Southern Virginia University IRB Procedures for Approval of Human Subjects Research

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List of Abbreviations

FDA – Food and Drug Administration
EPA – Environmental Protection Agency
IRB – Institutional Review Board
MRI – Magnetic Resonance Imaging
OHRP – Office for Human Research Protections
PI – Principal Investigator
SVU – Southern Virginia University

I. Introduction

Southern Virginia University (SVU) recognizes the importance of protecting the right, welfare and privacy of any persons who may choose to participate in human subjects' research. SVU also appreciates that potential research participants should be made aware/reminded of their rights, welfare and privacy, and the protections available to them as research participants, prior to deciding whether or not to participate in research. The United States Federal government requires that safeguards for research participants be provided and enforced for any research activities funded by federal grants. The necessary safeguards are a product of ethical principles that govern all research conducted at SVU. These ethical principals were first outlined in the Belmont Report, which was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The ethical principles are:

Respect for persons

Beneficence

Justice

Respect for Persons: this principle recognizes the dignity and autonomy of all people. Further, there are some populations with diminished autonomy or vulnerability to undue influence/coercion. These populations include children (anyone under the age of 18 unless they are legally emancipated), prisoners, individuals with mental or cognitive difficulties, fetuses, and any individual who is economically or educationally disadvantaged. To help ensure that this principle is met, the SVU Institutional Review Board (IRB) requires that all potential research participants engage in research activities willingly, after receiving information about the research activities from the Principal Investigator (PI).

Beneficence: this principle requires PIs to minimize harm and maximize benefit to research participants. Any potential risk to research participants, be it occupational, psychological, emotional, social, or academic, should be weighed against possible benefits of the research, both to the participants, and in terms of improvement of knowledge. Please note that payment of research participants is not considered a benefit that contributes to beneficence. The SVU IRB requires that risk:benefit analyses be included in all research protocols, and to the extent possible, risk:benefit analyses should be shared with potential research participants prior to initiation of any research activities.

Justice: this principle requires that the burden of participating in research be distributed equitably across all groups who may benefit from the research findings. In determining who to invite to participate in research, PIs should ensure that no groups are consistently invited to participate in research, and that no groups are consistently omitted from participating from research, if the research findings have potential implications for the omitted group(s). To ensure justice, the SVU IRB requires that all PIs explain why certain groups are or are not included in all research protocols applications.

The SVU IRB must review and approve all research conducted at SVU, or research that is conducted by faculty, staff, students or any other individuals affiliated with SVU. The funding status of the project is irrelevant (funded, not funded) – the IRB is required to review and approve all research activities prior to initiation of any research activities. The SVU IRB will also review and approve any research conducted by outside persons or groups, if that research involves SVU students, personnel, facilities, or data collected at SVU. As defined by Federal guidelines, "research" includes "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d). Research studies to be reviewed by the SVU IRB prior to initiation of any research activity include: pilot studies, class projects if the results of the project involve collection of data and the intent is to present the findings to an audience outside of SVU, independent research by faculty, staff or students with a faculty mentor, Honors theses. Any research conducted by SVU personnel must be reviewed regardless of whether the research takes place on campus or elsewhere (off campus, online, etc.).

All procedures described throughout this document are consistent with regulations published by the US Department of Health and Human Services (45 CFR 46, as amended and published in the Federal Register on June 18, 1991 and any subsequent amendments). The author of this document also consulted the IRB guidance documents at several other small liberal arts institutions (Alleghany College, Amherst College, Eureka College, Bryn Mawr College), which are based on the same federal standards, as well as the website of the US Health and Human Services Office for Human Research Protections (OHRP). The OHRP website is recognized as the definitive source for answering any questions related to human-subjects research.

II. Composition of Institutional Review Board

Per applicable federal guidelines, members of the IRB must come from 3 categories: 1) a member from the community with no affiliation with SVU; 2) a non-scientist; and 3) members qualified to discuss the research under consideration. Though the minimum number of individuals necessary to form an IRB is not specified, to ensure that all federal guidelines are met, and to ensure adequate breadth of scientific expertise, the SVU IRB will consist of at least the following:

<u>Voting Members of the SVU IRB</u>

- One member from the community not affiliated in any way with SVU
- One member from the SVU Psychology or Family and Child Development programs
- One member from the SVU Education or Business programs
- One non-science faculty or staff member from SVU
- One student

The SVU Provost will nominate 1 SVU-affiliated individual to serve as Chair of the IRB. The members of the IRB will elect an IRB secretary, who will keep minutes of all IRB minutes, and assist the Chair in coordinating interactions with PIs in a timely fashion.

The Chair of the SVU IRB will serve for a term of 3 years. All other members of the IRB will serve non-overlapping 3 year terms, beginning August 1st of relevant years. Serving multiple back-to-back annual terms is highly encouraged. Whenever possible, at least 3 of the IRB members (including the Chair when appropriate) in a new year should have served the previous year. This recommendation will not be enforced during the first year of the SVU IRB's operations.

IRB Operation

In addition to voting members of the IRB, members of the IRB may ask for an outside consultant to assist in evaluation of a research protocol, should the members of the IRB feel that their expertise is inadequate to fully understand a submitted research protocol. Such consultants would be invited to attend a meeting of the IRB, though they would not vote on any research protocols during the meeting.

