**Protocol Form**

**Using this document:**

* The purposed of this document is to provide you with a guide for providing the information that the IRB-SBS needs in order to review your protocol. Each question provides instructions as well as suggestions for completing the question. After every **Instruction** section, there is a **Response** area; please provide your answer in **Response** area.
* In addition, any blue underlined text is linked to related areas in our [Researcher’s Guide](http://www.virginia.edu/vpr/irb/sbs/resources_guide.html) on our [website](http://www.virginia.edu/vpr/irb/sbs/index.html). If you have questions about how to respond to a question, start with the Researcher’s Guide and then [contact](http://www.virginia.edu/vpr/irb/sbs/contact.html) our office for additional help.

**Submitting a protocol:**

* This document has three parts: **Section A “Investigator’s Agreement**,” **Section B “Protocol Information,”** and **Section C “Description of the Research Study.”** To submit a protocol, complete this document and email it and any accompanying materials (i.e. consent forms, recruitment materials, instruments) to [irbsbs@virginia.edu](mailto:irbsbs@virginia.edu). For more information on what to submit and how, please see [Submitting a Protocol](http://www.virginia.edu/vpr/irb/sbs/submissions.html).
* **Please note that we can only accept forms in Microsoft Word format and in this form only. Do not submit your responses in a separate document.** We do not accept hand-written documents (with the exception of the signature on the Investigator’s Agreement). Please submit the electronic form in its entirety; do not remove the signature pages from the document even though you will submit these pages as a pdf/hard copy. Do not alter this form; simply provide your responses in the **Response** area. **Forms that are not completed correctly will be returned to you and you will be required to complete them correctly before they are accepted. No exceptions!** If you need help using our form, please [contact](http://www.virginia.edu/vpr/irb/sbs/contact.html) our office. For tips and suggestions for completing the protocol, please see [Protocol and Informed Consent Tips](http://www.virginia.edu/vpr/irb/sbs/submissions_submit_tips.html).
* **Section A “Investigator’s Agreement”** must also be submitted with signatures. Signed materials can be submitted by mail, fax (434-924-1992), or email (scanned document to [irbsbs@virginia.edu](mailto:irbsbs@virginia.edu)). Signed materials can also be submitted [in person to our office](http://www.virginia.edu/vpr/irb/sbs/contact.html).
* In order to not delay your review, make sure that you (and any researcher listed on the protocol) have completed the [CITI training](http://www.virginia.edu/vpr/irb/sbs/training.html) in human subjects research.
* You will be contacted in 3-7 business days regarding your submission (depending on the protocol queue). Please see [Protocol Review Process](http://www.virginia.edu/vpr/irb/sbs/submissions_review.html) for more information.

**A. Investigator Agreement**

**BY SIGNING THIS DOCUMENT, THE INVESTIGATOR AGREES:**

1. That **no participants will be recruited** or data accessed under the protocol **until** the Investigator has received the **final approval or exemption letter** signed by the Chair of the Institutional Review Board for the Social and Behavioral Sciences (IRB-SBS) or designee.
2. That **no participants will be recruited** or entered under the protocol **until** all researchers for the project including the Faculty Advisor have completed their **human investigation educational requirement** ([CITI training](http://www.virginia.edu/vpr/irb/sbs/training.html) is required every 3 years for UVA researchers).
3. That any **modifications of the protocol or consent form** will not be implemented without prior **written approval** from the IRB-SBS Chair or designee except when necessary to eliminate immediate hazards to the participants.
4. That any **deviation from the protocol and/or consent form** that are serious, unexpected and related to the study or a **death** occurring during the study **will be reported promptly to the SBS Review Board** in writing.
5. That all protocol forms for **continuations of this protocol** will be **completed** and returned **within the time limit stated** on the renewal notification letter.
6. That **all participants will be recruited and consented as stated in the protocol approved** **or exempted** by the IRB-SBS board. If written consent is required, all participants will be consented by signing a copy of the consent form that has a non-expired IRB approval stamp.
7. That the IRB-SBS office will be notified within **30 days** of a **change in the Principal Investigator** for the study.
8. That the IRB-SBS office will be notified when **the active study is complete**.

