 1-2 times.

After you change into your bathing suit, you will climb into the underwater weighing tank. Briefly, you will sit quietly on the hanging seat in the tank, and when instructed, perform a maximal exhalation and then slowly lean forward just to the point that your head is completely underwater. You will remain motionless for 5-8 seconds until instructed by the technician to come back to the surface. It is very important that you blow all of the air out of your lungs and remain as motionless as possible while underwater. Should you develop any overpowering anxiety, you can always stand up before being instructed, as the depth of the water is only about 4½ feet. We will do at least four, but as many as eight, underwater weighings in all. Afterwards, you will climb out of the tank, dry off and change back into your street clothes.

4.21.1.4 Exercise Protocol: Venipuncture

Appropriate Applications
In various exercise studies, researchers may want to assess blood enzymes, blood lipids, hemoglobin, hormones, and serum parameters including glucose, electrolytes, or blood proteins that may be altered with physical exertion. The venipuncture may be taken prior to, during (with the subject stopped) and after exercise. For some studies that examine the graded effects of exercise on certain blood parameters, up to four blood samples may be taken via venipuncture (from different sites).

Test Description
Venipuncture (also known as phlebotomy) refers to a procedure in which venous blood is drawn into a small tube via needle insertion and aspiration. Steps taken by the phlebotomist to perform this procedure are to: wear safety (e.g. latex) gloves for reducing the likelihood of infection; position the subject in a seated position (unless blood is being taken from a subject standing on a treadmill stopped in the middle of an exercise protocol); clean the area (usually the antecubital fossa area) with alcohol and allow to air-dry; place an elastic band (tourniquet) around the upper arm to distend the veins; isolate the vein and insert the needle with a Vacutainer tube for aspiration. Upon removal of the needle, sterile gauze will be placed over the insertion site secured by tape. The subject will be encouraged to apply pressure to the site for several minutes to minimize bruising. The needle will be discarded into a hazardous waste (Sharps) container, which will be properly disposed.

Training/Supervision Needed
Only staff who are California-certified phlebotomists are allowed to perform blood draws. All certified phlebotomists will have had adequate experience to perform the blood draw without supervisory assistance; hence, no supervision will be necessary to perform a venipuncture.

Risks
Under normal conditions, there are minimal risks to the subject when performing venipuncture. These risks include: bruising; perforation of the vein leading to hematoma under skin; light-headedness or dizziness due to fear of needles; and infection.

Risk Management
Whenever blood is drawn, there is a small risk of bruising. Through this procedure, the risk for perforation of the vein is minimized. To minimize the risk of light-headedness or dizziness, each subject will have blood drawn in a seated position. Although infection is a risk with venipuncture, this is minimized by use of alcohol to cleanse the area prior to the blood draw, as well as the use of safety (latex) gloves by the phlebotomist, in accordance with the bloodborne pathogens standard of OSHA. In the case of individuals with a latex allergy, the laboratories have non-latex gloves available for use.

Potential Benefits
From the blood analyses, we will be able to better understand the acute and/or chronic effects of exercise on hematological, enzymatic, and hormonal changes. This information will aid in our understanding of exercise programs that can favorably modify, or yield deleterious effects to specific blood parameters.

Consent Content (Description of the Study section)
You will be asked to submit to a (or multiple) venous blood draw(s). All blood draws will be performed by certified technicians and follow established standard procedures. Usually, the amount of a single blood draw is about 5-7 ml or ~1 tablespoon.

Consent Content (Risks and Discomforts section)
The risk in blood sampling is minimal, although there is the risk of soreness, bruising, and/or swelling at the collection site. Risks will be minimized by employing a trained and certified technician who will follow standard procedures for safely drawing blood.

4.21.1.5 Exercise Protocol: Bone Mineral Density (DXA Scan)

Applications
Dual-energy x-ray absorptiometry (DXA) measurements are used to measure bone mineral density (BMD) and body composition. The National Osteoporosis Foundation recommends bone density scans for the following persons:

- All postmenopausal women under age 65 who have one or more additional risk factors for osteoporotic fracture (besides menopause);
- All women aged 65 years and older regardless of additional risk factors;
- Postmenopausal women who present with fractures (to confirm diagnosis and determine disease severity);
- Women who are considering therapy for osteoporosis, if BMD testing would facilitate the decision; and
- Women who have been on hormone replacement therapy for prolonged periods.

Additional populations that may be studied are athletes and children, as well as men. In addition, studies of body composition use the DXA technique as the new “gold standard” for determining lean tissue and fat mass.

Exclusion/Inclusion Criteria. Criteria specific to each new protocol will be provided by the investigator. The only general exclusion criterion is that pregnant women will not be scanned.

Test Description
Bone mineral density (BMD) will be assessed by dual-energy x-ray absorptiometry (DXA) using a Lunar DPX-NT densitometer (Lunar/GE Corp). All scans will be conducted in the fitness lab at the Center for Behavioral Epidemiology (C-BEACH), 9245 Sky Park Court, San Diego, CA. The scan sites most often assessed include the spine (L1-L4), hip, and total body. The DXA total body scans will be used to determine both total body BMD as well as body composition and regional fat distribution. The average scan time for each of these is approximately 3, 4, and 10 minutes for the spine, hip, and total body, respectively. The total time required for subject positioning and scanning is approximately 5, 8, and 12 minutes for the spine, hip, and total body, respectively. A typical appointment, therefore, requires approximately 30 minutes per subject for all 3 scans, or approximately 20 minutes for spine and hip only.

Quality assurance (QA) tests will be performed each morning of use. QA will be conducted using a standard with tissue-equivalent material with three bone-simulating chambers of known bone mineral content. In vivo BMD precision is 0.6-1.2% for the spine, 0.6-1.7% for the femoral neck, 0.6-0.8% for total-body mineral, and less than 1.5% for total body soft tissue mass (Mazess, Br J Radiology 70:109-110, 1997).

Subjects are instructed, prior to the day of their scan, to dress with clothing free of any metal and not to wear jewelry. Women are encouraged to wear a halter-top or something similar. If subjects arrive with any metal on their clothing, they are asked to change into shorts and t-shirt. A supply of these are kept in the fitness lab and laundered as needed. The subject is shown the DXA machine and told that the scan arm will move above them while he/she lies on the table. They are instructed to lie still and not to talk while the machine is scanning. The following is a description of how the subject is positioned for each of the three scans:

Spine. The subject lies supine with his/her hands on their shoulders (to keep the arms away from the lumbar spine). The technician first straightens his/her body by gently pulling from the ankles (this is not done with older subjects or those who, when asked before proceeding, report back pain). The scan arm is then brought to the start position. The technician then asks the subject to bend his/her knees while a box is placed beneath the lower legs. This is done to ensure that the spine is positioned correctly and kept in contact with the table. The technician then locates the anatomical site for starting the scan, which is
vertically aligned with the navel and 3-5 cm below it. Prior to touching the subject, the technician tells him/her to point to their navel. This is done to minimize the amount of palpation required by the technician. The subject is then asked to remain still while the machine scans.

