



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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) Does the research design minimize risks to subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(d) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(e) Is the information for study design and statistical methods adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(f) Is the proposed number of subjects adequate to answer the study questions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(g) Will personally-identifiable research data be protected to the extent possible from access or use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(h) Are any special privacy & confidentiality issues properly addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) Are risks reasonable in relation to benefits?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) Are psychological and social risks addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(d) Does the level of risk meet federal regulations for protecting children in research:			
• Minimal risk or	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Greater than minimal risk with prospect of direct benefit or	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Greater than minimal risk, with no direct benefit, but generalizable knowledge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(e) If risks are greater than minimal risks, are they minimized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(f) Does the study involve prisoners, pregnant women, fetuses or neonates? If yes, refer to the appropriate vulnerable subject population form.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment: _____

3. Selection of subjects is equitable

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

Comment: _____

4. Informed consent will be sought from each prospective subject and will be appropriately documented.

	Yes	No	NA
(a) Does the informed consent document include the eight required elements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) Is the consent document understandable to subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) Is the process for obtaining informed consent appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(d) Parental consent			
• Will it be obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• If a waiver is requested, is it justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(e) Assent			
• Will it be obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• If a waiver is requested, is it justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(f) Is the timing of assent/consent appropriate to the situation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(g) Are the personnel obtaining assent/consent appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(h) Is the person obtaining consent named on the consent form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(i) Is this person knowledgeable about the research and able to answer questions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(j) Is assent/consent obtained verbally?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(k) Is assent/consent obtained in written form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(l) Are plans for storage of consent documents appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment: _____

5. Subject privacy & confidentiality are maximized.

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

Comment: _____

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

Yes No NA

Comment: _____

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

Yes No NA

Comment: _____

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

Comment: _____