Of course you are as brainy and brawny as a UF Researcher…

A back-to-school research quiz

1. David McGee, a nurse at UF Health, would like to administer an anonymous Qualtrics survey to staff at UF Health in Gainesville and Jacksonville to assess their thoughts on the new patient documentation requirements that were implemented 6-months ago. He submitted his study to IRB-02 for review since he is not collecting PHI and is only administering an anonymous survey; however, he was surprised that it was not accepted for review. Which of the following is true?

   a. All anonymous surveys are exempt, meaning that Mr. McGee’s proposal was not accepted because IRB review was not required.
   b. Mr. McGee will need to submit to IRB-01 because IRB-02 does not accept research from UF Health staff.
   c. An internal/in-office IRB-03 joint review will also be needed since the study involves Jacksonville HSC staff.

2. Dr. Jacobs, an internal medicine resident, just submitted an expedited retrospective chart review in myIRB. In order for him to get IRB-01 approval, which of the following must be true?

   a. All data must be existing; meaning that the end date for his chart review cannot occur after the date he submitted the study in myIRB.
   b. He can be the PI on the study as long as it is minimal risk and his faculty mentor is listed as a Co-Investigator.
   c. On the Study Description SmartForm page, the study purpose; how data is being accessed; inclusion/exclusion criteria; coding of data; data analysis plan; data storage/security and de-identification plans; and the relationship that he or a Co-Investigator has to the subject population should be described.
   d. All expedited chart reviews require a Full Waiver of Consent and a HIPAA Waiver to enroll. His justification for a Full Waiver of Informed Consent is appropriate because review of 2000 records is too many people to consent.
3. Dr. Bowie’s behavioral questionnaire study was initially approved by IRB-01 two years ago; however, he has decided to share a limited data set with a collaborator at Brown University. Which of the following are true?

a. He must submit a revision to indicate that data will be sent outside of the covered entity for analysis, which could include an update to the protocol and ICF.

b. The limited data set can be sent with dates of service (date of evaluation, etc.), but no direct identifiers such as name and Social Security Number; however, a data use agreement (DUA) (which involves DSP and/or UF Privacy) will need to be executed.

c. The collaborator at Brown may need to get his own local IRB approval; whereas, a copy of the approval must be attached in Q3.0 of the Miscellaneous SmartForm page.

Quiz answers: (1) = b and c; (2) = a, b, and c; (3) = a, b, and c.