

APPENDIX III

REC Checklist for Initial Review

Title of Research: _____

Principal Investigator: _____

Primary Reviewer for the REC: _____

	YES	NO	N/A
Social Value			
1. Does the research have the potential to enhance the future health of society?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Has the community been involved with the planning of the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scientific Design			
3. Has a scientific committee approved the research?	<input type="checkbox"/>	<input type="checkbox"/>	
If No, are the elements of the study design (e.g., hypothesis, objectives, sample size, statistics, etc.) adequate to produce valid results?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Will the research be performed by qualified investigators and at proper facilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Does the study involve a placebo group, and if so, is there justification for including such a group?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Does the control group adequately represent the local standard of care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Are the experimental procedures adequately described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are there any other scientific issues that need to be addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Recruitment			
9. Is it clear who will be enrolled as research subjects or whose records will be used in the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO	N/A
10. Is the selection of subjects fair and equitable? (Consider purpose, setting, inclusion, and exclusion criteria)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the study have the potential for enrolling subjects who might be decisionally impaired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, a. will there be proxy consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. should the investigator assess the capacity of subjects to make their own decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the study involve any vulnerable groups? (e.g., pregnant women and fetuses, children, prisoners, decisionally impaired, institutionalized, socially or economically disadvantaged individuals, employees, students)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes: a. are additional safeguards needed to protect the rights and welfare of the vulnerable groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. state which ones are needed _____ _____			
13. Does any compensation for participation (e.g., financial, prospects of free medical care, etc.) represent an undue inducement to participate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Does the recruitment setting present any potential for coercion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Were all recruitment materials submitted? (posters, brochures, contact letters, TV, radio, newspaper ads)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Are the recruitment materials acceptable as submitted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk/Benefit Analysis			
Risks			
17. Are there physical or medical risks related to study participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Are there psychological or emotional risks related to study subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Are there social, economic, or legal risks related to study participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Are there risks to society in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Are risks adequately minimized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. If not, how can risks be further minimized? _____ _____			
23. What is the risk level of the research?			
<input type="checkbox"/> Minimal Risk <input type="checkbox"/> Above Minimal Risk <input type="checkbox"/> Too Risky			
Benefits			
24. Are there potential direct benefits to individual research subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Are there potential benefits for the future health of society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Will the community/country benefit from the results of the research after the research is over?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO	N/A
27. Have any post-trial agreements been developed with the sponsor/investigators?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analysis of Risks and Benefits			
28. Are the risks to subjects reasonable in relation to the anticipated benefits to the subjects and/or society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Confidentiality			
29. Are there adequate safeguards to protect subject privacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Are there adequate provisions to protect the confidentiality of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stored Tissue Samples			
31. Will there be any storage of tissue samples (blood/tissues)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Will there be any genetic analysis of the stored tissue samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Will a code be used to label the stored tissues? If yes, will the code contain any information that can potentially identify the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Will subjects have the option to withdraw their samples at any time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. How long will the samples be stored? _____			
36. Based on questions 32-35, are there safeguards to protect the privacy and confidentiality of the stored samples and the information from the stored samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Will any stored samples be shipped out of the country?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Informed Consent			
38. Is the researcher requesting access to records without informed consent? If yes, explain why this is justifiable: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Is the informed consent checklist completed, and is the consent form adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Is the short consent form needed for individuals who are illiterate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Safety Monitoring			
41. Are there procedures to monitor the safety data (i.e., serious adverse events, reasons for withdrawal/discontinuation) collected to ensure the safety of subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Is there a Data and Safety Monitoring Board (DSMB)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Are there any planned interim analyses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Recommendation

Approval

List nonbinding suggestions, if relevant: _____

Approval with Modifications

List modifications _____

Deferral

List issues _____

Disapproval

List issues _____

SIGNATURE OF PRIMARY REVIEWER

DATE