

**SAN JOSÉ STATE UNIVERSITY
ONE WASHINGTON SQUARE
SAN JOSÉ, CA 95192**

F17-1, University Policy, Protection of Human Research Subjects

Legislative History:

On October 23, 2017, the Academic Senate approved the following policy recommendation presented by Senator Schultz-Krohn for the Curriculum and Research Committee. This policy recommendation rescinds S08-7 and provides a Human Research Subjects policy that is in compliance with the Federal Government requirements. Federal regulatory changes were passed in January 2017 with the requirement that institutions have a policy reflecting these new regulations as of January 2018.

Rescinds and Replaces: S08-7

**Approved and signed by President
Mary A. Papazian on November 2,
2017.**

**UNIVERSITY POLICY
Protection of
Human Research Subjects**

- Whereas: San José State University recognizes the need to address the ethical issues concerning human research subjects; and
- Whereas: San José State University must have a current policy that complies with the Federal Regulations; and
- Whereas The San José State University Institutional Review Board has reviewed the current Federal Policy regulating Human Research Subjects (HRS); and
- Whereas: The San José State University HRS Policy **S08-7 does not comply with forthcoming Federal requirements;** and

Whereas: The suggested policy submitted by the SJSU Institutional Review Board to the Curriculum and Research Committee was reviewed and disseminated to the SJSU community for comment; therefore be it

Resolved: That S08-7 be rescinded, and be it further

Resolved: That the attached policy be implemented

Approved: 12-0-1

Vote: 10-16-2017

Present: Anagnos, Bacich, Buzanski, Cargill, Chung, Gilles (for Stacks) De Guzman, Liu, Matoush, Rodan, Schultz-Krohn

Absent: None

Workload Impact: Minimal; as needed, additional training for new members of the SJSU IRB Committee

Financial Impact: Minimal; cost for additional training as needed

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LIST OF ACRONYMS

- IRB – Institutional Review Board
- LAR – Legally Authorized Representative
- OHRP – Office of Human Research Protections
- PI – Principal Investigator

0.0 Intention

San Jose State University acknowledges and accepts responsibility for protecting the rights and welfare of human subjects in research. SJSU shall comply with all appropriate statutes governing human research. In addition, non-federally funded or unfunded research shall undergo the same review as if it were federally funded. This policy shall apply to all protocol submissions, including active protocols submitted prior to the 2018 effective date of this policy.

1.0 Definitions

1.1 Engaged Institution – SJSU is considered engaged in human subjects research when its employees or agents obtain informed consent, collect and analyze data, and/or obtain private individually identifiable data for the purposes of contributing to generalizable knowledge under the auspices of SJSU. Such activities trigger either the need for SJSU IRB review or entering into a reliance agreement with another engaged institution whose IRB will review the research instead of the SJSU IRB. The following are examples of scenarios describing the types of institutional involvement that would make SJSU **not** engaged in human subjects research:

- When an SJSU employee or agent consults on research but does not receive or possess identifiable and private information about persons participating in the study.
- When an SJSU employee or agent is engaged in research as a consultant through a non-institutional contract. In this case, research activities must occur outside of his/her institutional employment and he/she may not reference the institution in documents or publications associated with any reported outcomes.
- When an SJSU employee or agent performs commercial or other services for external investigators, provided that the services performed do not merit professional recognition or publication privileges; the services performed are typically performed for non-research purposes; or SJSU employees or agents do not administer any study intervention being tested or evaluated under the protocol.
- When SJSU employees or agents inform prospective subjects about the availability of research; provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators; provide prospective subjects with information about contacting investigators for information or enrollment; and/or seek to obtain the prospective subjects' permission for investigators to contact them.
- When SJSU permits use of campus facilities for recruitment, intervention, or interaction with subjects by investigators from another institution.

1.2 Exclusion – Activities that do not meet the definition of human subjects research as outlined in both sections 1.3 and 1.6 are excluded from oversight by the IRB and the Office of Research. Investigators may self-determine whether their work qualifies for exclusion by using a decision tool developed by the Office of Research for this purpose. Exclusion should not be confused with exemption, as described in section 4.2.1, a category of human subjects research for which there is limited oversight and which must be registered with the Office of Research.

