



# **INSTITUTIONAL REVIEW BOARD**

## **Guidelines for Researchers**

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## **Introduction**

*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research*\* was issued in 1978 by the President's National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report was a key document in the movement to institute federal regulations requiring institutional prior review and approval of human subjects research activities. Federal regulations were established in 1981 detailing the required review process to be followed by institutional review boards (IRBs) at all facilities conducting federally funded research. Like the majority of colleges and universities across the nation, Davenport University decided that the regulations should apply to all projects, funded or unfunded.

A new "Federal Policy for the Protection of Human Subjects" became effective in 1991. This policy, known as "The Common Rule," applies to 16 federal departments and agencies. The provisions derive from Department of Health and Human Services regulations, simplifying adherence to federal Human Subjects regulations, regardless of the federal agency funding the project.

## **Authority**

Davenport University requires all research projects involving human subjects to be reviewed and approved, or declared exempt, by the Davenport University IRB before a project is initiated.

The Davenport University IRB is charged with the responsibility for review and approval of human subjects research conducted by faculty members (full or part time), students, and staff of the University.

All research involving employees or students of the University must be reviewed by the IRB. The requirement for review applies whether the research is funded or unfunded, regardless of the source of funding or the site at which the research is conducted.

The Davenport University IRB operates in compliance with the U.S. Code of Federal Regulations, [Department of Health and Human Services \(DHHS\) Title 45 Part 46](#), entitled, "Protection of Human Subjects." A link to the DHHS regulations may be found in the Appendices and Links section of this document. Davenport University's IRB is registered with the [Office of Human Research Protections](#) (OHRP) and has an approved assurance from OHRP (Federalwide Assurance or FWA).

The IRB is responsible for determining that:

- The rights and welfare of the subjects are adequately protected
- The risks to subjects are outweighed by the potential benefits of the research
- The selection of subjects is equitable
- Informed consent will be obtained and, when appropriate, documented

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All applications submitted to the IRB must designate a faculty member or senior staff member in student affairs as the principal investigator. The University requires that responsibility for compliance with institutional guidelines and policies rests with a faculty member in the department in which the project will be conducted. Staff or students may actively participate in human subjects research activities, but the principal investigator of record on a research project submitted to the IRB must be a Davenport University faculty member or a senior staff member in Student Affairs.

The IRB has the authority to suspend or terminate approval of research when it is determined that the research has been associated with unexpected serious harm to participants or is not being conducted in compliance with the determinations of the IRB or the federal regulations on human subjects research. If the Davenport University IRB determines that a research project should be suspended or terminated for cause, the action will be reported to appropriate institutional officials, the head of any supporting Federal Department or Agency (if applicable), and the Office of Human Research Protections at the Department of Health & Human Services.

The responsibility for appointing and maintaining the Davenport University IRB rests with the Provost in consultation with the Deans of the Colleges and appropriate Department Chairs. Members are appointed to include faculty who represent the breadth of scientific and scholarly specialties, at least one member whose primary concerns are in a non-scientific area, and at least one member who is otherwise unaffiliated with the University. Appointments are for two years and are renewable. Continuity is ensured by staggered reappointment for subsequent years when possible.

### **Reporting and Communication**

The IRB is required to report promptly to the Provost and the HHS Office of Human Research Protections:

- Any serious or continuing noncompliance by investigators with the requirements and determinations of the Davenport University IRB
- Any suspension or termination of IRB approval for reasons of noncompliance or unexpected serious harm to subjects
- Any unanticipated problems involving risks to subjects or others encountered in the research

Davenport University IRB findings and actions taken on protocols are communicated to the University community on the Davenport University IRB website at [www.davenport.edu/academics/institutional-review-board-irb](http://www.davenport.edu/academics/institutional-review-board-irb).

## Review Categories

The following review categories are defined by regulation:

- Full Board Review
- Expedited Review
- Exempt from IRB Review

Applicants should consult the [OHRP decision chart](#) for guidance in determining the appropriate review category.

## Full Board Review

Review by the full Board is required for new and renewal applications that are determined to be ineligible for expedited review or exemption.

The review process requires submission of one signed “Human Subjects Research Review Form” (HSR-1; last updated February 2012), together with appropriate attachments (e.g., “Informed Consent,” “Oral Instructions to Participants,” advertisements) to the IRB. The PI and each research team member must complete [NIH or NIH approved Human Subjects Research training](#) and attach a copy of the certificate to the HSR-1 form if it is not already on file with the IRB. The application submission should be sent to [irb@davenport.edu](mailto:irb@davenport.edu).

