**INFORMED CONSENT FORM CHECKLIST**
**(For individual use; DO NOT SUBMIT)**

Does the consent form include the required elements of informed consent? (45 CFR 46.116)

☐ 1) Research

Statement that the study is research and participation is voluntary
Who is doing the research
The purpose of the study
List and describe the procedures to be followed
Anticipated duration of the participant's participation
If appropriate, state the condition(s) of participation, if any

☐ 2) Risk, discomforts

State the possible hazards, inconveniences, and risks the participant will undergo
If appropriate, state the procedure may involve unforeseeable risks
If appropriate, state that any significant new findings affecting risk will be reported to the participants.
If appropriate, state circumstances under which the participant's participation may be terminated
If appropriate, state any additional costs to the subject that may result from participation

☐ 3) Benefits

State the benefits to the participant or to others that might be expected from the research

☐ 4) Alternatives to participation

Disclose the alternate procedures the participant may choose

☐ 5) Confidentiality

Contain a statement of the extent to which the confidentiality of the data will be maintained
If appropriate, describe the procedures to be employed in maintaining confidentiality

☐ 6) Compensation for injury (If appropriate)

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

☐ 7) Whom to contact

Include the name, address and telephone number of the investigator, the investigator's faculty sponsor (for student applicants), and the chairperson of the IRB
Instructions as to who and how to contact someone if questions or problems should arise later on

☐ 8) Right to refuse, or withdraw without penalty

Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
If appropriate, specify the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

☐ 9) IF research involves the collection of identifiable private information or identifiable biospecimens:

Either:

a) 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

b) 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.

Additional elements, when appropriate:

- [ ] A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

- [ ] Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

- [ ] Any additional costs to the subject that may result from participation in the research;

- [ ] The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- [ ] A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

- [ ] The approximate number of subjects involved in the study;

- [ ] For research involving biospecimens, 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;

- [ ] A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

- [ ] A statement whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

- [ ] Is the consent form absent any exculpatory language?

  **"Exculpatory language" is defined as language that would imply that the investigator is being released from responsibility for any adverse effects caused by the study.

- [ ] Include appropriate signature and date lines (participant, investigator, and witness (if required)); this is not required for studies deemed exempt.

- [ ] Include a statement that research was reviewed (and approved if expedited or convened board review) by the USA IRB.