

**Policies and Procedures of the
Committee for the Protection of Human Subjects**

California State University, Sacramento

(Updated September, 2011)



SACRAMENTO
STATE

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**Policies and Procedures of the
Committee for the Protection of Human Subjects**
(Updated September, 2009)

Role of the Institutional Review Board

The Committee for the Protection of Human Subjects (CPHS) exists primarily to provide protection for human subjects who participate in research. Thus, the main focus of the committee when reviewing research protocols is on identifying the risks which may exist for participants. However, one of the ethical justifications for research involving human participants is the social value of advancing scientific knowledge and promoting human welfare. If a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put participants at risk or even to inconvenience them through participation in such a study. To this extent, the CPHS must also consider the soundness of the methodology that is proposed for a research study, so that it can determine whether “risks to subjects are reasonable in relation to . . . the importance of the knowledge that may reasonably be expected to result” [Federal Policy §46.111(a)(2)].

The University has obtained a Federalwide Assurance for the Protection of Human Subjects from the U.S. Department of Health and Human Services, by agreeing to follow the Code of Federal Regulations [see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>]. This designates the CPHS as the Institutional Review Board for our campus with the responsibility to review **all** research which involves the use of human subjects, regardless of the source of support for that research. The CPHS is required to (1) identify the risks associated with participation in a research study, (2) determine that those risks will be minimized as much as possible, (3) identify the probable benefits of the research, (4) determine that any risks are reasonable in relation to the benefits for the participants and the importance of the knowledge to be gained, (5) insure that participants will be given an accurate and fair description of any risks or discomforts and any anticipated benefits, and (6) determine how long to approve the research and the need, if any, for periodic review while the study is being conducted. The CPHS must also determine that there are adequate provisions to protect the privacy of the participants, to maintain the confidentiality of the research data, and to provide additional safeguards for any participants who are likely to be members of a vulnerable population.

Some departments have their own committees for reviewing research which involves the use of human subjects. Those committees must agree to follow the same standards as used by the CPHS and must operate under policies and procedures which have been approved by the CPHS. When those conditions have been met, the CPHS delegates to the departmental committee the authority to review and approve research in which the investigator is a Sacramento State student and which involves no risk to participants. Student research which does involve risk must be forwarded to the CPHS for review. Research in which the investigator is a member of the Sacramento State faculty, staff, or administration, or in which the investigator is not affiliated with the University but will use Sacramento State facilities or students, must always be submitted directly to the CPHS for review.

The CPHS usually approves research for a period of one year, which is the maximum allowed [Federal Policy §46.109(e)]. Investigators who need to continue their research beyond that time may request up to two one-year extensions. This request may be made in a brief letter to the committee which also confirms that there have been no changes in the targeted participants, the materials, or the procedures for the research and that participants have not had any adverse experiences thus far in the research. If there is a need to continue the research beyond a third year, a new protocol must be submitted and the committee must do a full review of the protocol.

In accordance with federal policy, some research projects may not be approved for a full year. This could occur, for example, because of the overall risk of the study or because some of the relevant information could not be provided at the time the protocol was first submitted (e.g., a fieldwork or ethnographic study where the nature of the questions to be asked is not determined until the study is underway).

The researcher is obligated to promptly inform the CPHS of any unexpected risks discovered while conducting the research and to promptly report any occurrence of serious harm to participants [Federal Policy §46.103(b)(5)]. Although the CPHS does not anticipate situations calling for the following actions, it does have the authority to observe, or to require a third party to observe, the consent process and the research itself [Federal Policy §46.109(e)] or to suspend or terminate approval of research that is not being conducted in accordance with requirements it has established or that has been associated with unexpected serious harm to participants [Federal Policy §46.113].

Research Covered by CPHS Policies

Any research or related activity that involves the use of Sacramento State time, facilities, resources, and/or students is covered by these CPHS policies. *Research* refers to a systematic investigation designed to develop or contribute to generalizable knowledge [Federal Policy §46.102(d)]. Activities sponsored by an outside agency which utilize Sacramento State resources are considered to be under the auspices of both the University and the outside agency. In this case, approval must be obtained from committees for the protection of human subjects of both Sacramento State and the outside agency.

Research or related activities involving the use of human subjects that are conducted by Sacramento State employees or students without the use of any University time, facilities, resources and/or students are not covered by these CPHS policies. Individuals conducting such research outside the auspices of the University should inform themselves of their legal responsibilities. Research conducted by students within an established Sacramento State course and in which the only participants are other students in the same course is not covered by these policies. Research in which the students in a course observe the public behavior of others but do not interact with them is also not covered by these policies. In both instances, the instructor of the course should be sure that appropriate research procedures are followed. Research in which the students in a course do interact with participants outside of the course (e.g., by conducting a survey) should be reviewed by the department's review committee.

For a “related activity” to be covered under the CPHS policies, a research component must be present. In general, if one of the goals of the investigation is an expansion of scientific knowledge, a research component is inherent in the activity, and the project should be reviewed by the CPHS.

Investigators affiliated with Sacramento State have the normal legal protections provided by the University, if their activities have CPHS approval and if they are working within the scope of their employment or University affiliation. If these conditions have not been met, the University will not be in a position to protect Sacramento State investigators performing research with human subjects.

Researchers not affiliated with Sacramento State who are planning to conduct research under the auspices of the University must submit their research for review by the committee. Such researchers must (1) provide evidence that their research has been approved by the appropriate administrative official at their parent institution (e.g., a dissertation chairperson), (2) provide evidence that their research has been approved by the appropriate human subjects committee at their parent institution, and (3) provide evidence of approval from the Sacramento State department and/or faculty where the research will be conducted.

Application Procedures

Researchers must submit eleven copies of their protocol to the Office of Research Administration, Hornet Bookstore, Suite 3400, mail code 6111, using the *Request for Review* (see Appendix A) available at www.csus.edu/research/humansubjects/ or at the Office of Research Administration. The application must include specific references to any attachments (e.g., consent forms, tests, interview questions) that are needed, and copies of those attachments must be included with each copy of the application. Do not attach lengthy grant applications, etc., as the committee is unable to review them. The relevant information from such documents should be summarized in the *Request for Review*.