Hip. The subject lies supine with his/her arms crossed over their chest. The feet are strapped to a plastic device such that the hip joints are medially rotated. The technician then locates the anatomical site for starting the scan, which is vertically aligned with the mid-thigh and approximately 7 inches below the anterior, superior iliac crest. The subject is then asked to remain still while the machine scans.

Total Body. The subject lies supine with his/her arms by their sides. Velcro straps are secured around the knees and ankles to hold the legs together. The subject is then asked to remain still while the machine scans.

Females who are minors will be accompanied by a parent or another adult when scanned by a male technician. The parent will sit just outside the door to the DXA room, but within clear view of the subject. California law does not permit anyone other than the technician and patient in the room during scanning.

Training/Supervision Needed
All scans will be conducted by experienced technicians certified by the state of California. California law requires all DXA facilities to be supervised by an M.D. Greg Gastaldo, M.D. and Medical Director of the Center for Optimal Health & Performance, will serve as the C-BEACH medical advisor and licentiate. He has ultimate responsibility for insuring safe and effective procedures regarding bone densitometry testing. He is available to assist investigators in interpreting scans, should this be requested. He is not required to be present during the scanning procedures. Technicians certified by the state of California will conduct all preliminary analyses of scans, unless the Principal Investigator of a particular project indicates that he/she wants to receive unanalyzed data. Some studies may have a designated reader at another site, but for analyses done at C-BEACH, any abnormal or questionable scans will be reviewed by both Dr. Gastaldo and the technician, with Dr. Gastaldo making the final interpretation.

Risks
Skin entrance dose of radiation is approximately 20 µSv for a spine and hip scan, and 0.2 µSv for total body. In practical terms, this is equivalent to the amount of radiation to which one is exposed during a cross-country airplane flight. Since the long-term effects of exposure to a fetus are not known, pregnant women will not be scanned. There are no other known risks associated with this procedure.

Risk Management
Only experienced and certified technicians are permitted to conduct scans. Given the extremely low dose of radiation, the benefits far outweigh the risks for any population tested. Young adults will have a baseline report for future comparison. Menopausal women and older adults will have objective data regarding their risk for osteoporosis, thus allowing them to discuss with their physicians possible preventive treatment. Since most insurance policies do not cover routine osteoporosis screening for persons younger than 65 years of age, participation in a research project in which BMD is assessed provides the participant with information that would otherwise cost between $150-300. For studies involving female subjects, the investigator will include relevant screening questions (see below) as part of the consent content.

Screening for Pregnancy. To insure that a pregnant woman is not scanned, a female will be scheduled for testing within 14 days of her last period. By including the following question in the screening process, relevant information can be obtained and used for scheduling without asking intrusive questions such as whether the subject is using birth control or whether she is sexually active.

Are you having menstrual cycles? Yes No
If yes, what is the date of the first day of your last period? __________
If you are in menopause, when did your periods stop completely? __________
Are you pregnant, or could you possibly be pregnant? Yes No
The use of a pregnancy test is also an option for screening purposes.

Adult women (18 years and older) will be asked only the following question: “Are you pregnant or could you possibly be pregnant?” A negative answer will suffice for proceeding with the scan. If the participant is unsure, or if requested, a pregnancy test will be conducted. For studies of postmenopausal women, the technician will ask the participant to confirm that she is in menopause.

Potential Benefits
The primary benefit is for women, particularly postmenopausal women, to assess and monitor bone mineral density and their risk of osteoporosis. However, testing may also benefit males who are at risk. Moreover, testing can detect the presence of fractures and determine the severity of osteoporosis.

Confidentiality of Data and Room Security
When not in use, the room in which the DXA is located is kept locked. Other than Drs. Hovell and Nichols and the C-BEACH administrative assistant, only persons trained in DXA operation have keys to the room.

Data collected each day are removed from the hard drive and stored on diskettes, which are kept in a locked file in each investigator’s office. Data transferred to a database for statistical analysis are coded; no identifying information will be used in data analysis.

Consent Content (Description of the Study section)
Dual-energy x-ray absorptiometry (DXA) measurements are used to measure bone mineral density (BMD) and body composition. For the DXA measurement, it is necessary to dress with clothing free of any metal and not to wear jewelry. We recommend that female participants wear a halter top or swim suit top, or something similar. If you forget and arrive with any metal on your clothing, we will have spare pairs of sweat pants and several t-shirts that you can wear while being scanned.

The DXA machine consists of a table with a scan arm that moves over your body while you lie on the table. The technician will position you for each scan. You will be asked to lie still and not talk while the machine is scanning. The entire procedure takes 10-20 minutes, depending on which scans are conducted.

Consent Content (Risks and Discomforts section)
The risk of harm from radiation with DXA machines is extremely small. The actual amount of radiation emitted for a total body scan is 0.2 μSv, which, in practical terms, is much less than the amount received during a cross-country airplane trip. However, the long-term effects of exposure to a fetus are not known, therefore, pregnant women are not scanned. For females: To ensure that you are not pregnant, we will ask you to schedule your appointment within two weeks of your last period. If you are unsure or cannot remember your last period, we will conduct a pregnancy test to confirm that you are not pregnant. For this we will have you collect a few drops of urine and we will use an over-the-counter test kit to determine pregnancy status.

Parental consent text if the subject is a minor female child: The assent form explicitly states that if your daughter is pregnant or could possibly be pregnant she cannot participate. To avoid embarrassing your child we have indicated on the assent form that she should simply tell us she does not want to participate, without giving us a reason. If your daughter qualifies for the study, we will ask her to tell us the date of her last menstrual period (if she has begun menstruating). We will then schedule her for her scan and other measurements within 2 weeks of her last period, thus ensuring that she could not possibly be pregnant when she is scanned.

Consent Content (Confidentiality of Data and Room Security section)
When not in use, the room in which the DXA is located is kept locked. Other than Drs. Hovell and Nichols and the C-BEACH administrative assistant, only persons trained in DXA operation have keys to the room.

Data collected each day are removed from the hard drive and stored on diskettes, which are kept in a
locked file in each investigator’s office. Data transferred to a database for statistical analysis are coded; no identifying information will be used in data analysis.