The IRB will make a judgment on the validity of the study as part of its assessment of the risk-benefit ratio because no risk to subjects can be justified if the study design is flawed to the degree that no useful information is likely to be forthcoming. The composition of the population to be recruited will be reviewed to ensure that equitable selection of subjects based on gender, age, or ethnicity has been taken into account in the design of the study.

By regulation, final action on protocols that require full review may be taken **only** at a legitimately convened meeting. A simple numerical majority of members must be present at a meeting, including a member whose primary concern is in a non-scientific area. In order for the protocol application to be approved, it must receive approval of a majority of members present at the meeting.

The range of actions that may be taken at a convened meeting are:

- The application may be approved
- The application may be tabled for response to questions or required modifications; discussion of the response must be conducted at a convened meeting
- The application may be approved with stipulations that are considered minor and require only simple concurrence by the investigator. The Chair or Chair’s designee reviews the response to minor stipulations; such cases do not require a convened meeting for final action.
- The protocol may be disapproved. In cases where a study is disapproved, the rationale for the action taken will be provided in written form. The investigator may request an appearance at a

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convened meeting to present arguments for reversal of a decision to disapprove, or the investigator may propose a change in the protocol based on the advice and counsel of the Davenport University IRB. Institutional officials cannot approve a protocol that has been disapproved by the Davenport University IRB. Therefore, there is no possibility of appeal of a Davenport University IRB approval to a higher university or federal official.

An application that has been approved by the Davenport University IRB may be subject to further review and approval or disapproval by officials of the University.

When a project receives initial approval, no protocol changes, consent form changes, amendments, or addenda may be made without re-review and approval. A copy of the HSR-1 form with the Chair's (or the Chair's designee's) signature is mailed to the principal investigator after each meeting.

The approval notice reiterates the investigator's obligation to report any unanticipated problems or adverse events. Approval is valid for one year. If a consent form is revised in association with an amendment review, it is valid only until the annual review date for the project.

### **Expedited Review**

In 1998, Department of Health and Human Services (DHHS) regulations were revised with regard to categories of research that are eligible for expedited review procedures. The list of research categories was expanded and clarified. Please note that only research projects that meet the regulatory definition of minimal risk qualify for the expedited review process.

The following two criteria must be met before a protocol may be considered for an expedited review process:

- The activity must present no more than minimal risk to subjects AND
- The protocol procedures must be listed as one of the categories in the regulations' list of procedures that qualify for an expedited review process.

In addition, DHHS regulations state that an expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.

The Research Categories defined by the federal government and listed below qualify for an expedited review process. The final decision on whether an expedited review process may be used rests with the IRB Chair or his/her designee.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

(a) Research on drugs for which an investigational new drug application (21 CFR Part312) is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of risks associated with the use of the product is not eligible for expedited review.)

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(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling).

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b) From other adults and children, considering the age, weight, and health of the subject, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.

3. Prospective collection of biological specimens for research purposes by non-invasive means.

(a) Hair and nail clippings in a non-disfiguring manner

(b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

(c) Permanent teeth if routine patient care indicates a need for extraction

(d) Excreta and external secretions (including sweat)

(e) Cannulated saliva collected either in an unstimulated fashion or stimulation by chewing gumbase or wax or by applying a dilute citric acid solution to the tongue

(f) Placenta removed at delivery

(g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

(h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques

(i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouthwashings

(j) Sputum collected after saline mist nebulation

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

• Examples:

(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy

(b) Weighing or testing sensory acuity

(c) Magnetic resonance imaging

(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography

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(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural belief or practices, and social behavior) or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened Davenport University IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the Davenport University IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The expedited review process requires submission of a Human Subjects Research Review Form (HSR-1) with the appropriate attachments to the IRB ([irb@davenport.edu](mailto:irb@davenport.edu)). The expedited review is conducted by the Chair or his/her designee. The following actions may be taken on applications that qualify for an expedited review process:

(a) The application may be approved as submitted.

(b) The application may be approved with restrictions, conditions, stipulations, or required modifications, including changes to the consent document. The investigator's response to approval with stipulations will be reviewed by the chair or his/her designee to determine if final approval may be granted.

(c) The application may be referred for discussion at a convened meeting.

The agenda for convened meetings is the mechanism by which Davenport University IRB members are notified of actions taken using an expedited review process. Members at the convened meeting may challenge an action taken through the expedited review process. The reviewer conducting the expedited review does not have the authority to disapprove an application. Disapproval is an action that may be taken only at a convened meeting.

