Informed Consent Checklist

Language Used in Informed Consent Materials:

- [ ] The language used is at or below the 8th grade reading level for adult subjects (or age-appropriate language for minors) and is free from jargon
- [ ] The language used does not assume consent (e.g., the consent is free from language like, "after agreeing to participate", "thank you for participating", etc.).
- [ ] The language used is not likely to produce undue influence (e.g., "we would really appreciate it if you participated in our study", "your participation is invaluable", etc.)
- [ ] The language used does not include any exculpatory language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal right, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Important and Required Elements of Consent:

- [ ] Includes a title of the research project
- [ ] Includes information regarding the P.I. and associate investigators with contact information (e.g., email/phone).
- [ ] Includes a statement that the study involves research.
- [ ] Includes a clear description of the research purpose.
- [ ] Includes a description of the research procedures in enough detail so that subjects can understand what they will be asked to do and can make an informed decision whether or not to participate.
- [ ] Includes a statement of expected participation duration/expected time commitment.
- [ ] Includes description of any real and direct benefits to subjects (note: expected/hopeful benefits of the research may also be included, but is not the same thing as direct benefits to the research subject).
- [ ] Includes a description of anticipated risks to the subject, even if no greater than minimal.
- [ ] Includes a statement of compensation, even if there is none.
- [ ] Includes a description of the extent to which confidentiality is maintained.

- [ ] Includes a statement that the research is voluntary and that deciding not to participate or to withdraw will not involve a penalty or loss of benefits to which the subject is otherwise entitled.
- [ ] Includes a statement of whom to contact for questions related to the study.
- [ ] Includes a statement of whom to contact about the rights of research subjects or to make a complaint.

Less Common Elements of Consent (If Relevant):

- [ ] Includes a description of any costs associated with participation.
- [ ] For research involving more than minimal risk, includes an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- [ ] Includes disclosure of appropriate alternative procedures or treatment.
- [ ] Includes a statement of use of data for future research (required when collecting private identifiable information or biospecimens).
- [ ] Includes a statement of contact information for follow-up studies.