

Confidentiality Agreements **Purpose, Legal Basis, Process,** **Types of Disclosures, Restrictions, Examples**

Purpose

- To define the restrictions on use and safeguards for minimizing risks of improper use or disclosure of personal records or PHI for research.
- To provide legal authority for the use or disclosure of personal records or PHI for research.
- Confidentiality Agreement must be established when personal records or PHI are used or disclosed for research without the written authorization of the person to whom the records pertain.
- Confidentiality Agreement = Data Sharing Agreement = Data Use Agreement

Legal Basis

- The legal default position for using or disclosing personal records for research – obtain written authorization.
- There are instances in which this is impossible or unfeasible – Without the ability to waive written authorization –
- Some research could not be conducted. (e.g., epidemiological research using large datasets with thousands of records)
- Some research would be unfeasible - costs and bias (obtaining signed authorization for disclosure of contact information to researchers)
- In 1977, the National Privacy Protection Study Commission concluded that medical records can legitimately be used for research without the individual's explicit authorization provided that certain criteria are met.
- These criteria were later incorporated into today's [laws and regulations](#) governing this process.
 - State laws: [RCW 42.48](#); [RCW 70.02](#)
 - Federal Regulations: [45 CFR 46.116\(d\)](#); [45 CFR 164.512\(i\)\(2\)](#)

Process

- For research uses and disclosures, the task of determining whether the criteria have been met falls to the IRB.

- The researcher must make the case that the waiver criteria have been met – for our review, the case for waivers is made on [Appendix I, Waiver of Consent/Authorization](#).
- We'll have another In-service training on waivers of authorization as well as waivers of consent, assent and parental permission – so no details today.
- After research application has been approved, WSIRB staff draft a Confidentiality Agreement based on the information in [Appendix G, Requests for Use or Disclosure of Records](#).
- Draft sent to data custodian and researcher for review; when finalized, signed by the researchers and the State Agency official responsible for the records used or disclosed.

Types of Disclosures

- Almost all disclosures of identifiable personal record information for research fall into two categories:
- Disclosure of substantive information on individuals in a study cohort: (diagnosis, TX, service utilization, costs, demographics, personal history, cognitive functioning, welfare information, employment history, criminal history, etc.) – Direct identifiers needed only if researcher is linking records across multiple record systems.
- Disclosure of contact information for study recruitment when potential subjects are selected from some record system: (name, address, telephone number, etc.) – Direct identifiers are obviously needed, but little substantive information, other than what defines the study's inclusion/exclusion criteria, needs to be disclosed.
- Some research will involve both types of disclosure (e.g., Practice Model Evaluation on today's agenda)

Restrictions

- Only the minimal necessary personal information needed to conduct the research may be used or disclosed.
 - We won't disclose the records of all Medicaid recipients if the research only involves diabetes
 - We won't disclose all the data elements in a file if the research only requires a subset of the data elements
 - We won't disclose direct identifiers unless they are needed for contacting subjects or for linking records across systems
 - We prefer whenever possible to disclose "limited datasets"

- The records used or disclosed can only be used in the specific research project for which they were requested.
- The records used or disclosed can only be used by individuals who are members of the research team and who have signed the Confidentiality Agreement.
- The records may not be disclosed to another party for any purposes not specified in the Confidentiality Agreement.
- All prudent steps must be taken to protect the confidentiality and security of the records used or disclosed.
- The records (or all direct and indirect identifiers in the records) must be destroyed at the conclusion of the research.

Examples

- Agreement 08.04
 - A very complex data linkage study using record information from a number of DSHS programs as well as DOH Death records, Employment Security, Washington State Patrol, Department of Corrections.
 - What will be disclosed is a limited data set
- Draft Confidentiality Agreement Template
 - To incorporate data security requirements in DSHS IT Security Policy Manual
 - To coordinate more closely with Central Contracts Services
 - Will be coordinating with DOH soon on same issues