Protecting High Risk Data in Illinois REDCap

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Background
While people may only think of clinical data that is available from electronic medical records as high risk data, many typical non-clinical research projects contain data that includes high risk data, such as individually identifiable health information and protected health information. There is a wealth of information about a research participant that could be considered high risk data, such as information about health status and provision of health care. There is also be non-health related data that should be protected as high risk data, such as criminal activity or financial information.

This document outlines requirements and recommendations pertaining to protecting high risk data.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), established rules protecting the privacy and security of individually identifiable health information. For example, the HIPAA Privacy Rule and Security Rule set national standards requiring organizations and individuals to implement certain administrative, physical, and technical safeguards to maintain the confidentiality, integrity, and availability of protected health information (PHI).

Illinois REDCap, like many other electronic data collection and management systems, is HIPAA-capable. It contains the necessary components for HIPAA compliancy, but it is the environment into which the software is installed that makes it compliant.

Therefore, HIPAA compliancy requires that certain practices, such as limiting access to high risk data and restricting export of high risk data, are thoroughly documented and communicated to users. As such, part of what makes Illinois REDCap HIPAA-compliant is YOU.

More information about HIPAA and HIPAA compliance at the University of Illinois, including the Privacy Directive, can be found at https://hipaa.uillinois.edu.

What is High Risk Data?
According to University Counsel and the University’s Information Security Controls, **ALL** of the following are designated *high risk data* and must be stored and transmitted in accordance with HIPAA standards:

- Health Information
- Individually Identifiable Health Information
- Protected Health Information (PHI)

This effectively means that Illinois researchers are expected to treat **ALL** health-related data (unless de-identified) as covered by HIPAA requirements—with the highest levels of privacy and security possible—*regardless of the source of the data*.

Further, the HIPAA Privacy Rule requires that investigators take reasonable steps to limit the use or disclosure of, and requests for, high risk data to the “**minimum necessary**” to accomplish the intended purpose. Illinois REDCap users are expected to operate at all times according to the “minimum necessary” standard (e.g., limit data access to necessary team members; do not export, share, or transfer data unless absolute necessary; etc.). See Required Strategies to Maintain the Security of Research Data in Illinois REDCap.

Health Information, Individually Identifiable Health Information, and Protected Health Information (PHI) are defined as follows:

1. **Health Information**
   - Any information, including genetic information, whether oral or recorded in any form or medium, that: (1) is created or received by a Health Care Provider, Health Plan, public health authority, employer, life insurer, school or university, or Health Care Clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an Individual; the provision of health care to an Individual; or the past, present, or future payment for the provision of health care to an Individual. (45 CFR § 160.103)

2. **Individually Identifiable Health Information**
   - Information that is a subset of Health Information, including demographic information collected from an Individual, and that: (1) is created or received by a Health Care Provider, Health Plan, employer, or Health Care Clearinghouse; (2) relates to the past, present, or future physical or mental health or condition of an Individual; the provision of health care to an Individual; or the past, present, or future payment for the provision of health care to an Individual; and (3) a. identifies the Individual, or b. with respect to which there is a reasonable basis to believe the information can be used to identify the Individual. (45 CFR § 160.103)

3. **Protected Health Information (PHI)**
   - A subset of Individually Identifiable Health Information that is (a) transmitted by Electronic Media; (b) maintained in any medium constituting Electronic Media; or (c) transmitted or maintained in any other form or medium. (45 CFR §160.103)
     - Note: Information pertaining to a patient who has been deceased for more than 50 years is no longer Protected Health Information. Protected Health
Information does not include Individually Identifiable Health Information in education records under FERPA or employment records held by a Covered Entity as an employer.

Again, Illinois researchers are expected to treat ALL health-related data (unless de-identified) as covered by HIPAA requirements—with the highest levels of privacy and security possible—regardless of the source of the data.