Alternatively, PIs may meet with members of the IRB in advance of an IRB meeting to discuss research protocols that have been submitted, or that are in preparation. The purpose of such meetings is to provide information or answer questions about the research project. These meetings may be requested by any member of the IRB, or the PI. Such a meeting should negate the need for an outside consultant to participate in the protocol review process.

Members of the IRB will recuse themselves from deliberations on any protocol in which they have an actual or potential conflict of interest (e.g., they are the PI, a co-PI, they have a financial interest in some aspect of the research or the outcome of the research). This action will be noted in the minutes.

For a meeting of the IRB to occur, and for the results to be binding, the following conditions must be met:

1. The Chair, or someone designated by the Chair to be Acting Chair, must be in attendance.
2. At least one non-scientist member of the IRB must be in attendance
3. A majority of the voting members (>50%) of the IRB must be in attendance.

If the above conditions are met, that quorum of the IRB will conduct business. All decisions will be deemed binding based on a simple majority of the voting members present. The IRB Secretary will record in the minutes all votes pertaining to research protocols in the following format: "Total Votes", number of votes "For;", number of votes "Opposed;", number of votes "Abstained." In the event that there are an equal number of votes "For" and "Opposed", the research protocol will be considered to be opposed by the IRB.

III. The Review Process

Any PI who is planning to conduct research involving human participants are responsible for seeking and receiving IRB approval prior to initiating any research activities. To be considered for IRB approval, a PI must complete all questions in the IRB Google doc protocol, and attach all

necessary files to the Google document. See Section X and the Appendices for examples of the questions to be answered and the forms to be attached. All documents must be submitted using Google documents. PIs should not send files to individual members of the IRB, except in response to emailed requests from IRB members.

Depending on the risks to participants in the study, and when the next scheduled IRB meeting is, review of submitted protocols may take up to a month. During that time, should questions arise, a member of the IRB assigned to review the protocol will reach out to the PI. Prior to submitting any protocol, any individuals listed in the protocol who will be interacting with research participants must complete training.

Training Requirements. Per Federal guidelines, all individuals who will be interacting with research participants must complete a training program that covers ethics and best practices in research involving human participants. Once training is completed, each individual must certify to the IRB that they have completed the training. The training can be completed in several ways. First, the IRB chair can meet with individuals or groups to provide the training in person. Second, individuals can review a Power Point presentation provided on the SVU IRB website. Once an individual has reviewed the Power Point presentation, send an email to the IRB Chair. Training must be completed every 2 years.

Initial Review of Research Proposals. All SVU-affiliated individuals should complete the online IRB submission form (as a Google document). Any students conducting research T SVU should submit their proposals to the faculty advisors. Faculty are responsible for the content of any student protocols submitted to the IRB if they are listed as a faculty mentor to the student. Any nonSVU-affiliated individuals who wish to conduct research at SVU should discuss their proposal with the SVU provost prior to submitting a SVU research proposal.

Once a complete protocol is submitted, the IRB Chair, or the full IRB will review the protocol for the degree of risk to human subjects, if any. Risk is broadly defined here to include any sort of harm or injury in any life domain (social, financial, emotional, academic, etc.). The categories of risk include “minimal”, or “greater than minimal.” Minimal risk is well defined by Federal regulations (Code of Federal Regulations: 45 CFR 46): A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical psychological examinations or tests. Greater than minimal risk would place research participants at risk for harm, whether it be social, physical, or psychological, or in any other domain of life. The IRB protocol forms are designed to assist both the PIs and the IRB in determining the level of risk to potential research participants. Once the IRB Chair has completed an initial assessment of risk, the protocol will be assigned to 1 of 3 categories of review (listed below). PIs are required to include their own assessment of risk, though the IRB Chair will have final say as to the level of risk for participants in a research study.

Categories of IRB Review:
The Chair of the IRB, after reviewing submitted protocols, will assign each protocol to a review category. There are 3 possible review categories:

(A) Exempt – no foreseeable risk to human subjects
(B) Expedited review – no more than minimal risk to human subjects
(C) Full IRB Review – greater than minimal risk to human subjects.

(A) Protocols involving no foreseeable risk will be considered exempt. Please note that exempt does not mean the protocol is exempt from IRB review and approval. Rather, exempt indicates that the protocol is exempt from further review following review and approval by the IRB Chair or their designee. Once an exempt protocol has been approved by a single reviewer (either the IRB Chair or their designee), research activities, as outlined in the approved proposal, may be initiated.
(B) If it is determined that the protocol involves minimal risk, an expedited review procedure will be followed. In this instance, the protocol will be reviewed by at least one other member of the IRB, designated by the IRB Chair. Depending on the complexity of the research, or the potential risk, additional reviewers may be used for expedited review.
(C) For any proposals involving greater than minimal risk, protocols will receive a full IRB review at the next scheduled IRB meeting. Full IRB review involves review by a minimum of 3 members of the IRB.

There are 4 possible outcomes following expedited or full review:

1. Approved – Any protocol that is approved may be initiated by the PI. Approvals are valid for 12 months. If the protocol will last beyond 12 months, the PI must notify the IRB Chair of the following:
    a. Status of the research project (including current research activities, total participants recruited, total participants completing the study, reason(s) for participants not completing the study, if known and applicable)
    b. Any changes to be made to the protocol
    c. Report on any adverse events, including those previously reported to the IRB. See Section VIII.