1.3 Human Subject – A living individual about whom an investigator (whether professional or student) conducting research:

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

Although an activity may be considered research, it may not involve human subjects. Except for the populations as defined in (i) and (ii) above, 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 information must be about a living individual to qualify as a human subject. Review of death records does not involve human subjects. However, analyses of identifiable biological specimens or identifiable private records of living individuals do require review and approval before analysis may begin.
- When an activity uses diagnostic or classification data for epidemiologic and analytic purposes that are not identifiable by individual or group and when such data are not proposed for a use that conflicts with the conditions under which the data were originally obtained.
- When research data are taken from the public domain and may include data traceable to known individuals or social groups who have clearly made both the information and their identities available for any forms of scrutiny and analysis within the limitations set by statutes concerning libel.
- When observed behavior takes place in a public arena or locale and is observed as aggregate behavior in such a way as to preclude any post-facto identification of individuals.

1.4 Identifiable Private Information – Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information is identifiable when the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

1.5 Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1.6 Research – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends,

signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or a court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- 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.
- Student classroom work intended as research practicum (see Section 2.3.2 for restrictions).

2.0 Scope of Policy

2.1 Federal Regulations

SJSU human research activities are to be conducted according to the requirements of the code of federal regulations [TITLE 45, PUBLIC WELFARE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46: PROTECTION OF HUMAN SUBJECTS](#) as if all SJSU research were federally supported. The federal regulations represent the minimum compliance requirements for human research activities

2.2 Other Applicable Regulations and Guidelines

2.2.1 State, Federal, and Tribal Law – Where state, federal, or tribal laws require more stringent principles, those will be applied.

2.2.2 Professional Associations – Where professional representative organizations such as the American Medical Association, the American Nursing Association, or the American Psychological Association, have established more stringent principles, investigators are encouraged to consider those principles when designing or submitting research proposals for review.

2.2.3 Foreign Countries – Where research takes place in foreign countries, comparable foreign statutes which provide additional protections for human subjects will also apply.

2.3 Applicability to Research When SJSU is an Engaged Institution

2.3.1 To Whom Does SJSU Policy Apply? Policies and procedures presented here are applicable to all research that, in whole or in part, involves human subjects if the research is sponsored by SJSU, or the research is conducted by or under the direction of SJSU employees, auxiliary employees, and/or students (including student/faculty collaborative research) under the auspices of SJSU. Student research must be supervised by a member of the faculty.

2.3.2 Student Research vs. Classroom Activities – Policies and procedures presented here

are applicable to any student-initiated and/or student conducted work that meets the definitions outlined in both sections 1.3 and 1.6.

Policies and procedures presented here are explicitly not applicable to courses that deal with established research methodology and which have been identified by faculty supervisors as research practicum. Numerous departments offer courses that require students to undertake small projects in which people are interviewed, observed, or otherwise serve as human subjects. 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 to be research as defined within the federal regulations and section 1.6 of this policy 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, target special populations, or include sensitive subject matter. The instructor of such a course is required to assure that procedures associated with, and data collected from, human subjects within these settings conforms to the ethical principles and guidelines established within the discipline and any other related rules.

If the course assignment produces results that may be of interest to the academic community, the IRB recommends that the student replicate the study under an IRB-approved protocol. The IRB does not have the authority to approve research retrospectively. If the primary intention of the student and faculty supervisor is to contribute to generalizable knowledge, then IRB approval is needed prior to commencement of the research.

2.3.3 Collaborative Research and Reliance Agreements – SJSU will abide by the single IRB mandate outlined in the federal regulations at [45 CFR 46.114 \(b\)\(1\)](#). When both SJSU and another domestic institution are engaged in collaborative research, only one IRB need review the IRB proposal. The non-reviewing institution will establish a reliance agreement with the reviewing institution. The reviewing IRB will be identified either by the funding agency, by the lead institution, or by consensus between the institutions.

2.4 Applicability to Research When SJSU is not an Engaged Institution

2.4.1 External Investigators with External IRB Approval – SJSU IRB approval is not needed in cases where a non-SJSU investigator conducts research at SJSU or recruits SJSU students or employees as research participants, provided that the investigator has obtained IRB approval from a supporting institution. The external investigator should register their IRB-approved work with the Office of Research using a form developed for this purpose. Nothing in this policy prevents SJSU department heads from declining to assist external investigators with their research endeavors.

2.4.2 External Investigators from Institutions Lacking IRBs – Federal regulations give common rule departments and agencies authority to enforce compliance directly against IRBs. For this reason, SJSU does not require its IRB to review research projects by external investigators who either come from an institution lacking an IRB or who are conducting research independent of any institutional support. SJSU will not take responsibility for or provide institutional support for external investigators' research activities.

3.0 SJSU Personnel Responsibilities and Authority

3.1 Principal Investigator —The principal investigator (PI) is responsible for conduct consistent with the ethical treatment of research participants and data. A PI is the individual in charge of a research project and must be qualified in the area of the proposed human subjects research. The PI must assume responsibility for compliance with the present policy. A student may not serve as PI but may be supervised by a faculty member to be a student investigator. PI responsibilities include:

- Completing the training requirement for the protection of human subjects in research as outlined on the Office of Research website and ensuring all research personnel are adequately trained.
- Submitting a complete proposal that is clearly written for a general audience.
- Adhering to all proposed actions that have been approved.
- Informing the IRB of any modifications to the proposed research.
- Informing the IRB of unanticipated problems, adverse events, or injuries within no more than one week (7 calendar days).
- Carefully monitoring research by students, staff, or associates conducted under the guidance and supervision of the PI.
- Complying with an SJSU IRB decision to suspend or withdraw its approval for the project.
- Applying all relevant professional standards.

3.2 Institutional Review Board (IRB) Members – The SJSU IRB is responsible for the appropriate review and oversight of human research activities. The IRB is a 13 to 15-member operating committee that is appointed by the Academic Senate and reports to the Curriculum and Research policy committee.

The IRB shall be comprised of persons from diverse backgrounds to promote complete and adequate review of research proposals involving human subjects, shall include both male and female members, at least one member whose primary expertise is in a nonscientific area, and at least one community member who is not affiliated in any way with SJSU. The IRB shall include one physician or licensed health professional, and may include an additional consultant for specific protocol reviews as needed.

Membership shall provide for one faculty member from each senate representative unit with an additional faculty member from each of the Colleges of Education, Social Sciences, and Applied Sciences and Arts

When research involving a category of vulnerable subjects (e.g., prisoners, children) or individuals with impaired decision making ability is to be reviewed, the IRB shall consider the inclusion in its reviewing body of one or more individuals who have as a primary concern the welfare of these subjects. In addition, federal Department of Education regulations require that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these subjects [[34 CFR 97.107\(a\)](#)].

IRB members from SJSU receive three-year appointments, which are renewable. Community members and students serve for one year. The Associate Dean and a qualified IRB staff person for the Office of Research serve as ex-officio members of the IRB, maintain IRB files, and process protocol reviews. The qualified staff member has voting status as an ex officio member of the IRB and may carry out administrative reviews for minimal risk research.

Recruitment of faculty and student members to serve on the IRB will be done through the normal Committee on Committees process for the seats designated for faculty and student members. All applicants will submit a one-page written statement describing their qualifications to serve on the board. When there are multiple applications for any seat, the Executive Committee of the Academic Senate will select individuals to serve. In considering potential IRB members, attention should focus on the person's research skills and experience and careful consideration of the balance of new and continuing members so the board retains experienced members yet also brings on new members.

IRB member responsibilities and authority include:

- Evaluating discipline-specific research proposals submitted by SJSU PIs to ensure that research involving human subjects is conducted ethically and according to institutional, state, and federal policies.
- Approving, requiring modifications, or disapproving (under convened committee) research involving human subjects conducted at SJSU or in the name of SJSU.
- Suspending or terminating (under convened committee) approval of research that is not being conducted in accordance with this policy and federal regulations or that has resulted in unanticipated serious harm to human subjects.

The IRB shall have access to all information and records necessary to conduct an adequate review of all proposed research involving human subjects to safeguard their rights and welfare. The IRB shall require that information that it deems necessary to protect the rights and welfare of human subjects be given to the subjects as part of the informed consent process.

The IRB shall apply the criteria for approval outlined in the federal regulations at [45 CFR 46.111](#).

3.3 Institutional Officer (IO) – SJSU's Institutional Officer, the Associate Vice President for the Office of Research, has administrative authority for the protection of human subjects. The IO responsibilities and authority include:

- Maintaining federal wide assurance with the Office of Human Research Protections (OHRP) at the Department of Health and Human Services.
- Reporting unanticipated harms to OHRP, when applicable.
- Proposing actions for various compliance issues, including suspension and termination of research. The IO may suspend research; only the convened committee may terminate research.

3.4 Other Institutional Officials – Research that has received IRB approval may be subject to further review by officials of the University; however, no official (including the IO) may approve and authorize research that has not been approved by the IRB.

4.0 Description of Procedures

4.1 Protocol Submission Procedures

4.1.1 Training Requirements – Prior to submission of a research protocol to the IRB, any SJSU employee planning to perform or to supervise student research involving human subjects must complete and file with the Office of Research an affirmation attesting to the successful completion of all training courses required of PIs. The nature of the training and access to it is provided on the IRB website.