4.21.1.6 Exercise Protocol: Lactate Threshold

Appropriate Applications
There are multiple reasons why the lactate threshold might want to be determined. Identification of the lactate threshold is the best predictor of performance over a range of endurance distances. Furthermore, training causes a shift in the exercise intensity at which the lactate threshold occurs, thus this test can be used to monitor training/detraining progression. In addition, laboratory protocols may use an exercise intensity based that is relative to above or below the lactate threshold.

Test Description
Briefly, the subject will perform a series of incremental exercise bouts during which ~50 µL of blood from a finger stick is analyzed for lactate concentration at the end of each bout. As exercise intensity increases, blood lactate concentration increases in a curvilinear fashion, and the intent of this test is to identify the workload at which blood lactate concentration begins rising exponentially. A brief (5-10 minutes) warm-up and cool-down are performed before and after a test. The initial bout begins at a very low intensity, which progresses to a near-maximal intensity. Each bout is usually 3-5 minutes in length, and depending upon the exercise mode, may be continuous or discontinuous. During treadmill testing, subjects must be stopped in order to sample blood (a discontinuous protocol); with cycling protocols, however, blood can be sampled while a subject is exercising, thus the bouts could be continuous. The number of bouts varies, but usually 5-8 bouts are performed.

Blood is sampled from a finger stick that has been cleaned with an alcohol swab. After allowing the finger to dry, a fingertip is lanced and the blood collected in one or two 50 µL heparin-coated capillary tubes. The blood is transferred via a pipette to a lactate analyzer for determination of lactate concentration. Sterile gauze is applied to the fingertip, and the subject instructed to maintain pressure for several minutes. As multiple samples are required for this test, for subsequent samples, the fingertip is squeezed to determine whether blood can still be sampled from the same stick, and if so, reduces the number of finger sticks that must be performed. Otherwise, additional finger sticks are performed on another site of the same finger or a different finger depending upon the subject's preferences. Total blood drawn during this test is less than 0.5 mL.

Training/Supervision Needed
Graduate students in the M.S. program in Exercise Physiology take coursework and have lab experiences to prepare them for these assessments.

Risks
The risk of a cardiac event is lower than it would be for maximal testing, however, the exact risk is not known. Any exercise bout may produce light-headedness, fatigue, possibly nausea, and delayed-onset muscle soreness. These side effects are usually minimized in fit subjects. They are also minimized by having a gradual warm-up as well as cool-down (at least 5 minutes each) and by having the subject refrain from eating for at least 2-3 hours before their test.

Under normal conditions, there are minimal risks to the subject when performing finger sticks that include: bruising; light-headedness or dizziness due to fear of needles; and infection.

Risk Management
Lactate threshold assessments are conducted in the Exercise Physiology Laboratory (ENS 255) and Annex Exercise Physiology Laboratory (ENS 111) at SDSU and in the Fitness Lab at 9245 Sky Park Court. Subjects who meet specific study criteria and who do not report cardiovascular disease or its symptomology, as screened with the Physical Activity Readiness Questionnaire (PAR-Q), will undergo an incremental exercise test on a selected ergometer (treadmill, cycle, rowing machine, hand-crank cycle).
Mild exercise is used to warm-up and cool-down before and after exercise, which minimizes the risk of injury or a cardiac event from the exercise.

Whenever blood is drawn, there is a small risk of bruising. Although infection is a risk with finger sticks, this is minimized by use of alcohol to cleanse the area for the blood draw. Latex gloves are worn by the technician at all times, and all contaminated materials are deposited in a biohazard container, in accordance with the bloodborne pathogens standard of OSHA. In the case of individuals with a latex allergy, the laboratories have non-latex gloves available for use.

Potential Benefits
If the intent of the test were to determine fitness level or predict endurance performance, this test would provide extremely valuable information to the subject. However, if the test were used to determine exercise intensity of another exercise protocol, results of this test would likely be of little interest to the subject.

Consent Content (Description of the Study section)
You will first perform a 5-minute standardized warm-up at a low intensity. Afterwards, you will perform several bouts of (treadmill or cycling) exercise, which increase in intensity. Each intensity will be 3-5 minutes in length; the entire test will contain five to eight stages. After each exercise bout, a small amount of blood will be sampled from a finger stick. Prior to the finger stick, the fingertip will be cleaned with an alcohol swab. The amount of blood drawn will be equivalent to only a few drops, and the total volume of blood taken will be less than a teaspoon.

Consent Content (Risks and Risks Management section)
Procedures that require blood samples to be collected have the risk of soreness, bruising and/or swelling at the collection site. Prior to each finger stick, the area will be cleaned with an alcohol swab. After the stick, you will be instructed to maintain slight pressure on the area to minimize additional bleeding.

4.21.1.7 Exercise Protocol: Exercise in the Heat

Appropriate Applications
Testing of subjects in a warm, humid environment can provide insight into the acute and chronic effects of exercising in the heat. Studies are performed to investigate the acute effects of exercise in the heat on the cardiovascular, metabolic, or thermoregulatory systems as well as the effects of acclimation on these systems to extreme environmental conditions.

Test Description
Subjects may exercise in the environmental chamber in the SDSU exercise physiology laboratory (ENS 255) for up to 2 hours per day. In heat acclimation studies, subjects may perform up to 10 days of exercise in the heated chamber. Air temperature will range from 32 to 43 °C (90 to 110 °F) at a relative humidity of 30-80%. During a test, heart rate, sweat rate, skin blood flow, sweat gland density, and core body temperature may be followed. Heart rate is measured using a heart rate monitor received from a transmitter strapped around the chest. Sweat rate is determined by pre- and post-exercise body weights. Skin blood flow is estimated using either a laser Doppler technique or venous-occlusion plethysmography. A laser Doppler probe is positioned on a forearm from which the signal is converted to units of blood flow. Venous-occlusion plethysmography estimates blood flow from the tension measured from a strain gauge positioned around the forearm while applying a blood pressure cuff to the upper arm. Sweat gland density is calculated by applying iodine-impregnated paper to the skin. Core body temperature can be measured in a variety of ways: The three most commonly used methods in our laboratory are tympanic, rectal, and esophageal measurements. Tympanic temperatures are measured with an infrared sensor inserted into the ear. When tympanic temperatures are performed, though, the design of the sensor prevents it from being inserted too far and injuring the ear. Rectal temperature is measured from a sanitized temperature probe inserted by the subject approximately 10 cm past the anal sphincter.
Esophageal temperature is measured using a single-use temperature probe inserted by the subject through a nostril to a length approximately 25% of the subject's height.