Sacramento State students must submit their applications, using their department’s approved forms and procedures, to their department’s human subjects review committee. Students should consult with their faculty sponsor about the department’s procedures. If the research is found to be acceptable and to be exempt or no risk by the department’s committee, applying the same criteria as would be used by the CPHS, the research does not need to be reviewed by the CPHS. Some departments with considerable experience in reviewing student research are also permitted to approve research at minimal risk. If the department finds that the research is acceptable, but the level of risk is greater than it is authorized to approve, the student must then submit a *Request for Review* to the university committee. The protocol must be signed by the faculty sponsor and must include evidence of the department’s approval for the research as one of its attachments. If there is no department or college-level committee to review the student’s research, the student must submit a *Request for Review*, with the faculty sponsor’s signature, directly to the university committee. In either case, the research may not begin until approval has been received from the CPHS.

Collaborative research, in which students and faculty work together but a faculty member is the primary investigator, must be submitted directly to the CPHS in the same way as other faculty research.

When submitting an application to the CPHS, researchers need to take into consideration the committee's deadlines for its regularly scheduled meetings and the possibility that the committee might request additional information and/or changes in the protocol and thus need to review the protocol again at a subsequent meeting. Applications should be submitted sufficiently early for them to be approved before the desired starting date for the research and before any deadlines of funding agencies.

Questions about Research Procedures and Application Procedures

Questions about the application procedures for human subjects approval may be directed to the Office of Research Administration, (916) 278-7565, or to any member of the committee. Questions about research procedures and minimizing risks should be directed to a committee member. Applicants are encouraged to contact a committee member whose professional field most closely corresponds to that of the researcher. Any exceptions to the policies outlined in this manual must be approved by the committee.

Structure of the Committee

The committee shall consist of at least five members with varying backgrounds. Members are expected to have appropriate professional expertise, maturity, and experience to thoroughly review a variety of research activities conducted at Sacramento State. They should also be sensitive to relevant professional standards, community attitudes and diversity, applicable laws, and institutional requirements. The committee shall not consist entirely of persons who are employees of or otherwise associated with the University, apart from their membership on the committee. The committee shall not consist entirely of members of the same sex or members of one profession. The committee shall include at least one member whose primary concerns are in a nonscientific area. No member of the committee shall be involved in the initial review or any continuing review of an activity in which the member is a researcher or a sponsor, except to provide information requested by the committee. The committee may invite individuals with competence in special areas to serve as non-voting reviewers when dealing with complex issues. A quorum shall consist of a majority of the committee's membership. Members of the committee are appointed by the Provost and Vice President for Academic Affairs. Appropriate administrative assistance and support for CPHS functions are to be provided by the University through the Office of Research Administration.

Department Review Committees

Departments in which a significant number of students are engaged in human subjects research (e.g., for master's theses, class research, or special projects) are expected to have a department-level committee to review such research. The department committee must consist of

at least three faculty members and must follow established procedures which have been reviewed and approved by the CPHS. In reviewing student research, the department committee must use the same criteria and standards as used by the CPHS. Under these circumstances, the CPHS delegates to the department committee the authority to approve student research which is found to be acceptable and to be either exempt or no risk. Department committees with an established history of careful reviews may also be allowed to approve student research which is minimal risk. Research which is found to have a higher level of risk than the department is authorized to approve, and research for which the department committee's decision is not unanimous or for which a committee member so requests, must be forwarded to the CPHS for review.

Review Process for Applications

Research protocols are forwarded to members of the committee in advance of the scheduled meeting dates to allow time for each member to individually review each protocol. The protocols are then discussed at the scheduled meeting by the full committee. A quorum, defined as a majority of the committee's membership, must be present for the meeting.

Researchers need to allow sufficient time for this review process to occur, including the possibility that the committee may request additional information and/or changes in the protocol and thus need to review the protocol again at a subsequent meeting. Researchers should also understand that committee members are faculty and others at Sacramento State who have volunteered to serve in this capacity in addition to their other obligations to the university. While the committee attempts to be as responsive as possible to researchers, it may not be able to respond as quickly as researchers sometimes request.

In particular, researchers need to understand that requesting an "expedited review" has a particular meaning under federal regulations, and that this type of review (described in the next paragraph) may actually require a longer amount of time than the usual process, contrary to expectations about the word "expedited." For this reason, when an expedited review is requested, the committee will usually consider that request only for an application that has a clearly stated explanation for urgency, is submitted at a time when there is more than one month between regularly scheduled meetings of the committee, could not reasonably have been submitted in a more timely fashion, and can possibly be reviewed using the "expedited" process more quickly than if it were reviewed at the next scheduled meeting.

When an expedited review seems appropriate, the chair of the committee will forward the protocol to at least two committee members for their independent review. If those committee members and the chair agree that the research falls within the categories for which an expedited review is permitted and that it involves no more than minimal risk, and also agree that the research can be approved, or conditionally approved with only minor modifications, the chair will so inform the researcher and notify the committee at its next meeting. If the reviewers do not agree on an action, or if any of them so request, the protocol will be considered ineligible for expedited review and will be placed on the agenda for the next meeting.

Level of Risk

The CPHS uses the following definitions when reviewing protocols to determine their level of risk to participants:

1. *Exempt*: Some categories of research are considered “exempt” under federal regulations. (The research **must still be reviewed** by the CPHS, however.) Examples include research in established courses on the effectiveness of instructional techniques, observational research on adults (but not children or minors) when the observations are recorded in a way that does not allow individual participants to be identified, reviews of pre-existing records or surveys that are completely anonymous, and studies which evaluate public service or benefit programs. For more specific information, see Federal Policy §46.101(b).
2. *No Risk*: Research is approved as “no risk” when no harm or discomfort is anticipated for participants.
3. *Minimal Risk*: Research is approved at “minimal risk” when the probability and magnitude of harm or discomfort anticipated for participants are no greater than what might be encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. (Note that only “minimal risk” is defined in the federal regulations.)
4. *At Risk*: Research is approved as “at risk” when the probability and/or the magnitude of possible harm (physical, psychological, social, or economic) from participation in a research study are more than minimal.