IRB members are required to complete a training requirement within one month of joining the committee. The nature of the training and access to it is provided on the IRB website.

4.1.2 Protocol Documents – The protocol shall provide a complete description of the purpose and background of the research, the methods and procedures used to recruit participants and obtain data, the data management plan, and the risks and benefits of the research. In the protocol, the PI shall make provisions for the adequate protection of the rights and welfare of prospective research participants, delineate the research team’s responsibilities toward the subjects involved in the research, and ensure that pertinent regulations are observed.

For all research, the PI is required to provide adequate information about the research to potential subjects so that an informed decision can be made regarding participation. The procedures for providing this information must be outlined in the protocol. The expectations for the consent process for both exempt and expedited research are outlined in section 5.0.

Regardless of the type of review that is applied to a research protocol (exempt, expedited, convened committee), all protocol submissions must be complete, written in a manner that is comprehensible to a general audience, and apply relevant professional standards and best practices, including the minimization of risk to participants and a plan to mitigate conflicts of interests and/or situations that present undue influence.

4.1.3 Protocol Routing – Protocols that present minimal risk to subjects, if not found to be exempt under an administrative review by a qualified IRB staff member for the Office of Research, shall be assigned to individual IRB members on a rotating basis by a qualified IRB staff member. IRB staff may screen protocols to ensure they are complete and coherent before routing them an IRB member.

Protocols that present greater than minimal risk to subjects, as determined by a qualified IRB staff member who is also a member of the IRB or by an individual IRB member, must be reviewed by the convened committee.

Subsequent modifications to approved protocols shall undergo an administrative review by a qualified IRB staff member for the Office of Research, unless the modifications increase the risks to subjects. Modifications that increase the risks to subjects shall be reviewed by an IRB member or by the convened committee.

4.2 Review Categories

4.2.1 Exempt Review and Registration – The federal regulations exempt several classes of research from IRB review. SJSU bases recognition of these exemptions on two assumptions: (1) the risk to participants in research is so minimal that requiring an IRB review represents unwarranted intrusion into the research process; and (2) investigators (faculty, students, staff) understand, accept, and will implement the principles of informed consent contained in this policy.

Table 1 lists the categories of research that qualify for exemption from IRB review under the federal regulations at [45 CFR 46.104](#). The table also shows how these categories apply to the

regulatory subparts protecting certain vulnerable subjects (pregnant women, human fetuses, and neonates; prisoners; and children). SJSU has adopted the application of the exemption categories to these protected groups according to the federal regulations. Table 1 outlines the type of consent process which SJSU requires of research qualifying for exemption. In most cases, a written consent notice is provided to subjects but documentation of consent (i.e., a signature on a consent form) is not required. The expectations for the consent process for all review categories are outlined in greater detail in section 5.0.

Exemption is not the same as exclusion. Investigators may not self-determine exempt status and must register a complete protocol with the Office of Research for activities that may qualify for exemption. Protocols shall be screened by a qualified IRB staff member and those protocols that are determined to be exempt from IRB review will undergo an administrative review by the Office of Research only. Registration is not complete until confirmation from the Office of Research has been received by the investigator. The Office of Research reserves the right to evaluate the risk to human subjects in research identified as exempt and to require formal IRB review if the risk is greater than minimal or if it is deemed that expedited or full review is required.

The federal regulations identify the concept of “limited IRB review” for some categories of exempt research at [45 CFR 46.111\(a\)\(8\)](#). For the purposes of SJSU policy, the limited IRB review is akin to an administrative review conducted by the Office of Research which takes into consideration the privacy and confidentiality protections afforded to subjects as well as the consent procedures outlined in the protocol (when applicable).

An administrative review can be conducted by a qualified staff member for the Office of Research. In cases where the work is also subject to a limited IRB review under the federal regulations, the review can be conducted by a qualified staff member who is also a member of the IRB or through an expedited review by an IRB member.

4.2.2 Expedited Review – An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson or a qualified staff member from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#). In reviewing the research, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. Only a convened committee may disapprove research protocols. IRB members are informed of initial review, continuing review, and protocol modifications using expedited procedures via a tracking system provided by the Office of Research.

Research is eligible for an expedited review if it presents no more than minimal risk to human subjects and involves procedures or activities outlined by OHRP and listed in Table 2.

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.

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, or reputation, 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 risk.

The expedited review procedure may not be used for classified research involving human subjects.