If a research study continues past 3 full years (36 months), the PI must reapply for approval of a new protocol.

2. Conditional Approval – A protocol that is conditionally approved requires minimal changes by the PI, who must then communicate those changes to the IRB Chair. If the IRB Chair is satisfied that the changes satisfy the concerns raised by the reviewer(s), the IRB Chair may approve the protocol without reconvening the full IRB. However, if the IRB Chair is not convinced that the changes made by the PI satisfy the reviewer(s) concerns, the IRB Chair may defer any further decisions about a protocol until the next full meeting of the IRB. Research activities may begin only after the protocol has been approved by the IRB Chair.

3. Deferred – Deferred protocols require substantial revision, and must be resubmitted to the IRB to be considered for approval. The revised protocol must provide the requested information and/or documentation. The revised protocol will be reviewed by the IRB at

the next regularly scheduled meeting. No research activities may take place while a protocol is in deferred status.

4. Denied – Due to the level of risk to participants, the IRB may deny a research protocol. Protocols may only be denied a meeting of the full IRB, with a majority of members present voting to deny the protocol being sufficient to deny the protocol. The IRB Chair or Secretary will provide the PI with a written explanation of the reasons for the denial. Investigators may not conduct any research activities that are included in a denied protocol. A PI may request that the IRB reconsider their decision at the next regularly scheduled IRB meeting.

At minimum, any approved protocol must be renewed annually, as noted above. For protocols involving greater than minimal risk, the IRB may require shorter periods of review (e.g., 3 or 6 months).

All decisions made by reviewers or the full IRB will be communicated to the PI(s) via SVU email. If the protocol is approved, the email will include the dates for which the protocol is valid. If the IRB reviewers are requesting revisions, the nature of the revisions will be outlined in a point-by-point fashion. Emails regarding denied protocols will include reasons for this decision. PIs may appeal any decision made by the IRB (see Section IV).

IV. Appeals

Should a PI dispute any decision made by the IRB (e.g., a denial, or request for substantial revisions), the PI may request, via email to the IRB Chair, that the IRB reconsider its decision during the next regularly scheduled meeting. The PI may provide written documents in support of their arguments, and/or the PI may appear before the IRB during the next meeting to discuss the protocol with the members of the IRB.
Following reconsideration by the IRB, if the PI remains unsatisfied with the decision of the IRB, the PI may appeal the decision of the IRB to the SVU Provost. While the SVU Provost can not overturn the decision of the IRB, the Provost may choose to mediate further discussion between the PI and the IRB. Once any mediation has occurred, the decision of the IRB is final. There are no further appeals possible.

V. Records Retention

Per Federal guidelines, copies of all research records must be kept by the IRB Chair for a minimum of 12 years following completion of the research. Records to be retained include, but are not limited to research proposals, informed consent documents, progress reports submitted by PIs, reports of any adverse events, all correspondence concerning the use of human participants in research, and minutes of IRB meetings.

VI. Timetable

The IRB will meet monthly during the academic year (August – April), as dictated by the volume of proposals to be received. The first meeting of the IRB will be in late August of each year (e.g., the week before classes start), so that any PIs wishing to start a protocol at the start of the fall semester may have the opportunity to seek approval of a protocol prior to the first day of classes. At the August meeting each year, the IRB Chair will present a calendar of once-a-month meetings to the members of the IRB for their review and approval. Once the IRB has approved the calendar, the IRB calendar will be forwarded to all SVU faculty and staff.

Protocols that qualify as exempt may be submitted at any time. PIs should expect to receive a decision from the IRB chair on exempt protocols within 2-3 business days.

Protocols that qualify as expedited may be submitted at any time. If the next regularly scheduled IRB meeting is within the next 2- 5 days, the protocol will be reviewed at the next IRB meeting. Otherwise (including expedited protocols submitted within 48 hours of a scheduled IRB meeting, the protocol will be reviewed during the next 3-5 business days. PIs should expect to receive a decision from the IRB Chair within 5-6 business days.

Protocols needing full review will be reviewed at the next regularly scheduled IRB meeting. Given the nature of these meetings, full review protocols must be submitted at least 5 business days prior to the IRB meeting at which they will be reviewed. Any full review protocols received less than 5 business days before the next regularly scheduled IRB meeting will be reviewed at the following IRB meeting (approximately 1 month later). PIs should expect to receive a decision from the IRB Chair within 48 hours of the IRB meeting.

PIs are responsible for working with the IRB Chair, or any member of the IRB, to determine the level of review their protocols will require. Members of the IRB may be used in an advisory capacity if there are questions regarding the review process or categories of review. Questions regarding protocol submission should be sent to the IRB Chair. Any protocols that receive conditional approval will be dealt with on an individual basis. The IRB Chair may approve changes if they feel that the revisions are adequate to address any concerns addressed by the reviewers. The IRB Chair may also defer any decisions to the next regularly scheduled IRB meeting if there are unresolved concerns about risk, or potential risk to human research participants.