The following descriptions provide additional information about some possible kinds of risks that may occur in research studies:

1. *Physical Harm*: An example of minor physical harm would be the pain associated with taking a blood sample from a vein. Note, however, that taking a blood sample could be a significant risk to a hemophiliac; participants should be screened for this condition if the research is to be considered minimal risk. Similarly, outdoor exercises that might be considered relatively safe for healthy adults could be dangerous for persons with asthma.
2. *Psychological Harm*: An example of psychological harm would be stress or feelings of guilt or embarrassment from thinking or talking about one’s own behavior or attitudes on sensitive topics such as drug use, sexual orientation, selfishness, or violence. These feelings may be aroused from being interviewed or from filling out a questionnaire. Another kind of risk would be invasion of privacy, for example, from covert observation (even in a public place) of behavior that participants would likely consider private. Still another risk of psychological harm occurs when there is inadequate protection for the confidentiality of data that has been given voluntarily (e.g., by retaining audiotapes or videotapes longer than is necessary to analyze the relevant information).

3. *Social and Economic Harm:* Some invasions of privacy or breaches of confidentiality could result in embarrassment or harm to a participant's reputation within his or her business or social group, a loss of employment, or criminal prosecution. Areas of particular sensitivity include such topics as alcohol or drug abuse, child or partner abuse, and sexual behavior.
4. *Inadequate Protection for the Confidentiality of Research Data:* Where identifiers of individual participants are not required by the design of the research study, none should be recorded. If identifiers are recorded, they should be separated, if possible, from the data; stored securely, with linkage restored only when necessary to conduct the research; and destroyed when they are no longer needed. More elaborate procedures may be needed in some studies, either to give participants the confidence they need to answer questions truthfully (e.g., promising to submit course grades before analyzing data from one's own students) or to enable the researcher to offer honest assurances of confidentiality. Even when participants are otherwise anonymous, there may be a danger of deducing the identity of individual participants by combining specific pieces of information collected during the research about the participants. Additional precautions may be needed to deal with these circumstances.

Online surveys also create additional challenges in protecting participants. See Appendix B for particular requirements that apply to such research.

In some studies, keeping the identity of participants confidential may be as important or more important than keeping the research data confidential. In those instances, any written record linking participants to the study may be a threat to confidentiality. Even in studies where this is not a concern, no lists should be retained identifying those who elected not to participate.

Where data are being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or orientation), protection of confidentiality consists of more than just preventing accidental disclosure of the data. There have been instances where the identities of participants, or research data about particular participants, have been sought by law enforcement agencies, sometimes by subpoena and with the threat of incarcerating an uncooperative researcher. Some investigators may need to obtain a federal certificate of confidentiality [Public Health Service Act §301(d)] to protect the privacy of their participants. The certificate protects the researcher from being compelled to provide the names or other identifying characteristics of research participants in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. (Its precedence over state law has been upheld in the New York Court of Appeals.) The certificate does not protect identifiable data that the participant may disclose about other people.

Informed Consent

Informed consent assures that prospective participants understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. It is a continuing

process, not just a piece of paper; especially in a lengthy study, it may be necessary to obtain consent on more than one occasion. It protects both the participant and the investigator, who otherwise faces legal hazards. Investigators may seek consent only under circumstances that provide prospective participants or their representatives sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the participants. If the prospective participants include persons who are unlikely to be familiar with specific technical terms, persons with limited verbal or cognitive skills, or persons whose primary language is not English, special care must be taken to ensure that both oral presentations and written consent forms are comprehensible to all participants. When participants may include members of a vulnerable population (such as children, elderly persons, prisoners, or economically or educationally disadvantaged persons), additional safeguards are needed to protect the rights and welfare of those subjects.

When children and/or adolescents are participants in a research study, the investigator must solicit both the assent of the children (see example in Appendix C-2) and the permission of their parents or guardians. (There are limited exceptions for situations in which the parents' interests may not adequately reflect the child's interests.) In certain circumstances, older adolescents may have the legal authority to give their consent even though they are not yet legally considered adults (i.e., are under the age of 18). Also, the Buckley Amendment requires parental consent for release of records or identifiable information about children in public schools, and instructional materials to be used in connection with research must be available for inspection by parents or guardians.

To minimize the possibility of coercion or undue influence, it is generally preferred that participants be recruited by open, written invitation rather than by personal solicitation. For similar reasons, it is also preferred that professors not solicit their own students as participants and that supervisors not include their own employees in research. If advertising will be used to recruit participants, the CPHS needs to review that advertising to be sure that the information will not be misleading to potential participants. Similarly, if participants are to be paid for their time, the CPHS needs to review the amount of the payment and provisions for full, partial, or no payment (for example, if a participant withdraws part way through the research) to assure that participants will not be unduly influenced by the payment.

In most cases, federal regulations require that participants sign a written consent form [Federal Policy §46.117], although the consent document is not a substitute for discussion of the relevant information with prospective participants. Participants must be given a clear and fair explanation of the research procedures, their risks and benefits, and provisions for confidentiality in the research. (See Appendix C for examples of consent forms and guidelines for constructing a consent form.) Each participant must provide informed consent prior to participation. The person who signed the consent form must be given a copy as a reference and reminder of the information conveyed.

A “short form” may sometimes be approved for the consent [Federal Policy §46.117(b)(2)]. This means that the information is presented orally to prospective participants without a written version of it in the consent document. The CPHS must review and approve a written summary of what will be presented orally. The participant must sign the short consent form (stating that the information has been provided orally), and a third person must witness the oral presentation and must sign both the short consent form and a copy of the written summary of the oral presentation. The investigator obtaining the consent must also sign the written summary. A copy of the written summary must be provided to the participants even though they are not asked to sign the written summary.