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| **Principal Investigator (print)** | **Date** |
|  |  |
| **Protocol Title** | **Protocol Number (SBS office only)** |
|  | |
| **Principal Investigator’s Signature** | |

**FOR STUDENT AND STAFF PROPOSALS ONLY**

**BY SIGNING THIS DOCUMENT, THE FACULTY ADVISOR HAS READ THE PROPOSAL FOR RESEARCH AND AGREES:**

1. To **assume overall responsibility** for the conduct of this research and investigator.

2. To **work with the investigator**, and with the SBS Review Board, as needed, in **maintaining compliance with this agreement**.

3. That the **Principal Investigator is qualified to perform this study**.

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| **Faculty Advisor (print)** | **Date** |
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| **Faculty Advisor’s Signature** | |

**The SBS Review Board reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.**

**Protocol Form**

**B. Protocol Information**

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| **IRB-SBS Protocol Number (assigned by SBS office, leave blank):** | | |  | | | |
| **IRB-SBS Grant Approval number:** (If you received a Grant Approval prior to submitting a protocol, please include the number issued by our office. If you did not submit a Grant Approval Form, please leave this line blank.) | | |  | | | |
| **Submission Type** (delete all those that don’t apply): | | | **New Protocol**  **Resubmission of previously rejected protocol**  **Updated protocol form (includes all previous modifications)**  **Reopening expired protocol**  **4th Year Submission** | | | |
| **Protocol Title:** | | |  | | | |
|  | | |  | | | |
| **Principal Investigator:** | | |  | | | |
|  | Professional Title: | |  | | | |
|  | School (Curry, Medical, Arts & Sciences, etc): | |  | | | |
|  | Department (CISE, Family Medicine, Psychology, etc): | |  | | | |
|  | Campus Box number: | |  | | | |
|  | Mailing Address (only if campus box number is not available): | |  | | | |
|  | Telephone: | |  | | | |
|  | UVA e mail address (no aliases, please):  *Your computing ID is used for tracking your IRB CITI training.* | |  | | | |
|  | Preferred e-mail address for correspondence (if applicable): | |  | | | |
|  | You are (delete all those that don’t apply): | | **Faculty**  **Graduate Student**  **Undergraduate Student**  **Staff** | | | |
|  | This research is for (delete all those that don’t apply): | | **Class project**  **Master’s Thesis**  **Doctoral Dissertation**  **Faculty Research**  **Other (please describe)** | | | |
|  | Primary contact for the protocol (if other than the principal investigator): | |  | | | |
|  |  | Contact’s Email: |  | | | |
|  |  | Contact’s Phone: |  | | | |
| **Faculty Advisor:** | | |  | | | |
|  | School (Curry, Medical, Arts & Sciences, etc): | |  | | | |
|  | Department (CISE, Family Medicine, Psychology, etc): | |  | | | |
|  | Campus Box number: | |  | | | |
|  | Telephone: | |  | | | |
|  | UVA e mail address (no aliases, please):  *Your computing ID is used for tracking on-line human subjects training.* | |  | | | |
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| **Other Researchers\*:** | | |  | | | |
|  | Please list all other researchers in this study that are associated with UVA.\* Please provide the following information for each researcher: Name, UVA email address (no aliases, please.) | |  | | | |
|  | Please list all other researchers not associated with UVA.\* Please provide the following information for each researcher: Name, Institution, Phone Number, Mailing Address, Email Address. | |  | | | |
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| [**Funding Source**](http://www.virginia.edu/vpr/irb/sbs/resources_guide_fund.html)**: If research is funded, please provide the following:** | | |  | | | |
|  | Name of the funding source (NIH, NFS, Robert Wood Johnson Foundation, etc) | |  | | | |
|  | Type of funding source (delete all that **don’t** apply): | | Federal grant  Private grant (non-profit institution)  Private grant (for profit institution)  Local Virginia government  Virginia Commonwealth grant (Non-UVa State fund)  Non-Virginia government grant  UVa grant  Sub Contract | | | |
|  | Describe the funding source (optional unless you selected “sub contract” above) | |  | | | |
|  | funding period (month/year): | |  | | | |
|  | grant number: | |  | | | |
| **Paying Participants:** If you are paying participants using State or UVa funds (including grants), you are required to complete the **UVa or State Funds Study Payment Procedures Form.** (Please describe your payment process in question 3-b in the next section.) **Please mark an “x” in the appropriate box (to the right):** | | | I am paying participants using State or UVa funds (including grants) and will include the UVa or State Funds Study Payment Procedures Form. |  | I am not paying participants or I am not using State or UVa funds (including grants). |  |
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| **Anticipated start date for collecting and analyzing data:** | | |  | | | |
| **Anticipated completion date for collecting and analyzing data:** | | |  | | | |