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When a project receives approval through an expedited review process, written notification is provided to the principal investigator. The notice will state the period of approval. No protocol changes, consent form changes, amendments, or addenda may be made to the application without re-review and approval.

### **Exempt**

Broad categories of research that do not use living human subjects or that normally present little or no risk of harm to subjects may be exempt from formal review by the IRB. In general, most social, economic, and education research is exempt if the only involvement of human subjects in one or more of the following categories: (a) the use of survey and interview procedures; (b) the observation of public behavior, or (c) the study of existing data, documents, records, and specimens.

One copy of a signed “Human Subjects Research Review” (HSR-1) form with appropriate attachments form (including a copy of the [NIH training certificate](#), unless it is already on file) should be sent to the IRB ([irb@davenport.edu](mailto:irb@davenport.edu)). For projects that are funded by a federal agency, a copy of the grant or contract must be appended. The application will be reviewed by the Chair or his/her designee. An investigator must receive approval from the IRB before he/she begins the research project.

Department of Health and Human Services regulations contain categories of social, educational, and economic research activities that may be considered exempt. The categories are described below. By regulation, exemptions DO NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. A written response will be sent to the PI to indicate either: (a) the proposed research is exempt and may be conducted without IRB review; or (b) the project is not exempt. The investigator will be notified as to why exemption was not allowed.

Department of Health and Human Services exempt categories include:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special educational instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
  - b. Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. EXCEPTION: Department of Health and Human Services Regulations (46.401) state that parts of Exemption #2 do not apply to research with children. Therefore, projects involving educational tests and/or survey procedures involving children **MUST** be submitted for IRB review.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph two (2) of this section, if:
  - a. The human subjects are elected or appointed public officials or candidates for public office, or
  - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine:
  - a. public benefit or service programs
  - b. procedures for obtaining benefits or services under those programs
  - c. possible changes in or alternatives to those programs or procedures, or
  - d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies:
  - a. If wholesome foods without additives are consumed, or
  - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

### **Undergraduate Course Projects**

If a course, as part of the curriculum, regularly requires research involving human subjects, the course instructor for each section must complete a Human Subjects Research Review (HSR -1) form, signed by the instructor and the Department Chair, only once per academic year unless the curriculum is substantially changed or a new instructor is assigned to the course. Note that the course approval for research may be used **ONLY** for projects that are eligible for the exempt category. A general statement of the requirements for the projects for the course and copies of the instructor's and the chair's [NIH certificate](#) must be on file with the IRB. The faculty member must maintain a Protocol File for each course assignment involving human subjects research.

### **Renewal Applications and Continuing Review Requirements**

All protocols approved by the IRB are subject to continuing review. Federal regulations require continuing review of research "not less than once per year." Federal agencies have made it very

clear that they expect IRBs to review applications for continuing review before the approval date expires. Submission of a renewal application after approval has lapsed is not acceptable.

Administrative extensions will not be granted. Projects for which the required reports or renewal application were not submitted in time to allow review within the designated approval period (one year or less) are considered terminated. New subjects may not be enrolled and subjects involved in a study must be removed from a protocol for which approval has lapsed. The IRB will consider on a case-by-case basis whether removal of subjects from a lapsed protocol would adversely affect subjects already enrolled.

When initial approval is granted, the approval notice will indicate the period of approval. Approval may require continuing review based on numbers of subjects enrolled, quarterly reports, semi-annual reports, or annual reports. The investigator must acknowledge in writing that he/she understands the reporting requirements. Regardless of the required reporting period, investigators have a continuing responsibility to inform the IRB of any circumstances or new information that might change the perception of a favorable risk/benefit assessment.

The Davenport University IRB will determine if a renewal application qualifies for an expedited review procedure or requires review at a regularly convened meeting. Applications that qualify for expedited review procedure will be listed on the agenda with that designation, and copies of the applications will not be provided to each member. Applications that do not qualify for an expedited review process must be discussed at a convened meeting. A copy of each continuing review application that requires discussion at a convened meeting will be provided to each member as part of the agenda packet. At the convened meeting, the Davenport University IRB will determine if re-approval is appropriate. The range of actions that may be taken includes:

1. The renewal application may be approved
2. The renewal application may be tabled for response to questions or required modifications
3. The renewal application may be approved with minor stipulations that require only simple concurrence by the investigator. The response to minor stipulations may be reviewed by the Chair or the Chair's designee; such cases do not require a return to a convened meeting for final action.
4. The renewal application may be disapproved. In cases where a renewal application is disapproved, the rationale for the action taken will be provided in written form. The investigator may request an appearance at a convened meeting to present arguments for reversal of a decision to disapprove, or the investigator may propose a change in the protocol based on advice and counsel of the Davenport University IRB.