A waiver of written consent or using an alternate method to document consent may only be considered if (1) the research involves no more than minimal risk, (2) the waiver or alteration will not adversely affect the rights and welfare of the participants, (3) the research could not reasonably be carried out without the waiver or alteration, and (4) whenever appropriate, participants are provided with additional pertinent information in a debriefing after their participation [Federal Policy §46.116(d)]. Furthermore, especially in studies which involve the collection of sensitive information (e.g., sexual or criminal activity), a request to waive written consent may be considered only if (1) the only record linking the participant to the research would be the consent document and the main risk in the research would be the potential harm from a breach of confidentiality (in this case, participants must be asked whether they want documentation of their consent, and they may elect to sign a consent form or not), or (2) the research is no more than minimal risk and involves no procedures for which written consent would normally be required outside of the research context [Federal Policy §46.117(c)]. The CPHS may still require that a written statement of pertinent information be provided to participants who do not sign a consent form.

It may be appropriate to waive written consent (but not informed consent) for fieldwork studies where the nature of the continuing interactions with the researcher is not easily reduced to a consent form. For some observational studies of people who are not aware that they are being observed or who are unaware that their behavior is being recorded for research purposes, it may be appropriate to completely waive the consent requirement if the knowledge to be gained is important, but such research can also raise serious ethical concerns about protecting the privacy of the unwitting participants. Similarly, it may be appropriate to waive the consent requirement for studies of pre-existing records if the information contained in the files is not particularly sensitive, the investigator has devised procedures to protect the confidentiality of the information to be collected, and the study could not practicably be carried out if consent were required.

Sometimes investigators plan to withhold information about the real purpose of the research, or even to give participants false information about some aspect of the research. This means that the participant’s consent may not be fully informed. The degree to which this is acceptable depends on whether the information to be withheld would influence the decision of prospective subjects about participating in the research. When subjects have unwittingly participated in research or have knowingly participated in research that involved some form of deception, they should be debriefed afterward with pertinent information about the study whenever this can be

done in a way that reduces rather than produces pain, stress, or anxiety.

Although institutions are not required to provide care or payment for research injuries, the CPHS generally expects investigators to provide a way for participants to obtain at no cost any services necessitated by research injuries. This information needs to be provided in the consent form. In any case, the consent process must not involve the use of any exculpatory language through which the participant is made to waive or to appear to waive any of his or her legal rights, or releases or appears to release the investigator, sponsor, institution, or their agents from liability for negligence [Federal Policy §46.116].

Actions of the Committee

When reviewing a research protocol, the committee may decide to approve the research, to conditionally approve the research with a request for minor modifications, to request that the protocol be resubmitted with additional information and/or more substantive modifications, or to disapprove the research (in general, disapproval would only occur if the committee finds significant risks in the research that cannot be minimized, or when recommendations from the committee for minimizing such risks have been declined by the investigator). The chair may communicate these initial decisions by e-mail to the researcher, particularly when the committee has requested modifications to the research. A letter indicating approval of the research will be sent when the protocol is fully approved. The chair is authorized to act on behalf of the committee to either approve the minor modifications submitted in response to a conditional approval or refer the revised protocol to the committee for its review.

When making these decisions, the committee also makes its judgment of the level of risk in the proposed research. Protocols may be classified as exempt or approved as involving no risk, minimal risk, or more than minimal risk. Risks must be considered reasonable for the research, appropriate procedures must be used to minimize any risks, and the potential benefits of the research must outweigh the potential risks.

Requests for Reconsideration

If an applicant believes that a decision of the committee or changes requested by the committee are incorrect, unfair, or improper, the applicant may submit a request for reconsideration to the committee. The request should be made in writing to the chair of the committee and should include the reasons for disagreement with the committee's action. The request for reconsideration will be considered by the full committee, and the applicant will be invited to attend the meeting of the committee.

Unanticipated Risks

Any unanticipated problems involving risk to participants or others must be immediately reported to the committee. The report should clearly identify the protocol number assigned by the committee to the research and the original date of approval. It should describe the number of

individuals affected, the type of adverse reaction, how this adverse reaction was or may be related to the research procedures, and any other relevant information about the individuals affected.

Requests for Modification

Any significant changes to a previously approved protocol must be submitted to the committee as a request for modification of the protocol. Examples of significant changes include a different or additional principal investigator, an intention to recruit participants from a different source, changes in the consent form, changes in any materials or equipment used in the project, changes in the research procedures, or the discovery of previously unidentified risks in the research. A letter describing the proposed changes, and clearly outlining the reasons for those changes and any benefits or risks of those changes, should be addressed to the chair of the committee. The letter should begin with a brief summary of the nature of the research, and it should clearly identify the protocol number assigned by the committee and the original date of approval. The committee will respond with a letter indicating its approval of the proposed changes or, if it is unable to approve the changes, its request for additional information or for alternative changes.

Requests for Extension (Now called Continuing Review)

If the research will extend past the expiration date of CPHS approval for the study, the investigator will need to ask for a renewal. A letter requesting this extension should be addressed to the chair of the committee. The letter should clearly identify the protocol number assigned by the committee and the original date of approval. It should include a brief summary of the nature of the research project and the work accomplished to date. Do not attach lengthy progress reports on the research, as the committee is unable to review them. The letter should say that there have been no changes in any materials, equipment, or procedures for the research, if that is the case, or describe any changes which have been made. It should also report whether there have been any adverse reactions among participants so far. When the committee has approved an extension for the research, a letter will be sent confirming that approval.

When requesting such an extension (continuing review), the researcher needs to take into consideration the committee's deadlines for its regularly scheduled meetings. Requests for extension (continuing review) must be submitted sufficiently early for them to be approved before the expiration date of the prior approval and before any deadlines of funding agencies. The committee is unable to send a reminder notice to the researcher about this obligation.

