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* * * Exempt Application * * *

There are six categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). Select from the following applicable categories to determine if your research is exempt from expedited or full committee review. If your research qualifies under one or more of the exempt categories, proceed with the following application. If not, complete expedited or full review application.

NOTE: The exemption categories below do not apply to research involving prisoners, subjects vulnerable to coercion, persons considered to be legally incompetent, and certain types of research with children as noted below. Additionally, categories 1 thru 5 do not apply to research regulated by the Food and Drug Administration (FDA).

Select one or more of the following paragraphs:

1. EDUCATIONAL PRACTICES: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content of the assessment of educators who provide instruction. This includes most:

   i) Research on regular and special education instructional strategies; OR

   ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR (INCLUDING VISUAL OR AUDITORY RECORDING): Research involving these procedures is exempt, IF one of the following is correct:

   i) Any information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR

   ii) Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; OR

   iii) Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be identified, directly or through identifiers linked to the subjects, AND an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7) and the research is not subject to 45 CFR 46 Subpart D.

   *This exemption does not apply to children except for research involving observation of public behavior when the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior".

3. RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS in conjunction with the collection of information from adult subjects through verbal or written response (including data entry) or audiovisualrecording, if the subject prospective agrees to the intervention and information collection,is exempt, IF

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

   ii) Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at

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risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; OR

iii) Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be identified, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7)

X 4. EXISTING DATA: Secondary Research involving collection or study of existing data, documents, records, or biospecimens, for which consent is not required is exempt, IF:

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

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

iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subpart 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 1.512(b); OR

iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 298(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. 5521, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501et seq.

5. RESEARCH AND DEMONSTRATION PROJECTS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF DEPARTMENT OR AGENCY HEADS: This research is exempt IF it is designed to study, evaluate, or otherwise examine:

i) Public benefit or service programs;

ii) Procedures for obtaining benefits or services under those programs; OR

iii) Possible changes in or alternatives to those programs, OR

iv) 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 of consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 115A of the Social Security Act, as amended.

NOTE: Each Federal department or agency conducting or supporting 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.

6. TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES: This research is exempt, IF:

i) Wholesome foods without additives are consumed; OR

ii) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR

iii) A food is consumed that contains an agricultural chemical or environmental contaminant at or below the level

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found to be safe by the FDA or approved by the EPA or the FSIS of the USDA

7. STORAGE OR MAINTENANCE OF INFORMATION FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED: The protocol is eligible for exemption if:

i) It involves storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use; AND

ii) All the identifiable information or identifiable biospecimens that are to be stored and/or maintained for secondary research have been or will be collected for another "primary" purpose; AND

iii) Broad consent for the storage or maintenance of their identifiable information or identifiable biospecimens for secondary research use will be obtained from ALL subjects; AND

iv) The protocol does not include any activities that do not qualify for exemption; AND

v) The protocol is not for an FDA regulated clinical investigation; AND

vi) The IRB conducts a Limited IRB Review and makes the determinations required by 45 CFR 46.111(a)(8)

8. SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use is eligible for exemption, if the following criteria are met:

i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); AND

ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; AND

iii) An IRB conducts a Limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; AND

iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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* * * Purpose,Study Procedures, Collaborative Research and Background * * *

Title

Biomedical Exempt example

Complete Sections 1 - 10. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose of the study

a) Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

xx

2. Background

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a) Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations (with attached bibliography) if applicable.

xx

3. Collaborative Research

a) If any non-SCU institutions or individuals are engaged in the research, explain here.

xxx

b) If any non-SCU institutions or individuals are collaborating in the research, attach any relevant IRB approvals in the Attachments section

4. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., interventions/interactions with subjects, data collection, photographing, audio- and/or videotaping), including follow-up procedures.

xxx

b) Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

xxx

c) State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

xxx

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* * * Subject Population (a-c) * * *

5. Subject Population

a) Describe proposed subject population, including criteria for study inclusion and exclusion (e.g., age, health status, language). If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for the restrictions.

xx

b) State total number of subjects planned for the study and how many must be recruited to obtain this sample size. Explain how number of subjects needed to answer the research question was determined.

xx

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c) Indicate whether any proposed subjects are children/minors, prisoners, pregnant women,those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence. State rationale for their involvement.

xx

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* * * Risks/Discomforts * * *

6. Risks/Discomforts

a) Describe all known risks, discomforts associated with study procedures, whether physical, psychological, or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting probability and magnitude of potential harm.

xx

b) In case of overseas research, describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research (e.g., differences with U.S. culture).

xx

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* * * Confidentiality * * *

7. Confidentiality

NOTE: A copy of <a href=http://it.scu.edu/policies/homepage.shtml target=_blank> SCU Data Security Policy is available at http://it.scu.edu/policies/homepage.shtml

a) Explain how subject privacy will be protected and how confidentiality of subject information will be maintained. Discuss who will have access to study records/specimen and how the records will be secured.

xx

b) Will subjects be asked to give permission for release of identifiable data (e.g., information, videotapes), now or in future? If so, explain here and include appropriate statements in consent materials.

xx

c) Will data be collected anonymously (i.e., no identifying information from subjects will be collected/ recorded that can be linked to the study data)? (NOTE: Data is not anonymous if there is a code linking it to personally identifiable information. Also, audio and video

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recordings are generally not considered to be anonymous.)

xx

d) If using existing data/biological specimen, will the researchers have access to a code linking the data to personally identifiable information?

xx

e) If identifying information will be collected and linked to data/specimen, explain at what stage identifiers will be removed from the data/specimen. If identifiers will be retained, explain why this is necessary and how confidentiality will be protected.

x

f) If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.

xx

g) Indicate whether research data/specimen will be destroyed at the end of the study. If data will not be destroyed, explain why, where, in what format, how long it will be retained and who will have access to it.

xx

h) Explain how data collection instruments, audiotapes, videotapes, photographs, etc. will be stored and who will have access to them. Indicate at what point they will be transcribed and/or destroyed (if ever).

xx

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* * * Potential Financial Conflict of Interest * * *

8. Potential Conflict of Interest

Please answer the following questions a through e:

a)	N	Do any of the involved Investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), providers(s), of goods or subcontractor(s)?
b)	N	Do any Investigators or their immediate family have any financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?
c)	N	Is any Investigator(s) a member of an advisory board with the Sponsoring company?
d)	N	Do any investigators receive gift funds from the Sponsoring company?
e)	N	Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding,

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cooperative research, or by providing study drugs or equipment.

If you answer Yes to any of the questions above, you must file a Conflict of Interest disclosure statement.

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* * * Attachments * * *

9. Attachments

Add appropriate attachments (e.g.,appropriate informed consent to include California experimental subjects Bill of Rights, HIPAA, questionnaires, surveys, advertisements, reference list, investigator's brochure, etc.) in this section.

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* * * Assurance * * *

Assurance

Obligations of the Principal Investigator are:

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes;

Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded;

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days;

Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review;

Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

The Principal Investigator has read and agrees to abide by the above obligations.

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