Training/Supervision Needed
Graduate students in the M.S. program in Exercise Physiology take coursework and have lab experiences to prepare them for these assessments. These individuals will have been prepared for giving instructions to subjects for inserting probes.

Risks
The rectal or esophageal probe may produce mild discomfort while inserted. The risk of a cardiac event from exercising in the heat is lower than it would be for maximal testing, however, the exact risk is not known. Any exercise bout may produce light-headedness, fatigue, possibly nausea, and delayed-onset muscle soreness. These side effects are usually minimized in fit subjects. They are also minimized by having a gradual warm-up as well as cool-down (at least 5 minutes each) and by having the subject refrain from eating for at least 2-3 hours before their test.

Risk Management
Core body temperature will be monitored during the exercise test. If a subject's core temperature exceeds 39.5 ºC, the test will be terminated and the subject removed from the environmental chamber. Only single-use probes will be used to measure esophageal temperature.

A negative pregnancy test is required of all female subjects before beginning an exercise experiment in the heat. SDSU students may take a urine pregnancy test at the SDSU Student Health Center; she will need to provide the investigator with a copy of the test results. If the subject is not a SDSU student, we will provide a urine pregnancy test that will be administered and read in the lab.

Potential Benefits
In heat acclimation studies, subjects may be able to exercise longer and with less fatigue and discomfort after becoming acclimated.

Consent Content (Description of the Study section)
You are being asked to exercise in the environmental chamber, which will be set to XX ºF and a relative humidity of XX%, for XX minutes (and for XX consecutive days). In order to monitor that you are not becoming overly heated, your tympanic (or rectal or esophageal) temperature will be followed. Tympanic temperature is measured by inserting a temperature probe in the ear and holding it for a few seconds until the temperature is registered. (Rectal temperature is measured with a probe inserted in your rectum. You will do this yourself in the privacy of the changing room by inserting the probe to the mark indicated on the cable and/or esophageal temperature is measured with a probe inserted through a nostril into the esophagus to the point indicated on the cable.) Before and after the exercise, your weight will be recorded. To measure blood flow, a laser Doppler will be attached to your forearm and/or a strain gauge sensing devise will be placed around your forearm and a blood pressure cuff around the upper arm.

Consent Content (Risks and Discomforts section)
You may experience discomfort and briefly gag when you insert the esophageal probe. You may also experience mild irritation of the nose and throat both during and after the experiment. Should your temperature exceed 39.5 ºC, we will terminate the test and remove you from the chamber. If you feel uncomfortable during any part of this study, you may choose to terminate your participation.

If a participant is removed from the heat chamber because his/her rectal temp reaches 39.5 C, they will be monitored continuously to watch for a decrease in temperature (which usually occurs very quickly when seated in the lab, which is kept at 23 C. If their core temperature does not start to go back down after 10 min of rest in 23 C, a fan and ice will be applied to their arms and legs, and they will continue to be monitored until their temperature drops below 38 C.
4.21.1.8 Sweat Rate Via Pilocarpine Iontophoresis (consent content only)

Consent Content (Description of the Study section)
We will measure your forearm (or other body part) sweat rate using a Macroduct Sweat Collection System. This system works by stimulating sweat production in a small area (about 3 inches) of your forearm by using a small, nonshocking electrical current. You may feel a mild tingling sensation, but nothing more. Many individuals report that they cannot feel anything. A total of approximately 10 drops of sweat will be collected from your forearm using a collection pad. The entire procedure, including prep time, takes about 30 minutes.

4.21.2 Genetic Testing

If the study involves genetic testing, there may be added risks to the subject. Within the IRB protocol, address issues pertaining to confidentiality of information collected. State whether or not the genetic information collected about the subject could pose a risk to them if released (e.g., denial of health insurance because of known predisposition to illness). Identify genes of interest to this research, how blood samples will be coded and stored, whether laboratory results will be made available to subjects and whether results will become part of the subject’s medical record.

Address potential use of samples in other genetic research and whether or not the discoveries may have significant therapeutic or commercial value. To protect subject privacy, all information that links the subject’s specimens and DNA to his/her identity must be removed prior to use in any research conducted outside of this specific study so that the sample provided to others for research purposes cannot be traced back to the individual subject.

4.21.3 Non-FDA Approved Products

Address safety and efficacy concerns for studies that involve non-FDA regulated botanical products. Provide evidence to suggest that the product being tested is safe for use with humans at the dose level planned for use in this study.

4.21.4 Screening for Pregnancy

To insure that a pregnant woman is not included in research that may be harmful to her or her fetus, procedures to screen for pregnancy must be included in the protocol. The IRB has approved the following screening procedures: Prior to testing, ask female participants to disclose the start date of her last menstrual cycle. If she has not menstruated within the last 14 days, the participant will need to schedule testing to occur within 14 days of the start of her next cycle. The research investigator can make a urine pregnancy test kit available to participants to use as confirmation of pregnancy status. If the pregnancy test indicates a negative result for pregnancy, the test may be conducted. If a positive pregnancy result is indicated, the subject is not eligible to participate in testing.

4.21.5 Internet Research

As Internet research has become more and more common, guidance to assist investigators in developing research protocols in compliance with the ethical standards applied to standard survey and observational research is needed. Research conducted in the virtual world of the Internet is subject to the same IRB review process and human subjects protections as research conducted in the physical world. The main concerns of the IRB for protecting subjects involved in research on the Internet are informed consent, protection of privacy and confidentiality. These concerns pertain to survey and observational research conducted with human participants on the Internet.
4.21.5.1 Informed Consent

The informed consent process is reviewed by the IRB to determine whether appropriate information regarding the study (e.g., study purpose, participant involvement, risks, benefits, confidentiality) is provided to the prospective subjects.

Survey Research

Similar guidelines to obtaining consent for exempt research apply in anonymous, Internet survey research. A statement containing the following information to obtain consent for survey research conducted on the Internet will be reviewed by IRB:

Describe why the study is being conducted.

State who is being recruited and why they have been chosen.

Explain what each participant will be asked to do and estimate how long it will take to complete the task.

Emphasize that participation is voluntary.

Clarify whether participant's information will be anonymous (no identifiers, including on-line pseudonyms) or confidential. If confidential, indicate whether any information linked to the individual's identity (in the physical or virtual world) will be used.

Describe incentives/compensation offered or costs that may be incurred.

Explain added risks associated with privacy violations and strategies developed to reduce the risk of privacy loss or breach of confidentiality.

Provide contact information including the name of the investigator, department, phone number and E-mail address for inquiries. Include the IRB telephone number and E-mail address (IRB@mail.sdsu.edu) for questions related to their rights as a participant in research.