**Which Units Must Follow the HIPAA Privacy and Security Rules?**
The University of Illinois at Urbana-Champaign is a “hybrid entity” under HIPAA, meaning that only certain units are considered “covered components,” also called healthcare components (HCCs).

Current HCCs on our campus include:
- Interdisciplinary Health Sciences Institute (IHSI)
- National Center for Supercomputing Applications (NCSA)
- School of Social Work
- Technology Services
- College of Applied Health Sciences – Speech and Hearing Services
- Illinois Neuro Behavioral Assessment Laboratory (INBAL)
- Occupational Safety and Health Department (OSH)

However, due to the fact that HCCs are limited in how they can share high risk data with non-HCCs, ALL units (“covered” or not) are expected to store and transmit health-related information as if they are covered by HIPAA. Further, HCCs are not permitted to disclose high risk data to non-HCCs without a Business Associate Agreement (BAA). For more information about these requirements, please refer to [https://hipaa.uillinois.edu/](https://hipaa.uillinois.edu/).

**U of I System HIPAA Training**
Because Illinois REDCap is housed in a HIPAA-provisioned Amazon Web Services (AWS) space, ALL users who will be accessing Illinois REDCap must complete U of I System HIPAA training, regardless of whether they reside in a “covered component,” and regardless of whether they will be working with high risk data.

HIPAA training is administered by the U of I System. Training is coordinated so that most people are only required to complete HIPAA training once per year. However, some users may be required to complete HIPAA training more than once in a year if their access requirements change. Annual HIPAA training is required. Failure to complete the annual training may result in suspension of Illinois REDCap access until training is completed.

To obtain access to HIPAA training, users must first complete the Illinois REDCap User Request Form. If you belong to a HIPAA-covered component (e.g., School of Social Work) and/or have already completed U of I System HIPAA training, you will have the option to upload your HIPAA training completion certificate to your Illinois REDCap User Request Form.
Within one week of submitting your Illinois REDCap User Request Form, you will receive a link via email to access U of I System HIPAA training. Please follow these steps:

1. Click the emailed link to access and complete the U of I System HIPAA training (approx. 1.5 hours)
2. Save and email your HIPAA training completion certificate to redcap-admin@illinois.edu
   - Note: The IHSI REDCap team is not automatically notified when training has been completed. Therefore, it is essential that you save and email the PDF of your certificate directly to redcap-admin@illinois.edu.

Upon receipt of your HIPAA training completion certificate, the IHSI REDCap team will grant you Illinois REDCap access (may take up to 2 business days).

Compliance Documentation

- The Principal Investigator or designated Project Administrator (e.g., lab manager, research coordinator) is REQUIRED to submit a copy of one of the following compliance documents to the IHSI REDCap Team prior to moving the project to production and collecting data:
  - University Institutional Review Board (IRB) approval letter from the Office for the Protection of Research Subjects (OPRS)
  - Not Human Subjects Research (NHSR) letter from the Office for the Protection of Research Subjects (OPRS)
  - University Institutional Animal Care and Use Committee (IACUC) approval from the Division of Animal Resources (DAR)

- If the project is conducted at more than one institution, the project owner attests that appropriate regulatory approvals (non-Illinois) have been obtained prior to data collection.

- A data use agreement (DUA) may be required when working with a limited data set in which high risk data has been obtained from a clinical partner. Since a limited data set contains identifiers, the HIPAA Privacy Rule states that covered entities (e.g., clinical partners) must enter into data use agreements with recipients (e.g., researchers). Some third parties also require a DUA regardless of whether the data is considered a limited data set. A DUA must:
  - Establish the permitted uses and disclosures of the limited data set;
  - Identify who may use or receive the information;
  - Prohibit the recipient from using or further disclosing the information, except as permitted by the agreement or as permitted by law;
  - Require the recipient to use appropriate safeguards to prevent a use or disclosure that is not permitted by the agreement;
  - Require the recipient to report to the covered entity any unauthorized use or disclosure of which it becomes aware;
  - Require the recipient to ensure that any agents (including a subcontractor) to whom it provides the information will agree to the same restrictions as provided in the agreement;
  - Prohibit the recipient from identifying the information or contacting the individuals; and
Define 1) data elements to be received and processed and 2) systems or services that will house and process the limited data set