Records and Reporting Requirements

Researchers are required to obtain and keep, for a period of three years after the conclusion of the research, documentary evidence of informed consent from the participants.

Departmental committees are required to provide a summary of their current policies and procedures to the CPHS and to resubmit those documents when there are any substantive

changes. Departmental committees are also required to provide an annual summary of their actions and to make available, upon request, the protocols they have reviewed, so that the CPHS can determine whether its policies are being followed at the department level.

The CPHS is required to maintain documents related to each of its activities, including applications (and attachments) received, requests for modification or extension of approval, reports of adverse reactions, correspondence with investigators, minutes of meetings (with details of committee deliberations), and a list of CPHS members. These records must be maintained for at least three years after the conclusion of the research. Records related to specific research activities are not open to persons who are not members of the committee, other than for auditing functions by federal agencies engaged in the protection of human subjects.

Protocol Number 09-10-____
(Assigned by Office of Research)

Appendix A
**Request for Review by the Sacramento State
Committee for the Protection of Human Subjects** (Revised 09/2009)

Submit 11 copies of this form and any attachments to the Office of Research Administration,
Hornet Bookstore, Suite 3400, mail code 6111. Please **type** your responses or use a word processor.
Handwritten forms will be returned without review.

Project Title: _____

Funding Agency (if any): _____

Name(s) and affiliation(s) of Researchers: _____

Mailing address (or Department and campus mail code): _____

Telephone and e-mail address for researcher

Anticipated starting date

Name of faculty sponsor (for student research)

E-mail address of sponsor

1. Who will participate in this research as subjects (e.g., how many people, from what source, using what criteria for inclusion or exclusion)? How will you recruit their participation (e.g., what inducements, if any, will be offered)? How will you avoid any conflict of interest as a researcher?

2. How will informed consent be obtained from the subjects? Attach a copy of the consent form you will use. If a signed written consent will not be obtained, explain what you will do instead and why. (See Appendix C in *Policies and Procedures* for examples of consent forms, an example of an assent form for children, and a list of consent form requirements. Also see the section on *Informed Consent* in *Policies and Procedures*.)

3. How will the subjects' rights to privacy and safety be protected? (See the section on *Level of Risk* in *Policies and Procedures*. For online surveys, also answer the checklist questions at the end of Appendix B in *Policies and Procedures*.)
4. Summarize the study's purpose, design, and procedures. (Do not attach lengthy grant proposals, etc.)
5. Describe the content of any tests, questionnaires, interviews, etc. in the research. Attach copies of the questions. What risk of discomfort or harm, if any, is involved in their use?
6. Describe any physical procedures in the research. What risk of discomfort or harm, if any, is involved in their use? (The committee will seek review and recommendation from a qualified on-campus medical professional for any medical procedures.)
7. Describe any equipment or instruments and any drugs or pharmaceuticals that will be used in the research. What risk of discomfort or harm, if any, is involved in their use? (The committee will seek review and recommendation from a qualified on-campus medical professional for the use of any drugs or pharmaceuticals.)
8. Taking all aspects of this research into consideration, do you consider the study to be "exempt," "no risk," "minimal risk," or "at risk?" Explain why. (See the section on *Level of Risk* in *Policies and Procedures*.)

For protocols approved as “at risk”, the researcher is required to file a quarterly report with the committee that describes the recruiting of subjects, progress on the research, interactions with the sponsor, and any adverse occurrences or changes in approved procedures. In addition, the committee reserves the right to monitor “at risk” research as it deems appropriate.

Signature of Researcher

Date

Signature of Faculty Sponsor
(for student research)

Date

Signature of your department or division chair confirms that he or she has had an opportunity to see your human subjects application.

Signature of Department/Division Chair

Date

Questions about the application procedures for human subjects approval may be directed to the Office of Research Administration, (916) 278-7565, or to any member of the committee. Questions about how to minimize risks should be directed to a committee member. Applicants are encouraged to contact a committee member whose professional field most closely corresponds to that of the researcher. See www.csus.edu/research/humansubjects/ for a list of committee members and the current year’s due dates for submitting an application.

*To assure prompt review of your application,
ALL researchers should complete this checklist:*

- Have you written an appropriate answer for each question on the application form? (Please do not attach research proposals, grant applications, etc. as the committee cannot read such documents.)
- Have you answered all of the questions on the application form? (Please enter "N/A" if a particular question does not apply to your research.)
- Have you provided an e-mail address and a phone number where you can be reached on the application?
- Have you (and all co-researchers) signed the application form? Has your department or division chair also signed the application form?
- Have you included your consent form with your application? Does that consent form identify you as the researcher and your department?
- Does your consent form clearly describe what participants will be asked to do in your research? Does it clearly describe any direct benefit they will receive as a result of their participation? Does it clearly describe any risks they will be exposed to during their participation, and what you will do to minimize those risks?
- Have you included with your application any screening forms that will be used to determine the eligibility of participants for your research?
- Have you described in your application any potential conflict of interest between your role as a researcher and any other relationship you may have with the participants or with an organization that is a source of your participants? This could occur if some or all of the participants are your students, employees, co-workers, friends, etc. Have you also described how you will avoid any such conflict of interest?
- Have you included with your application all tests, questionnaires, surveys, interview questions, focus group questions, etc. that will be used in your research?
- Have you checked the grammar and spelling throughout all of your documents?
- Have you prepared 11 copies of your complete application packet, including all attachments, for the committee? Does one of those copies have original signatures?
- Have retained an electronic copy of your application that can be edited and resubmitted with any changes requested by the committee? (This will be forwarded to your Dean.)