Federal regulations describe the general requirements for informed consent and allowable waivers at

[45 CFR 46.116](#) and [45 CFR 46.117](#) respectively. The fundamentals of informed consent are discussed in greater detail in section 5.0 of this policy.

4.2.3 Convened Committee / Full Review – If the research is not eligible for an exempt or expedited review because it involves more than minimal risk to subjects, the protocol must be reviewed by the convened IRB membership at the monthly meeting. Full review will take place with a quorum of the IRB, defined as a majority of the total membership, including at least one member whose primary concerns are in a nonscientific area. Research protocols shall be distributed to the full membership at least one week in advance of the scheduled meeting. A protocol shall be approved if it receives the approval of a majority of those members present at the meeting. A primary reviewer is identified to present a specific protocol to other members in attendance. Following presentation and discussion, the committee will vote on a motion to either: 1) approve the protocol as it stands; 2) request revisions to the protocol to secure approval; 3) request that additional information be provided prior to further review by the convened committee; or 4) disapprove the protocol.

The IRB shall apply the criteria for approval outlined in the federal regulations at [45 CFR 46.111](#) and shall approve the research if:

- Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits from the research.
- Selection of subjects is equitable, considering the purpose of the research, the setting, and the population from which subjects will be recruited, with special consideration for vulnerable populations and/or subjects who may be vulnerable to undue influence or coercion.
- Subjects are fully informed of their rights and of the potential risks and benefits of participation in the research.
- Informed consent will be obtained from each prospective subject, as needed, and appropriately documented unless a waiver of documentation of consent is granted.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, protecting the privacy of subjects, and maintaining the confidentiality of data.

4.2.4 Continuing Review – Continuing annual review for approved protocols that qualified for exemption or expedited review is not required unless modifications to the ongoing research

significantly change the risks to subjects or the IRB has documented the need for continuing review for a specific protocol.

Protocols approved under a convened committee must undergo a continuing review at least annually. Investigators are responsible for submitting an extension request for continuing review prior to the expiration date of the protocol approval.

Regardless of the type of initial review (exempt, expedited, convened committee) or whether continuing review is needed, investigators are responsible for communicating any changes or modifications to the approved research protocol to the IRB. Submitting modification requests to an approved protocol and obtaining approval for the modification is required before the modification can be implemented except where the modification is necessary to eliminate apparent immediate hazards to subjects.

4.3 Communication between the IRB and Investigators

4.3.1 Written Communication to Investigator – Protocol forms, including consent templates, shall be provided on the IRB website.

Approvals, recommendations, restrictions, conditions, or disapprovals shall be communicated to the PI in written form. Reasons for disapproval shall be set forth in detail with IRB recommendations for modification of the proposal.

4.3.2 Written Communication from Investigator – All changes to a protocol in response to IRB recommendations must be made in writing.

4.3.3 Appeal Procedures – If an investigator believes that his/her protocol has been disapproved because of incorrect, unfair, or improper evaluation by the IRB, s/he may appeal to the IRB chairperson. Likewise, if an investigator believes requests made by an IRB member are unfair or improper, s/he may appeal to the IRB chairperson. If the IRB chairperson upholds the disapproval or the IRB request made by an individual IRB member, the investigator shall show cause in writing within 3 weeks after the negative decision as to why the IRB decision should be reversed. The appeal shall be considered by a full convened committee review.

4.3.4 Compliant Procedures – Complaints about failure to protect human subjects participating in research activities covered by this policy shall be made in writing to the IRB chairperson and to the Associate Vice President for the Office of Research.

Upon receipt of a complaint, the IRB Chairperson and one IRB member shall investigate the complaint and shall make a report with a recommended action to the full IRB and to the AVP for the Office of Research. If the report includes recommendations to modify or terminate approval for the activity, the chairperson shall convene the IRB no later than the next scheduled meeting to discuss the complaint and all other pertinent information. After reviewing all the evidence and addressing all appropriate questions, the IRB may decide to affirm the appropriateness of the activity, to request modification(s), or to terminate approval for the activity. The IRB decision shall be communicated to the complainant, the PI, and the AVP for the Office of Research in writing.

4.3.5 Reporting Procedures for Unanticipated Problems, Adverse Events or Injuries — Any unanticipated problems, adverse events or injuries to human subjects during the course of the research must be reported to the IRB via the Office of Research promptly, within no more than

one week (7 calendar days), by the principal investigator, using a form designated for this purpose that is posted on the IRB website.