**De-Identification**

University Counsel has determined that high risk data may only be de-identified using the Safe Harbor Method (§164.514(b)(2)). The University of Illinois does not recognize the statistical determination de-identification method. According to HIPAA, there are 18 pieces of information, or “identifiers,” linked to high risk data that must be removed in order to consider data to be de-identified using Safe Harbor:

1. Names
2. All geographical identifiers smaller than a state, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
3. Dates (other than year) directly related to an individual
4. Phone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers (SSNs)
8. Medical record numbers (MRNs)
9. Health insurance beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Uniform Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger, retinal, and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code except the unique code assigned by the investigator to code the data

High risk data is considered de-identified according to this method once these 18 specific identifiers linked to the research participant have been removed. In essence, de-identifying the data removes all information that could reasonably be used to re-identify the participant. Attention must be given to check that all 18 specific identifiers are removed, wherever those identifiers appear. Further, the user must have no actual knowledge that any residual information can identify an individual.

If you have questions about de-identifying your data, please consult with the IHSI REDCap Team at redcap-admin@illinois.edu or the Office for the Protection of Research Subjects (OPRS) at irb@illinois.edu.
Anonymous Code Systems and Re-Identification
After de-identification of high risk data researchers are permitted to use an anonymous code system, which assigns a code or other means of record identification to allow that information to be re-identified or linked to the research dataset.

The mechanism for assigning codes and re-identifying records (the “key”) must not be:
- Derived from the identifiers (e.g., using a participant’s initials in lieu of their name)
- Used for any other purpose other than for re-identification
- Disclosed to others outside your research group
- Stored on any machines, including those used for data collection/analysis

If you are working with high risk data, you must keep your code stored with high risk data, such as in a Box Health Data Folder, HIPAA-approved Amazon Web Services account, or Illinois REDCap. If you are working with high risk data in Illinois REDCap, you must store your identity key(s) as a separate form or survey and limit access. See “Entering research data” section under Required Strategies to Maintain Security of Research Data in Illinois REDCap.

Details about this process should be listed in your Institutional Review Board (IRB) protocol (see Compliance Documentation).

Limited Data Sets
A "limited data set" contains identifiers. A limited data set pertaining to health information is therefore ALWAYS high risk data. A Data Use Agreement (see Compliance Documentation) may be required if the limited data set originates with a clinical partner or other third party.

Identifiers that may remain in the information disclosed in a limited data set include:
- Dates such as admission, discharge, service, DOB, DOD
- City, state, five digit or more zip code
- Ages in years, months, days, or hours

HIPAA-Approved Tools at Illinois
The following systems/services meet certain requirements established by the HIPAA Security Rule and therefore are approved to process, store, or collect high risk data:

- Amazon Web Services (AWS)
  - HIPAA accounts must be requested at https://aws.illinois.edu
  - Requires systems deployed to meet "high risk" standard of the Illini Secure security controls found at https://cybersecurity.uillinois.edu/controls
  - Generally requires additional IT support and resources
  - Ideal for processing high risk data (e.g., running scripts)
- Box Health Data Folder (BDHF) via U of I Box
  - BHDFs must be requested at https://hipaa.uillinois.edu/protecting-phi-with-box-health-data-folders/
“Syncing” and unsupported third-party Box integrations are not permitted
- Ideal for storage of high risk data, including protected health information (see What is High Risk Data?)

