Glossary of Key IRB Terms

This glossary of terms is designed to help Principal Investigators (PIs) and their Faculty Sponsors (i.e., research supervisors) understand the language used in human-subjects research and IRB documents. These definitions are intended to serve as a quick reference only; they do not replace the content of any section of the IRB application, the application checklist, or web site.

**Adverse event**—any unanticipated problem that arises in connection with research involving human subjects.

**Application packet**—the SAGU IRB application packet consists of:

1. An accurately and completely filled IRB application form, with all required fields answered
2. All relevant appendices required by the application, including the following:
   - the academically approved\(^1\) research proposal
   - the informed consent template(s)—one or more, depending on the complexity of the research design
   - institutional approval of the study at the research site, if appropriate
   - the data-collection instrument(s)—one or more, depending on the complexity of the research design
   - permission letter(s), if relevant, granting access to copyrighted data-collection instruments

**Archival data**—data that have been previously collected for another purpose and made available to the researcher by either open access or special permission.\(^2\) As an example, US census data, often decades old, are routinely reexamined by historical and psychological researchers.

**Assent**—affirmative agreement by a legal minor to participate in research. Mere failure to object (absent affirmative agreement) cannot be construed as assent.

**Conflict of interest**—a conflict between the private interests and the official responsibilities of a person, or between the person’s diverse official responsibilities.


**Coercion**—an act of compelling a person to behave involuntarily in a certain way (whether through action or inaction) by use of threats, intimidation, or some other form of pressure or force.

**Confidentiality agreement**—a written agreement executed by a PI and a research assistant, technician who will gain access to identifiable personal information in the process of collecting or analyzing research data obtained from human subjects.

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\(^1\) Approved by a student’s primary advisor or research supervisor functioning as a member of a given department or school.

\(^2\) Such permission must be documented.
Data collection—“the process of gathering and measuring information on variables of interest, in an established systematic fashion that enables one to answer stated research questions, test hypotheses, and evaluate outcomes.” Examples of data collection include administering a questionnaire to a clearly defined group of people, and conducting individual semi-structured interviews.

Data-collection instrument—a data-collection tool or device designed to capture analyzable information. This broad definition includes “tests, questionnaires, inventories, interview schedules or guides, rating scales, and survey plans or any other forms which are used to collect information on substantially identical items from 10 or more respondents.” Examples include the Wechsler Adult Intelligence Scale, and the public opinion polls utilized by the Pew Trust and the Barna Group.

Data-storage confidentiality—the process of keeping data collected during the study private and non-identifiable (with reference to the human subjects participating in the study). Essential aspects of data confidentiality include the following:

- the coding system used to protect the identity of the human subjects
- the location at which the data are stored
- the time frame for keeping the secured data
- the method(s) by which collected data are stored and maintained
- the means by which the data are destroyed after completion of the study

Faculty sponsor—a faculty member tasked with guiding, overseeing, and eventually approving a student researcher’s activities. Application to the IRB must be submitted by the faculty sponsor, ensuring he or she fully endorses the PI’s proposed methodology, especially in reference to interaction with human subjects.

FERPA (Family Education Rights and Privacy Act)—“a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. FERPA gives parents certain rights with respect to their children’s education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students” (US Department of Education: https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html)

Generalizable knowledge—information obtained from human subjects that has the potential to be expanded from isolated circumstances (e.g., classroom exercise) to a broader context typically identified as “the body of knowledge” in the academy.

HIPPA (Health Insurance Portability and Privacy Act)—a Federal “regulation designed to protect personal information and data collected and stored in medical records. . . . [HIPPA] established a national standard to be used in all doctors' offices, hospitals and other businesses where personal

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3 https://ori.hhs.gov/education/products/n_illinois_u/datamanagement/dctopic.html
4 Data include audio and video recordings.
5 This period is typically three years after the study’s completion.
6 The methods adopted must satisfy the minimal requirements established by relevant bodies with oversight capacity/authority of some form; this includes those tasked with enforcing HIPPA and FERPA and other regulations.
medical information is stored. In addition to protecting personal medical information, HIPPA also give patients the right to view their medical records and request changes if the data is incorrect.” (http://www.businessdictionary.com/definition/HIPPA-privacy-rule.html)

**Human subject**—a living individual about whom an investigator conducting research\(^7\) obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. In research proposals, human subjects are often labelled *research participants* and *informants*.

**Identifier**—any information\(^8\) that may link an individual to the data provided by participating in the research project. Identifiers are typically key demographic descriptors such as gender, age, ethnicity, marital status, SES, and sexual orientation. Other identifiers include contact information (address, email, phone numbers) and issued information (social security number, driver’s license).

**Informed consent**—consent\(^9\) freely and voluntarily provided by a human subject (or his/her legal representative) to participate in a research study after a researcher has presented detailed explanation of the study and the rights of the human subjects involved. Informed consent **must** be obtained prior to data collection from human subjects. The presentation must include the following details:

- what the study entails, including all relevant procedures and processes
- what is expected of him or her as a participant in the study
- the confidential nature of data-collection, data-analysis, and data-storage, together with the researcher’s pledge to maintain information privacy
- how the data collection will be accomplished (including audio/video recording of responses)
- stressors or risks that may be associated with participation in the study

**Minimal risk**—“the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46.102(i)).

**Modification**—minor or major change in an approved procedure or document in a research proposal. A modification may be initiated by the IRB or the principal investigator.

**NIH certificate**—a certificate\(^10\) awarded after successful completion of an online course entitled “Protection of Human Research Participants”; the course is offered by the National Institute of Health. (https://phrp.nihtraining.com/users/login.php).

**Non-disclosure agreement** (see “Confidentiality agreement”)\(^11\)

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\(^7\) See the definition of *Research* in this document.

\(^8\) See also *Sensitive information* in this document.

\(^9\) See also *Assent* in this document.

\(^10\) This certificate documents that the researcher has studied federal guidelines regarding research with human subjects, has satisfactorily passed a series of brief quizzes on components of those guidelines, and has thereby demonstrated adequate knowledge about research with human subjects. The NIH certificate is viewed by the SAGU IRB as valid for three years.

\(^11\) If the researcher plans to use third-party assistance, the Confidentiality Agreement must be included in the initial or revised IRB application.
Non-research inquiries—inquiries conducted for purposes other than making a contribution to generalizable knowledge. Activities potentially included in this category are (1) course assignments completed by students for the purposes of instruction and research-skills development, and (2) institutional research for private (internal) consumption.

Principal investigator—typically a graduate student completing a research project as part of a degree program, having designed a study to address a research problem of relevance to human subjects. An example is a doctoral-level student completing a PhD dissertation and working largely alone under faculty supervision (sponsorship).

Private information—information about one’s behavior occurring in a setting in which one holds a reasonable expectation that no observation or recording is taking place, or that the behavior will not be made public. \(^{12}\)

Protected groups—a category of human subjects requiring a special level of protection during research due to their potential vulnerability (e.g., prisoners, pregnant females, subjects under the age of 18, and cognitively impaired individuals).

Research—“a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes” (45 CFR 46.102 (d)).

Research site—the venue or location at which data are collected, typically from human subjects or archived data files. Examples include a local church sponsoring a ministry intervention, a mental health clinic, and a school district.

Sensitive information—information (about a human subject) that is best categorized as
- descriptive .......... (e.g., age, race, residence address, social security number, driver’s license number)
- attitudinal .......... (e.g., sexual preference, racial attitude)
- financial ............ (e.g., banking details, history of bankruptcy)
- behavioral ........... (e.g., use of alcohol or drugs, sexual history, all forms of illegal behavior)
- medical.............. (e.g., medical history, diagnosis, treatment, prognosis)
- mental-emotional(e.g., psychiatric history, diagnosis, treatment, prognosis)

Vulnerable population (see “Protected groups”).

\(^{12}\) See 45 CFR 46.102 (f).