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Biomed Refresher 2 – Genetics Research

Massachusetts Institute of Technology Affiliates - Data or Specimens Only Research

Quiz

Instructions: Please provide an answer for all questions. Each question is one point. Click on the Submit button to register your answers. After submitting your answers, the correct answer to each question and an explanation will be displayed. Navigational links to the next module will also be provided.

All quiz questions count towards your score. You should answer all questions.

Question 1

A researcher is investigating the genetic biomarkers of adult subjects with autism. The research study involves a single blood draw (about one teaspoon of blood) and then genetic analysis of the specimen. How should the researcher inform prospective subjects about the potential risks of harm of this genetic research study?

- ☐ By minimizing the risks and emphasizing the importance of the work to finding the "Cure" for autism.
- ☒ **By carefully disclosing (without overstating) the possibilities of economic or insurance bias and of social stigma to the subject and potentially to others in the subject's family.**
- ☐ By noting that most genetic research risks are quite low and the blood sample will be coded and not contain the subject's name.
- ☐ By emphasizing the risk of bruising from the blood draw.

Question 2

A researcher conducting a study on the incidence of mutations to the MDR-1 gene in breast cancer has preliminary evidence of a link between mutated MDR-1 and early recurrence. The researcher begins a new trial using prospectively collected tissue samples to further examine the link between the genetic abnormality and disease progression. He believes that he may want to re-contact some or all of the tissue donors (subjects) if the research indicates a positive link between MDR-1 mutation and early disease recurrence. What is the best procedure for an investigator planning to re-contact study subjects who provided tumor tissue for the

study?

- ☐ Subsequent re-contact of subjects from a genetic study in which identifiable data is collected is permissible only if the patient's physician approves.
- ☒ **The investigator should disclose the intention to re-contact during the consent process. That is, before acquiring and analyzing the sample for research.**
- ☐ The samples and genetic information should be initially coded. The investigator could break the code to contact subjects as he deems necessary.
- ☐ There is no best course - such re-contact presents too many risks for the subject and thus is always unethical.

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Monday – Friday

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