Confidentiality and Data Integrity

You are a new coordinator helping a PI who does long-term outcomes studies comparing standard of care drug regimens. The PI sees about 1500 patients per year, and about 1200 of these patients enroll as research participants. When you ask where the research files are, the PI takes you to a paper file room filled with clinical records. You ask which files are the research participants' records, and the PI tells you all the records are together – clinical and research. Curious, you look at them and see that they do include research consent and HIPAA forms, along with all the patient's clinical care information. However, you don't see the long-term outcome surveys, which are sent to participants at least monthly for a year (and sometimes for up to five years). When you ask the PI where these surveys are, he points to his hanging file drawer and says that you should keep them in the drawer and then once a month enter them into the study database. When you ask where they are filed after, he says you can shred them after entry. What do you do?

- **Objective:**

- **Scope:**

- **Steps:**

- **Tool:**

IRB Approval

Your PI has an annual data monitoring committee meeting coming up. She asks you to clean up the study data set prior to sending it off to the biostatistician for interim analysis. You don't work on the project, but you did the original IRB application. For some reason, a lot of the fields don't match up with what you'd remembered submitting on the IRB application. What do you do?

- **Objective:**

- **Scope:**

- **Steps:**

- **Tool:**

Falsification of Records

You are part of a large team conducting a long-term quality of life project. Participants have a study visit at their home that includes a blood draw and an extensive interview every 6 months for 10 years. While one of your colleagues is away for a 3-week vacation, you and two others cover his patients, conducting home study visits and scheduling upcoming visits. While you are calling participants to schedule upcoming visits on behalf of your colleague, a couple of them say they haven't had a visit in at least a year. When you look in the records, you note that there are blood test results and interview data entered. You ask your colleagues if they have had anything like this come up, and they both admit to having at least one participant tell them the same thing, despite the existing data of their recently completed visit. What do you do?

- **Objective:**

- **Scope:**

- **Steps:**

- **Tool:**

Loss of Records

Your PI has requested that you archive the study records for a project that you hadn't worked on. The PI has already redacted all identifiers, and you just need to ensure all the documentation for the archive files are complete. You decide to count the consent and HIPAA forms to make sure the numbers correspond to the numbers of participant records. Surprisingly, you've got different numbers of each: consents, HIPAAs, and participant files. What do you do?

- **Objective:**

- **Scope:**

- **Steps:**

- **Tool:**

Adverse Events Analysis

Your PI asks you to look over her FDA annual report for an investigator-initiated IND trial of a drug used in vascular surgery patients. You note that despite having enrolled 25 participants over the year for this intervention, the PI reports no adverse events have occurred to date. When you inquire, she clarifies that because this is a sick population, all events that have occurred are expected as natural disease progression, so tracking and reporting is unnecessary. What do you do?

- **Objective:**

- **Scope:**

- **Steps:**

- **Tool:**