VII. Changes to Approved Protocols

Only IRB approved research methods may be used as part of an approved protocol. PIs are required to submit any requested changes to the IRB prior to implementing the changes, including adequate time for the IRB to review the requested changes. Any changes in research methodology, procedures for collecting data, or research focus must be submitted to the IRB, along with appropriate supporting documentation as applicable. For example, if an unforeseen risk to participants becomes apparent during the research, the PI is responsible for updating the Informed Consent in a timely fashion, and submitting the updated documents to the IRB for

review. Caveat: A PI may unilaterally change approved research procedures only when such changes mitigate an immediate hazard to human research participants. Such unilateral changes must be reported to the IRB within 24 hours using an "Adverse Event" form.

Any changes in the subject pool, that were not anticipated and included in the approved protocol, must be submitted to the IRB for review prior to any changes in recruitment or study population. Any anticipated changes of this nature should be included in the original protocol submission, along with an assurance that a standardized recruitment technique will be used for all study participants, regardless of population.

All changes to a previously approved study, including changes to the protocol and/or the consent form, must be added to a new, written document with an updated version date. For a given research project, there may only be 1 active protocol, with any associated documents (e.g., informed consent).

Minor changes to a protocol may be approved by the IRB Chair or another member of the IRB if designated by the IRB Chair. Minor changes are those changes that (a) do not result in a significant increase in risk to the participants, or (b) do not change significantly the composition of the subject pool.

Unanticipated Problems. The PI will notify the IRB Chair immediately in writing of any occurrence of any adverse events or unanticipated problems, as such problems relate to the risk to human participants. This written communication will include a description of the changes that PI made, and proposes making, in response to the problem. Depending on the nature of the problem, and the nature of the changes outlined by the PI, the IRB Chair may suspend the research protocol pending full review of the changes by the full IRB. If a protocol is suspended, no further research activities may take place unless and until the suspension is lifted.

VIII. Concluding and Continuing Projects

Study Close Out: Once the data collection phase of a project is complete, the PI should notify the IRB Chair in writing using the XXX form. Once the form has been approved by the IRB Chair, no further research activities, other than data analysis (and associated manuscript preparation or presentation preparation) may take place. Should the PI wish to recruit additional participants, a new protocol will need to be submitted and approved prior to recruiting any additional participants.
Until the XXX form is submitted, the protocol will be considered active, and PIs will be expected to file an annual Study Continuation form.

Should a PI leave SVU for any reason (retirement, other employment), all protocols must be closed out prior to leaving SVU, or transferred to other PIs. This requirement also includes protocols for which the PI was serving as a faculty mentor for a student, as only faculty and staff may serve as PIs. In the event that the PI is unable or unwilling to close out all of their

active protocols, the IRB Chair will administratively close all of the PIs active protocols. This action only applies to PIs who have left SVU.

Review of Continuing Projects: All active protocols are required to complete an annual Study Continuation form. This form is due one year from the date the study was approved, or 1 year from the date the last study continuation form was approved. If a study continuation form is not approved by the IRB Chair prior to 12 months elapsing from the time a study was approved, the protocol will be suspended until the Continuation form has been approved. Please allow the IRB at least 14 days to review a Continuation form. If there is a possibility that the risk to participants may increase, then the completed Continuation form and accompanying documents must be submitted at least 1 month prior to the expiration of the previously approved protocol.

Each continuation form must include (a) a status report on the progress of the research; (b) the number of participants recruited, number of participants signing informed consent, and the number of participants completing the study; (c) any adverse events or unanticipated problems; (d) amendments or modifications to the previously approved protocol; (e) a copy of the current informed consent document, if applicable; (f) a summary of any new literature on the research topic that is relevant to the risk:benefit assessment, potential risks to research participants, and the choice of research methodology.

Exempt Review Studies – Protocols that were determined to be exempt are not required to submit continuation forms. However, Study Close Out forms should be completed for these studies upon completion of data collection, as noted above. The IRB Chair may follow up with PIs on Exempt protocols to confirm that the studies are ongoing. Should a PI wish to make any changes to a previously approved Exempt protocol, a Study Continuation form may be used to do so. No changes may be implemented until the IRB Chair or their designee has approved the changes.

Expedited Review Studies – The IRB Chair may re-approve Expedited Review protocols, provided that there are no changes in the level of risk that would increase the risk to participants beyond minimal risk (as defined above). Should the IRB Chair feel that the level of risk has changed, the IRB Chair may defer the re-approval until it can be reviewed by the full IRB at the next regularly scheduled meeting. Study Close Out forms are approved by the IRB Chair.

Full IRB Review: Review of ongoing Full review studies will occur at the next regularly scheduled IRB meeting. The IRB Chair must receive all relevant documents to distribute to the members of the IRB not less than 7 days in advance of the meeting when the review is to take place.

IX. IRB Communications

A. IRB Communication with the SVU Campus

The IRB Chair will send an email to all division chairpersons during August of each year. The purpose of this email will be to ask the chairpersons to assist the IRB Chair in estimating the

number of human participant research projects that may be started by faculty within their division during that academic year. This email and the ensuing discussions will serve as reminders of the IRB review process for all research involving human participants (with exceptions noted above).

All IRB meeting times will be noted on the SVU calendar. IRB meetings are not public meetings.