- Illinois REDCap
  - Access must be requested at [https://healthinstitute.illinois.edu/redcap](https://healthinstitute.illinois.edu/redcap)
  - REDCap training ([https://projectredcap.org/resources/videos/](https://projectredcap.org/resources/videos/)) and U of I System HIPAA training (link provided after submission of Illinois REDCap User Request Form) must be completed prior to access to establish baseline familiarity with the application
  - Ideal for collection of high risk data

Additional administrative, physical, and technical safeguards have been instituted to meet the remaining requirements, including mandatory de-identification in order to export, share, or transfer data.

**Required Strategies to Maintain Security of Research Data in Illinois REDCap**

**Entering research data**
- Customize user rights/roles according to “minimum necessary” standard and review routinely
  - Custom rights can be assigned to an individual user
  - Custom roles (with rights you can preset) can be assigned to multiple users
User rights table with default settings for adding a user ‘with custom rights’ or creating a new role:

<table>
<thead>
<tr>
<th>Project Design and Setup</th>
<th>User Rights Groups</th>
<th>Data Access</th>
<th>Data Export Tool</th>
<th>Reports &amp; Report Builder</th>
<th>Calendar</th>
<th>Data Import Tool</th>
<th>Data Comparison Tool</th>
<th>Logging</th>
<th>File Repository</th>
<th>Record Locking Customization</th>
<th>Data Quality (create/edit rules)</th>
<th>Data Quality (copy/Create)</th>
<th>Create Records</th>
<th>Rename Records</th>
<th>Delete Records</th>
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• Restrict/limit access to forms and surveys containing high risk data, including identity key(s), according to “minimum necessary” standard
  - It is recommended that only the Principal Investigator and/or designated Project Administrator (e.g., lab manager, research coordinator) have access to identity key(s)
• Flag identifiers when creating new fields
  o If your field label calls for identifying information (i.e., one of the 18 HIPAA identifiers), you must choose YES next to Identifier
Exporting research data

- Restrict/limit Data Export user rights according to “minimum necessary” standard
  - For example, non-Illinois (i.e., external) collaborators should not have Data Export rights

User rights table when “No Access” to Data Export is selected:

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• Export and/or transfer de-identified data ONLY and according to “minimum necessary” standard
  o Ensure that “Remove all tagged identifier fields” is checked prior to exporting and/or transferring data

If you must export and/or transfer data with identifiers for the purpose of analysis, please contact the IHSI REDCap team and your unit IT professional(s) for assistance prior to export/transfer with secure data transfer and local requirements.
Utilizing Surveys in Illinois REDCap

REDCap has two online survey options, a private survey and a public survey.

- The **private survey** utilizes a participant's email address and REDCap sends a unique survey URL to each individual participant. Participants may only take the private survey one time.
- The **public survey** option involves a REDCap survey URL that can be posted on a website, emailed to a mailing list, etc.

Important:
- Only one-time, short-term surveys (≤ 1 month in duration with survey expiration date clearly indicated) may utilize the “Save & Return Later” option; all other surveys **may not use** this function.
- Further, the following option should **never** be checked: “Allow respondents to return without needing a return code.”
- In accordance with our security protocol, this will be reviewed by the IHSI REDCap Team prior to moving projects to production.

![Survey Access](image-url)
Additional Resources

- Illinois REDCap Homepage: https://healthinstitute.illinois.edu/redcap
- U of I Amazon Web Services Info: https://aws.illinois.edu
- U of I Box Health Data Folders Info: https://hipaa.uillinois.edu/protecting-phi-with-box-health-data-folders/
- U of I Cybersecurity Controls and Data Classification Info: https://go.illinois.edu/dataprivacy
- U of I HIPAA Homepage: https://hipaa.uillinois.edu/
- U of I Office for the Protection of Research Subjects: https://oprs.research.illinois.edu/
- U of I Office of the Vice Chancellor for Research – Animal Care and Use: http://research.illinois.edu/regulatory-compliance-safety/animal-care-and-use
- U.S. Dept. of Health and Human Services De-Identification Info: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html
- Vanderbilt University’s REDCap Homepage: https://projectredcap.org/