

Institutional Review Board (IRB) Principles & Practices

The Northwest University IRB operates according to principles that are consistent with those that guide other review boards in the U.S., in addition to those principles that guide activities at NU. These include the following: (1) Informed Consent, (2) Risk/Benefit, (3) Confidentiality, and (4) NU & Professional Standards.

Informed Consent

Informed Consent refers to a minimum standard for recruiting humans as research subjects. In essence, this means that potential research participants must be provided sufficient information (“informed”) so as to be able to make a decision, free of any coercion, to participate (“consent”) or not participate in a study.

The concept of providing potential participants with sufficient information is often misunderstood to mean that the entirety of the study (purposes, hypotheses) must be divulged to the participants in advance. That is not typically required. Indeed, such actions can often bias the results. Rather, the overall area of study, along with the general types of procedures used may be explained to participants. Detailed information about the hypotheses can be provided in a debriefing after participation is completed. A few examples will clarify what is intended.

- Medical researchers often compare a control group whose members take a placebo, to an experimental group whose members take a drug with pharmacological properties. This controls for the effects of expectation on the part of the participants (and researchers). However, it would be unacceptable to surreptitiously give someone a placebo if that person was expecting medicine. Yet, knowledge that one is using a placebo defeats the purpose of the placebo. Researchers solve these problems by informing all potential participants that they may receive either a placebo or actual medication, but that their actual statuses cannot be revealed until the end of the study.
- Psychologists often assign people to groups that are defined by the type of psychological situations in which they are placed. For example, one group might perform a memory task while classical music plays in the background, and another group might perform the same task while country music plays in the background. The purpose of the study is to determine the effects of different types of music on memory performance. However, the researcher does not have to reveal all of this to participants at the beginning. It is sufficient to inform participants that they will take part in a study of memory or perhaps information processing. At the end of the study, the full purposes can be revealed to participants.
- There may be instances in which open trials of some type of treatment (behavioral, psychological, medical) are used. In these instances, a type of therapy or treatment is delivered to a group and no control or comparison group is used. Under these circumstances a full disclosure of the study purposes at the beginning of the study may be appropriate.

Once a participant consents to a study, that participant may withdraw consent at any time and for any reason, without any penalty. Additionally, participants are not required to justify or explain their reasons for withdrawing consent. In that sense, “consent” is an ongoing process. Consent also implies that the decision to participate is not coerced. While token payments of money or goods may be offered for participation, the amount of money or value of the goods must be appropriately minimal (that is, the money or goods must be

“resistible” under ordinary circumstances). This also means that if a professor offers extra-credit towards a grade for participation in research, an alternative extra-credit activity must be provided to those students who want extra credit but do not want to or cannot participate in research.

By definition, people under the age of 18 years cannot consent to participate in research. Therefore, not only must the underage child agree to participate, but a parent or guardian must also provide consent. The same principle of an appropriate substitute providing consent applies to other populations such as patients committed involuntarily to hospitals or other treatment facilities, prisoners, and cognitively disabled people. Typically, the treating institution will maintain policies as to who may provide substituted consent for those who agree to participate in research.

Risk/Benefit

Risk/Benefit refers to the principle that the level of risk to which research participants are exposed must be proportional to the reasonably expected benefits (for both the participant and society in general). At one end of the spectrum, patients dying of a terminal illness might reasonably participate in a drug study that offers some hope of a cure (individual benefit), the advancement of our knowledge about a terminal disease (societal benefit), yet carries the danger of harmful side effects (risk). Historically, the research conducted at NU has been toward the other end of the spectrum, where the benefits have been increased knowledge in an area that has to do more with quality-of-life than life-and-death issues, or increased educational experiences. As such, it is not appropriate to subject participants to high or even moderate levels of risk.

Risk is not restricted to physical or medical harm, but also includes psychological harm (such as stress or embarrassment). It is not appropriate to perform relatively low-benefit research on participants that may leave them feeling embarrassed, ashamed, or stressed about their responses. Many of the classic studies in Social Psychology that were performed in the 1950’s and 1960’s would not be permitted under current guidelines. These include Asch’s conformity studies where participants were socially pressured into giving incorrect responses; Milgram’s obedience studies where participants were pressured to turn up the level of electrical shock supposedly given to other participants; Zimbardo’s Stanford Prison Experiment where college students role-played prisoners and guards for extended periods of time.

Because of risk/benefit issues, active deception as a research method will be permitted only under limited circumstances, where the results of the deception would not be expected to unduly embarrass or stress participants. Deception does not refer to temporarily withholding information about the true nature of the study until completion (see *Informed Consent* above). Examples of acceptable and unacceptable levels of deception follow.

- **Acceptable:** A researcher studies incidental learning by showing participants video clips from movies. The participants are led to believe that the purpose of the study is to rate the level of humor in older compared to newer movies. After viewing and rating the movie clips, participants are then presented with a surprise memory test about the content of the clips. This would not be expected to induce disproportionate levels of stress or embarrassment. Furthermore, incidental learning can only be tested on people who were not expecting a memory test.
- **Unacceptable:** A researcher administers a personality questionnaire to participants and provides false feedback about personal issues, then asks participants to rate their levels of anxiety and depression.

Confidentiality

Procedures for maintaining the confidentiality of research participants' information must be planned and specified as part of the IRB application process. Names of participants can never be placed on data that are stored. Code numbers must be used, instead. The master list linking names with code numbers must be stored separately from any data, and only the researchers identified in the IRB application may have access to the list. All data and participant information must be stored in locked cabinets or other containers, inside of locked offices. Those with keys to the locks must be appropriately restricted. Participant confidentiality must be maintained in all reports and published results of the approved studies. No information may be reported or published that would allow other people to infer the identities of the participants.

NU and Professional Standards

Research approved by NU necessarily carries implications beyond the immediate research results. A student or faculty member who does research represents the entire NU community (which is larger than current students and employees). As such, materials and procedures must reflect sensitivity to broader community standards, and not just those of the particular subgroups to which the researcher may belong. With the availability of online resources, a number of recent studies have used websites such as youtube.com in experiments and studies. While it is possible that the researcher and researcher's peers routinely watch movies that may contain explicit violent or suggestive content, there are many within the NU community that would find such content offensive. While the IRB retains final authority over such issues, researchers are encouraged to reflect on community standards when selecting materials and procedures for review.

Professional standards relevant to each discipline must also be followed. For example, researchers may only administer treatments or interventions that are consistent with their level of training and professional approval. Drawing blood, administering psychotherapy, and taking medical measurements are activities restricted to qualified persons under the proper supervision.

IRB Practices

1. Researchers must fill out completely the IRB application available on the Provost's website. If researchers can legitimately answer "No" to all of the items in Section I, then the abbreviated form can be used. An abbreviated application does not require review by the full committee.
2. The IRB application must be submitted via email to irb@northwestu.edu.
3. Incomplete applications will be returned without committee review.
4. The IRB does not review research methodology or scientific integrity.
5. Applications submitted by the first business day of the month will be reviewed no later than the last week of the same month. The IRB will does not meet July or December.
6. IRB review and approval is required of any research that involves data collection from human participants. Projects that require review are typically those that are used for scientific or instructional purposes. Exclusions from the review requirements are as follows:
 - Classroom examinations
 - Course evaluations (typically done at or near the end of the semester)

- Program assessments of the type that are typically used for internal evaluation or NWCCU accreditation reports
- Market analyses by Advancement, Alumni or other NU departments seeking to collect data for the promotion of NU enrollment and the advancement of its mission
- Classroom data collected for instructional purposes from students enrolled in the class (e.g., collecting blood samples for blood-typing in a Human Biology class, surveying students for opinions about a social issue in a Social Psychology class)
- Research involving previously collected documents, records, or other data available to the public