**\* Please only list researchers that are working directly with human subjects and/or their data. All researchers listed on the protocol must complete the IRB-SBS Training or provide proof of completing IRB training at their institution. If you have any questions about whether a researcher should be listed on the protocol or if a researcher has completed training, please contact our office (irbsbshelp@virginia.edu). Proof of training can be submitted to our office via fax (434-924-1992), by mail (PO Box 800392 Charlottesville, VA 22908-0392) or by email (**[**irbsbs@virginia.edu**](mailto:irbsbs@virginia.edu)**).**

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| **C. Description of the Research Study** |
| 1. **Study Overview:** Give a brief overview of your project. Consider the following when framing your response:    * + What is your purpose in conducting this research? What makes the project interesting and worth doing?      + Include information about the study’s logistics (where and when it will be conducted, what instruments you will use, etc). What will you be asking participants to do, and what do you hope to learn from these activities?      + If your study has more than one phase, please clearly map out the different phases.      + If your study is a multi-site study, please describe. |
| **Response 1: (enter response below this header)** |
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| 1. **Participants: Please describe as best you can the population(s) you plan to work with.** Please describe them in the terms that are most pertinent to your project. We need to understand how working with them will further your research objectives and what steps need to be taken in order to minimize risk to them. **Please respond to questions a-e in this section.** |
| * 1. Please fill in the following blanks below. If you are working with more than one population, please provide information for each group. |
| **Response 2-a: (enter response below this header)** |
| Age:  Gender:  Race:  Estimated number of participants: |
|  |
| * 1. Describe how participants will be identified and selected to participate in the study. Are there specific populations that you will be targeting and if so, why? Are there potential participants that you will exclude from the study and if so, why? |
| **Response 2-b: (enter response below this header)** |
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| * 1. Is the population and/or individual participant “[risk-sensitive](http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_risk.html)”? (You will have an opportunity to discuss the risks in more detail in the “Risks” section.) Is the population and/or individual participant “[vulnerable](http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_vuln.html)”? (This issue relates to the participant’s capacity consent; you will have an opportunity to discuss your consent procedures in more detail in the “Consents” section.) |
| **Response 2-c: (enter response below this header)** |
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| * 1. Will you deceive and/or withhold information from the participants about the study? If so, please justify why deception and/or withholding information from the participants is necessary and describe the deception. Using deception requires specific consent forms and processes; please describe this process in the **Consent section** under **Response 3-a** and **3-b**. |
| **Response 2-d: (enter response below this header)** |
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| * 1. What special experience or knowledge do you have that will allow you to work productively and respectfully with your participants? What special experience or knowledge does your faculty sponsor have in relation to your research participants? |
| **Response 2-e: (enter response below this header)** |
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| 1. **Consent:** [Consent](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent.html) is an on-going process that starts when you first inform your participant about the study through your recruitment/advertising efforts and ends when the participant’s data are no longer needed. The federal regulations require a [formal consent process](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_inform.html) takes place where you provide participants with specific information about the study (usually provided in the consent form, see General Consent Template) and the participants are required to sign the form. Not [every study will fit this](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_notrequired.html) mold and there are some [alternative methods](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_special.html) for conducting the formal consent procedure. **In general, the Board needs to understand how participants will be recruited and consented to participate in the study.** Please note that if your study qualifies for [exemption](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_notrequired.html), you will not be required to follow the federal regulations for consent, but the Board may require that you provide information about the study to the participant. **Please respond to questions a-d in this section.** |
| * 1. How will you [approach/recruit](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_recruit.html) participants to participate in your research? **Please provide all materials used to contact participants in this study. These materials could include letters, emails, flyers, advertisements, etc. If you will contact participants verbally, please provide a script that outlines what you will say to participants.** |
| **Response 3-a: (enter response below this header)** |
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| * 1. What is your [consent process](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_basic.html)? Who will present the consent information and how will it be presented? How will you [document consent](http://www.virginia.edu/vpr/irb/sbs/resources_guide_consent_doc.html)? Are your participants able to sign a form, and if not, how will you document consent? Will you use more than one form (if you use more than one version of the consent form, each form needs to have a unique title in order for our staff to keep track of the different forms)? When and where will participants receive the consent form? Who will give them the consent form? Will you pay participants? |
| **Response 3-b: (enter response below this header)** |
