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Biomed Refresher 2 – Regulations and Process

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

Hospitals routinely and systematically collect information on various services they provide. For example, they may collect data from the pharmacy to see if drugs are being dispensed accurately, or they may hand out satisfaction questionnaires to assess if patients are happy with the service being provided to them. Which of the following is the best reason to explain why these data collections may not require prior IRB approval?

- ☐ Entities as large as hospitals are generally considered exempt from the requirement to submit proposed activities to their local IRBs.
- ☐ If the data are collected in a coded manner, with no actual names attached to them, then the activity is not considered research, and therefore does not require IRB approval.
- ☐ All systematic collections of data on humans must be considered human subject research, requiring IRB approval.
- ☒ **The hospitals are collecting these data with the intent to maintain or better their individual services and facilities programs, with no intent to share or report the results with any other entity.**

Question 2

Which of the following activities would not constitute human subjects research under the Common Rule?

- ☐ A study that requires collecting a portion of a participant's health information obtained during standard clinical care.
- ☐

A study using a quality of life questionnaire in which the participants reveal answers about how they perceive their health during receipt of clinical care.

- ☐ Research involving the implantation and study of an investigational pacemaker.
- ☒ **A study of cancer rates across various states using only public health records.**

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