IRB requirements will be introduced to new faculty and staff each year as part of their onboarding experience.

IRB information will be included on the SVU website.

B. IRB Communication with Principal Investigators
The IRB will send the PI an email communicating its findings and actions taken on each submitted protocol. Approved protocols are approved for 1 year, unless a shorter term is specified in the email to the PI due to an unusual degree of risk. PIs are expected to print and retain a copy of all correspondence with the IRB, including all materials submitted to the IRB (any files pertaining to the submitted protocol).

The IRB will contact each PI during the 11th month of an approved protocol to verify the status of each protocol, and to allow the PI time to submit the appropriate forms for the following year (close out, renewal of an approved protocol, etc).

C. IRB Communications with SVU Administration
The Chair of the IRB, or a member of the IRB appointed by the Chair, will send the Provost an annual report on IRB activity. This report will include, at a minimum, the number of protocols submitted in each category, and a summary of the IRBs decisions for each category of protocol (i.e., number of protocols approved, denied, etc).

The Chair of the IRB, or a member of the IRB appointed by the Chair, will immediately report the following the SVU Provost: 1. Any unanticipated problems involving risks to human subjects; 2. Any serious non-compliance by a SVU-affiliated Principal Investigator or student, or 3. Any suspension or termination of an approved IRB protocol prior to the anticipated expiration date of the protocol.

X. Proposal Components

All research proposals to be submitted to the SVU IRB must include the following:

- A clear and concise statement of the research hypothesis/hypotheses, written in terms that are understandable to non-scientist members of the IRB
- The purpose of the project

- A full description of all procedures, including debriefing procedures as appropriate. Copies of any materials to be provided to research participants during the study (e.g., questionnaires, surveys, or other research material) must be provided to the SVU IRB before the protocol will be considered for approval. Links to online content may be used in lieu of paper copies if research subjects will also view the materials online.
- A description of the population participants will be recruited from, including sex and racial composition. Justification for inclusion or exclusion of any sub-population must be provided (e.g., if males are being excluded, why; if only married students are being included in a research study, why?).
- A complete description of how participants will be recruited, along with any accompanying materials, including copies of all recruitment materials that potential participants may see (e.g., flyers to be posted on campus, posts to be made on a social medial platform or Amazon's mTURK, etc.). If subjects are being offered any sort of reward for participating (e.g., extra credit, gift cards, money), this should be outlines in the recruitment section of the protocol. The SVU IRB will have final say on whether an offered reward is coercive. It is anticipated that for many research studies conducted by SVU-affiliated faculty and students, the research population will be SVU students, who may be offered extra credit. If only a subset of SVU students will be recruited for a particular study (e.g., athletes only, or only female students), justification for including/excluding other sub-populations must be provided.
- A discussion of any and all risks to participants, and how any such risks will be minimized. Any protocols that do not minimize potential risk to participants may only do so for scientific evaluation of those specific risks, and such protocols will require full IRB review.
- Forms indicating the PIs opinion of exempt, expedited or full review (copies shown in the accompanying Appendices).

XI. Research Conducted at Other Institutions

Any research activities, being conducted by SVU-affiliated personnel in whole or in part at other institutions, must also be approved by the IRB of the other institutions (e.g., if collaborating with colleagues from another university, the other university's IRB must also approve the protocol). The SVU IRB will require proof that the other IRB has approved, or is ready to approve an equivalent protocol. Upon request from any member of the IRB, PIs are asked to provide contact information for the relevant IRBs.
In cases where research is being conducted with community partners who do not have an IRB, signed letters of support from appropriate staff/administrators at the community partner should be included with the originally submitted IRB protocol.

XII. Criteria for Review Categories

The criteria used to determine review category are outlined below. Please note – should you have any questions about the likely review category of a study to be proposed, please reach out to any member of the SVU IRB.

A. Exempt Review

Research that occurs with a pre-existing classroom setting, including labs and supplemental instruction sessions, are completely exempt from the IRB review process, if and only when certain criteria are met. For a classroom-based research project to be exempt from IRB review, all items in Part A (below) must be met. Part A determines risk to participants. At least 1 item from Part B must also be met. Part B examines research methodology.

For research not taking place in a classroom setting, to qualify for exempt status, items 1-7 in Part A, and at least 1 item from Part B must apply. Any proposed research that does not meet this standard will be subject to expedited or full IRB review, depending on the nature of the research.

Part A – all must apply in full

1. The research does not involve the use of prisoners, fetuses, pregnant women, the seriously ill, or any individuals with mental or cognitive impairments.
2. The research does not involve any individuals under the age of 18.
3. The research does not involve deception.
4. All research procedures are free of foreseeable risk to the subject.
5. Additionally, the research does not involve the collection or recording of any behavior, which, outside of the research setting, could reasonably place participants at risk of criminal or civil liability, or could damage a participant's financial standing, employability, insurability, or reputation.
6. The research does not involve the collection of information regarding sensitive aspects of participant's behavior (e.g., drug/alcohol use, illegal conduct, sexual behavior, violations of the Honor Code).
7. The research does not require a waiver from informed consent procedures.
8. The research is not collecting any data outside of normal pedagogical practice for the course (only applies to research related to the scholarship of teaching and learning).

Part B – at least 1 must apply

1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular or special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, oral histories, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., data are collected in such a way that no direct or indirect identifiers link collected data to a specific participant).
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (see point 2).
4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (ii)

procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives, or foods with contain additives at or below levels 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 of the U.S. Department of Agriculture.
6. Research involving web-based surveys, and the collected data are anonymous.

B. Expedited Review

For a research project to be eligible for expedited review, all items in Part A, AND at least one item in Part B MUST apply:

Part A – all items must apply

1. The research does not involve as participants prisoners, fetuses, pregnant women, the seriously ill, or individuals who are cognitively or mentally compromised.
2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the participants at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.
3. The research does not involve the collection of information regarding sensitive aspects of the participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of this research present no more than minimal risk to the subject ("Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance or routing physical or psychological examinations or tests.

Part B – at least 1 item must apply

1. Research involving existing identifiable data, documents, records, or biologic specimens (including pathologic or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes. [NOTE: These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or-video-recordings, names will be recorded, even if they are not directly associated with the data).]
2. Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves; b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input or significant amounts of energy into the subject or an invasion of the participant's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally

occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

3. Collection of data from voice, video, digital or image recordings made for research purposes where identification of the participants and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, or reputation.
4. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing surveys, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies).
5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation or public behavior. [NOTE: Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or-video recordings, names will be recorded, even if they are not directly associated with the data).]
6. Research that involves mild deception. [NOTE: Deception must be scientifically justified and de-briefing procedures must be outlined in detail. Based upon the judgement of the reviewers, some protocols involving deception may qualify for expedited review. If other cases, the deception will be of sufficient consequence to require full IRB review. See description of Full IRB Review in Part C, below]
7. Prospective collection for research purposes of biologic specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.
8. Research previously approved by the convened SVU IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related activities; and (iii) the research remains active only for long-term follow-up with participants; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; or (d) where no new participants have been enrolled and no additional risks have been identified.

C. Full IRB Review

Full IRB review is required if ANY of the following apply to the proposed research:

1. The research involves prisoners, fetuses, pregnant women, the seriously ill, or individuals with mental or cognitive impairments as participants.
2. The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the participants at risk of criminal or civil liability,

be stigmatizing, or be damaging to the participants' financial standing, employability, insurability, or reputation.

3. The research involves the collection of information regarding sensitive aspects of the participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve more than minimal risk to the participants. The risk may be actual or perceived. "More than minimal risk" means that the probability and magnitude of physical or psychological harm or discomfort likely to be experienced in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.
6. The research involves deception, an the nature of the deception is considered of sufficient consequence to require consideration by the full IRB. (Deception of lesser consequence may be eligible for expedited review – see Section XIV).

XIII. Components of Informed Consent

Participants must have sufficient information to make and informed deception to participate in the research study. If subjects cannot give informed consent, it must be obtained from their legal representative(s). For example, when participants are minor (under 18), or when they are mentally incapacitated, the consent of a legal representative is required. Whenever possible the SVU IRB supports having individuals who cannot provide consent provide assent (equivalent to consent, but provided by individuals who are unable to provide consent, due to age or cognitive impairment).

SVU Principal Investigators are required to use the standard SVU Consent Form (See Appendix A). This consent form requires PIs to provide a description of the research in everyday language (language that can be understood by a high school graduate). This description must include the following, unless the purpose is being withheld as part of scientifically justified deception:

- A statement that this is a research project
- The purpose of the research, or if deception is involved (See Section XIV), a statement to the effect that "We cannot explain all of the details of the experiment at this time, but they will be explained fully at the conclusion of the experiment."
- The expected duration of the participant's involvement in the research
- The anticipated number of participants participating in the study
- A description of the research procedures that provides enough information for potential participants to understand what they are volunteering to perform.
- A description of any foreseeable risks or discomforts the participants may be subject to due to participating in the research.

The consent form also includes standard wording that shall not be modified by the Principal Investigators. The standard wording includes:

- A statement regarding anonymity and confidentiality of collected data. If data identifying the participants will be maintained, indicate who will have access to identifying data.

- An explanation of whom to contact for pertinent questions about the research (generally the PI), and whom to contact about research participants' rights and research-related injury (the current IRB Chair).
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without loss of benefits to which the participant is otherwise entitled.
- A statement preceding the signature block guaranteeing the legal age of the participants: "In signing below, I affirm that I am 18 years of age or older." For online surveys: "By clicking 'yes' below, I affirm that I am 18 years of age or older, and meet the other requirements to participate in this study."
- Dated signatures for participant and investigator, or representative of the investigator (does not apply to web-based surveys).
- The witness signature may be the investigator unless otherwise specified by the IRB (does not apply to web-based surveys).

Whenever practical, active consent (signing a piece of paper, or clicking a button to indicate consent) should be used. In limited cases, the SVU IRB will consider the use of passive consent (requiring potential participants to opt out, instead of opting in). Any requests to use passive consent will be reviewed by the full IRB at the next regularly scheduled meeting. Reasons for requesting to use passive consent should be outlined in the research proposal.

