REC Checklist for Initial Review

Title of Research: .....

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Principal Investigator: .....

Primary Reviewer for the REC .....

Social Value

	Yes	No	N/A
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

	Yes	No	N/A
3. Has a scientific committee approved the research?	☐	☐	☐
4. Will the research be performed by qualified investigators and at proper Facilities?	☐	☐	☐
5. Does the study contain 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 the any other scientific issues that need to be addressed?	☐	☐	☐

Subject Recruitment

	Yes	No	N/A
9. Is it clear who will be enrolled as research subjects or whose records will be used in the research?	☐	☐	☐
10. Is the selection of subjects fair and equitable? (consider purpose, setting, inclusion and exclusion criteria)	☐	☐	☐
11. Does the study has the potential of 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 & fetuses, children, prisoners, decisionally impaired, institutionalized, socially or economically disadvantaged individuals, employees, students)/	☐	☐	☐
If yes			
a. If so, are additional safeguards needed to protect the rights and welfare of the vulnerable groups?	☐	☐	☐
b. If yes, state which ones are needed			

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13. Does any compensation for participation (e.g., financial, prospects of free medical care, etc.) represent an undue inducement to participate? ☐ ☐ ☐

14. Does the setting of recruitment represent a coercive concern? ☐ ☐ ☐

15. Were all recruitment materials submitted? (poster; brochures; contact letters; TV, radio, newspaper ads) ☐ ☐ ☐

16. Are the recruitment materials acceptable as submitted? ☐ ☐ ☐

Risk/Benefit Analysis

Risks

	Yes	No	N/A
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?

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23. What is the risk level of the research?

☐ Minimal Risk

☐ Above Minimal Risk

☐ Too Risky

Benefits

	Yes	No	N/A
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?	☐	☐	☐
27. Has any post-trial agreements been developed with the sponsor/investigators?	☐	☐	☐

Analysis of Risks and Benefits

	Yes	No	N/A
28. Are the risks to subjects reasonable in relation to the anticipated benefits to the subjects and /or society?	☐	☐	☐

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Confidentiality

	Yes	No	N/A
29. Are there adequate safeguards to protect subject privacy?	☐	☐	☐
30. Are there adequate provisions to protect the confidentiality of the data?	☐	☐	☐

Stored Tissue Samples

	Yes	No	N/A
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 the safeguards to protect the privacy and Confidentiality of the stored samples?	☐	☐	☐
37. Will any stored samples be shipped out of the country?	☐	☐	☐

Informed Consent

	Yes	No	N/A
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

	Yes	No	N/A
41. Are there procedures to monitor the safety data (i.e, SAE, reasons for withdrawal/ discontinuation) collected to ensure the safety of subjects?	☐	☐	☐
42. Is there a Data and Safety Monitoring Boards (DSMB)?	☐	☐	☐
43. Are there any planned interim analysis?	☐	☐	☐

Compensation for Injury

	Yes	No	N/A
44. Has provisions been made for compensation for any injury that occurs as a direct result of this study?	☐	☐	☐

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Recommendation:

Approval ☐

List non-binding suggestions, if relevant

Approval with Modifications ☐

List modifications

Deferral ☐

List issues:

Disapproval ☐

List issues

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