Informed Consent Checklist

The HHS regulations at 45 CFR part 46 for the protection of human subjects in research require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless (1) the research is exempt under 45 CFR 46.101(b); (2) the IRB finds and documents that informed consent can be waived (45 CFR 46.116(c) or (d)); or (3) the IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

Informed consent must be written in a way that promotes prospective participants' (or their legally authorized representatives') comprehension of the project, including the key information (within the first few pages of the informed consent form) needed to help them understand reasons why a person may or may not want to participate in the research. Sufficient details about the project need to be provided in a readily understandable manner (i.e., organization, wording, lack of jargon) for them to make a well-informed decision to participate or not.

The following basic elements must be present in any informed consent document. Informed consent documents missing any required components will be returned to the investigator for correction or clarification.

Basic Elements	**Yes**	**No**
"Key Information" 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		
A statement that the study involves research		
An explanation of the purposes of the research		
The expected duration of the individual's participation		
A description of the procedures to be followed		
Identification of any procedures which are experimental		
A description of any reasonably foreseeable risks or discomforts to the participant		
A description of any benefits to the participant or to others which may reasonably be expected from the research		
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant		
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained		
For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained		

An explanation of whom to contact for answers to pertinent questions about the research and participant's rights, and whom to contact in the event of a research-related injury to the participant		
A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits, to which he/she is otherwise entitled		
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.		
The approximate number of study participants		

Additional Elements, as appropriate	**Yes**	**No**	**NA**
A statement that the intervention may involve risks to the individual (or to the embryo or fetus, if the individual is or may become pregnant), which are currently unforeseeable			
Anticipated circumstances under which the individual's participation may be terminated by the investigator without regard to the subject's consent			
Any additional costs to the individual that may result from participation in the research			
The consequences of an individual's decision to withdraw from the research and procedures for orderly termination of participation by the individual			
A statement that significant new findings developed during the course of the research, which may relate to the individual's willingness to continue participation, will be provided to the individual			
A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility **OR** A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies			
A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit			
For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing			