1) What is the research about and why is it being done?
2) What do researchers hope to learn and who might benefit from it?
3) Who is funding the study?
4) Who has reviewed and approved the study?
5) Who is being asked to volunteer to be in the study?
6) Why are you, specifically, being asked to participate?
7) When is the study expected to be completed?
8) How will the findings of the research be shared and would you be informed personally?
9) What kind of study is this?
   a) Is it a clinical trial?
   b) How many groups (or arms) are there?
   c) Is assignment to groups randomized, or could you choose?
   d) Will any of the groups receive a placebo or an inactive treatment?

10) What would you have to do? What kind of medications, procedures, or tests would you have?
11) Will you have to go anywhere to participate in the study?
12) Will the study involve a novel or untested intervention that is considered experimental?
13) Would you be told if you are given the intervention being tested?
14) How long would your participation last?
15) Would you be given the results of any study tests or procedures that are done?
16) If you have a disease or condition that is being studied in the research and you choose not to participate, what treatments or procedures are available to you? Would you still have access to the research intervention outside of the study?
17) If you have a disease or condition that is being studied in the research, ask if your doctor is also a researcher on the study. If so, who would watch out for your best interests as a patient?
18) How would being in this study affect your daily life?
19) How would being in this study affect your current medical care?
Risks Involved

20) How much do the researchers know about the risks of the research intervention—especially if the intervention is novel or experimental? Does the intervention have FDA approval or oversight?

21) What are the short- or long-term risks, discomforts, or unpleasant side effects? How likely are they to occur, and are any of them severe?

22) What are the researchers doing to minimize risks, discomforts, or unpleasant side effects?

23) Is there anything you could do to minimize your risks during the study?

Privacy and Confidentiality

24) How would your biological materials (such as blood samples), data (such as test results), or other personal information be used or shared?

25) How would your privacy and identifiable private information be protected?

26) What could happen to you if your identifiable private information were disclosed to others?

Financial Considerations

27) Will participating in the study cost you anything? For example, would you have to pay for certain tests or procedures, or the study drug? If so, what is the estimated cost and would it be covered by health insurance?

28) If you were harmed while participating in the study, who would pay for the necessary medical care?

29) Will there be any travel or other study-associated costs (for example, child care) and will researchers provide any money to cover those costs?

30) If the research offers financial compensation, how much is offered and when would you receive it?

Additional Considerations

31) Would you, personally, benefit from participating in the research? If so, how?

32) How much time will you have to think about your options before making a decision?

33) If your doctor is also the researcher on the study and you decide not to participate, would this decision affect your current medical care?

34) Who should you contact if you have questions about participating in the research?

35) Who should you contact if you have concerns about the research itself?

36) What happens if you volunteer to participate now, but decide to quit the study later?