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| * 1. Are any of your participants [unable to consent](http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_vuln.html) (i.e. vulnerable population)? These populations include (but are not limited to): minors (participants under the legal age of consent), prisoners, and participants with diminished mental capacity. These participants generally need a parent (or surrogate) consent form and a participant assent form (prisoners being the likely exception unless they are minors too). |
| **Response 3-c: (enter response below this header)** |
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| * 1. What is your [relationship](http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_vuln_coerce.html) to your participants? Do you know them personally or hold any position of authority over them? Do any of the researchers (including the faculty advisor) have positions of authority over the participants, such as grading authority, professional authority, etc.? Are there any relevant financial relationships? |
| **Response 3-d: (enter response below this header)** |
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| 1. [**Materials/Data collected**](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data.html): For most SBS studies, the risk to participants often lies in the information that is collected from them. Thus the manner in which the data are collected, how they are stored, and how the data are reported in your research is an important part of determining the risk to participants. When you develop your procedures, consider **minimizing or eliminating the collection of** [**identifying information**](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_identify.html)where possible and **provide justification** as to why it needs to be collected. **Please respond to questions a-d in this section.** |
| * 1. Are any of the [data already collected](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_arch.html)? (If you are only using archival data, please use the Archival Data protocol form instead of this form.) Are the data [publicly available](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_arch_pds.html) or part of a [private collection](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_arch_privateds.html)? Please describe the data set(s) and provide a list of data fields you will use (when applicable). What will you do to protect the [confidentiality](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_confid.html) of the pre-existing data? |
| **Response 4-a: (enter response below this header)** |
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| * 1. What will you do to protect the [privacy](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_privacy.html) of your participants? Describe the [process for collecting data](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_method.html) from your participants. What will you do to protect the [confidentiality](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_confid.html) of your participants? Describe the kinds of information you will gather and the material forms it will take. Describe the level to which the participant’s identity will be known, if that information will be collected (and why), and how the [identifying information](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_identify.html) will be linked with the participant’s data. If you don’t intend to collect identifying information, describe your process for keeping the data anonymous. |
| **Response 4-b: (enter response below this header)** |
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| * 1. Will you use audio recordings, photographs, video recordings or other similar [data recording devices](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_tools.html)? Please justify why it is necessary to use these devices, how you will use them, and what you will do with the data after they are collected. |
| **Response 4-c: (enter response below this header)** |
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| * 1. How will your materials be [stored](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_storage.html)? Discuss both how you plan to store it while you are collecting and actively analyzing it, and your [long-term plan](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_retention.html) for maintaining it when the active research phase is finished. How will your data be reported in your study? Will you report the results in aggregate or will individual data be discussed? |
| **Response 4-d: (enter response below this header)** |
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| 1. [**Risks**](http://www.virginia.edu/vpr/irb/sbs/resources_guide_risk.html): Almost any intervention into other people’s lives carries with it the potential to cause them social, psychological, physical, or legal harm. However, not every interaction will put a participant at risk beyond what is considered [minimal](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_mr.html). **Please describe to the Board the potential risks and the probability of harm to the participants in your study.** In this section, consider the following when framing your response:  * [Describe the risks](http://www.virginia.edu/vpr/irb/sbs/resources_guide_risk_review_protocol.html) to the participants in your study. Does your study include “risk-sensitive” participants (as identified in the Participants section)? What is the probability that harm could occur? * Describe what you will do to [minimize those risks](http://www.virginia.edu/vpr/irb/sbs/resources_guide_risk_reduce.html). Describe what you will do if a [harmful situation occurs](http://www.virginia.edu/vpr/irb/sbs/maintaining_unexpected.html). * Would a loss of [confidentiality](http://www.virginia.edu/vpr/irb/sbs/resources_guide_data_confid.html) of any of your materials put participants at risk? If so, how will you prevent this from happening? |
| **Response 5: (enter response below this header)** |
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| 1. [**Benefits**](http://www.virginia.edu/vpr/irb/sbs/resources_guide_risk_benefits.html): Benefits help to outweigh the risks to the participants, though not every study will have direct benefits to the participants. In this section, consider the following when framing your response:  * Will there be any benefits to the participants in your study? If so, what are they? * What is the general importance of the knowledge you expect to gain? |
| **Response 6: (enter response below this header)** |
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