Data Access Training

Data Stewardship Training for Collaborators

Access to Identifiable Oncology Data at Fred Hutch

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Welcome!

You are provided this training because you have been or will be granted access to identifiable patient information as part a collaboration with Fred Hutch (FH).

This training is to make sure individuals who access this data understand their roles and responsibilities, including the use of safeguards based on the nature of the data, the data's criticality, and the level of risk associated with its improper access and use.

This training, along with others, such as Human Subjects Training, are safeguards for you, your employer and FH.

Purpose of this Training

Stewardship

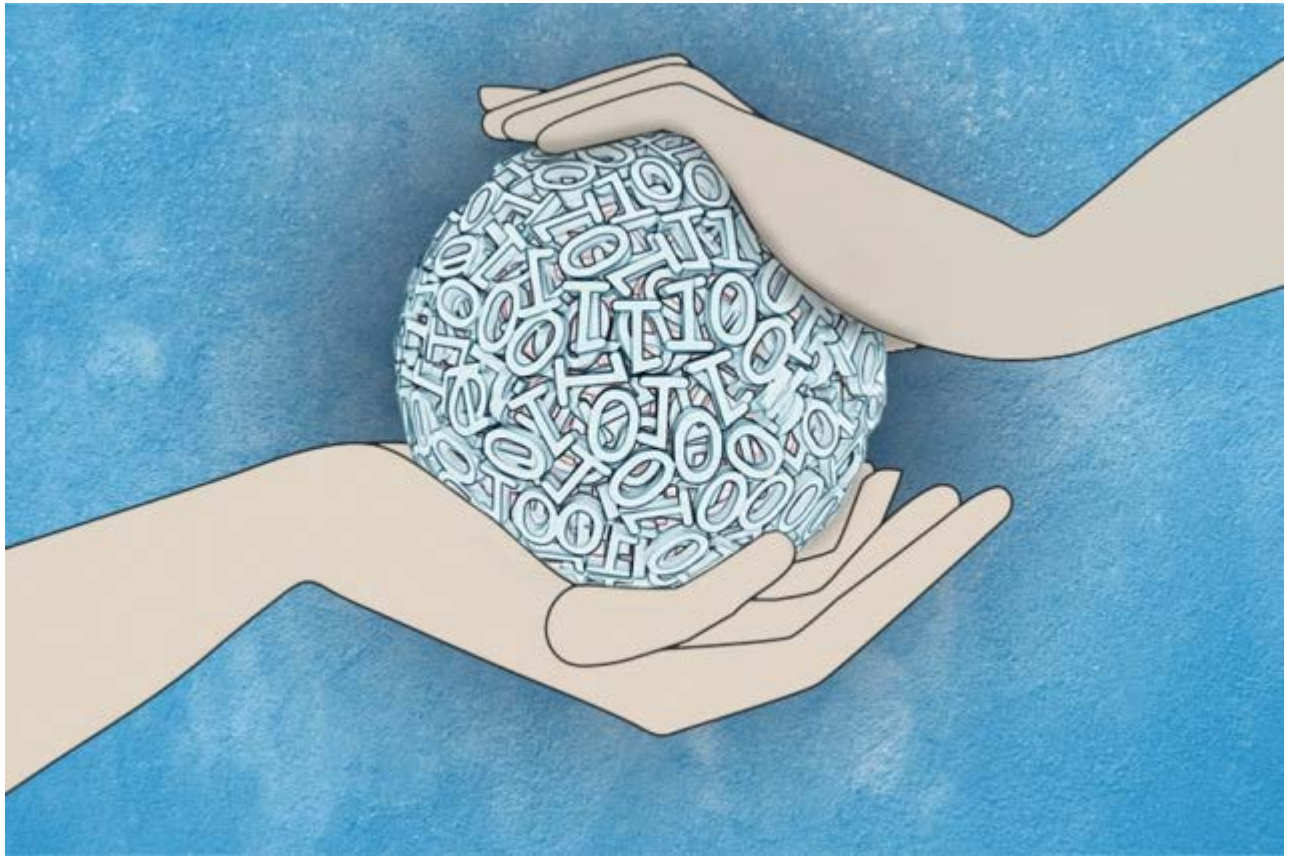
What is Identified Human Data

Data used in Research

Security and Handling of Identified Human Data

Reporting Data Misuse and Remediation

Why Stewardship Matters



Why We Care About Stewardship

Strong stewardship maintains our legal, regulatory and ethical responsibilities as an institution.

Strong stewardship represents our commitment to current and future patients, who are the primary owners of this information. Without such stewardship, FH, its collaborators and affiliates break the trust and social contract with patients and research subjects whose information we use.

FH also has strong and fundamental relationships with care hospitals and doctors, such as at UW and SCCA. These care providers are the primary stewards and secondary owners of the information. Data stewardship is our commitment to them, as well. Maintaining the trust of these providers ensures FH has the information resources needed to continue its mission.

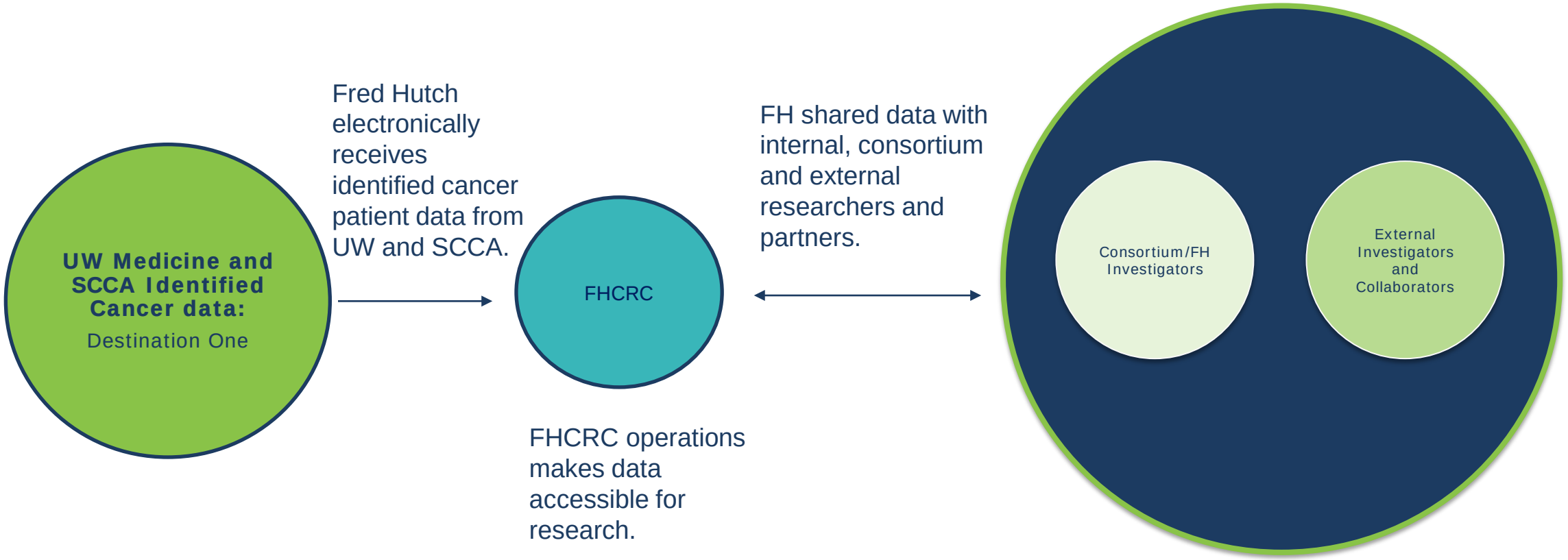
Why You Care About Stewardship

Because you collaborate with us and receive our data, your organization and you as a team member accept our ethical and legal responsibilities associated with medical research.

Identified data is regulated on a federal and state level and subject to FH institutional policies. Relevant privacy and security regulations and requirements, as well as federal and state enforcement rules, begin when the information is generated and flow down to you and your organization.

Accidental or intentional unauthorized exposure/use within your organization or between your organization and an outside entity may result in reputational harm to your organization and informational harm to the patients who own the data.

Stewardship and Where the Data Come From



What is Identified Human Data?

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Health care data are identifiable when

1. it includes one or more of the 18 HIPAA* identifiers, **or**

2. enables someone to conclude *on a reasonable basis* the data can be used to identify an individual, including coded health information.

* Health Information Portability and Accountability Act

The 18 HIPAA Specified Identifiers

The following identifiers apply to the patient, the patient's family, household and employer:

- name, location, dates, telephone numbers, fax numbers, e-mail addresses, social security numbers, medical record numbers, health plan numbers, account numbers, license numbers, vehicle ID's, device ID's, URLs, IP addresses, biometric ID's (finger and voice prints), full face images, and any other unique identifying number or code

De-Identified Human Data

De-Identified data bears very small risk that a patient can be re-identified. This is done by removal of the 18 HIPAA identifiers and/or coding and statistical methods to block re-identification.

Regardless of whether the data you see is identified or de-identified, you should not have Social Security Number, Driver License number or other financial account numbers associated with the shared data. If so, please report to your supervisor or FH immediately.

Using Identified Data Under Research

Human Subjects Protection

- Research which uses identified human data is considered Human Subjects research. As a result, use of identified data is subject not only to federal HIPAA laws, but also federal Human Subject Protection laws.

- Human Subject Protection law requires a researcher to submit a research plan (a protocol) to the FH Institutional Review Board (IRB) for approval. The IRB is a committee which reviews all protocols involving humans or human data to ensure research methods sufficiently protect human subjects from all forms of harm. IRB Committee maintains oversight of the research work for the life of the protocol.

Authorization – Access to Data

- Identified data may only be used with authorization.
- Generally, identified data can only be used for research after the patient provides authorization for his/her data.
- If the patient does not authorize use, the IRB can authorize use in the patient's stead.

Data Use Principles

Once allowed access to identified data, all who work with the data must adhere to the following overarching federal requirements (“principles”):

Adherence to the institutional/FH Information Security Policy and Standards. Fred Hutch Classifies identified human data as Restricted, the highest risk class.

“Minimum Necessary Use” - the researcher must make efforts to request, disclose or use only the minimum amount of Protected Health Information needed to accomplish the intended purpose of the use, disclosure, or request.

Collaboration Not Conducted Under Research

If you are receiving identified data as a collaborator for reasons other than research, you will be receiving this data under a data use agreement. Good data stewardship requires you to understand the data use agreement which allows the sharing of data within the collaboration.

Adherence to FH Information Security Policy and Standards.

Using identified data will not fall under Human Subjects Protection, but likely under full HIPAA requirements. Relevant privacy and security regulations and requirements, as well as federal and state enforcement rules, flow down to you and your organization.

Security and Handling of Identified Human Data

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Fred Hutch Information Security Policy

- Identifiable data is considered Restricted Information under the FH Information Classification and Handling Policy.

- This standard flows down to FH collaborators and is summarized in the next two slides.

FH Restricted Information Policy

Restricted Information requires special protection and is intended for internal use only on need-to-know basis between authorized users. Unauthorized disclosure, destruction, or alteration of Restricted Information could be expected to cause serious to catastrophic harm to Fred Hutch, its property, or its personnel. Examples of such harm include, but are not limited to temporary cessation of operations, harm to patients and participants, loss of rights to receive funding.

Examples of such data include:

- Protected Health Information or PHI
- Proprietary business information
- Computer passwords/encryption keys

FH Restricted Information Standard

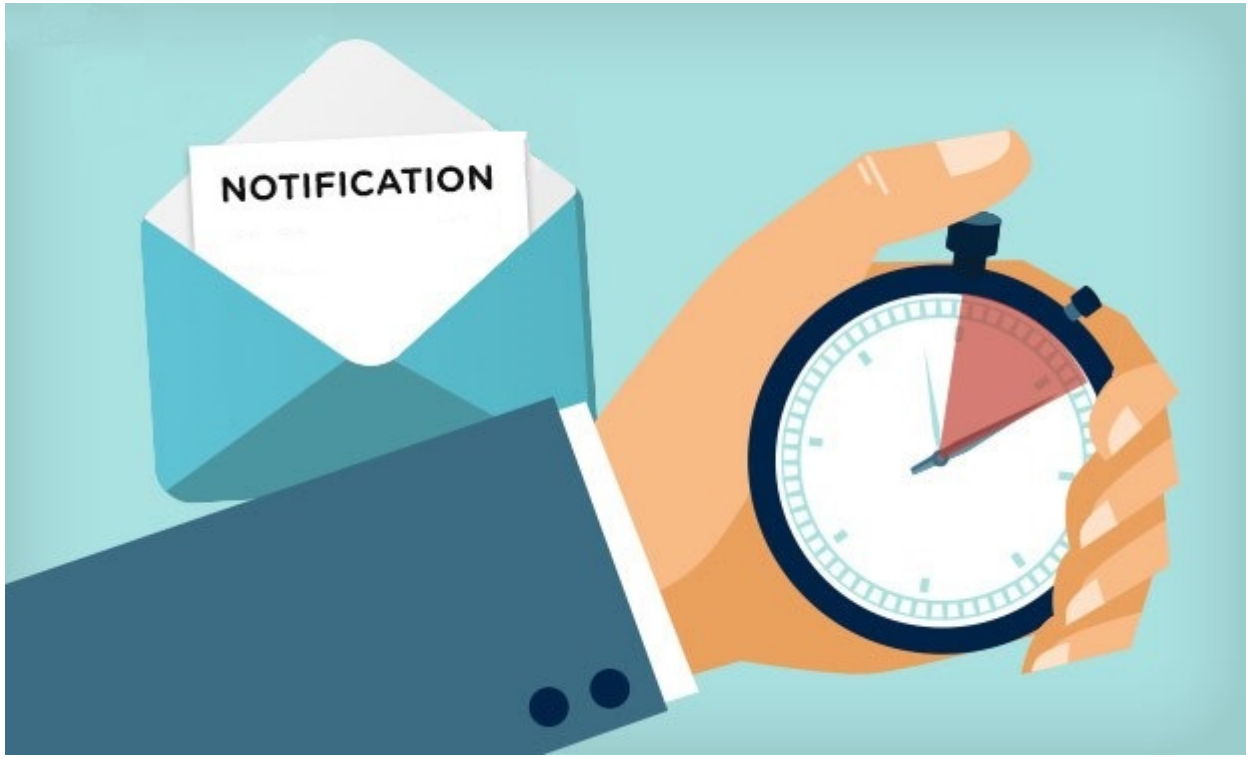
- ❑ Must be handled by Fred Hutch employees and non-employees according to Fred Hutch Policy, summarized below.
- ❑ Should only be accessed and/or used for an approved purpose.
- ❑ Must be **securely** maintained and transmitted:
  - Password Protected
  - Access controlled
  - Encrypted in transit and rest
  - Audited access and logging
- ❑ Cannot be shared with others not authorized to receive it.
- ❑ Loss or suspected loss should be reported immediately to the Fred Hutch Help Desk at 206.667.5700.

Handling FH Restricted Information

Access to Restricted Information has the following responsibilities:

- To not re-disclose any Restricted Information to any person or entity not authorized to receive such information.
- To not remove Restricted Information from Fred Hutch/Collaborator managed environment unless authorized to do so.
- To report to my superior or FH if I have reason to believe the confidentiality or security of my password or access to information has been compromised.

Reporting Misuse of Identified Human Information



Reporting Misuse

Regardless if you are an employee or non-employee affiliate..

Regardless if the data is shared for research or non-research purposes..

Intentional and unintentional misuse of the data - including unauthorized or unauthorized and unsecured use/disclosure - needs to be reported to FH within 24 hours of first awareness.

Contact your supervisor, call FH Security/Compliance at Mike Nescot, HDC Security (206.667.3618/mnescot@fredhutch.org) or Fred Hutch Office of the General Counsel at 206-667-1224.

Notification of Misuse

Unauthorized, or unauthorized and unsecured use of identifiable human data by FH collaborators will likely result in notification to the care providers or hospitals which provide FH with the information.

Unsecured exposure of data owned by **a large number of unique patient** individuals may result in a **HIPAA reportable event with civil penalties**.

If the collaboration is under research use, **notification to the FH Institutional Review Board (IRB) is required.**

The Institutional Review Board (IRB) has **discretionary power to suspend or terminate work on a collaboration** if that collaboration is considered a research project.

Your intentional or unintentional misuse of identified data under research may result in permanent reputational harm to the research Principal Investigator.

Q & A: Unauthorized Disclosure

Can a researcher use or share identified information for reasons outside the study protocol? No. The disclosure or use of identified data violates scope of the patient-signed authorization or the IRB approval. This is unauthorized use.

What happens if identifiable research data somehow become open-facing to the public, such as via the internet? This represents an unauthorized and unsecured disclosure. Notification to FH is required. Disclosure/use of unauthorized, unsecured identified data may also require notification to the IRB and the hospital or provider which is the source of the data.

What happens if identifiable research data on a non-encrypted smartphone is lost? Because the phone is not encrypted (password protection is not sufficient), this is also an unauthorized, unsecured disclosure and notification is required.

Summing It Up: Managing Shared Risk

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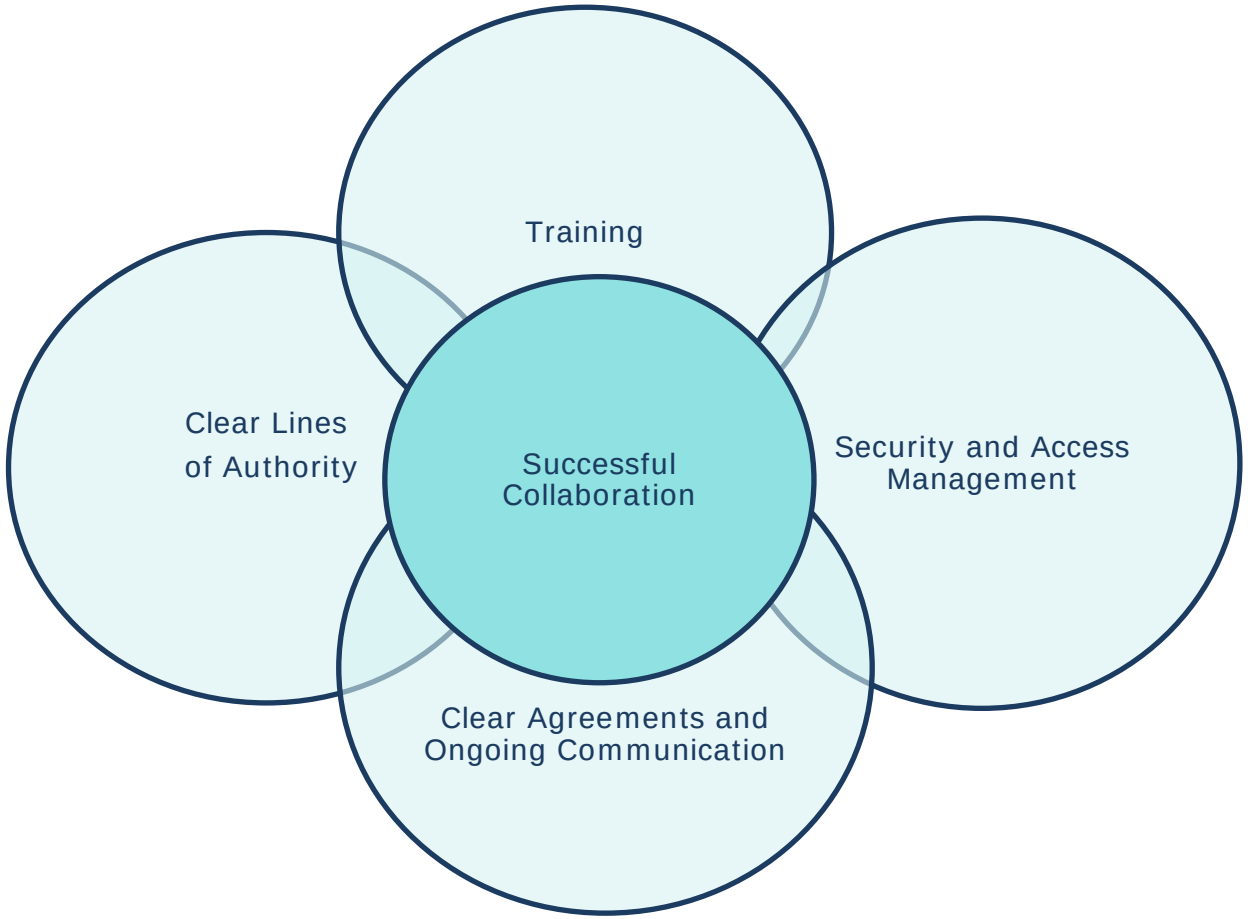

QUESTIONS ?

Any questions about this training session can be directed to Susan Glick at sgglick@fredhutch.org.

THANK YOU