Institutional officials cannot approve a protocol that has been disapproved by the Davenport University IRB. Effectively, therefore, there is no possibility of appeal of a Davenport University IRB disapproval to a higher university or federal official.

### **Impact of the Continuing Review Process on Federal Grant Continuation Applications**

Grant applications may not be submitted with a pending human subjects approval date nor may they be submitted with an approval date beyond one year from the initial review. Davenport University IRB review and approval must be completed before the continuation (e.g., NIH) funding is submitted.

### **Unanticipated Problems that Affect Risks to Subjects**

If adverse consequences or unanticipated side effects are encountered in the course of a study, or new information becomes available that could change the perception of a favorable risk/benefit ratio, the principal investigator is responsible for informing the Committee **PROMPTLY**.

A copy of every adverse event report, letter, or form submitted to an outside agency (e.g., a federal agency) should also be forwarded to the Davenport University IRB within seven working days after discovery. The Davenport University IRB will make the final determination regarding protocol changes required due to adverse event reports.

### **Protocol File**

The principal investigator must maintain a protocol file. The file should include the following items:

- a. A copy of the protocol application signed by the Chair or the Chair's designee
- b. Copies of all correspondence with the IRB
- c. A copy of the original approved consent document
- d. The original of each consent form signed by subjects enrolled in the research protocol. It is the responsibility of the principal investigator to assure that a copy of the consent form is provided to each subject enrolled in a research study.

## **APPENDICES AND LINKS**

### Links:

<http://www.davenport.edu/academics/institutional-review-board-irb>  
<http://phrp.nihtraining.com/users/login.php>  
<http://ohsr.od.nih.gov/>  
<http://www.hhs.gov/ohrp/>  
<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>  
<http://www.wcsu.edu/irb/>

### Forms:

Human Subjects Research Review (HSR -1): Checklist  
Human Subjects Research Review(HSR -1): Cover Sheet  
Human Subjects Research Review (HSR -1): Form  
Project Completion Report (HSR-2)  
Renewal Application (HSR-3)  
Amendment to Original IRB Certification (HSR-4)  
Adverse Event Form (HSR-5)  
Sample Informed Consent Form  
Sample Alternative Informed Consent Form  
Sample Oral Instructions to Participants



## INSTITUTIONAL REVIEW BOARD

### Glossary of Terms

**Note:** The definitions below are taken from the US Department of Health and Human Services, Office of Human Research Protection's *Institutional Review Board Guidebook* ([http://www.hhs.gov/ohrp/archive/irb/irb\\_glossary.htm](http://www.hhs.gov/ohrp/archive/irb/irb_glossary.htm))

**Adverse effect:** An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

**Assent:** Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

**Assurance:** A formal, written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulations the procedures through which compliance will be achieved.

**Belmont Report:** A statement of basic ethical principles governing research involving human subjects issued by the national Commission for the Protection of Human Subjects in 1979.

**Benefit:** A valued or desired outcome; an advantage.

**Children:** Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted  $\{(5\text{ CFR }46.401(a))\}$ .

**Clinical Trial:** A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

**Cognitively Impaired:** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

**Cohort:** A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

**Competence:** Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

**Contract:** An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant (See also "Grant").

**Control (Subjects) or Controls:** Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

**Descriptive Study:** Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).

**Emancipated Minor:** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home.

**Equitable:** Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**Expedited Review:** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

**Full Board Review:** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

**Grant:** Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant (see also "Contract").

**Incapacity:** Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.

**Incompetence:** Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.

**Independent Variables:** The conditions of an experiment that are systematically manipulated by the investigator.

**Informed Consent:** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence {Federal policy §116; 21CFR 50.20 and 50.25}.

**Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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.

**Non-Affiliated Member:** Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).

**Office for Protection from Research Risks (OPRR):** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (*45 CFR Part 46*) governing research involving human subjects.

**Permission:** The agreement of parent(s) or guardian to the participation of his/her child in research {*45 CFR 46.402(c)*}.

**Principal Investigator:** The scientist or scholar with primary responsibility for the design and conduct of a research project.

**Prospective Studies:** Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

**Protocol:** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**Quasi-Experimental Study:** A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups.

**Random, Random Assignment, Randomization, Randomized:** Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

**Research:** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

**Respect for Persons:** An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**Retrospective Studies:** Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

**Review (of Research):** The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, review may, if deemed appropriate, also be conducted on a continuous or periodic basis.

**Risk:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

**Statistical Significance:** A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

**Surveys:** Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

**Variable:** An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

**Voluntary:** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.