Observational Research

Observational research conducted on the Internet is subject to IRB review. Examples of observational research include monitoring chat room discussions, tracking frequency of Internet use or following consumer patterns of behavior on the Internet. For Internet observational research, the IRB recommends the following procedures to obtain consent:

Prior to initiating observation or data collection from a particular site, the investigator will contact the domain host, webmaster or equivalent to provide a description of the study and request that information about the study be presented to the community. Should the host agree, study information is presented to the community for discussion. If the community indicates agreement to the host, the investigator is notified of permission to access the site.

New users that join once the research has begun must be informed of the research in the first welcome message from the domain host, webmaster or equivalent.

The user/prospective subject should have an opportunity to refuse participation in the observational research study.
NOTE: Deception in observational research, where the investigator identity is concealed or falsified on the Internet must include solid rationale to support the methodology and must meet criteria to waive the informed consent process (refer to 45 CFR 46.116).

4.21.5.2 Privacy & Confidentiality

Survey Research

Confidentiality and privacy are of particular importance for Internet research, given that information may be stored and accessed for indefinite periods of time. The investigator must assure the IRB that data collected will only be accessible to the investigator.

If there are plans to collect data via the Internet, efforts to enhance participant privacy and reduce risks associated with a breach to confidentiality must be considered. The protocol must address the following issues as they pertain to data collection and submission procedures utilizing the Internet.

Privacy/Access. Describe procedures planned to protect participant identity when entering and submitting data via the Internet. For example, will the subject have a user name and/or password to gain access to the study site? If so, develop instructions for the participant to use when creating a user name or password that enhances protection of her privacy (e.g., not using own name, not sharing password, etc.). Will data be transmitted in encrypted format? In an anonymous survey, will a name-blind survey URL be assigned to each individual survey to guarantee privacy?

Confidentiality of Data. Develop procedures to advise a participant on how to prevent another computer user from gaining access to his/her data. This concern focuses on accessing a computer for data entry that is shared with others (e.g., form auto complete feature, Password Saving feature). Caution the participant to finish the survey in one setting and to shut down the computer after the assessment is completed.

Secure Data Storage. Incorporate procedures to not include the participant's name or identifiers within the database. Develop a coding scheme to protect subject privacy and confidentiality of data. Describe how/whether data will be backed-up and kept in a secure location, how long date will be stored, who will have access to the data collected.

Describe systems in place to prevent unauthorized persons (hackers) from accessing the database. For highly sensitive topics, IRB recommends that the subject have the option of printing out a blank copy of the survey and mailing it back to the investigator.

If an incentive will be offered and subjects will need to provide contact information (i.e. an email address, phone number, etc.), explain how anonymity or confidentiality will be maintained.

Observational Research

Investigators conducting observational research studies on the Internet must consider the perception that contributors have regarding the privacy and confidentiality of the information that they disclose. The investigator must also abide by rules that govern the on-line community regarding disclosure of information outside the realm of the group. The investigator must consider the degree to which publication of information disclosed on the website could place subjects at risk. Given the search capabilities of the Internet, even direct, anonymous quotes from subjects could be linked back to the subject with a verbatim search of that direct quote. Investigators must ensure the IRB that all possible precautions have been taken to ensure subject privacy and confidentiality.

These guidelines are evolving as Internet research becomes more prevalent. Each research study is unique and poses different ethical issues and challenges for human subjects protections. Although
Internet research may offer great benefit to science, it is imperative that human participants in these studies are adequately informed of the research and protected from associated risks.

Prisoner Research:

1. **PERMITTED RESEARCH INVOLVING PRISONERS** (under the Code of Federal Regulations 45 CRF 46.305):

   (A) 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;

   (B) 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;

   (C) 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

   (D) 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.

*Definition of Minimal Risk in prisoners: Risk of physical or psychological harm that is no greater in the probability and severity than that ordinarily encountered in the daily lives, or in the routine medical, dental, or psychological examinations of healthy persons [45 CFR 46.303(d)]

Definition of a prisoner: An individual involuntarily confined in a penal institution, including persons (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g. for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)]

2. **THE LAW**

   Research with prisoners must comply with the requirements of 45 CFR 46 in addition to the 7 following protections:
   1. The research must represent one of the four permissible categories or the additional category per waiver (June 20, 2003).
   2. Possible benefits to the prisoner, when compared to their normal living conditions, do not interfere with their ability to adequately assess risks and benefits in their "limited choice environment."
   3. Risks associated with the research are commensurate with those that would be acceptable to non-prison populations.
4. Selection procedures are fair to all prisoners and free from the influence of prison authorities or other prisoners/controls must also be selected from prisoners.

5. Study information must be presented in language that the population can understand.

6. Assurance that parole boards will not use prisoner participation in making decisions/prisoners are informed that participation will not affect their parole

7. Provisions for treatment/care/examinations have been made for follow-up care after the end of participation/subjects are informed of this fact. (The length of individual’s sentences must be taken into account. (The committee makes the determination whether these provisions are warranted.)

3. CALIFORNIA LAW:
   California Penal Code sections 3500-3523 refers to the usage of prisoners in research. The stipulations are primarily the same as those outlined in 45 CRF 46.305, except:

   1. All biomedical research must adhere to California Penal Code section 1706.
   2. Informed consent can be waived in behavioral research when the department determines that it is unnecessary or inhibits the conduct of research.
   3. It is stipulated that behavioral modification techniques may only be used if they:
      a. Are medically and socially acceptable methods
      b. Do not inflict permanent physical or psychological injury
   4. Consent forms must contain:
      a. The expected recovery time of the subject after completion of the study.
      b. The manner in which subjects may receive prompt treatment for research-related injuries (does not have to be embedded in the consent form, but prisoners must be provided this information in writing).
      c. Although witness signatures are not required, it is permissible for researchers to obtain witness signatures on consent forms to further prevent undue influence.

   The Department’s responsibilities:

   1. The department will also evaluate all research.
   2. Behavioral research cannot be conducted on prisoners until the department provides approval.


IRB Discussion Forum promotes the discussion of ethical, regulatory and policy concerns with human subjects research.
List-Post: irbforum@irbforum.org, http://www.irbforum.org/discussion
List-Subscribe: http://www.irbforum.org/user


Updated October, 2008
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5.0 Informed Consent Guidance

5.1 Consent Purpose

The Office for Human Research Protections (OHRP) states that "informed consent is one of the primary requirements underpinning research with human subjects; it reflects the basic principle of respect for persons." Informed consent is the knowing consent of an individual or his/her legally authorized representative, which is obtained without undue inducement or element of force or coercion. Obtaining informed consent does not end with a signature on a piece of paper. It is a process in which the subject receives enough information about a study to make a decision about participation in the research. The subject should have up-to-date information about the requirements of the study during all phases of participation. The process involves reading, understanding and signing an informed consent document as well as discussing the details of study participation with a knowledgeable member of the research team.