STUDENT researchers must also complete this checklist:

- Have you met with your faculty advisor before preparing your application? Has your faculty advisor thoroughly reviewed all of your materials before you submitted your application?
- Have you provided an e-mail address and a phone number where you can be reached on the application? Did you also include your home address on the application?
- Have you included the name of your faculty advisor and that person’s e-mail address on your application?
- Has your application been signed by you, any co-researchers, and your faculty advisor? Did you submit an original copy of your application with all of those signatures?
- Does your department have an approved Human Subjects committee that reviews student research projects? (As of July 2009, the approved departments are Child Development; Communication Studies; Criminal Justice; Economics; Educational Leadership & Policy Studies; Kinesiology & Health Science; Nursing; Psychology; Public Policy & Administration; Social Work; Sociology; Special Education, Rehabilitation & School Psychology; and Teacher Education.) If your research is in one of these departments, it must be reviewed and approved by that department’s committee first. Has your department’s committee completed the following form?

DEPARTMENT HUMAN SUBJECTS COMMITTEE APPROVAL

Project Title: _____

Student Researcher: _____

Faculty Sponsor: _____

The _____ Department’s human subjects committee has reviewed and approved this application. It requires review by the CPHS because the research is considered (*circle one*) Minimal Risk or At Risk.

Name of department’s human subjects chairperson

E-mail address of chairperson

Signature of department committee’s chairperson

Date

Appendix B Requirements for Online Surveys

As methods of computer- and internet-based research with human participants become more widely used, they present expanded opportunities for conducting surveys while also creating new challenges in complying with requirements for the protection of research participants. The CPHS believes that computer- and internet-based research protocols must address the same risks (e.g., psychological stress, feelings of guilt or embarrassment, invasion of privacy, inadequate protection of confidentiality) and provide the same level of protection as the more traditional non-electronic methods of research involving human participants. All studies, including those using computer and internet technologies, must:

- ensure that the procedures meet the principles of voluntary participation and informed consent
- maintain confidentiality of the information obtained from or about human participants
- adequately address the possible risks to participants, including psychological, social, and economic risks

The purpose of these guidelines is to help researchers develop computer- and internet-based research protocols that provide protection for human participants comparable to more traditional research methodologies, and to explain the additional information that researchers must provide when they submit applications that involve online surveys to the CPHS.

Recruitment

As with any other research study, the recruitment materials for online research and the context in which the recruitment takes place (including electronic methods such as posting a message on a newsgroup or creating a website to recruit participants) must be reviewed and approved by the CPHS.

Investigators should be aware that authentication (establishing the qualifications and/or identification) of respondents is a major challenge in computer- and internet-based research, and one that threatens the integrity of research samples and the validity of research results. If the respondent population is not the population that was originally targeted by the researcher, the resulting data may not reflect what the researcher intended to assess. Investigators are advised to take steps to authenticate their respondents. For example, investigators can provide each participant (in person or by U.S. mail) with a Personal Identification Number (PIN) to be used for authentication in subsequent computer- and internet-based data collection.

Online Data Collection and Storage

The CPHS requires that any data collected from human participants over computer networks

be transmitted in an encrypted format. This helps to ensure that any data intercepted during transmission cannot be decoded and that individual responses cannot be traced back to an individual respondent. The highest level of data encryption should be used, within the limits of availability and feasibility. Researchers are cautioned that encryption standards vary from country to country, and that there are legal restrictions regarding the export of certain encryption software outside U.S. borders.

If a server is used for data storage, any personal identifying information should be kept separate from the data, and the data should be stored in an encrypted format.

Informed Consent

1. Internet consent documents should be written like a cover letter and should include all of the elements of a regular signed consent, including the confidentiality disclaimer given below. The consent line should say, “By completing this survey, you are agreeing to participate in the research”. Internet-based surveys should include “I agree” and “I do not agree” buttons on the website for participants to click their choice of whether or not they consent to participate.
2. The following statement must be included in the consent form: “Your responses will be kept confidential to the degree permitted by the technology used. However, no absolute guarantees can be given for the confidentiality of electronic data.”
3. The consent form must disclose that if a participant completes an anonymous survey and submits it, the researcher will be unable to remove anonymous data from the database should the participant wish to withdraw it.
4. Depending on the level of risk in the research, the CPHS may not be able to waive the usual requirement for obtaining a signed written consent from participants. In that case, the researcher will need to distribute a printed consent form and acquire a signature before the participant is given information about how to access the online survey.

Survey Software Checklist

The following checklist specifies the protections which the CPHS expects any online survey software to have. The answer for each question should be “Yes”. An answer of “No” to any of questions 1-4 or 6 would disqualify the survey software from being approved. Researchers should contact their survey software company to determine whether the software meets these criteria. The application submitted to the CPHS must include the researcher’s answers for these questions and the supporting evidence from the company.

1. Informed consent

- Does the software provide the researcher with a record that captures the participant's consent before starting the survey?
- Is that record logged with a time and date stamp (e.g., "respondent #12 consented at 21:27:13 on 05-Jun-2008")?

2. Secure transmission

Information can be sent to and from websites either in clear text (*http* protocol) that could be read if intercepted by a third party, or in encrypted format (*https* protocol) that could not be read by a third party intercepting the information.

- Does the survey software use *https* encryption?
- Does the software prevent a respondent from accidentally entering survey data via the *http* protocol instead of the *https* protocol (i.e., does the server display an error message or automatically re-route the respondent to an *https* page)?

3. Database security

- Is access to the research database limited to authorized persons by means of a username and password?
- Has the software company that maintains the research database signed a confidentiality agreement that prevents it from improperly accessing or disclosing the information contained in research databases?

4. Server security

- Are the servers that contain the research data located in a data center that has physical security and environmental controls?

5. Backups

- Is the data backed up nightly?
- Is there a limited time period in which a deleted dataset can still be retrieved but after which the data will be permanently destroyed? (The investigator should inquire how long this time period is.)

6. IP addresses

- Is the respondent's IP address masked from the researcher?

