Biomed Refresher 2 – Records-Based 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 director of a smoking cessation service at a university decided to publish a paper on whether quit rates were higher among clients who were offered as an incentive either a Moonbeams Coffee Shop's latte coupon or a pre-paid telephone card. The director was testing a hypothesis that coffee drinkers were less likely to quit smoking than telephone users. To do this, he proposed using outcome data on smoking cessation collected by the service, which would be extracted from the university's files and placed in a separate database with no identifying information other than sex, date of birth, zip code of Moonbeams where the coupons were used, and the telephone number of the research subject. Would this research be eligible for exemption?

- Yes. This is not really research and thus there is no need to contact the IRB.
- Yes. No identifiers are being collected and thus there is no need to contact the IRB.
- **No. The investigator may be able to identify subjects based on telephone numbers and birth dates, so this should not be considered exempt.**
- Yes. These records should be publicly available.

Question 2

An investigator has proposed a multi-site study of PSA (Prostate Specific Antigen) test results among patients with prostate cancer. The research involves only review of medical records at institutions in several states. The investigator will not collect any identifying information on the

subjects, only their PSA scores and ages (which will be collected in a range format so as to not have the person's specific age). The investigator may correctly conclude that:

- **IRB review, or similar process, may be required because generally investigators are not able to determine for themselves if their own research is exempt.**
- No IRB review is necessary because the data is de-identified.
- There is no need to contact any IRBs because this research is very low risk and would surely be exempt.
- All institutions will require review by the full IRB because risks of the research are not minimal.

Question 3

A large HMO has teamed up with several other large HMOs to study falls and footwear. The investigator proposes to review 5,000 medical records across 10 institutions of individuals injured during the last three years from a fall, so she has enough power to detect whether there is a greater number of falls among people who wear clogs. Because individuals wear so many different types of shoes, she will need to review a large number of records to find those few individuals who fit this category. From the medical records, she plans to extract the type of shoe the individuals wear. She will not re-identify the individuals and will not contact the individuals. Which of the following is likely to be the level of review determined as appropriate by the IRB?

- (●) **Exempt from the regulation, as the study presents no greater than minimal risk and does not collect identifying information.**
- ( ) Limited IRB review required, as a condition of exempt research category.
- ( ) Convened IRB review required, because the study involves the use of private information from multiple institutions.
- ( ) Expedited review required, as the study presents no greater than minimal risk but involves the use of medical records that contain sensitive information.

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