Piedmont HEALTHCARE

Institutional Review Board

GENETIC AND OTHER SAMPLE RESEARCH GUIDANCE

For genetic research and when samples are stored for future, unknown research, the following items need to be addressed in the informed consent form:

a) Will the samples include identifiers which would link them to the subject?
    a. Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. The participant should decide whether they want to let the researchers keep the sample but get rid of all identifying information. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.
b) Is the subject able to request at a later date that the samples be destroyed? If yes, describe the process.
    a. Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact. Clearly indicate the point where withdrawal of specimens is no longer an option (if they have been stripped of identifiers and the link destroyed).
c) Will the samples be shared with other investigators or be used for unrelated research?
    a. Explain that you are seeking permission to store their unused samples for possible future use. State that they need to make a decision about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.
d) The Risks section must include social risks (insurability, employability, etc…)
e) If genetic testing is done, inform participant if results will be provided or not and explain why.
f) Explain that participants do not give up ownership of their sample; they give up ownership of any technology that may be developed form it.
    a. Add this clause:"The information that is obtained from the analysis of your sample may be used scientifically and may be used by the sponsor in other research. The analysis of your samples may contribute to the creation of new diagnostic tests, new medicines or other uses that may be commercially valuable to the sponsor. You will receive no financial benefits and may not receive any health-related benefits from such developments."
g) Briefly explain how confidentiality will be maintained.
h) If subjects will be contacted in the future or if their specimens will be stored or used for unrelated research, then please include separate check box options and initial lines for each issue. See examples below:

☐ I want my [TYPE OF SAMPLE] sample to be used for the tests indicated above. _____(initials)

☐ I do not want my [TYPE OF SAMPLE] sample to be used for the tests indicated above. _____(initials)

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored for future testing. _____(initials)

☐ I do not give permission for my [TYPE OF SAMPLE] sample to be stored for future testing. _____(initials)

☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project. _____ (initials)

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about: Specify_____ . _____(initials)