An unanticipated problem is characterized as being:

- (1) Unexpected (in terms of nature, severity, or frequency) in relation to the IRB-approved research procedures described in protocol documents;
- (2) Related or possibly related to participation in research; and
- (3) Suggests that the research places subjects or others at greater risk of harm than was previously known.

An adverse event or injury is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease temporally associated with the subject's participation in the research. Adverse events encompass both physical and psychological harms.

A qualified IRB staff member shall triage such reports and any follow up information to the AVP for the Office of Research and the IRB chair. The IRB chair shall determine whether any corrective actions or substantive changes are required to the protocol with the assistance of at least one other IRB member or a sub-committee designated by the chair. The AVP for the Office of Research shall determine whether further reporting to other institutional officials or to OHRP is required.

The PI shall be notified by the Office of Research of any corrective actions or changes the IRB has determined are needed. These may include, but are not limited to: modification to selection criteria; modification to consent documents; provision of additional information to previously enrolled subjects; implementation of additional procedures for monitoring subjects; suspension of enrollment of new subjects; suspension of research procedures.

4.4 IRB Records and Reports

4.4.1 IRB Documentation – The IRB shall prepare and maintain adequate documentation of IRB activities. Records of specific human subjects research activity shall be maintained for three years after termination of the last IRB approval period for the activity. Records shall include the following:

- Current IRB membership and operating procedures.
- Copies of all human subjects research proposals reviewed, with all pertinent materials that accompany the proposals, progress reports, and any reports of unanticipated or adverse events.
- Minutes of IRB meetings in sufficient detail to show names of attendees, actions taken with the votes specified, basis for requiring changes in or disapproving human subjects research, summaries of discussions of controverted issues and their resolution. If any member has a conflicting interest regarding any research, the minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
- Reports of continuing review activities, including the rationale for conducting continuing review of research that would otherwise not require it.
- Copies of all IRB correspondence.

4.4.2 IRB Reporting – The IRB shall report promptly to OHRP these matters of information:

- Any serious or continuing noncompliance by research investigators, SJSU, or its agencies with the requirements of this policy.
- Any unanticipated problems or adverse events that meet the OHRP reporting criteria.
- Suspension or termination of IRB approval (with a statement of reasons for the IRB action), when required by OHRP.

4.4.3 Audits of Research Activities – The Office of Research and the IRB have the authority to obtain any original research records from the PI for the purposes of auditing the research activity for compliance; records that may be requested include, but are not limited to, signed consent documents and raw data.

5.0 Fundamentals of Informed Consent

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 (LAR) which is obtained without undue influence or coercion. Obtaining informed consent is a process in which an individual is given enough information about a study to make a decision about whether to participate in the research. The consent process involves discussing the details of study participation with a knowledgeable member of the research team, as well as reading and signing a consent form to document that the process has occurred. The consent process must be conducted in a way that facilitates the comprehension of prospective subjects.

5.1 Investigator Responsibilities – It is the responsibility of the research team to provide complete information about a study and to obtain meaningful informed consent from the subject or his/her LAR prior to enrolling them in the study. Guided by the federal regulations at [45 CFR 46.116](#), SJSU requires investigators to maximize the meaningfulness of the consent process by:

- Providing complete information about the study, including beginning with a focused and concise presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons one might or might not want to participate in the research. The standard elements of consent outlined in section 5.3.2 can be considered to satisfy the key information that must be communicated to subjects at the outset of the consent process.
- Facilitating comprehension by using layman’s language and text that is well-written and has been proofread.
- Using a clean and clutter free presentation in written consent documents.
- Describing and following alternatives to written consent for subjects with limited reading skills, who are illiterate, or who are members of a distinct cultural group or community for whom signing documents is not the norm.
- Conducting the consent process in the primary language of subjects and providing them with translations of written documents.
- Providing information about the limits to confidentiality, such as mandated reporting, when appropriate.

- Conducting the consent process under circumstances that offer the subject or the LAR sufficient opportunity to consider whether the subject should or should not participate, including minimizing the possibility of undue influence or coercion, and refraining from the use of exculpatory language.

Where documentation of consent is required or utilized by the research team, the PI is required to maintain such documentation for three years.

Consent is not required for access to identifiable private information from stored records or directly via oral or written communication with prospective subjects for the purposes of recruitment, screening, and determining eligibility for participation as long as there are adequate confidentiality and privacy safeguards for these preparatory-to-research activities.