Children and other protected classes of research participants

Federal regulations provide higher standards of protection for individuals belonging to certain classes of research participants, such as prisoners, the seriously ill, mentally or cognitively compromised adults, and minors (children of any age prior to their 18th birthday). In the case of prisoners, there are valid concerns that the coercive environment of a prison may compromise the inmate's voluntary participation. With other protected classes, the issue is the ability of the participants to provide adequate, informed consent, either because of physical/cognitive limitations, or because of age. Therefore, there are additional informed consent requirements.

Excluding exempt research (e.g., naturalistic observation), all research with children requires signed consent forms from a parent or legal guardian. Passive consent may be used at the discretion of the IRB, and would only be approved in cases where the research would otherwise be classified as exempt. Additionally, the minor child, if of sufficient age to be verbal and able to write, must give his/her own assent, or agreement to participate. Such assent must follow an explanation – at a level appropriate to the individual's age, maturity, experience and condition – of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should not be asked if they wish to participate in the research or not. Mere failure to object on the part of a child should not be construed to be assent. In any research proposal involving children as participants, the PI should indicate: 1) how assent with be obtained (what the investigator will say to the child and whether or not the child's parent(s) or guardian(s) will be present); and 2) how assent will be

documented. The child may either sign a very brief assent form or verbally indicate a willingness to participate.

If the research is to be conducted in an institutional setting outside of SVU, the IRB also requires permission from an appropriate institutional official. Within a school system, permission of a school superintendent or principal, along with participating teachers will be sufficient.

Waiver of signed informed consent
There are some situations where a signed informed consent may not be required:

(1) If the principal risks are those associated with a breach of confidentiality concerning the participant's mere participation in the research (e.g., studies on potentially sensitive topics such as illegal drug use, other illegal conduct, or sexual behavior); AND if the consent document is the only record linking the participant with the research; OR
(2) If the research presents no more than minimal risk and involves procedures that do not require written consent when they are performed outside of a research setting; OR
(3) In the case of certain kinds of research (e.g., anthropological or sociological), if the objectives of the research would be compromised by signed informed consent forms given the nature of the culture under investigation.

If the PI believes a research project meets 1 or more of the above guidelines, s/he must petition the IRB for a waiver of informed consent as part of the research proposal. Any request for waivers of informed consent will be reviewed by the full IRB at the next regularly scheduled meeting. The specific justification for the waiver of informed consent will be documented in the IRB minutes.

XIV. Deception

Deception involves withholding information from participants that might affect their decision to participate in the study. The IRB regards very seriously any use of deception, since withholding information violates the fundamental ethical principle of autonomy. However, it is recognized that there are certain types of research that would not be possible without deception (e.g., some studies within the fields of criminal justice or social psychology), and deception is permissible under federal regulations as long as it is scientifically justified and appropriate protections are provided.

Deception occurs in varying degrees of severity. In its most basic form – incomplete disclosure – participants are told only part of the research design, or some of the anticipated risks. The only information that is typically withheld is the experimental hypothesis. This is done to ensure that participants provide unbiased responses. More severe examples of deception include (a) deceiving participants about the purpose of the research, (b) deceiving them about the status of other individuals whom they believe to research participants (confederates), or (c) deceiving them about the status of individuals supposedly outside of the experiment (e.g., persons allegedly needing help in a study of altruistic behaviors). The most extreme form of deception

occurs when participants are not even aware they are research participants until after the experiment has concluded (this does not apply to naturalistic observation, as the natural environment is not changed by the PI in naturalistic observation).

The SVU IRB endorses the following principles of best practice regarding the use of deception in research studies:

- Deception should never be employed if there is an alternate way of studying the research question without deception
- Incomplete disclosure (to protect the research hypothesis) is acceptable only if the project follows the practices outlined below.
- Every experiment involving deception must include the following provisions:
    - The consent form must advise participants that they are not receiving all of the relevant information prior to the experiment, but they will be full informed at the end of the experiment (via debriefing procedures). The IRB recommends language along the lines of "We cannot explain all of the details of the experiment to you at this time, but they will be explained to you at the conclusion of the experiment."
    - Participants must receive a thorough debriefing at the conclusion of the experiment, including a disclosure of the deception and an explanation of why it was necessary for the experiment. A complete debriefing script must be approved as part of the study's methodology, outlined in the original research proposal.
    - To restore participants' autonomy (that is, to restore their right to decide to participate based on complete information), PIs must, at the conclusion of the debriefing, offer participants the opportunity to withhold the use of their data if they are unhappy with the deception.

References

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education and Welfare

Eureka College IRB Procedures for Approval of Human Subjects Research

Office for Human Research Protections (OHRP) IRB Guidebook, U.S. Department of Health and Human Services

Office for Human Research Protections (OHRP) Human Subjects Regulations Decision Charts, U.S. Department of Health and Human Services.
https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

Protection of Human Subjects, Title 45 Code of Federal Regulations Part 46, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks

Appendices

Appendix A: Informed Consent Form

Purpose of Research
(To be completed by research team)

Provide to the participant of the purpose, risks, benefits and expected duration of the participation and the procedures of the study.

Consent
I, _____, state that I am over 18 years of age and that I agree to participate in a research study being conducted by _____. I acknowledge that _____ has informed me that my participation in this study is voluntary, that I may refuse to participate or withdraw my participation at any time without penalty or loss of benefits, and that all data that I contribute will remain confidential. The purpose, risks, benefits and expected duration of my participation, and the procedures of the study (including the identification of any procedures that are experimental) have been explained to me, and I am competent to understand them. I understand that this study involves minimal risk. This consent is being signed prior to participation in the study.