Appendix C
Constructing a Consent Form

Federal regulations require that the following information be provided to prospective participants when obtaining consent [Federal Policy §46.116(a)]:

- (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 which 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 which 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 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 compensation and 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 about the rights of research subjects, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, the following additional information must also be provided to subjects [Federal Policy §46.116(b)]:

- (1) A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be discontinued by the investigator without the subject'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 which might affect the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

Several examples of consent forms, for studies with different levels of risk, and one example of an assent form for children, are shown on the following pages. These are adapted from protocols which have been reviewed by the committee, and they are meant to provide specific information about the kind of content and language that should appear in a consent form or an assent form. Thus, they are not templates, and researchers will need to look at all five examples and adapt the guidelines reflected in these examples to the investigator's particular research situation. Italicized headings at the beginning of a paragraph are merely reminders of the major topic in that paragraph; such headings do not necessarily need to be included in a consent form. Please keep in mind that the consent form must provide the information a subject would need to weigh the risks and benefits of participating in the research, and that the benefits to the individual participant may be different from the overall benefits of conducting the research study.

Appendix C-1 shows a consent form for a study which is considered "no risk," because the risks inherent in the research are effectively eliminated by the confidentiality protections built into the research procedures. Appendix C-2 shows an assent form suitable for asking children to participate in the same research; note that it is much shorter and the language is much simpler than the corresponding consent form for adults. Appendix C-3 shows a consent form for research which is considered "minimal risk" because the confidentiality provisions, while appropriate and good, cannot completely eliminate all of the risks in the research. Appendix C-4 shows a consent form for research in which the magnitude of risk is substantially higher, although the probability of risk is still quite small and made even smaller by health screening procedures that would disqualify some potential participants. Taking all of these factors about the physical risks into consideration, this study is considered "minimal risk." Appendix C-5 shows a consent form for research in which the probability as well as the magnitude of risk is higher than usual. Although the study uses the best protections available for its psychological risks, it is considered an "at risk" project. See the earlier sections of this manual on *Level of Risk* and *Informed Consent*.

If a waiver of written consent or an alternate method of documenting consent is requested in a protocol, the investigator must still clearly indicate how the research will be explained to each subject, how the consent of the participants will be obtained, and who will validate the act of consent. In some instances the committee can waive the requirement of a signed written consent form, but only rarely can it waive the process of obtaining informed consent, and only if the participants are not placed at any risk by doing so.

Appendix C-1
Example of a “No Risk” Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by Dr. _____ in the Biological Sciences Department at California State University, Sacramento. The purpose of the study is to investigate the naturally-occurring frequencies of certain human DNA identity markers. This information is important because of its implications for the accuracy of human identity testing.

(research procedures) You will be given a sterile Q-tip and asked to gently swab the inside of your cheek to collect a small sample of cheek cells. Your Q-tip will then be placed in a plastic bag for safe and sterile transport to a laboratory where the DNA will be extracted and analyzed.

(risks) This procedure is completely safe and is not associated with any known health risks.

(Benefits) You may not personally benefit from participating in this research. However, DNA studies like this have led to clearer evidence of guilt or innocence in criminal cases, more accurate resolution of paternity conflicts, and increased ability to identify victims of war and natural or man-made disasters.

(confidentiality) Your cheek sample will be labeled in a way that it cannot be traced back to you by the technicians handling your sample. Your participation in this study will also be kept confidential. However, the results of the study as a whole may be shared with the scientific community and become a matter of public record. Once your profile for the DNA markers we are studying has been obtained, your cheek sample will be destroyed. Furthermore, no other genetic testing will be done on your sample. Any sample remaining in the laboratory two years after you provided it will also be destroyed, regardless of whether the sample has been successfully tested.

(compensation) You will receive \$2 for providing your DNA sample.

(contact information) If you have any questions about this research, you may contact Dr. _____ at (916) 278-xxxx or by e-mail at xxxxxxx@csus.edu.

You may decline to be a participant in this study without any consequences. Your signature below indicates that you have read this page and agree to participate in the research.

Signature of Participant

Date

Appendix C-2
Example of an Assent Form for a Child
(compare to the consent form for an adult on the previous page)

Agreement to Participate in Research

_____ at Sacramento State is asking you to participate in a research project on how to use the DNA from cells in our bodies to distinguish one person from another. This research is important because it may help, for example, when it is necessary to identify the people in a crime scene investigation.

You will be given a Q-tip and asked to gently wipe it inside your mouth against your cheek. Your Q-tip will then be placed in a plastic bag and sent to a laboratory for testing. The results from the testing, and your participation in this research, will be kept private.

Your parents have already been asked whether it is OK with them for you to be in this research, but if you decide not to participate, no one will be upset with you. Please write your name and today's date on the line below if you are willing to be in the research.

Signature of Participant

Date

Appendix C-3
Example of a “Minimal Risk” Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by _____, a student in Psychology at California State University, Sacramento. The study will investigate factors related to academic success among college students.

(research procedures) You will be asked to complete several questionnaires about your academic abilities, your personal traits and values, and your relationships with other students, family, and friends. The questionnaires may require up to an hour of your time. If you agree to be contacted, you may also be asked later to participate in a focus group discussion with about five other students on these topics. The focus group discussion could also last up to one hour.

(risks) Some of the items in the questionnaires may seem personal, but you don’t have to answer any question if you don’t want to. Some of the topics in the focus group discussion may also seem personal, but you may participate as much or as little in the discussion as you wish.

(benefits) You may gain additional insight into factors that affect success in college, or you may not personally benefit from participating in this research. It is hoped that the results of the study will be beneficial for programs designed to encourage students to remain in college.

(confidentiality) You were asked to print a copy of your academic record from My Sac State and bring it with you today. To preserve the confidentiality of that information, you will be asked to use a black marker to remove any information that would personally identify you, such as your name, address, and social security number. Your responses on the questionnaires will be anonymous. Only first names will be used in the focus groups, and you may use something other than your real name if you wish. With the permission of everyone in the group, the focus group discussion will be audio taped. Those tapes will be destroyed as soon as the discussions have been transcribed, and in any event no later than one year after they were made. Until that time, they will be stored in a secure location. Only group results for the project will be reported.