Investigators should strive to implement a process and create a consent document(s) that reflects the commitment he/she has taken to ensure that subjects are protected. Consent form templates are available to use as a foundation, however, consent forms should be carefully tailored to fit the target audience to whom it is directed in order to secure an informed and voluntary decision from subjects.

5.2 Consent Process and Procedures

The following procedures should occur during the informed consent process (45 CFR 46.116):

- The prospective subject and/or the parent/guardian:
  - receives adequate information in an appropriate setting to make an informed decision about participating in the proposed research,
  - receives information about the nature and expectations of the research, including risks and benefits using language and terminology that is clear and understandable,
  - has an opportunity to ask questions and receive answers about the study,
  - retains the right to refuse or withdraw from the study at any time without penalty,
  - receives copies of the approved consent form(s) and the Research Participant’s Bill of Rights when relevant.

- The investigator retains the signed copy of the consent document and the Research Participant’s Bill of Rights (when applicable) for three years after study completion.

5.3 Alternative Consent Procedures (45 CFR 46.116 (6c))

The IRB may approve a consent procedure that does not include or changes the basic consent requirements or even waive the requirement to obtain informed consent when the following applies and can be documented:

“(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.”

The IRB may also approve a consent procedure, which does not include or alters the basic consent requirements or even waive the requirement to obtain informed consent when the following applies and can be documented:

“(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 the waiver or alteration;
Please note: The regulations referenced do not preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.”

5.4 Components of a Consent Form

The following information should be included in an informed consent document per 45 CFR 46.116(a,b) and per SDSU IRB policy:

a statement that the subject is being asked to participate in a research study.

the name and degrees of all investigators involved in the study. Indicate the department and institution with which the investigator(s) is affiliated. If the investigator is a student, include the name of the person supervising the research.

an explanation of what the study is designed to determine or assess using language that is clear to the target audience.

the number of subjects being recruited for the study and the eligibility criteria used to identify prospective participants.

a description of procedures that the subject will be asked to follow.

the location(s) where the research will be conducted.

the amount of time study participation will require of the subjects.

a description of any risks or discomforts the subjects might encounter as a result of participation and provisions made to address these risks or discomforts.

a statement to describe potential benefits to science and society that may result from this research.

a description of any benefits the subjects can expect as a result of participating in the study.

a description of the extent, if any, to which confidentiality of records identifying the subject will be maintained (include the procedures for using and storing data and include who will have access to the data).

a description of where all research records will be kept and for how long (this includes video and audio files).

a description of any incentive offered and what is required of the subject to obtain the incentive. If the subject is offered a payment, state the amount, formula for proration should the subject or investigator choose to discontinue participation, and when payment will occur. If an incentive is not offered, state that the participant will not be paid to participate in this study.
an explanation of procedures that are experimental.

appropriate alternative procedures or courses of treatment that might be available or advantageous to them.

contact information of study personnel and IRB for the subject should he/she have questions or concerns about participation in the research.

a statement that participation in the study is voluntary and that he/she can withdraw consent and stop participation at any time without penalty or loss of benefits allowed.

Sample consent forms can be found on the Division of Research Affairs website at: http://gra.sdsu.edu/research.forms.

Signatures for Informed Consent

Unless a waiver of documentation of consent has been granted (see “Waiving Requirement to Document Consent” below), include a signature and date line for the participant and the investigator (or individual administering the consent form) to complete. Label the signature lines as “Research Participant/Subject” and “investigator” (or “study representative if the individual administering the consent form is not the principal investigator). In addition, include space for the subject and the investigator (or individual administering the consent form) to print their name.

5.5 Structure of a Consent Form

The following points are strongly encouraged to enhance the readability of the consent form:

Target a 6th to 8th grade reading level avoiding technical jargon.

The consent document should be written in the second person (using the "you" pronoun).

Use a font size appropriate for the population targeted (11 or 12 point minimum).

Use clear paragraph/section headings to allow the potential subject ease of access to specific study information.

Double space between paragraphs.

5.6 Obtaining Parental Permission (45 CFR 46.408)

Parental permission is required when recruiting children or minors as subjects in research. In California, a minor is identified as a person under the age of 18 years. Parental permission must be obtained in advance of enrolling a minor subject into a study. The Informed Consent form format is used when developing a Parental Permission form. Text should reflect the activities that the child (and the parent, if they are also considered a subject) will be asked to participate in as a research subject. If the consent form is being developed to obtain parental permission only, the signature line is labeled "Parent or Guardian of Minor Child." The child subject's name is also printed to indicate the child for whom they are giving permission. A sample parental permission form can be found on the Research Affairs website at: http://gra.sdsu.edu/research.forms.

For more detailed information about the requirements for obtaining parental permission see section 4.11.4 of this guidebook.
5.7 Obtaining Assent/Dissent from Minors (45 CFR 46.408)

Assent is demonstrated by a child's agreement to participate in research. In California, a child is a person who is under the age of 18 years (unless legally emancipated). It is required that the investigator makes adequate provisions to solicit assent from children unless the IRB waives this requirement. To determine whether the child is able to assent really depends on the child's age and maturity. If the child is considered to be capable of providing assent, whether or not assent is documented is also determined by the IRB. When assent is obtained, an assent form should be constructed that targets the child's level of reading and language use. The assent should include basic information about the study and how the child will be involved. If the parent gives permission for the child to participate and the child assents to participate, then he/she may be enrolled in the study. A sample child assent form can be found on the Research Affairs website at: http://gra.sdsu.edu/research.forms.

For more information about the requirements for obtaining child assent see section 4.11.3 of this guidebook.

5.8 Disclosing a Financial Interest to Subjects

It is generally recognized that a research investigator has an ethical responsibility to disclose a possible conflict of interest to potential research subjects as part of the consent process. The IRB asks investigators to provide information within the protocol to indicate whether they or any other person responsible for the design, conduct, or reporting of this research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by, the research. If the investigator reports a financial interest with the study sponsor and the conflict can be managed, it is expected that the consent form will adequately inform subjects of the relationship as well as procedures used to minimize the effect the relationship may have on the study. (The following website has more information about disclosure of financial interests to research participants as well as other important policies pertaining to the conduct of research: http://aspe.hhs.gov/sp/coi/refts.htm).

5.9 Documentation of Informed Consent (45 CFR 46.117)

In most cases, informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.

