

GENERAL CONSENT FORM CHECKLIST FOR YOUR CONSIDERATION

Per 45 CFR 46.116 (a)(5):

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

ITEMS		Yes	No	Comments
1.	Is the general purpose of the study stated; what the researcher expects to learn?			Comment
2.	Is the subject's right to choose to participate indicated?			Comment
3.	Is the expected duration of the subject's participation stated?			Comment
4.	Is there a statement indicating why and how a subject was selected as a possible participant? Are the population and number of subjects identified?			Comment
5.	Are the procedures to be followed in the study clearly described (time, frequency, nature of information asked, observations, etc.)?			Comment
6.	Is there a statement of possible risks, discomforts or inconveniences that the participants may reasonably expect?			Comment
7.	Are any substantial or likely benefits to subjects identified?			Comment
8.	Is there any standard treatment withheld or alternative procedures available disclosed?			Comment
9.	Is subject confidentiality explained? (Use of tapes, photos, data, etc.)			Comment
10.	Are subjects' compensation and costs of participating in the study identified?			Comment
11.	Is where the subject can contact the investigator to have questions answered indicated?			Comment
12.	Is there a statement that participation is voluntary?			Comment
13.	Is the subject's right to a written copy of the consent form stated?			Comment



14.	Is there a statement that expresses that the individual's signature indicates a willingness to participate? Are the appropriate signature and date spaces included?			Comment			
15.				Comment			
If research involves identifiable private information or identifiable biospecimens:							
16.	Is there a statement that identifiers might be removed from the identifiable private information?			Comment			
17.	Is there a statement that the information could be used (even if identifiers are removed) for future research without additional consent, if applicable? If not applicable, is the subject's information will not be used or distributed for future research studies stated?			Comment			