5.2 SJSU-Specific Requirements

5.2.1 Exempt Research – Investigators must utilize the most appropriate consent option discussed in section 5.3 for their research. SJSU requires a consent process for research that is granted exempt status by the Office of Research. However, documentation of consent is waived for most exempt research except where the subjects are minors or where other laws or regulations require a participant’s written authorization. Table 1 summarizes the type of consent process which SJSU requires of research qualifying for exemption.

5.2.2 Parental Permission – 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 even if the research qualifies for exemption. The exception to the requirement for parental permission is for college students providing their consent for participation in school-based research, such as enrolling in a business or psychology department subject pool for extra credit. The standard elements of consent, as outlined in section 5.3.2, are 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.

5.2.3 Assent – The assent of children is required in cases where obtaining assent is appropriate, regardless of whether the protocol undergoes an administrative review for exemption or an IRB review. In determining whether a child is capable of assenting, reviewers shall take into account the age, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol or for each child, as is deemed appropriate during the review. If the reviewer determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under the same circumstances in which consent may be waived in accordance with section 5.4. The PI is required to provide an explanation in the IRB protocol of how assent will be obtained or a justification for why it would not be appropriate to obtain assent in a specific case.

5.2.4 Translations – Non-English speaking persons must be presented with a consent form and other written materials in their primary language. The investigator must provide the IRB with translations for review and approval prior to recruiting subjects. It is recommended that the investigator secure preliminary IRB approval of the English documents prior to having them translated. The IRB does not require that a certified translator perform the document translation, but the IRB does require a verification of the accuracy of the translation(s). The verification may be provided by a member of the Department of World Languages, an individual who has the equivalent of a bachelor’s degree in that language, an individual who has received an education through secondary school with that language as the language of instruction, or from a certified translator. Research team members may translate their research documents if they are fluent in the language, but they may not verify their own translations.

5.3 Types of Informed Consent

The Office of Research shall provide templates for all consent options discussed below, including consent notice, a standard consent form for adults, and a parental permission form.

5.3.1 Consent Notice – This type of document or script can be used for research that qualifies for exemption. It includes all of the information needed to help prospective adult participants make an informed decision about whether or not to participate in the research, but this document does not include a place for participants to indicate with a signature that they agree to take part in the research. This means that the reviewer is asked to waive the requirement for documented (signed) consent. This option can be used when the study is either:

- (1) No greater than minimal risk and involves no procedures for which written consent is normally expected, or
- (2) The only record linking the participants to the research would be the consent document and the primary risk would be potential harm resulting from a breach of confidentiality (e.g., an anonymous survey).

At a minimum the consent notice should include:

- (1) The investigator’s name, institutional affiliation, academic status, and contact information.
- (2) The purpose of the study.
- (3) A brief description of what subjects will be asked to do and the time involved.
- (4) That participation is voluntary and that the person may withdraw at any point.
- (5) How data will be recorded and maintained as well as who will have access.
- (6) A description of incentives/compensation offered or costs that may be incurred.

The signature line on the standard consent form is replaced with a statement such as “your completion of the survey indicates your willingness to participate. Please keep this information for your records and do not write any information that could identify you on the survey.”

The consent notice must be in the primary language of the participants.

The consent notice option may not be used with parents or legal guardians consenting for participants in their care – written consent is needed in those cases from the LAR.

5.3.2 Standard Elements of Consent – This form includes all of the required information designed to help prospective participants make an informed decision about whether or not to participate in the research. This form can also be used to seek permission from parents of minors

and other types of guardians who are LARs. The form must be in the primary language of the participants or their LARs and must include a signature line and date line for the consenting individual to sign. The form must also be signed by the primary investigator and a copy provided to the participant and/or LAR.

The standard elements of informed consent as outlined in the federal regulations at [45 CFR 46.116\(b\)](#) are:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others that may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- (9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

5.3.3 Additional Elements of Consent – The following elements of information, when appropriate, shall also be provided to each subject or their LAR:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- (3) Any additional costs to the subject that may result from participation in the research;

- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- (6) The approximate number of subjects involved in the study;
- (7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

5.3.4 Verbal Consent (Standard Consent Short Form and Script) – This method may be used in circumstances where oral presentation of consent information is necessary (e.g., participants are illiterate in their primary language or they come from an oral rather than written tradition). The standard consent form is presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a script of the information that is presented to the participant must also be provided to the IRB for approval and there must be an impartial witness to the oral presentation. The witness and the PI must sign both the script and the short form, while the participant must sign the short form only and is given a signed copy for his/her records. The short form usually contains appropriate contact information in addition to the statement that the elements of informed consent have been presented orally. The oral presentation and short form must be provided in the primary language of the participant.