Unless the IRB has authorized revisions to the consent procedure, the consent form must include all elements identified within the federal regulations (45 CFR 46.116). The IRB-approved consent form may be read to the subject or to the subject's legally authorized representative in addition to allowing the potential subject an opportunity to review the consent document and ask questions before signing the consent document.

5.10 Waiving Requirement to Document Consent (45 CFR 46.117(c))

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

"(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. If this is the case, the investigator will ask the subject whether he/she wants to sign the document that links him/her to the research. The subject's wishes for documentation will dictate whether or not a signed consent form is needed."
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context."

If the IRB approves waiving the requirement for documenting consent, the investigator may be asked to provide the subject with a written statement regarding the research.

5.11 Signature of Project Representative

The project representative (principal investigator, study coordinator or designated project representative) also signs the consent to verify that the consent process is complete. When obtaining consent, the setting and timing of explaining the research must be conducive to good decision-making. The project representative should see that everything is done to enhance the prospective subjects’ comprehension of the information and their ability to make a choice. The person signing as the project representative should be knowledgeable about the study, able to present information using easily understood terminology, and one who can identify and resolve any remaining questions.

5.12 Short Form Written Consent (46.117(b)(2))

The regulations also allow for consent to be documented by signing a "short form" that states only that the required elements of informed consent have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, the IRB will approve a written description of the consent statement that is orally presented to the prospective subject. In addition, a witness to the oral presentation is required. Following the oral presentation, the prospective subject/legal representative will sign the "short form" if he/she decides to participate in the research. The witness verifies the consent process by also signing the "short form" and the consent statement that is presented orally to the subject. A copy of the consent statement is then given to the subject or the representative, in addition to a copy of the signed "short form."

5.13 Consent Translation

Both DHHS regulations (45 CFR 46.116) and FDA regulations (21 CFR 50.20) require that informed consent be obtained in a language that is understandable to the subject (or the subject's legally authorized representative), and documented in writing (46.117 and 50.27, respectively). Non-English speaking subjects must be presented with and sign a consent form that is written in their primary language. The investigator must provide the IRB with a language appropriate translated consent document for review and approval prior to recruiting subjects. It is recommended that the investigator secure IRB-approval of the English consent document prior to translating the consent form. The SDSU IRB does not require that a certified translator perform the document translation. However, the IRB does not verify the accuracy of the translated consent document and the investigator must provide assurance to the IRB that the consent or assent form has been adequately translated. The IRB recommends that the investigator either hire a certified translator or verify the translation using a back-translation procedure. For example, translation of a document to Spanish using the back-translation method involves translation of the English document to a Spanish version. The Spanish version of the document is then translated back to English by another bilingual individual. The original English version is then compared to the English version of the Spanish-translated document for accuracy. If the two documents are comparable, the translation would be considered adequate.

5.14 Special Considerations

5.14.1 Obtaining Consent of Non-English Speaking Persons
The consent document must be written in a language that is understandable to the subject and presented to the potential subject by a person who is fluent in the individual's language. See preceding section for more detail.

5.14.2 Obtaining Consent from Cognitively Impaired Persons

If participants are identified as being cognitively impaired, it may be necessary to include additional procedures during the consent process to ensure that the prospective subject understands the information that is being presented about the study. This may involve adding questions at the end of each section of the consent document to use in assessing participant comprehension of the consent content. This mechanism allows for the investigator to clarify the participant's understanding of specific aspects of the study as the consent process occurs (e.g., After the Description of the Study section, include the following questions: Do you understand what will happen during the testing phase? The training phase?).

*If Screening for dementia will occur the following information should be included:*

**Prior to testing:**

To participate in this study you must take some screening tests. These tests are for research purposes and are not designed to make any type of medical diagnosis. Nevertheless, sometimes the results of these tests can suggest the possibility of a medical problem. If this happens with your tests, we will advise you of this and give you copies of the results so that you may consult with your doctor.

**When screening test results indicate possible medical problem:**

The results of your screening tests are not within the range that would qualify you to participate in this study. Sometimes, results like yours can be related to a medical condition but this test is only one measure and by itself may have no significance. We suggest that you consult with your doctor for further evaluation. We will provide you with copies of the results that you can take to your physician.

5.14.3 Internet Research

The consent information should explain added risks associated with privacy violations and strategies developed to reduce the risk of privacy loss or breach of confidentiality. See the section entitled Internet Research (section 4.21.5) for more information on this topic.

5.14.4 Deception or Incomplete Disclosure

In studies involving deception or incomplete disclosure, information about the details of the study hypothesis or research question to subjects may be abbreviated or withheld during the consent process. However, subjects should be provided with enough general information about the study or experiment to understand and make an informed decision about whether or not they want to complete the study tasks or expose themselves to potential risks involved in study participation. Subjects should be debriefed about the true nature and purpose of the study after their participation has ended. Additional information on deception in research can be found on the American Psychological Association website at: [http://www.apa.org/ethics/code2002.html#8_07](http://www.apa.org/ethics/code2002.html#8_07)

5.14.5 Debriefing
In behavioral research involving deception, an ethical practice is to debrief subjects after their participation. The debriefing statement should be presented both orally and in writing. Debriefing procedures should include a written statement that will be summarized and then given to subjects to take home to read in more detail if they choose. Along with a description of the deception involved and an explanation about the true purpose of the research, include a statement to inform subjects of their right to withdraw their data from the study and still receive course credit if they feel upset or uncomfortable with the deception involved. Referral information should also be provided to the subject should participation in this study raise personal concerns that he/she would like to discuss with a clinical professional.

5.15.4 Obtaining Consent in Exempt Research

A signed consent form is generally not required for research classified as exempt. However it is customary to provide adequate information about the research to potential subjects so that an informed decision can be made. The investigator can deliver this information verbally or both verbally and in writing. The appropriate mode of delivery will depend on study administration procedures. The consent statement includes information needed for a participant to make a decision regarding participation and is presented in a language easily understood by the target audience.

When applying for IRB review, the investigator submits the text to be used to obtain informed consent.

The consent statement for exempt research usually contains the following information:

Identify who is conducting the study including institutional affiliation and academic status.

Describe why the study is being conducted.

State who is being recruited and why they have been chosen.

Explain what each participant will be asked to do and estimate how long it will take to complete the task.

Emphasize that participation is voluntary.

Clarify whether participant's information will be anonymous (no identifiers) or confidential. If confidential, indicate whether any information linked to the individual's identity will be used.

Describe incentives/compensation offered or costs that may be incurred.

Provide a department number and point of contact for telephone inquiries. Include the IRB telephone number for questions related to their rights as a participant in research.

