Supplement 2: Site Questionnaire-Informed Consent Process

Description of Consent Process for <institutional name deleted for peer review> Study ##

Please provide a description of the consent process your site uses to enroll Study ## participants. In describing your site's consent process, provide a description of the issues in the table below. Please use the format provided and include all of the issues below in your description. Describe what is typical, but you should also include the range of procedures that may sometimes occur. Feel free to add anything that would help us better understand your site's consent process, but be succinct, if possible.

Consent Process Template	
Site Name:	
Questions	**Description**
1. How do participants find out about a <institutional name deleted for peer review> clinical trial?	
2. Who administers the informed consent process (e.g., the study coordinator, the PI, co-investigator, other [specify])?	
3. Do you introduce principles of informed consent separately from discussion of the Study ##-specific informed consent form? If so, how?	
4. Do you use the short consent form? If so, please explain specifically how.	
5. What language(s) are used in the consent process?	
6. Are interpreters (professional/non-professional) used? Please, specify.	
7. Do you use phone interpreters?	
8. How long does the informed consent process usually take?	
9. Are patients allowed to defer their decision until a later time? For example, can they take the consent home to read?	
10. If yes to #9, who follows up with the patient and when?	
11. Does this follow-up usually require more than one encounter with the patient?	
12. Do you read the consent form aloud, verbatim, to the patient? If yes, under what circumstances? Or does the patient read the consent form silently?	
13. How do you handle the consenting of low literacy and illiterate patients?	
14. How do you handle the consenting of other vulnerable patient populations (e.g., those with physical disabilities like blindness or deafness)?	
15. What information is explained to the participant (i.e., what topics are covered?)	
16. Do you assess understanding of what has been explained by the person administering the consent process or read by the patient? If so, how?	
17. Are materials or props of any type used during the consent process to help explain the topics? If so, please describe them and how they are used.	
18. May friends/family members accompany the patient during the consent process?	
19. Is the consent process interactive (like a dialogue), or more didactic (with the provider essentially imparting information)? Please elaborate.	
20. If patients have questions or concerns, is there some issue/area that these questions/concerns usually relate to? Explain.	
21. In the case of illiteracy, who signs the consent form?	
22, If a patient's signature is in a non-Roman script, is this signature acceptable? Please describe.	
23. Does your site require a witness to the signature in any or all cases?	
24. Is the patient given a signed or unsigned copy of the consent form?	
ADDITIONAL COMMENTS	
25. What changes do you believe would improve the informed consent process?	
26. What additional tools or materials would be useful to improve comprehension during the informed consent process?	
27. Additional comments?	