(compensation) You will not receive any compensation for participating in this study.

(contact information) If you have any questions about this research, you may contact _____ at (916) xxx-xxxx or by e-mail at xxxxxxx@csus.edu.

Your participation in this research is entirely voluntary. Your signature below indicates that you have read this page and agree to participate in the research.

Signature of Participant

Date

Appendix C-4
Example of a “Minimal Risk” Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by _____ and _____, who are graduate students in Kinesiology at California State University, Sacramento. The purpose of the study is to investigate the effects of three strategies for pacing yourself (perceived exertion, heart rate, or power output) on performance in exercise tests.

(research procedures) After completing a health history questionnaire to assess your risk factors for cardiovascular disease, you will be asked to perform exercise tests on an electronically braked bicycle and muscular strength tests using a weight machine. For some of these tests, you will wear a heart rate monitor and/or a nose clip and headgear to measure your oxygen consumption. The tests will be conducted on five separate days in the exercise physiology laboratory at Sacramento State and will require up to 30 minutes each day.

(risks) Exercise stress testing involves a risk of possible injury or even heart attack, but these risks are considered very small. The risk for heart attack is estimated to be less than 0.04% for people who are suspected to have cardiovascular disease, and substantially less than that for people who are in good health, have few or no risk factors for cardiovascular disease, and have no symptoms of cardiovascular disease. It is essential for you to provide accurate information on the health history questionnaire to be sure that you fall in this low risk category. Muscular strength testing involves a risk of muscle strain. You will experience increased blood pressure, rapid breathing, increased heart rate, sweating, muscular discomfort, and fatigue during the testing procedures for this study. It is also possible that you will experience an alteration in heart rhythm. There is no risk associated with wearing a nose clip and headgear to measure your oxygen consumption, and no risk is anticipated for wearing a heart monitor. All equipment is tested regularly for safety. If you experience any chest pain, tightness, or other abnormal discomfort during the testing procedures, you should notify the researcher immediately. All of the researchers are trained in emergency procedures if the need should arise.

(benefits) The exercise tests may provide you with information about your current state of health and physical fitness. The information may also be helpful in developing or altering an exercise program to enhance your physical fitness.

(confidentiality) All results obtained in this study will be confidential. Your individual performance will not be reported, only the results of all participants as a group. Information you provide on the consent form and the health history questionnaire will be stored separately from data for the exercise tests; the exercise test data will contain no personal information about you.

(compensation) You will not receive any compensation for participating in this research. In the event of an emergency, initial medical treatment would be available at the Sacramento State

Student Health Center. However, if you were to require any other medical care as a result of participating in this research, you would need to contact your personal physician at your own expense.

(contact information) If you have any questions about this research, you may contact _____ at (916) xxx-xxxx or send e-mail to xxxxxxx@csus.edu, or call _____ at (916) xxx-xxxx or send e-mail to xxxxxxx@csus.edu.

Your participation in this research is entirely voluntary. You are free to decide not to participate, or to decide at a later time to stop participating. The researcher may also end your participation at any time. By signing below, you are saying that you understand the risks involved in this research and agree to participate in it.

Signature of Participant

Date

Signature of Witness

Date

Appendix C-5
Example of an “At Risk” Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by Dr. _____ in the Student Health Center at University of California, Davis, and Dr. _____ in the Student Health Center at California State University, Sacramento. The study is about ecstasy and its relationship with behaviors that transmit HIV, the virus that causes AIDS, and psychological outcomes. The study will involve approximately 300 participants.

(research procedures) You will be interviewed and asked written questions about your mental health, sexual behaviors, and drug and alcohol use. The interview may last up to 4 hours but will usually last from 2 ½ to 3 hours. You will be asked to provide three hairs from your scalp; these will be tested for drugs and will be destroyed during the testing. You will be asked to take two computer-based and two paper-and-pencil cognitive tests.

(risks) Some of the questions could make you feel uncomfortable or upset because you may become more aware of your risks from the use of drugs, including your risk of infection with HIV, or because of the highly personal nature of other questions you may be asked. You are free, however, to decline to answer any questions you do not wish to answer or to stop the discussion at any time. If you experience any psychological discomfort during the study, and want help at that time or any time after completing the research, you may call Psychological Services at the Sacramento State Student Health Center at (916) 278-6416. There could also be momentary discomfort when three hairs are removed for the hair sample.

(benefits) The interview could increase your awareness of HIV risk behaviors and other risks of drug use. However, you may not benefit personally from this research. The information you provide may help health professionals to better understand how the use of ecstasy and other drugs affects people’s other behaviors and psychological states.

(confidentiality) A federal certificate of confidentiality has been obtained to protect against research records being subpoenaed by courts of law. Additionally, participants will be identified only by a randomly assigned ID number in any data collected for this research. All research records, including these consent forms, will be stored in a locked file cabinet in a locked office. No individuals will be identified in any reports or publications that may result from this study, and no academic institutions will be identified in any such reports or publications.

(compensation) To compensate you for your time in the interview, you will be paid at the rate of \$10 per hour immediately following the interview. If you are physically or psychologically injured as a direct result of the research procedures, you will receive medical treatment at no cost. The University of California does not provide any other form of compensation for injury. Psychological treatment will be available through Psychological Services at the Sacramento State

Student Health Center at (916) 278-6416.

(contact information) If you have any questions about this research, please ask now. If you have questions at a later time, you may contact Dr. _____ at (916) xxx-xxxx or by e-mail at xxxxxxx@ucdavis.edu.

Your participation in this research is entirely voluntary. You may decide not to participate in this study without any consequences. You may also change your mind and stop participating in the research at any later time without any consequences, or the investigator may decide to discontinue your participation in the study at any time. Your signature below indicates that you have read and understood this consent form and agree to participate in the research.

Signature of Participant

Date

Signature of Investigator

Date