WORKSHEET: Criteria for Consent

The purpose of this worksheet is to provide support for IRB members reviewing research consent process(es) and documentation.

(LAR = "subject's Legally Authorized Representative").[1]

1. **Consent Process (**Check if "**Yes**". All must be checked)

- The investigator will obtain the legally effective informed consent of the subject or LAR[2].
- The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether to participate.
- The circumstances of consent minimize the possibility of coercion or undue influence.
- Information to be given to the subject or LAR will be in language understandable[3] to the subject or LAR.
- The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- 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 LAR's understanding of the reasons why one might or might not want to participate.
- There is no exculpatory language[4] through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.

[1] This document satisfies AAHRPP elements I.1.E, I.1.F, I.7.C, I-9, II.1.E, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, III.1.F

[2] LAR = "subject's Legally Authorized Representative"

[3] "Understandable" means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms) *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

[4] FDA considers exculpatory language to be language that has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

- Consent will disclose the elements in **Section 3: Elements of Consent Disclosure**

2. Long Form of Consent Documentation (Check if "**Yes**" or "**NA**". All must be checked.)

☐ The written consent document is accurate, complete, and consistent with the protocol.

☐ The written consent document embodies the elements in **Section 3: Elements of Consent Disclosure**

☐ The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.

☐ The subject or LAR will sign and date the consent document.

☐ The person obtaining consent will sign and date the consent document.

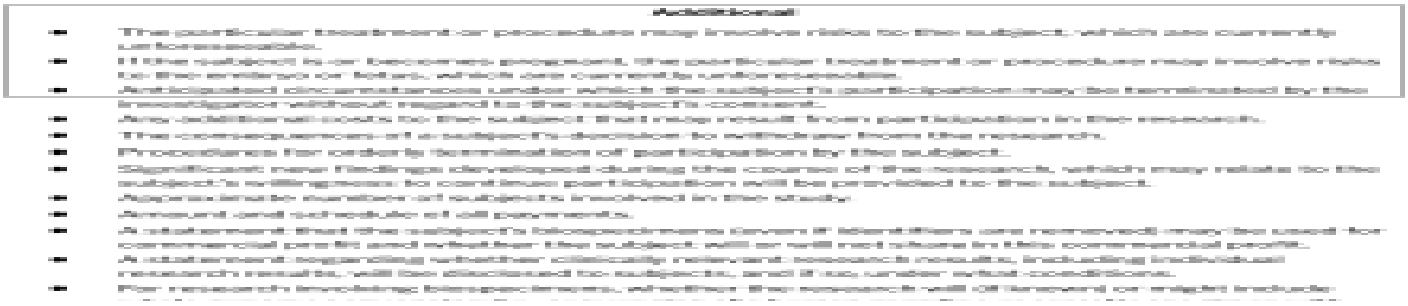
☐ A copy of the signed and dated consent document will be given to the person signing the document.

☐ If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **("NA" if no signature line) NA:** ☐

☐ When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **("NA" if all subjects are able to read) NA:** ☐

3. Elements of Consent Disclosure[5] (Check if "**Yes**" or "**NA**". All must be checked.)

[5] For additional guidance for FDA-regulated research on the elements of consent (including examples and recommendations on language), please see *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download



4. Additional Considerations for Electronic Consent (Check if "Yes" or "NA". All must be checked)

- Electronic consent document includes all elements in **Section 3-Elements of Consent Disclosure**
- The date of the electronic signature will be captured.
- Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.
- Electronic consent process includes age-appropriate materials to facilitate comprehension.
- Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.
- Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
- Measures are present to ensure that subjects have access to all of the consent-related materials, including hyperlinks or other external documents.
- Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.
- The informed consent process outlines in detail how any included documents will be utilized.

Required for More than <u>Minimal Risk</u> Research

- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
- Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

- Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.