NEW YORK INSTITUTE OF TECHNOLOGY
Institutional Review Board for the Protection of Human Participants
Northern Blvd, Old Westbury, NY 11568
516-686-7488 http://www.nyit.edu/ospar/irb/

IRB REVIEWER'S CHECKLIST

Name of PI:_____ **Date of IRB review:** ____/____/____

Protocol title: _____

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

	Yes	No	NA
(a) Is the hypothesis clear? Is it clearly stated?	☐	☐	☐
(b) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?	☐	☐	☐
(c) Does the research design minimize risks to subjects?	☐	☐	☐
(d) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?	☐	☐	☐
(e) Is the information for study design and statistical methods adequate?	☐	☐	☐
(f) Is the proposed number of subjects adequate to answer the study questions?	☐	☐	☐
(g) Will personally-identifiable research data be protected to the extent possible from access or use?	☐	☐	☐
(h) Are any special privacy & confidentiality issues properly addressed?	☐	☐	☐

Comment: _____

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

	Yes	No	NA
(a) Are reasonably foreseeable risks described?	☐	☐	☐
(b) Are risks reasonable in relation to benefits?	☐	☐	☐
(c) Are psychological and social risks addressed?	☐	☐	☐
(d) Does the level of risk meet federal regulations for protecting children in research:			
• Minimal risk **or**	☐	☐	☐
• Greater than minimal risk with prospect of direct benefit **or**	☐	☐	☐
• Greater than minimal risk, with no direct benefit, but generalizable knowledge?	☐	☐	☐
(e) If risks are greater than minimal risks, are they minimized?	☐	☐	☐
(f) Does the study involve prisoners, pregnant women, fetuses or neonates? If yes, refer to the appropriate vulnerable subject population form.	☐	☐	☐

Comment: _____

3. Selection of subjects is equitable

	Yes	No	NA
(a) Are inclusion/exclusion criteria adequate to protect subjects?	☐	☐	☐
(b) Are inclusion/exclusion criteria for each subject group described?	☐	☐	☐
(c) Is there equitable gender and minority representation? If not, explain.	☐	☐	☐
(d) Is the source of subjects described?	☐	☐	☐
(e) Are letters of cooperation from recruitment sites provided?	☐	☐	☐
(f) Does the study involve subjects from vulnerable populations?	☐	☐	☐
(g) Have additional safeguards for vulnerable subjects been included?	☐	☐	☐

Comment: _____

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with 45 CFR 46.116 and will be appropriately documented.

	Yes	No	NA
(a) Does the informed consent document include key information essential to decision making and appearing at the beginning of the consent form?	☐	☐	☐
(b) Is the consent document understandable to subjects?	☐	☐	☐
(c) Is the process for obtaining informed consent appropriate?	☐	☐	☐
(d) Parental consent			
• Will it be obtained?	☐	☐	☐
• If a waiver is requested, is it justified?	☐	☐	☐
(e) Assent			
• Will it be obtained?	☐	☐	☐
• If a waiver is requested, is it justified?	☐	☐	☐
(f) Is the timing of assent/consent appropriate to the situation?	☐	☐	☐
(g) Are the personnel obtaining assent/consent appropriate?	☐	☐	☐
(h) Is the person obtaining consent named on the consent form?	☐	☐	☐
(i) Is this person knowledgeable about the research and able to answer questions?	☐	☐	☐
(j) Is assent/consent obtained verbally?	☐	☐	☐
(k) Is assent/consent obtained in written form?	☐	☐	☐
(l) Are plans for storage of consent documents appropriate?	☐	☐	☐

Comment: _____

5. Subject privacy & confidentiality are maximized.	Yes	No	NA
(a) Are study data anonymous (no way to link to the individual)?	☐	☐	☐
(b) Are study data confidential (linked by code to names or medical record numbers)?	☐	☐	☐
(c) Provisions to protect confidentiality:			
• Are data/specimens stored without identifiers?	☐	☐	☐
• Is the key to the code kept separate from data?	☐	☐	☐
• Is access to research data limited to researchers?	☐	☐	☐
(d) Does the project involve collection of private health information (PHI)?	☐	☐	☐
(e) Is there adequate provision for monitoring the data collection to insure safety of subjects?	☐	☐	☐
(f) Are provisions for protecting privacy adequate?	☐	☐	☐
(g) Are the provisions for maintaining confidentiality adequate?	☐	☐	☐

Comment: _____

6. Do the research investigators have appropriate expertise to perform their responsibilities in the study?	☐	☐	☐

Comment: _____

7. Do the research staff have appropriate expertise to perform their responsibilities in the study?	☐	☐	☐

Comment: _____

8. How often should this study be reviewed? ☐ 6 months ☐ 12 months ☐ Other _____

Comment: _____