Checklist for Research Proposal

Project Director or Investigator(s): _____

If student, please provide faculty mentor: _____

Today's date: _____ Department: _____

Project or Grant Title: _____

Project end date (start date will be the date the project is approved by the IRB): Where will the research be done? _____ _____

Project Type (check the one that applies)

- ❑ Faculty research
- ❑ Student research (under faculty direction)
- ❑ Student class project (under faculty direction)
- ❑ Federal grant application
- ❑ Non-federal grant application
- ❑ Thesis or dissertation

If class project, list semester, class/course no. and faculty member _____

If federal or non-federal grant application, list source: _____

Instructions: Please check all applicable items in Parts A-D, and attach a complete research proposal that addresses the items outlined in Parts E and F. Research activities will only be considered for exemption from further review when all items in Part A and at least one item in Part C apply. Otherwise, the proposal will be submitted under expedited review.

Part A:

- ❑ The research does not involve children under 18 years of age, individuals with intellectual disabilities, prisoners, economically disadvantaged persons, elderly, or individuals with physical disabilities. (Exception: research with subjects under the age of 18 may still be subject to exempt review if they are participating in projects that fall under categories 1, 3, 4, 5, and/or 6 in Part C. Studies under Part C-2 that include minors should be submitted for expedited review.)
- ❑ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or damaging to financial standing, employment, or reputation.

- ❑ The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (i.e., drug or alcohol use, illegal conduct, sexual behavior).
- ❑ The procedures of this research present no more than minimal risk to the subject (where minimal risk means that the probability of harm or discomfort anticipated in the proposed research are no more than ordinarily encountered in daily life or physical/psychological tests and examinations). Participants will be fully informed about the benefits and risks associated with the project or study.
- ❑ Data sources that are clearly identified (such as interviews, surveys, existing project data, services received, grades, existing school records, focus groups, etc.)
- ❑ Participation in this project or study is voluntary and informed consent or assent, in the case of minors, will be obtained.
- ❑ The research will protect all participants' privacy and personal information.
- ❑ Research that involves deception (NOTE: deception must be scientifically justified and debriefing procedures must be outlined in detail.)

Part B: (Check all that apply in each group from which you will be collecting data for your project.)

- ❑ College Students — Expected number of participants _____
- ❑ SVU-affiliated Faculty or Staff — Expected number of participants _____
- ❑ General Public, online survey — Expected number of participants _____
- ❑ Children under 18 — Expected number of participants _____
- ❑ Other — Expected number of participants _____

Anticipated total number of participants _____

Part C: (Check all of the following that apply to your project or study and attach an explanation at the end of this section as to why your proposed research falls into the indicated category).

- ❑ 1.) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- ❑ (2.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- ❑ (3.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii)

federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- ❑ (4.) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- ❑ (5.) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or levels or payment for benefits or services under those programs.
- ❑ (6.) Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed or b) if a good 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 Inspective Service of the U.S. Department of Agriculture.

Explanation:

Part D:

Please indicate which categories (if any) your research falls into, and please provide an explanation as to how your research falls into any of the checked categories:

- ❑ Clinical studies of drugs and medical devices
- ❑ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- ❑ Prospective collection of biological specimens for research purposes by noninvasive means
- ❑ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- ❑ None of the above

Part E: Please provide the information that is requested below. A separate document/research proposal may be attached.

1. Briefly describe (a) the project or study and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used, design and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests, or other instruments are to be used, include a brief description and one copy of the instruments.

2. What will you do with the results of your study? (i.e.: contributing to generalizable knowledge, publishing, sharing at conference, etc.)?
3. Specify who the project participants or research subjects will be. How many participants do you plan to recruit? Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which individuals will be subjected.
4. Please indicate any inclusion or exclusion criteria for participants:
5. Specify the steps that will be taken to insure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.
6. Describe how, when, and where individuals will be first contacted about their interest in participating in the study (i.e.: face-to-face, email, flyers, advertisements, phone call, internet site, etc.)
7. Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape, and audio materials.
8. Describe how, when, and where the informed consent process will take place and who will obtain informed consent. If the participants are not able to give legal consent, explain how assent will be secured. Please provide a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to the participant.
9. a) Describe any potential risks to participating individuals—physical, psychological, social, legal, or other; b) include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and c) in research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.
10. (a) Describe the benefits and/or any compensation that the participating individuals can expect and (b) describe the gains in knowledge that may result from the project or research study.
11. If deception is to be employed, provide a scientific justification for its use and describe the debriefing procedures. (NOTE: if the research is such that a debriefing cannot be carried out, the project must be submitted for full committee review.)
12. Does the funding source have any potential for financial or professional benefit from the outcome for this study or project? If yes, please explain. If not applicable, write N/A.

Part F:

Please attach all that apply to your proposal. (Check the ones you've included with proposal)

- ❑ Informed Consent Form(s): first page(s) on letterhead
- ❑ External support proposal or award letter
- ❑ Letters of approval from cooperating entities
- ❑ Research methods (research design, data source, sampling strategy, etc)
- ❑ Questionnaires, surveys, or other data-gathering forms
- ❑ Letters, flyers, questionnaires, etc., that will be distributed to the study subjects

- ❑ Copy of thesis/dissertation, approved proposal, or prospectus
- ❑ If the research is part of a research proposal submitted for federal, state, or external funding, submit a copy of the FULL proposal

Notes: 1) The information should be in sufficient detail to allow the IRB to determine if the study can be classified as EXEMPT under Federal Regulations 45 CFR 46.101(b). 2) Be sure to send electronic attachments, applications, and materials to irb@svu.edu

In submitting this application, I certify that: (check when completed)

- ❑ I have successfully completed the IRB Required Tutorial.
- ❑ I have read and understand the protocol and method of obtaining informed consent, as outlined by SVU's policies, and will follow them during the period covered by this research projects.
- ❑ I intend to comply with the letter and spirit of SVU IRB Policies.
- ❑ I agree to comply with federal, state, and local laws regarding the protection of human participants in research.
- ❑ I will submit any future changes to the research project to the IRB for review and approval prior to implementation, as these may alter the exempt status of the project.
- ❑ I agree that any new findings that develop during the course of this study that may affect the risks and benefits to participants will be promptly reported to the IRB in writing.
- ❑ I agree that any adverse events that occur in the course of this study will be promptly reported to the IRB in writing.
- ❑ I agree and understand that records of the participants will be kept for at lease three (3) years after the completion of this research.
- ❑ I may begin research when the IRB gives notice of its approval.

Signature: _____ Date:_____