You are being asked to be in a research study that will try to (briefly describe research objectives).

Your participation will involve (briefly describe procedures) and take about (specify approximate length of participation). [And consider including the approximate number of subjects involved in the research.]

There are no known risks associated with being in this research. OR Possible risks associated with this research include…. [And consider including There may be risks which are unknown at this time.]

[Consider including You will be told about any new information that might change your decision to be in this study.]

You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this research.

Select either Your alternative is to not participate in this study. OR Your alternative(s) to participating in this study include(s)…

[Consider stating whether there might be additional costs to the subject for participating.]

Contact (insert name) at (insert phone number) for questions, concerns or complaints about the research or if you think you have been harmed as a result of joining this research. Contact the Western Institutional Review Board (WIRB) if you have questions about your rights as a research subject, concerns, complaints or input: 1-800-562-4789. WIRB is a group of people who perform independent review of research.

The study staff will share the records generated from this research with the sponsor, regulatory agencies such as the US Food and Drug Administration and the IRB. (Describe any other parties...
who may receive the identifiable information). This information is shared so the research can be conducted and properly monitored. The people receiving this information may not be required to protect it and your information may be redisclosed without your permission. If you do not provide permission to use your information you cannot be in the study.

This permission will not end unless you cancel it. You may cancel it by sending written notice to the study doctor at [insert contact information]. Any information collected before you withdraw may still be used.

Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating.

[And consider including] Your part in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to changes made in the study plan;
- insert the specific reasons for discontinuation listed in protocol.

[Consider including] If you leave the study early, you may be asked to make a final visit. This is usually done for safety reasons.]