

A P P E N D I X 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 _____ | | | |
| <hr/> | | | |
| 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? _____ | | | |
| <hr/> | | | |
| 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