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

	YES	NO	N/A
10. Is the selection of subjects fair and equitable? (Consider purpose, setting, inclusion, and exclusion criteria)	☐	☐	☐
11. Does the study have the potential for enrolling subjects who might be decisionally impaired?	☐	☐	☐
If Yes, a. will there be proxy consent?	☐	☐	☐
b. should the investigator assess the capacity of subjects to make their own decisions?	☐	☐	☐
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)*?	☐	☐	☐
If Yes: a. are additional safeguards needed to protect the rights and welfare of the vulnerable groups?	☐	☐	☐
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?	☐	☐	☐
14. Does the recruitment setting present any potential for coercion?	☐	☐	☐
15. Were all recruitment materials submitted? *(posters, brochures, contact letters, TV, radio, newspaper ads)*	☐	☐	☐
16. Are the recruitment materials acceptable as submitted?	☐	☐	☐

Risk/Benefit Analysis

Risks

17. Are there physical or medical risks related to study participation?	☐	☐	☐
18. Are there psychological or emotional risks related to study subjects?	☐	☐	☐
19. Are there social, economic, or legal risks related to study participation?	☐	☐	☐
20. Are there risks to society in general?	☐	☐	☐
21. Are risks adequately minimized?	☐	☐	☐

22. If not, how can risks be further minimized? _____

_____

23. What is the risk level of the research?

☐ Minimal Risk ☐ Above Minimal Risk ☐ Too Risky

Benefits

24. Are there potential direct benefits to individual research subjects?	☐	☐	☐
25. Are there potential benefits for the future health of society?	☐	☐	☐
26. Will the community/country benefit from the results of the research after the research is over?	☐	☐	☐

	YES	NO	N/A
27. Have any post-trial agreements been developed with the sponsor/investigators?	☐	☐	☐

Analysis of Risks and Benefits

28. Are the risks to subjects reasonable in relation to the anticipated benefits to the subjects and/or society?	☐	☐	☐

Confidentiality

29. Are there adequate safeguards to protect subject privacy?	☐	☐	☐
30. Are there adequate provisions to protect the confidentiality of the data?	☐	☐	☐

Stored Tissue Samples

31. Will there be any storage of tissue samples (blood/tissues)?	☐	☐	☐
32. Will there be any genetic analysis of the stored tissue samples?	☐	☐	☐
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?	☐	☐	☐
34. Will subjects have the option to withdraw their samples at any time?	☐	☐	☐
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?	☐	☐	☐
37. Will any stored samples be shipped out of the country?	☐	☐	☐

Informed Consent

38. Is the researcher requesting access to records without informed consent?	☐	☐	☐

If yes, explain why this is justifiable: _____

_____

39. Is the informed consent checklist completed, and is the consent form adequate?	☐	☐	☐
40. Is the short consent form needed for individuals who are illiterate?	☐	☐	☐

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?	☐	☐	☐
42. Is there a Data and Safety Monitoring Board (DSMB?)	☐	☐	☐
43. Are there any planned interim analyses?	☐	☐	☐

Recommendation

Approval

List nonbinding suggestions, if relevant: _____

_____

_____

_____

_____

Approval with Modifications

List modifications _____

_____

_____

_____

_____

Deferral

List issues _____

_____

_____

_____

_____

Disapproval

List issues _____

_____

_____

_____

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_____ _____

SIGNATURE OF PRIMARY REVIEWER DATE