**iProtocol Text Boxes**

**UVA IRB-SBS**

This document is a “working document” and the purpose is to help you to prepare your responses for the text boxes in the iProtocol online protocol form.

* You are not required to complete this form but instead it is provided in case you would rather type in a Word document and paste the content into the online text boxes rather than typing in the online text boxes directly. Please note that the text boxes have spell check but other formatting features such as bolded text, italics, etc. will not be copied and the text boxes do not have formatting options. Bullets will be copied (though not perfectly).
* Do not submit this document to our office! It is not the protocol form and will not be processed as a submission.
* This form does not represent every question on iProtocol but the text boxes only; you will be able to provide other information about your study through yes/no questions, check boxes, short field responses, etc.
* Some of the questions below may not apply to your study and the questions in iProtocol will help you determine what is relevant to your study.
* You will have the option to upload documents, images, etc., to iProtocol in multiple places throughout the form (study overview, recruitment and consent, data tools). If you have a nicely outline table that describes the study plan, feel free to upload it to the study overview section, for example, rather than having to write a lengthy paragraph.

**Study Overview:**

What is the purpose in conducting this research? How does this study contribute to the advancement of knowledge and why is it worth doing?

What will participants do in this study? Please provide an overall summary of the study plan. Where and when it will be conducted? What do you hope to learn from these activities? If the study has more than one phase, clearly map out the different phases. You will be required to describe the study components in more detail in later sections but use this paragraph to help your IRB reviewer to understand the general outline of the study.

**Participant Group**

*You will have the option to create more than one participant group in iProtocol. This can be useful if you have multiple groups in your study who contribute at different levels in the study. You are not required to create multiple groups and for many studies, one group will be sufficient. If you create multiple groups, you will answer these questions for each group.*

Describe the participants in this group. What criteria will qualify a participant for the study? Are there exclusion criteria that will prevent someone from participating?

(If participants will be paid) describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

**Participant Summary**

*This section will apply to all the Participant Groups and will be answered only once.*

What special experience or knowledge does the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators) have that will allow them to work productively and respectfully with the participants in this protocol?

What is the relationship between the participants of this study, and the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators)? Does the Principal Investigator, Faculty Sponsor, or the Research Team (Sub-Investigators) know any of the participants personally or hold any position of authority over the participants (including but not limited to: grading authority, professional authority, etc.)? Are there any relevant financial relationships?

**Recruitment and Consent**

*This section will apply to all the Participant Groups and will be answered only once. If you have more than one Participant Group and the consent process is different for each group, you will need to describe each process when responding to these questions.*

How will participants be approached or contacted for recruitment into the study? Include information about how contact information will be obtained for the participant and what materials will be used to recruit participants.

What is the consent process for this study? Who will present the consent information and how will it be presented?

**Data Tools**

*Use this section to describe the individual elements in your study that you will use to collect data (survey instruments, observation protocols, education tests, etc) or data that was already collected (i.e. archival data). If you are using more than one element, it is possible you could complete this section more than once. Depending on the data, not every question in this section will be relevant (and the questions in iProtocol will help you determine what is relevant to your study).*

Describe this Data Tool. What does/will the data consist of? If a data set will be used, include the data fields to be used.

*Depending on whether you are collecting identifying information with the data, you will be ask either the following two questions:*

What identifiers will be connected to the data and will you have access to those identifiers?

Why is it necessary for you to retain participant identifiers? Will the identifiers be connected to the data or kept separate for contact purposes only?

*Or you will be asked this question if no identifying information is linked to the data:*

How will you receive the data so that the data are not linked to identifying information?

**Permission to Access Data**

*If you are required to obtain permission to access the data and/or participants, you will describe that process here. You will also be asked to provide documentation for obtaining permission.*

Describe the rules or restrictions and how you will navigate that process:

**Data Report and Storage**

*This set of questions will only be asked and will apply to all “Data Tools.”*

How will data/materials be stored? What measures will be taken to secure these data during collection and analysis? If the data includes recordings, what will be done with the recordings? Describe the long-term plan for maintaining the data when the active research phase is completed.

How will data/materials be reported for this study? Will the results be reported in aggregate or will individual data be discussed?

If a participant decides to withdraw from the study, how will you handle their data?

**Risks and Benefits**

*This set of questions applies to all participant groups and will be asked only once.*

(If the loss of confidentiality or privacy is a risk to participants) what will be done to protect participants from loss of confidentiality and/or privacy?

Describe any remaining potential risks to participants. For example, are any of your participants or participant groups "risk-sensitive"? Include information about the probability of harm (i.e. how likely it is that harm will occur). What will be done to reduce risk to participants? If something unexpected involving risk happens, how will you handle it?

Describe the overall benefit of this study.

**Continuation Protocol**

*If this protocol is a continuation request for a previously approved protocol and the project was undertaken, you will need to respond to the following:*

Describe what you did during the past year in the following text box.

**Modifications to a previously approved protocol**

*If you are modifying a previously approved protocol you will need to respond to the following:*

Provide the rationale for changing the protocol described in this study.

**Unexpected Event: previously approved protocol**

If a negative event occurred in relation to a previously approved protocol and the event is not described as a possibility in the previously approved protocol or did not occur within the parameter described (i.e. an increase in frequency or severity), describe the event:

What was done to negate the incident or minimize risk? If no action was taken, describe why this was the case.

If the negative event was the result of not following the protocol, please describe: