

## Overview

This standard relates to the IRB's systematic evaluation of the protection of privacy and confidentiality in proposed research. These concepts follow directly from the Belmont Report's principle of respect for persons, as well as individual autonomy. The consent process described in the next section (II-7) informs prospective subjects how their individual data will be used, and who will see them, so that they can make an informed decision over the use of data obtained about them by agreeing or declining to participate.

Data may be anonymous (the individual's privacy is completely protected by not recording primary identifiers (e.g., names, addresses, etc.) or secondary identifiers (e.g., information that may otherwise identify them)), or confidential. The Rutgers University IRB uses the following definitions, available in the [Informed Consent guidance](#) on the ORSP website:

Definition of Anonymous: Data are recorded such that no identifier whatsoever exists to link a subject's identity to that subject's response.

Definition of Confidential: A documented linkage between a subject's identity and his or her response in the research exists. The investigator provides assurance in the protocol and in the informed consent document that the identity of any individual subject will not be revealed in any report of the study.

The IRB reviews the procedures investigators propose to use to protect their subjects' privacy. It is incumbent on investigators to be accurate in describing the data use and longevity, and to protect the data throughout its life according to the agreement they have made with research subjects. Doing so can be challenging, especially in sponsored research. Investigators are obligated to report breaches of data privacy and confidentiality to the IRB.

The following topics are included in this Standard:

- A. [Privacy of research participants](#)
- B. [Confidentiality of identifiable data](#)

## REFERENCES:

AAHRPP Standard II-6. The Research Review Unit, including IRBs, systematically evaluates the protection of privacy and confidentiality in proposed research.

ORSP Website, [Informed Consent Guidance](#).

### A. Privacy of research participants

The privacy of research participants is a fundamental ethical concern. The IRB reviews proposed research design, including recruitment methods, the informed consent process, and the investigator's proposed procedures and resources to protect identifiable data, if it is to be collected. Complete protection of participants' privacy through anonymous data collection is to be preferred when it is feasible. The following topic, [Confidentiality of identifiable data](#), provides further detail on how the IRB evaluates these provisions.

**Definition of Anonymous:** Data are recorded such that no identifier whatsoever exists to link a subject's identity to that subject's response.

Examples of anonymous research: (1) a subject fills out and mails back to the investigator a questionnaire that does not provide the subject's name, social security number, phone number, or any other identifier; (2) the investigator interviews subjects by phone and notes responses, but does not have any record connecting any response to any phone number.

This method is preferred, whenever feasible, in all social and biomedical research which collects sensitive information, and is especially to be considered in research with vulnerable populations. However, if these methods are not feasible, then it is acceptable to use [confidential identifiable data](#).

#### REFERENCE:

AAHRPP II-6.A. The RRU has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy of research participants during and after their involvement in the research.

## B. Confidentiality of identifiable data

### **What is the definition of “Confidentiality”?**

The ORSP Informed Consent Guidance web page offers the following clarification:

**Definition of Confidential:** There exists a documented linkage between a subject's identity and his/her response in the research, and the investigator provides assurance in the protocol and in the informed consent form that the identity of any individual subject will not be revealed in any report of the study. Example of confidential data: a subject's data record is assigned a code, and a "master list" that links the code to the subject's identity is maintained in a secure location.

Sample text in the Informed Consent document: "The information in the study records will be kept strictly confidential. Data will be stored securely in a locked cabinet and/or restricted-access computer and will be made available only to persons conducting the study unless you specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link you to the study."

The IRB determines the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk.

### **How does the IRB evaluate investigators' provisions to protect confidentiality?**

Applications for initial and continuing review require investigators to document the adequacy of their security mechanisms for storage and release of participants' identifiable private information during and after the conclusion of proposed research studies.

The Rutgers IRB Application requires this specific documentation:

9. DATA STORAGE/DISPOSITION:
  - a. Describe how you will keep your data secure and maintain confidentiality during the course of your project:
  - b. Describe how you will ultimately dispose of your data (notes, drafts, lists of subjects, photographic records, tapes, computer disks, etc.) after you have completed your research (e.g. shredding, burning):

The majority of research reviewed by the Rutgers University IRB are in the areas of social and behavioral research. Rutgers University holds investigators responsible for understanding and adhering to the confidentiality standards and guidelines developed by relevant professional associations and scholarly disciplines. Examples of such standards are available to researchers and IRB members at the following links:

- American Psychological Association: <http://www.apa.org/ethics/code2002.html>.
- Social psychology website list of references for research ethics: <http://www.socialpsychology.org/methods.htm#ethics>

Where appropriate, investigators' protocols provide enough information for the IRB to evaluate whether:

- Methods to shield participants' identity adequately protect participant privacy.
- There is a long-range plan for protecting the confidentiality of research data.
- The consent form and other information presented to potential research participants adequately and clearly describe confidentiality risks.
- The informed consent process and the informed consent document make clear that government agencies, sponsors, and funding entities may access their information.

### **What is a certificate of confidentiality and how is it obtained?**

The Federal Department of Health and Human Services (DHHS) developed the Certificate of Confidentiality (CoC) to protect institutions and researchers from the compulsory and involuntary release of individually identifiable research information.

A CoC is issued to the research institution for a single, specific research study, and is appropriate when the research information is sensitive, and disclosure could bring about harm to subjects. The CoC protects against the release of sensitive information gathered in biomedical, behavioral, clinical or other research for use in federal, state, or local civil, criminal, administrative, legislative or other legal proceedings. *For example, a Certificate can be used by the researcher to avoid compelled "involuntary disclosure" from subpoenas and court orders of identifying information about a research subject.*

An investigator applies to DHHS for the certificate (Note: DHHS does not have to be funding the project nor does funding whatsoever need to exist for the research). To obtain a CoC for a project, the investigator must show all of the following:

- The project is research-based or research-related
- The institution's IRB has approved the project
- The project will collect sensitive information whose disclosure could harm the subjects.

Investigators must be aware of limitations, one of the most important of which is that the CoC does not protect against voluntary ("mandatory") reporting by an investigator of child abuse or other violence, or knowledge of communicable disease. The existence of the CoC and its limitations should be discussed with subjects and documented as part of the Informed Consent process.

Further information about the CoC can be found on-line at:

<http://grants1.nih.gov/grants/policy/coc>.

REFERENCES:

AAHRPP II-6.B. The RRU has and follows written policies and procedures to evaluate proposed arrangements for protecting the confidentiality of identifiable data, when appropriate, during and after the conclusion of the investigation.

ORSP Informed Consent Guidance:

<http://orsp.rutgers.edu/Humans/downloads/Expedited/icguidanceprep2.htm>

Certificates of Confidentiality: Public Health Service Act Section 301(d), 42 U.S.C. Section 241(d). Protection expanded to health research generally: Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, Section 163.

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