IRB Review CHECKLIST

- ☐ 1) Risks to participants are minimized
- ☐ 2) Risks to participants are reasonable in relation to anticipated benefits, if any
- ☐ 3) Selection of participants is equitable
- ☐ 4) Informed consent will be sought from each prospective participant or the participant's legally authorized representative
- ☐ 5) Informed consent will be appropriately documented
- ☐ 6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- ☐ 7) Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- ☐ 8) Where some of all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.
- ☐ 9) Certificate of completion of Collaborative Institutional Training Initiative (CITI)

ELEMENTS OF INFORMED CONSENT

Basic Elements

- ☐ a statement that the study involves research
- ☐ the purposes of the research
- ☐ the duration of the participant's participation
- ☐ procedures to be followed
- ☐ identification of experimental procedures
- ☐ risks or discomforts to the participant;
- ☐ any benefits to the participant or to others
- ☐ confidentiality protections
- ☐ whom to contact for answers to pertinent questions
- ☐ compensation or medical treatments if injury occurs?
- ☐ whom to contact in the event of a research related injury
- ☐ a statement that participation is voluntary
- ☐ statement that refusal to participate will involve no penalty or loss of benefits (if appropriate)
- ☐ participant may discontinue participation at any time without penalty

Additional elements (if appropriate)

- ☐ possibility of currently unforeseeable risks
- ☐ circumstances for termination by the investigator
- ☐ costs to the participant or their insurance
- ☐ consequences of participant's decision to withdraw
- ☐ procedures for orderly termination of participation
- ☐ statement that significant new findings will be provided
- ☐ approximate number of participants

Consent forms must NOT include any exculpatory language through which the participant or representative is made to waive or appear to waive any of the participant's legal rights, or releases, or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.