_____ _____
Signature of participant Date

_____ _____
Signature of witness Date

Please contact _____ at _____ if you have any questions about the research.

Please contact _____ at _____ if you have any questions about your rights as a participant, or in the event of a research-related injury.

If you would like to receive a summary of the results at the conclusion of the study, please write your email address here: _____

Appendix B: 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:_____

Appendix C: Study Continuation/Close Out

Project Director or Investigator(s): _____

If student, please provide faculty mentor: _____

Today's date: _____ Department: _____

Project or Grant Title: _____

Instructions: If you are in need of a periodic review of a continuing project, please fill out part A and submit to the IRB. If you need to make a revision to a previously approved project, please fill out part B and submit to the IRB.

Part A:

Project start date and anticipated end date:

Where has the work been done? Where will the continuing work be done?

Has your project changed it's involvement with participants or individuals from any special/vulnerable populations?

- ❑ Yes
- ❑ No

How many participants have been recruited to participate in the study?

How many have dropped out of the study?

When do you plan to stop recruiting participants, if you haven't already?

Please give a short summary of what you have completed so far:

Have there been any unanticipated problems with the study that should be brought to the IRB's attention?

- ❑ Yes
- ❑ No

If yes, please explain what they are:

Please provide a detailed plan of what you hope to accomplish in the next year:

Part B:

Project start date and anticipated end date:

Has your project changed it's involvement with participants or individuals from any special/vulnerable populations?

- ❑ Yes
- ❑ No

Please provide an explanation as to how your project/study has changed since it was recently approved by the IRB. Given your answer, the IRB may present you with additional forms to be completed.

Appendix D: Checklist for IRB Reviewers

Please provide the name of the applicant and their project title: _____

If applicant is a student acting under faculty direction, please provide name of faculty member: _____

What is the applicant's project status?

- ❑ New Project
- ❑ Revision to Previously Approved Project
- ❑ Periodic Review of Continuing Project

New Project Guide/Checklist:

Please give a brief summary of the applicant's project and their plans to execute the project:

Please provide any comments, questions, or concerns you have about the project:

Does their project involve participants or individuals from any special/vulnerable populations?

- ❑ Yes
- ❑ No

Do they properly explain how privacy and information of the participants will be protected?

- ❑ Yes
- ❑ No

Did they provide a copy of their consent form?

- ❑ Yes
- ❑ No

Do they describe the details of their project and purpose in sufficient detail?

- ❑ Yes
- ❑ No

Do they sufficiently describe how they will recruit/contact participants?

- ❑ Yes
- ❑ No

If you selected no to any question from 2-5, do you recommend that the IRB Chair contact the investigator, or refer the protocol for full IRB review?

Are there any risks associated with their project? If so, what are they?

Did the applicant describe these potential risks in detail; outlining emergency plans and safety precautions?

- ❑ Yes
- ❑ No

Are you comfortable moving forward with the proposed study?

- ❑ Yes
- ❑ No *if no, see IRB chairman
- ❑ Maybe

*The next 7 questions are only for projects that qualify for **expedited/full** review

Does their research include clinical studies of drugs and/or medical devices?

- ❑ Yes
- ❑ No

Does their study include the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture?

- ❑ Yes
- ❑ No

Does their study include prospective collection of biological specimens for research purposes by noninvasive means?

- ❑ Yes
- ❑ No
- ❑ Maybe

Does their study include the collection of data through noninvasive procedures?

- ❑ Yes
- ❑ No
- ❑ Maybe

If yes to any of the above questions, do they accurately depict how their research falls into that specified category?

If no, why is this protocol classified as expedited or full review? (e.g., risk involved?)

Did they attach all forms, surveys, letters, proposals, etc. necessary?

If not, please ask IRB chair to obtain necessary forms.

Revision to Previously Approved Project Guide/Checklist:

Why is the P.I. requesting a revision to their project?

Has their project changed it's involvement with participants from any special/vulnerable populations?

- ❑ Yes
- ❑ No
- ❑ Maybe

Does the study need to move to expedited/full review if it isn't already?

- ❑ Yes
- ❑ No

Did they provide a sufficient explanation as to how their project has changed and how they are moving forward?

- ❑ Yes
- ❑ No

Do you feel comfortable re-approving this project?

- ❑ Yes
- ❑ No *if no, see IRB chairman

Periodic Review of Continuing Project Guide/Checklist:

Has their project changed it's involvement with participants from any special/vulnerable populations?

- ❑ Yes
- ❑ No

Does the study need to move to expedited/full review if it isn't already?

- ❑ Yes
- ❑ No

Have they had a significant number of individuals drop out of the study?

- ❑ Yes
- ❑ No

Did they project a sufficient summary of what they have completed so far?

- ❑ Yes
- ❑ No *if no, please follow up with applicant

Have there been any unanticipated problems with the study that need to be brought to the IRB's attention? If so, what are your recommendations for minimizing/preventing similar problems in the future? (change to protocol, deny protocol, etc.)

Do you feel comfortable re-approving this project?

- ❑ Yes
- ❑ No