UT Southwestern HRPP Guidance on ISAC Review for Human Research

This guidance document is intended to clarify when the Information Systems Acquisition Committee (ISAC) at the University of Texas Southwestern Medical Center is required for human subject research studies and how the review provides vital support to ensure the institution and participants are protected.

1. About ISAC

ISAC governs the acquisition of information systems, related equipment, and software for the UT Southwestern Medical Center campus. As part of the review, ISAC intends to:

- Reduce institutional technology risk
- Decrease redundancy and technology sprawl
- Drive cost savings

For many human subject research studies using technology, ISAC will ensure that the systems are secure, that the technology is compliant with applicable State of Texas laws, and that the confidentiality and privacy measures are appropriate. ISAC review is in addition to IRB review, based on the below criteria. The ISAC's review focuses on technologies proposed for use in a human research study, and not the study itself.

Learn more about ISAC on the Committee's website.

2. ISAC Review Criteria

Below are the six criteria for studies and their associated new technologies that would trigger ISAC review. A study would only need to meet one of the following six criteria in order for ISAC review to be required.

1) **The study will involve electronic storage (e.g., an Electronic Data Capture system or EDC) or processing of UTSW personally identifiable information (PII) through either a non-UTSW third party, mobile application, or non-UTSW online platform.**

❓ **What is UTSW data?**
- ISAC review is not required when the data are deidentified.
- UTSW data includes information collected or generated or stored by, or accessible via, a system or service or process owned by UTSW. This could include extracting data from UTSWT EPIC, REDCap, shared drive, or any other UTSW resource. This could also include accessing any paper record where that record is owned by UTSW.
- If a participant enters the data themselves into an external system (like another institution's REDCap), this is not considered to be UTSW data, and ISAC review is not required.
- If the data is extracted from an affiliate site and is not stored or recorded at UTSW (such as accessing Children's EPIC and recording data in an Excel file stored on a UTSW shared drive), this is not UTSW data and ISAC review is not required.

❓ What is personally identifiable information (PII)?

- PII includes any data that can be used to identify a participant. This includes Protected Health Information (PHI).
- It is important to remember that not all identifiable data is necessarily protected health information under the HIPAA Privacy law (not all identifiable data will be health related information used for treatment, payment, or operations).
- Refer to the "Individually Identifiable Health Information" definition in the HRPP Policy and Procedure Manual Glossary for a complete definition of what could be considered to be identifiable.
- Examples of identifiable data includes names, dates, unique codes or identifying numbers (including medical record numbers).
- If any identifiable data that is also UTSW data is sent externally to UTSW, ISAC review is required.

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2) To conduct the study, it will be necessary to create a website hosted at UTSW or on the UTSW domain (UTSouthwestern.edu, UTSouthwestern.org, and/or UTSWMed.org) that will be publicly accessible to the internet.

❓ Why does ISAC need to review websites?

- When any website is created that will be available to the internet, there are laws requiring accessibility compliance. Failure to comply with these laws can result in significant financial penalties for UTSW. ISAC review ensures that any website created complies fully with these accessibility requirements.
- In addition to the accessibility requirements, the creation of any website accessible from the internet represents an opportunity for a malicious attack on our infrastructure. Through ISAC, Information Security tests the website's security to ensure that there are no vulnerabilities for an attack to be successful.

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3) To conduct the study, a new mobile application (app) will be developed or is currently under development.

❓ Why does ISAC need to review the creation of mobile apps?

- Similar to the creation of a website, through ISAC, Information Security evaluates and tests mobile applications to ensure that security provisions are appropriate to prevent attacks on UTSW infrastructure and in compliance with Texas Administrative Code requirements.
- In addition, ISAC will review the development of the applications to ensure that the confidentiality provisions to protect the data are appropriate. This will include the collection of the data from the participant, the transfer of the data from the user's phone to the central storage server, and the protections for the server itself.
- If a study requires that an existing application be downloaded (and not created by UTSW or a UTSW investigator) to a participant's smartphone, this **does not** require ISAC review or approval.

4) UTSW funds will be used to purchase software (including mobile apps) or hardware and related services over $15,000 in order to conduct the study.

❓ **Why does ISAC need to review the purchase of software?**
- If a study will require the purchase of software or hardware over $15,000, ISAC will ensure that the acquisition follows Purchasing guidelines. and that there is no system already screened by ISAC for use campus wide.
- ISAC has a list of reviewed software systems available on its website. Prior approvals are specific to a technology, intended use, and department, and do not imply pre-approval of an ISAC request.

5) An external or vendor system will integrate with a UTSW system, e.g., Epic, for study conduct.

❓ **What is ISAC reviewing when an external system will integrate with a UTSW system?**
- As with the website and the mobile application, the direct connection, or integration, of an external system to a UTSW system, such as Epic, represents a significant security concern. ISAC will review the proposal and ensure that the connection will not open UTSW to significant risks.

6) UTSW will need to enter into an agreement to purchase "cloud" storage or computing infrastructure (e.g., Dropbox, Amazon WebWeb Services) to conduct the study.

❓ **Why does ISAC need to review the purchase of "cloud" systems?**
- The Texas Legislature passed a law in 2021 called TX-RAMP that includes requirements for state institutions to follow if cloud storage or infrastructure will be purchased. ISAC will review the purchase and the proposal and ensure that the requirements of TX-RAMP are met.
- Contracts must be in place to store sensitive UTSW data on a non-UTSW infrastructure. UT Southwestern OneDrive is the preferred cloud storage solution and is available to all UTSW employees.

3. How to submit to ISAC for Review

All requests for ISAC review should be submitted in ServiceNow.

4. Will Study Activation (Greenlight) be held until ISAC Review is completed?

No. A study requiring ISAC review may be activated when the IRB receives proof that the ISAC review request has been submitted. The IRB understands that some activities requiring ISAC review may not be implemented until long after the study has been activated. However, ISAC approval is required prior to use of systems meeting criteria found in Section 2, ISAC Review Criteria.