TriHealth

Genomic Sub Study Checklist

Must complete and submit with new study if a genomic sub study is involved

1. What is the purpose of the testing to be performed, the tissue repository or database?

2. What body fluids, tissues or data will be studied and/or stored?

3. What tests will be performed on the samples to be obtained?

4. How will participating subjects be selected?

5. Is participation optional ☐ or mandatory ☐ ?

6. How and where will specimens be obtained?

7. Will the specimens be stored for future and/or presently undefined study?

8. What are the provisions for protecting the confidentiality of tissue samples or data?

9. Could the results of these studies result in any commercially valuable products?

10. Will the samples be anonymous ☐, de-identified ☐, or identifiable ☐?

11. How/where will samples be stored in a secure manner and for how long?

12. Do the subjects have the option of having all data and tissue related to this study destroyed?

13. What will happen to research data and tissue if a subject elects to withdraw from study?

14. What will be done with the information obtained on individual subjects?

a) Does the information have clinical, diagnostic or therapeutic implications for the individual subjects?

b) Will subject/ parents/ relatives be informed of research results and their meaning? Will subject/ parents/ relatives be informed of research results and their meaning?

15. Will the family members be protected against disclosure of medical or other personal information about themselves to other family members?

16. Will the possible psychological and social risks of genetic research be adequately considered in the consent process?

17. Will appropriate counseling be provided, both as a part of the consent process and when communicating test or other research results to subjects?

18. Will subjects be informed about the possibility of important incidental findings such as paternity, disease, or conditions other than the one that are the focus of the study?

19. Will the data be protected from disclosure to third parties, such as employers and insurance companies?

20. Do the plans to publish or present data from this study threaten the privacy or confidentiality of participants?

21. Will results be reported to the subjects' physicians for clinical use?