5.3.5 Broad Consent –In accordance with the recommendations of the CSU IRB Working Group, SJSU chooses not to apply the broad consent option and the corresponding exemption categories at [§11.104\(d\)\(7\)](#) and [§11.104\(d\)\(8\)](#). The broad consent option enables the creation of data repositories that are primarily of interest to institutions that support biomedical research and clinical trials. Apart from potentially being a source of confusion for PIs in the social and behavioral sciences, the broad consent option raises questions about data ownership, security concerns, and burdensome tracking requirements that have yet to be addressed by regulatory guidance.

5.4 Waivers

5.4.1 Waiver of Documentation of Consent – An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- (1) The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;
or

- (3) If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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

5.4.2 Waiver of Some or All Consent Elements – The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in sections 5.3.2 and 5.3.3, provided the IRB finds and documents all of the following:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The research could not practicably be carried out without the requested waiver or alteration;
- (3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (5) Whenever appropriate, the subjects and/or LARs will be provided with additional pertinent information after participation.

Table 1. Exemption Review Categories

Exemption Category SJSU	Application to Subparts and to Consent at
<p>(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p>	<p>Pregnant women Human Fetuses and Neonates (subpart B): exemption applies.</p> <p>Prisoners (subpart C): exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p>Children (subpart D): exemption applies.</p> <p>Consent: Notice for adults except when other policies require participant written authorization (e.g., FERPA). Written parental consent required except for college students providing consent for their participation in school-based research.</p>
<p>(2) Research that only includes interactions</p>	<p>Pregnant women Human Fetuses and</p>

<p>involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:</p> <p>(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;</p> <p>(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or</p> <p>(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §ll.111(a)(7).</p>	<p>Neonates (subpart B): exemption applies.</p> <p>Prisoners (subpart C): exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p>Children (subpart D): (i) and (ii) exemption applies if PI does not participate in the activity being observed; (iii) exemption does not apply.</p> <p>Consent: Notice for adults except when other policies require participant written authorization (e.g., FERPA, HIPAA). Written parental consent required except for college students providing consent for their participation in school-based research.</p>
<p>(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:</p> <p>(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;</p> <p>(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or</p> <p>(C) The information obtained is recorded by the</p>	<p>Pregnant women Human Fetuses and Neonates (subpart B): exemption applies.</p> <p>Prisoners (subpart C): exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p>Children (subpart D): exemption does not apply.</p> <p>Consent: Notice for adults except when other policies require participant written authorization (e.g., FERPA, HIPAA).</p>

<p>investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §11.111(a)(7).</p> <p>(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no interventions that are offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.</p> <p>(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.</p>	
<p>(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:</p> <p>(i) The identifiable private information or identifiable biospecimens are publicly available;</p> <p>(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;</p>	<p>Pregnant women Human Fetuses and Neonates (subpart B): exemption applies.</p> <p>Prisoners (subpart C): exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p>Children (subpart D): exemption applies.</p> <p>Consent: Not applicable unless another policy applies (e.g., FERPA). [Note: SJSU PIs who have access to individually identifying health info are not covered by (iii) of this exemption, unless the covered entity providing the access is a collaborator in the research and there is a business associate contract between the covered entity and</p>

<p>(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA at 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or</p> <p>(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 <i>et seq</i></p>	<p>the SJSU PI].</p>
<p>(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of</p>	<p>Pregnant women Human Fetuses and Neonates (subpart B): exemption applies.</p> <p>Prisoners (subpart C): exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p>Children (subpart D): exemption applies.</p> <p>Consent: (i) of this exemption covers the SJSU notice requirement.</p>

<p>otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.</p> <p>(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.</p>	
<p>(6) Taste and food quality evaluation and consumer acceptance studies:</p> <p>(i) If wholesome foods without additives are consumed, or</p> <p>(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.</p>	<p>Pregnant women Human Fetuses and Neonates (subpart B): exemption applies.</p> <p>Prisoners (subpart C): exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p>Children (subpart D): exemption applies.</p> <p>Consent: Notice for adults. Written parental consent required except for college students providing consent for their participation in school-based research.</p>

Table 2. Expedited Review Categories

<p>(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <p>(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.)</p> <p>(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.</p>
<p>(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <p>(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the</p>

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 gumbase 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 regulations for the protection of human subjects. 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, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the regulations for the protection of human subjects. 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.

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

* Children are defined in the 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." [45 CFR 46.402\(a\)](#).