Additional instructions for filling out the Protocol Template

Descriptive Title: (Choose a title that you like as changing it later means changing all the paperwork which is time consuming. Also, this title will appear on many study documents including those that participants see so please keep that in mind.)

Short title: A very shortened but descriptive title to use for referencing the project internally. Pick what you will use when discussing the project.

Investigators:
PI:
CO-I (s):
Study Coordinator: Many studies will not have a study coordinator. A member of the research team, either the research assistant or research manager, will be lead study coordinator for IRB purposes in order to request research access as needed.

Study Description and Project Aims:
What do you aim to do in this study? List the purpose of your study, as well as the objectives and aims that you will accomplish along the way to be successful. Some studies will have a hypothesis as well, include one if applicable.

Subject Background and Significance:
Keep it brief, but justify why there is a need to do this research. This section should be based in the literature and identify the gap your study will fill and why it is important to do so. Include a list of references. The university makes available and the department encourages the use of Endnote for managing references and citations.

Lay Description:
Include a paragraph that describes the study so that anyone can understand it. (If your study description and project aims section is straight forward enough it can be used.)

Participant Numbers:
What is your anticipated sample size? If it is a pilot study you will still need to provide a specific number. If not a pilot you will need a calculation for statistical significance or a number that is backed up by the literature. If you are conducting a chart review list the highest number of charts that may be reviewed in order to located the number needed that meet inclusion criteria for the study.

Recruitment: Describe where your participants will be recruited from (e.g. the emergency department, etc.) and how they will be recruited (e.g. personal contact, study flyer, etc.) Note whether or not you will be using an informed consent document, or requesting some type of alteration or waiver of consent and why.

Project Methods and Design:
Design - briefly describe the type of study you are doing, the methodology, and the methods. For example, observational, quantitative, questionnaire, etc. Make clear what procedures are being done for research purposes only and what (if any) procedures are being done as part of standard of care or standard educational process.

Inclusion criteria - What population will your sample be drawn from (e.g. >18, have sickle cell disease, are a 3rd year medical student at MCG)
(Note if you are including any vulnerable populations as defined by the IRB -minors, employees, pregnant patients, prisoners, students, etc.)

Exclusion criteria - Who will not be eligible for your study for safety or other reasons? e.g. pregnant, or <18, or someone who has not completed X training, etc.

Bias - Address possible sources of bias and how you are going to control for them.

Data Management - State how are you going to manage and store the data e.g. paper surveys, electronic Excel spreadsheet, IT assigned BOX account, etc. Note if your data will be identifiable, deidentified, coded or anonymous. Also note if you will need to access PHI.

Data analysis:
Describe how you will analyze the data and any statistical tests that will be used, also whether or not a power calculation will be done (descriptive statistics, t test, etc.)

Risk:
Risk/benefits of study. If the study is clinical in nature this section needs to be very specific and also written in lay person language for the consent document.

Location of study:
Hospital/offices/other. If it is a multisite study or you are conducting the study off campus this needs to be stated.

Data Sheet:
You must include one or more datasheets. This includes any data sheet that will be given to participants, filled out by study team members, or used to aggregate the data for storage and analysis. This includes data that is collected electronically as well e.g. via Qualtrics. Include a version date in the footer and a space for participant code or identification number if needed.

EXAMPLE DATA SHEET

Ketamine's effect on Intraocular Pressure and Intracranial pressure in Adult Patients

Date Time
Reason for Sedation____
Current medications____
Any prior head injuries, neck injuries, known brain pathology? Y N
Any prior eye injuries, glaucoma, or surgeries? Y N
Weight Height BMI

List any medications given within 60 minutes of the sedation

Med/Amount		

Amount of Ketamine (list quantity and time given)

Ketamine	Time	Amount

Measurement – Pre sedation

Time:	Tonometer (R)	Tonometer (L)	ONSD (R)	ONSD (L)
1				
2				
3				
Average				

Measurement – Pre procedure

Time:	Tonometer (R)	Tonometer (L)	ONSD (R)	ONSD (L)
1				
2				
3				
Average				

Measurement – Post procedure

Time:	Tonometer (R)	Tonometer (L)	ONSD (R)	ONSD (L)
1				
2				
3				
Average				

Measurement – Post sedation

Time:	Tonometer (R)	Tonometer (L)	ONSD (R)	ONSD (L)
1				
2				
3				
Average				

Version Date: Participant ID or Code: