

OVERVIEW OF LEGAL & SECURITY ISSUES WITH IDS



Government is Entrusted with Sensitive Material

For example: Ricin,
infectious disease agents,
nuclear material, etc.

Government even trusts
contractors with these
materials.

Compelling public interest

But there are strict
security provisions in
place!



Privacy vs. Confidentiality



Privacy Applies to the Person

- The way potential participants are identified and contacted
- The setting that potential participants will interact with the researcher team and who is present during research procedures
- The methods used to collect information about participants
- The type of information being collected
- Access to the minimum amount of information necessary to conduct the research

Confidentiality Applies to the Data

- An extension of privacy
- Pertains to identifiable data
- An agreement about maintenance and who has access to identifiable data
- What procedures will be put in place to ensure that only authorized individuals will have access to the information, and
- Limitations (if any) to these confidentiality procedures
- In regards to HIPAA, protection of patients from inappropriate disclosures of Protected Health Information (PHI)

Source: UCI Researchers (<http://research.uci.edu/cascade/compliance/human-research-protections/docs/privacy-confidentiality-hrp.pdf>)

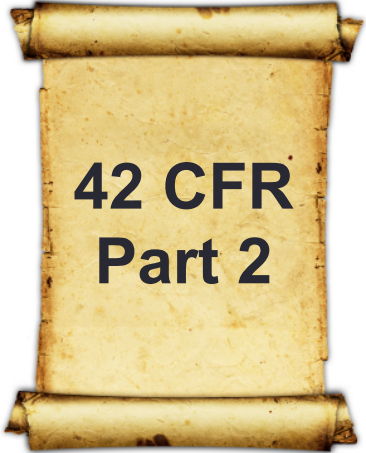
Identifiers and Protected Information are Security Issues



Relevant Federal Statues



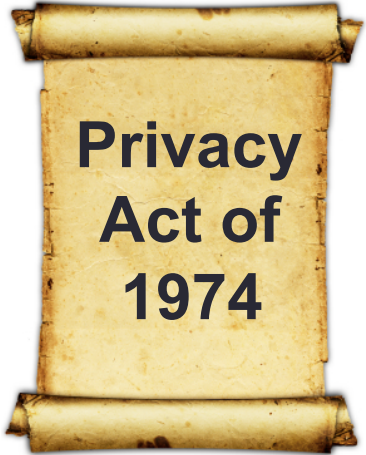
FERPA

A scroll representing FERPA, with the text "FERPA" in bold black font.

**42 CFR
Part 2**

A scroll representing 42 CFR Part 2, with the text "42 CFR" and "Part 2" in bold black font.

HIPAA

A scroll representing HIPAA, with the text "HIPAA" in bold black font.

**Privacy
Act of
1974**

A scroll representing the Privacy Act of 1974, with the text "Privacy", "Act of", and "1974" in bold black font.

Exemptions and Exceptions

- Research
- Evaluation
- Planning
- Auditing

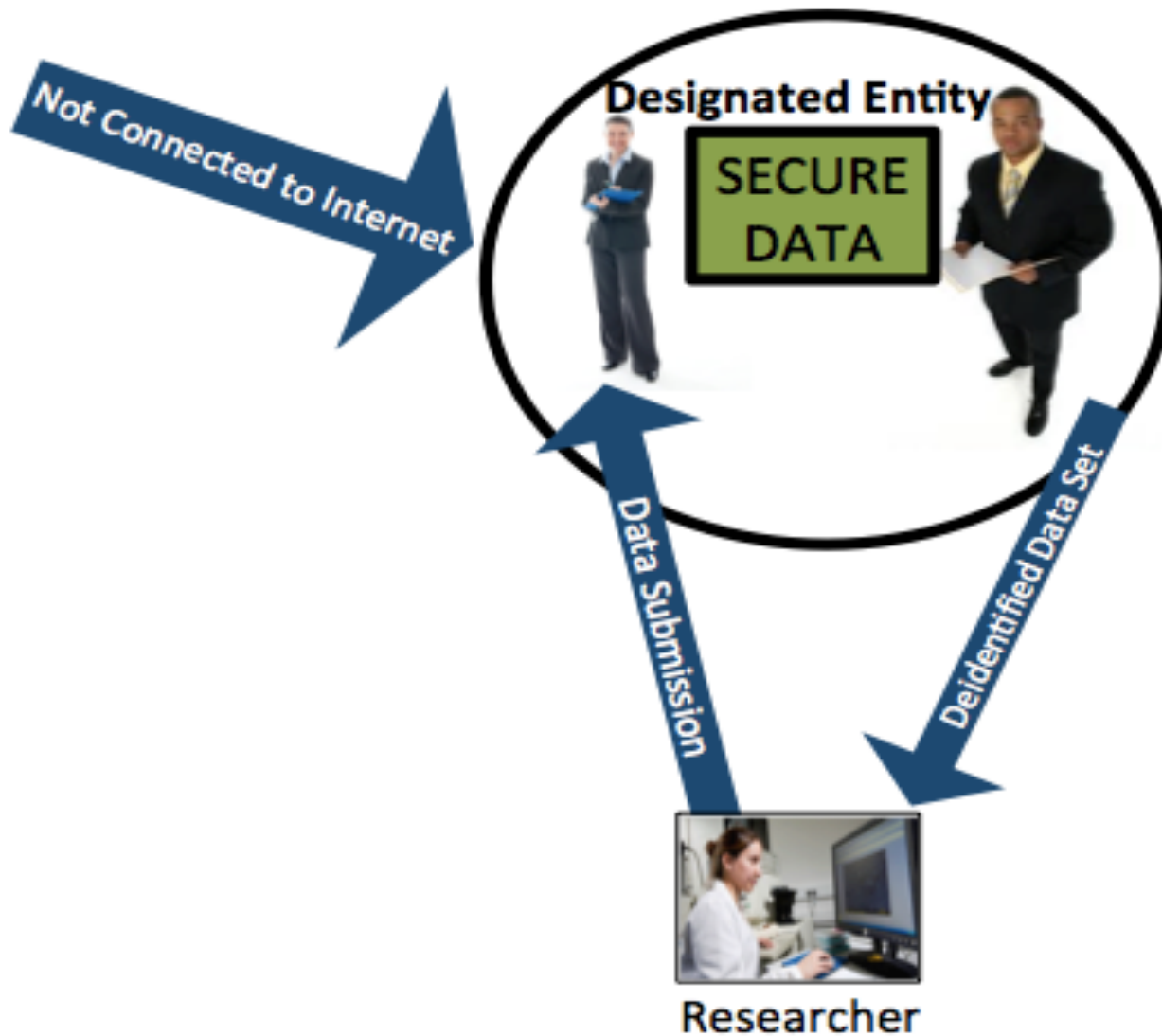
OR

“Routine
Uses” that
include those

External Storage of Protected Records is Permissible

- Business Associate Agreements (HIPAA)
- Designated School Officials (FERPA)
- Evaluation and Research Contractors
- All must observe security requirements and non-disclosure rules.

IDS Best Practices



NOTE:

Technological advances enable encryption keys to replace the transfer or use of identifiers from any dataset--even among data sharing agencies.

Potentially Identifiable Data: “Limited” Datasets

CERTIFICATION OF VITAL RECORD

CITY OF AUSTIN

STATE OF TEXAS

CERTIFICATE OF BIRTH

BIRTH NUMBER

1. Name: First [REDACTED]		Middle [REDACTED]		Last [REDACTED]		2. Date of Birth [REDACTED]		3. Sex [REDACTED]	
4a. Place of Birth: Country [REDACTED]		4b. City or Town (If outside city limits, give precinct no.) [REDACTED]		5. Time of Birth [REDACTED]		6a. Parent(s) - Surname, First, Middle, etc. [REDACTED]		6b. If Parent Birth, Birth 1st, 2nd, 3rd, etc. [REDACTED]	
7a. Place of Birth ☐ Clinic ☐ Doctor's Office ☒ Licensed Birthing Center ☐ Hospital ☐ Residence ☐ Other (Specify) [REDACTED]		7b. Name of Hospital or Birthing Center (If Not Institution, Give Street Address) [REDACTED]							
8a. Attendant's Name and Mailing Address [REDACTED]		8b. Certifier - I certify that this officiant was alive at the place and time and on the date as stated. [Signature: D. [REDACTED]] [Title: [REDACTED]] [Date Signed: 1/1/04]							
9a. ☐ MD ☐ DO ☐ CNM ☐ Midwife ☐ Other (Specify) [REDACTED]		9b. Attendant ☐ Midwife ☐ Family Administrator ☐ Designer ☐ Other (Specify) [REDACTED]		11. Date of Birth [REDACTED]		12. Birthplace (State or Foreign Country) [REDACTED]			
10a. Name: First [REDACTED]		Middle [REDACTED]		Maiden Surname [REDACTED]		13a. City or Town [REDACTED]		13b. Street Address or Rural Location [REDACTED]	
10b. Residence - State [REDACTED]		10c. County [REDACTED]		10d. City or Town [REDACTED]		10e. Inside City Limits ☒ Yes ☐ No			
11a. Mother's Mailing Address (If Same As Residence, Enter Zip Code Only) [REDACTED]		14. Date of Birth [REDACTED]							
15a. Registrar's File Number [REDACTED]		15b. Date Received by Local Registrar [REDACTED]		15c. Signature of Local Registrar [REDACTED]		16. Date of Birth [REDACTED]		17. Birthplace (State or Foreign Country) [REDACTED]	

S260697

This is to certify that this is a true and correct reproduction of the original record as recorded in this office, issued under authority of Section 191.051, Health & Safety Code.

APR 16 2004

ISSUED

Roger [Signature]
LOCAL REGISTRAR

WARNING: IT IS ILLEGAL TO DUPLICATE THIS COPY.

Includes Dates, Diagnoses,
or Researchers own data



DUA

Requires a Data Use Agreement

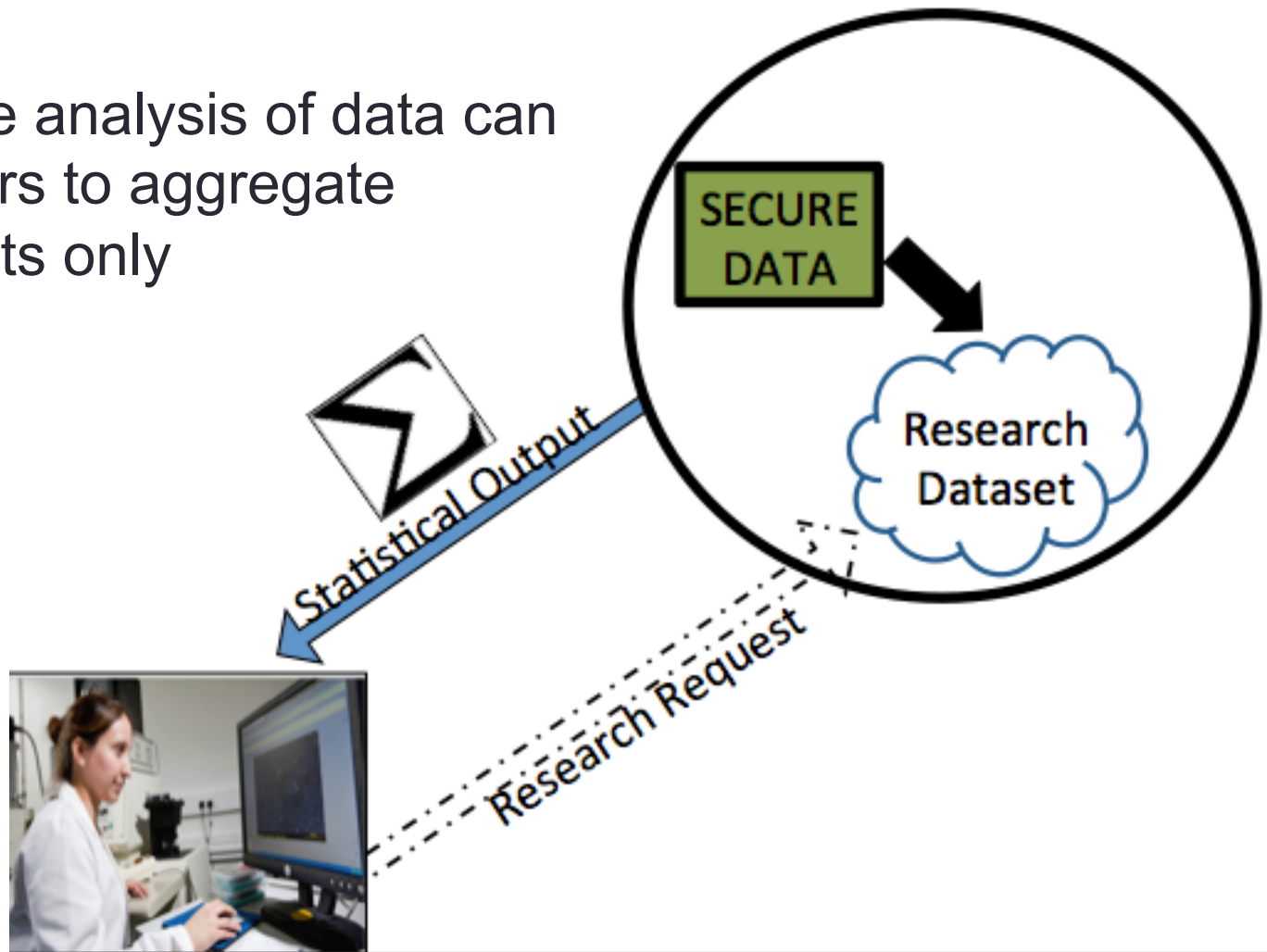
Again, Technology is Advancing...

- Methods to disturb data (inserting noise) makes even limited datasets 99% non-reidentifiable.



Advancing Technology Continued

- Further, remote analysis of data can limit researchers to aggregate statistical results only



Most Research Only Requires
Deidentified Data

In Summary

- Security, not privacy, of confidential data is the most important issue.
- Laws permit data sharing and linkage without patient, student, and client consent for research, evaluation, or "routine uses."
- But security policies and procedures should limit persons who have access to identifiers, and researchers should access only limited or deidentified datasets.

Data Sharing: An Evolving Field---In Sum

- Encryption may remove any identifiers being shared among agencies
- Random disturbances can make virtually all limited datasets deidentified
- Remote access and analysis technologies may limit researchers' access to data to statistical output only
- These technological advances may make record linkage and access minimally risky because re-identification will be impossible.