5.15.5 Consent Forms with Collaborating Institutions

Investigators who, either due to affiliation or engagement of more that one institution in research, may be required to obtain IRB approval from all institutions with which they are affiliated. The IRB encourages investigators to work with each institution's IRB toward developing a consent document that meets with requirements of both institutions. This is preferred to having two or more approved consent documents that are used to document informed consent from each subject.
6.0 Commencing Research

6.1 Investigator Responsibility

Protecting the rights and welfare of the research subject is a shared responsibility of the IRB and the investigator. Ultimately, the investigator is responsible for carrying out the study ethically and responsibly. This includes the application and monitoring of ethical practices, compliance with state/federal regulations and institutional practices, and supervision/training of research staff. Individuals conducting research under the auspices of SDSU are required to comply with relevant federal and state regulations and institutional policy for the protection of human research subjects.

6.2 Faculty Advisor's Responsibility when Supervising Student Research

Student initiated research involving human subjects, whether dissertation, thesis or other research projects, must be supervised by an authorized faculty member (check with your particular department or with Graduate Affairs 619-594-5213 to determine who is eligible to be an authorized faculty member) to insure the compliance with procedures and regulations relating to the protection of human subjects. The Supervising faculty member is responsible for understanding the federal regulations that govern research involving human subjects, the Belmont Report and the Institution's Assurance prior to supervising a student who involves human subjects in research. In addition, faculty supervisors are responsible for providing guidance and mentoring to students in the following areas:

Ensure the student has an appropriate understanding of the federal regulations that govern research involving human subjects, the Belmont Report and SDSU's Assurance

Meet with the student investigator to monitor the study progress, including protocol compliance. Arrange for an alternate faculty sponsor to assume these duties when unavailable (vacation or sabbatical).

Assist student in handling research related problems, including significant or untoward adverse event reporting.

Students will verify that their faculty advisor has agreed to comply with the stated responsibilities when submitting their IRB application.

Master's students will receive electronic verification from the IRB, once their human subjects protocol is submitted. This letter may be used to verify the IRB review process has been initiated when signing up for 799A.

6.3 Institutional Responsibilities

SDSU's Assurance with the U.S. Department of Health and Human Services identifies responsibilities of the institution, the research investigator and the IRB related to human subjects protections issues. The SDSU assurance authorizes the SDSU IRB to serve as the Institutional Review Board for this campus.

6.4 Modifications & New Findings

Federal regulations require that any revision to previously approved research involving human subjects receive IRB approval in advance of implementation except when necessary to eliminate apparent
immediate hazards to the subject (45 CFR 46.103 (b)(4)(iii)). A modification is defined by the IRB as a change that does not alter the overall character or purpose of the original project. Minor changes that do not adversely alter the overall risk-benefit profile of the study may receive review by subcommittee. The convened committee reviews proposed changes that may affect the willingness of enrolled subjects to continue participation and/or increase the risk to research subjects.

Within the modification request, the investigator is asked to provide a complete description of and rationale for the proposed modification and to address the effects of the modification on risks, benefits, management of risks, and informed consent. Any new findings in the literature that may influence the study procedures, risks or benefits must also be described to the IRB.

The modification should also include changes to the consent process to inform subjects of new findings, changes in procedures, risks and benefits to study participation. An IRB approval stamp will be applied to the revised and approved consent form for studies that are at the Expedited or Full Committee review level when the modification approval is completed. Procedures used to inform and document consent of previously enrolled subjects affected by the modification should be addressed.

6.5 Adverse Event and Unanticipated Problems Reporting

The SDSU IRB requires investigators to report any problems that arise during the course of an IRB-approved research study. Serious adverse events or unanticipated problems that are life-threatening or have resulted in serious injury or death must be reported to the IRB immediately whenever possible or within at least 48 hours from the onset of the incident. All other problems must be reported to the SDSU IRB within 5 days.

To report a problem that is associated with the study, access the protocol within the vIRB online IRB-application system (available through the SDSU web-portal to all faculty and registered graduate students at: http://sdsu.edu/webportal). To complete and submit an adverse event report, go to the Protocol Main Menu, click on “Adverse Events” under “Protocol Maintenance” and follow the instructions. For more information and consultation, contact the IRB office directly via Email at: IRB@mail.sdsu.edu or telephone: 619-594-6622, Monday through Friday from 8:00AM to 4:00PM.

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 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 or not 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/policy/AdvEvntGuid.htm, p. 10).

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 or 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.

6.6 Continuing Review of Approved Protocols (45 CFR 46.109(c))

Research projects reviewed at the expedited or full Committee review level must be reviewed at least annually. Research projects reviewed at an Exempt review level may be reviewed anywhere from 1-5 years. The initial IRB approval expires one year following its award, unless otherwise stipulated by the committee. Determination for more frequent review is based on the degree of risk associated with participation and/or the involvement of subjects that require additional protections as defined by the Department of Health and Human Services.

A continuation of approval is needed if: 1) subject recruitment and/or data collection is continuing or 2) data is being analyzed that was collected on this project. A final report is necessary if all procedures are completed that involve human subjects (e.g., recruitment, data collection and analysis). To apply for continuation of approval or to indicate a final report, the investigator completes a Report of Progress form online. Research that was initially reviewed by the convened committee will receive continuing review by the convened committee unless identified as not exceeding a minimal level of risk at the time of its initial review. Request for continued approval should be submitted in accordance with the appropriate deadline date as posted on the IRB schedule.

In conducting continuing review of research the IRB will review:

- The number of subjects accrued;
- A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- Any relevant multi-center trial reports;
- Any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed consent document.

6.7 Site Monitoring

Continuing review may also involve a site visit to the research facility by an IRB representative. The goal of the site visit is to assess whether the protocol is being carried out as approved by the IRB. A secondary goal is to provide assistance to the investigator and key personnel, as needed, to increase understanding of the ethical principles associated with human subjects protections and federal regulations. Specific areas targeted for review of the protocol includes: recruitment methods and materials; measures; eligibility criteria; compensation; informed consent procedures, IRB records; data management and record keeping. Relevant study materials (e.g., correspondence, recruitment materials, subject files, measures, etc.) are made available for review during the site visit (as required by 45 CFR 46.109(e)). The IRB may recommend a site visit for research studies that involve vulnerable populations, a longitudinal design and/or procedures exceeding minimal risk. A site visit may also occur if a serious adverse event has occurred or a complaint has been registered.
6.8 Suspension or Termination of Approval

The IRB may suspend or terminate the approval of research that is not being conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects (45 CFR 46.109(a)).