**Key Information Tips:**

* Think of this key information section as the abstract for your informed consent document.
* All procedures that are described in the key information section should also be described in detail further down in the document under the “Procedures to be followed” section.
* The Key Information section is meant to be brief, but the amount of information that should be included will depend on the nature of the research.
* It is important to note that the Key Information section should include a summary of why an individual may want to participate, but should also include information about why an individual may not want to participate in the research

Below is a list of items ***to consider*** including in your key information section:

* + Does the study use drugs or devices that are not approved?
  + Does the study include any procedures that a participant may find alarming?
  + Is there an extensive time commitment (number of visits and amount of time each visit may take) that may influence a research participant’s willingness to participate?
  + Are there foreseeable risks, discomforts, and/or inconveniences that may impact the individual’s decision to participate?
  + Are there limitations on daily activities or the addition of daily activities?
  + Are there potential costs to participants?
  + Is there significant exposure to radiation that may impact a potential participant’s willingness to participate?
  + Are there any expected benefits from participation?
  + Are there alternative procedures/courses of treatment that the participant could choose rather than participate in the research?
  + Are there potential sub-studies participants may be asked to participate in?
  + Are there any essential study design elements such as randomization, the use of placebo, crossover design, or washout requirements from current effective treatments?
  + Would participants be asked to stop taking their current medications?
  + Is there a specific procedure or are there a number of visits that may make it difficult to take part in the study?

**Example 1:**

This study has four parts: (1) You and your child will be invited to the DEF456 laboratory at Vanderbilt University to learn about the study and complete questionnaires. (2) Your child will be asked to wear a mobile electrocardiogram (ECG) and answer surveys on a smartphone. In addition, you and your child will be asked to complete a family activity and have a 10-minute discussion on a day you select. (3) At the end of the four days, you and your child will be invited back to Vanderbilt University to answer some additional questions, return the study tools, and receive your compensation. (4) Three months later, you will be invited to complete a survey online at your home. You and your child may find some of the tasks boring, tedious, or distressing, and it may be a new experience for your child to wear the ECG. Through their participation in this study, your child may gain a better understanding of their stressful experiences and emotions. However, you may not benefit personally from participation.

**Example 2:**

This study will compare how quickly you can return to your everyday activities after surgery. You will be asked to do exercises while wearing a special shoe that measures the amount of weight you put on your leg. These exercises will be done 5 times as a part of your physical therapy appointments. Wearing the shoe may be uncomfortable. You will be asked to answer questions about your symptoms while you are in the study, but the questionnaire will not include your name. Additional data will be collected from your medical record. You will be paid up to $100 for completing the study.

**Example 3:**

The purpose of this study is to compare the effects, good and/or bad, of BB8675309 in study participants with ABBB8675309 is an experimental drug that is administered directly into the spine. This study is a double-blind, placebo-controlled study which means you may be receiving placebo rather than the study drug throughout your participation.

Total study time involved will be 25-30 months. You will have 16 study visits, with each lasting 6-8 hours each. In month 9, you will have a longer visit (8-10 hours). You may not be able to take Anti-anxiety medication during scheduled scans and if such medication is required you may have the scheduling of assessments changed.

You may not travel in the following forms for at least (3) days after administration of the study drug: air travel, scuba diving, hot air balloon. A study companion may also be asked to participate to assist with data collection.