UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

Data Security Considerations

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With increased needs for technology solutions and electronic tools for conducting clinical research, it is important to recognize who has responsibility for determining if those tools are appropriate for clinical research use. Hint, it's not the IRB.

Contributing Authors: NC TraCS Regulatory, SOM IT Security, UNC OHRE, SOM CRSO

When certifying a study submission in IRBIS, the Principal Investigator (PI) is confirming that he/she will utilize appropriate technology for the data or information he/she will have, collect or share in the study, meaning the **responsibility lies with the PI**. Upon completion of the IRB application, each study is designated a data security tier (I, II, or III) which specifies the data security requirements based on the sensitivity of data involved. This designation can be found in the Data Security Requirements Addenda available in IRBIS.

Identifying appropriate technology, settings, and accounts in relation to the study needs and requirements is often very complex. It is always recommended to consult with School of Medicine IT (or the school's designated Information Security Liaison, if outside the SOM) when making decisions regarding technology (e.g., electronic platforms, communication methods, computer/database requirements). For the most direct route to consultation with School of Medicine IT, visit the UNC ITS website, click "Request Something Else" and indicate "SOM IRB security consultation/ question" in the request field.

Addressing broad technology needs

The SOM CRSO is currently involved in evaluating several technology needs and potential solutions, including masking outgoing phone calls to study participants, obtaining electronic informed consent, and collecting electronic signatures. We will disseminate these resources as soon as they become available. If you are aware of other broad technology needs or would like to share ideas for possible SOM-wide solutions, please contact us at crso@med.unc.edu.

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