Tips

1. Alternate text for many sections is provided in the instructions to tailor the document appropriately for the type of study being described. The federally required elements of consent are also provided.
2. Use multiple consents tailored for each study group in unblinded studies where different subject groups undergo significantly different procedures or schedules.
3. Use subheads within sections that require extensive detail.
4. Use a logical order for the topic within each section. For example, in the risk section, begin with research related risks that are expected, likely, and serious. Conclude with rarely expected risks and convey the likelihood.
5. Insert hard page breaks if the page breaks at a place that makes it hard for the reader to follow such as right after a subhead.
6. Do not use text smaller than 12 point.
7. Use at least 1.5 spacing between paragraphs.
8. Discuss only one or two ideas per paragraph.
9. Keep paragraphs short.
10. Avoid compound sentences.
11. Use shorter, simpler words whenever they can convey appropriate meaning.
12. Define or explain medical terms, procedures, and technical or complex words.
13. Use U.S. measurements for metric measurements, or both. State 2 teaspoons rather than 10 MLs.
14. Use regular time not military time. For example, say 1 p.m. rather than 1300 hours.
15. Do not use exculpatory language, that is, language that indicates somebody (the researchers or UM) is free from blame.
16. Write in the ‘second person,’ For example, instead of "The patient will be asked some questions about her medical history, then she will have a small amount of blood drawn,” state, "You will be asked some questions about your medical history, then a small amount of your blood will be drawn."
17. Do not imply ‘cut and paste’ protocol sections or include elaborate details of the procedures of the protocol.
18. Do not include highly scientific objectives or hypotheses that are of little relevance to the participants. These may bias your results or confuse participants.
19. Consider what the participant would want to know.

Examples of Protocol Language vs. Subject-friendly Language Text

Protocol or Scientific Language	Subject Friendly Language
If there is a history of hypertension, alternative methods of contraception are indicated.	If you have high blood pressure, use some other kind of birth control
This study is being conducted to assess the impact of DFG-995 and/or therapeutic intervention on the DXK Anxiety scale, to assess efficacy.	The study will compare treatment with a drug, treatment with counseling, and no treatment, to see which treatment works best to treat anxiety.
We believe that therapy will be most effective for highly anxious participants pre-disposed to confusion and depression.	Many people find that work and family stress makes them feel anxious and sad.
To participate, you must have medically documented anxiety or depression, not requiring hospitalization; no clinically significant medical condition judged by the investigator to compromise safety, and no atypical anxiety syndromes due to anticholinergic drugs, or metabolic neurogenetic disorders, or other degenerative diseases.	To participate, you must be feeling anxious or sad. You should not participate if you have ever been hospitalized because of these kinds of feelings. If your anxiety is caused by a medical problem, you may not be able to participate. There are many reasons why you may not be able to participate. It is important to discuss your full medical history with the study doctor. We must also review your medical record.
At visit 1 you will have your blood pressure taken lying down and standing up. You will answer questionnaires “overall anxiety scale” and “SAGM”. Your blood will be drawn for tests of iron, creatinine, hematocrit, liver function and other tests. You will be Randomized to group A, B, or C At visit 2 if you are in group A, your visit will occur in 4 weeks and you will have your blood pressure measured lying down and standing up. If you are in group B, your visit will occur in 6-12 weeks, after you have been assigned a counselor, and you will have your blood pressure measured while lying down and standing up…At visit 3 you will have your blood pressure measured…etc.	During the study, you will be randomized into one of three groups. Random means by chance, like flipping a coin. You have an equal chance of being in any of the three groups. Below is an explanation of what will happen at each visit, no matter what group you are in. Then there is a section explaining what extra things will happen depending on what group you are in. Also consider using tables, flow charts, graphs, or calendars in addition to text.

During the study, you may be prescribed aspirin for headaches. Aspirin can cause stroke, stomach upset, death, ulcer, or severe allergic reaction.	During the study, you may be prescribed aspirin. Aspirin often causes mild stomach upset. In very rare cases, it can cause stroke, death, ulcer, or severe allergic reaction. To reduce this risk, we will monitor you for side effects whenever aspirin is given.
No studies exist regarding the possible teratogenicity of study drug during pregnancy.	It is not known whether study drug could cause birth defects.
This study involves filling out surveys, so there are no risks to this study.	You may feel uncomfortable answering questions that contain personal information. You may choose not to answer those questions.
The likelihood of contracting an infection is less than 1%.	The chance of infection is less than 1%, which means less than one in one hundred people get an infection