



### **2.7.2 Protection of Human Subjects**

The University of San Diego safeguards the rights and welfare of human subjects involved in all research projects conducted under University auspices. “Research projects conducted under University auspices” means research conducted by any University employee, student, or agent either in the course of his or her University responsibilities or when using the University’s name, symbols, property or services in connection with the research.

Human Subjects Researchers – University employees, students, and agents who are or who are expecting to be engaged in such research – must be familiar with this policy. Part One of this policy applies to all Human Subjects Researchers. Part Two of this policy, including the procedures, forms, and other instruments at the end of or referred to in Part Two, applies to Human Subjects Researchers whose research either (1) is supported or regulated by federal or state governments, departments, or agencies, or (2) regardless of funding source, falls within a category listed in section I of Part Two.

#### **Part One – In General**

The responsibility of Human Subjects Researchers will be guided by the University’s Catholic identity and mission statement, and by generally accepted ethical principles for human subjects research. The University adopts the report of the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research, commonly known as The Belmont Report, ([www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)), as its statement of these generally accepted ethical principles.

Although the primary focus of The Belmont Report is on biomedical and behavioral research, its discussion of Basic Ethical Principles and Applications is easily adapted to most other types of research involving human subjects. Individual University units (the Schools and the College being the units for the academic areas, and Vice Presidential areas being the units for the non-academic areas) are encouraged to develop their own rules or procedures that adapt or supplement The Belmont Report to meet their research disciplines or needs.

Each Human Subjects Researcher must provide evidence to the University’s Institutional Review Board (IRB), prior to engaging in research covered by this policy, that he or she is familiar with The Belmont Report, with the responsible University unit’s rules or procedures governing human subjects research, and with this policy. Evidence of familiarity may be (1) taking a course in which these materials are covered in class and assessed, (2) satisfactorily taking an examination authorized by the IRB on these

materials, (3) attending a seminar sponsored by the IRB on the ethical principles governing human subjects research, or (4) by resort to other mechanisms deemed appropriate by the academic unit with jurisdiction.

University vice president, deans, department heads, and program supervisors are charged with the implementation of Part One of this policy. To this end, they have responsibility: (1) to assure that Human Subjects Researchers within their units are familiar with The Belmont Report and any other rules or procedures of their unit governing human subjects research; (2) to authorize projects involving research on human subjects that are proposed by Human Subjects Researchers within their units; and (3) to determine which research projects submitted to them for authorization, in addition to those indicated in section I of Part Two, should also be submitted to the IRB for review.

### **Part Two – Projects Subject To IRB Oversight**

All Human Subjects Researchers whose research is governed by this Part must (1) familiarize themselves and comply with 45 Code of Federal Regulations Part 46 if engaged in medical or biomedical research, and with any other laws and regulations pertaining to their research; and (2) submit their research proposals to the University's Institutional Review Board (IRB) for review. The IRB has authority to approve, require modifications in, or disapprove research projects governed by this Part.

#### **I. Research Governed by this Part.**

Research projects of Human Subjects Researchers are governed by this Part if they fall in any of the following categories.

- A. The project is supported, in whole or in part, by funds or equipment provided by the federal government, a state government, or any federal or state governmental agency.
- B. The project encompasses research over which a federal department or agency has specific responsibility for regulating as a research activity.
- C. The project involves human subjects taking part in biomedical or clinical research, or in behavioral research where the research activities reasonably could be expected to place participants at risk of physical or psychological harm. The determination of risk lies with each individual researcher.
- D. The project includes members of vulnerable populations who are relatively or absolutely incapable of protecting their interests. These populations include: 1) children; 2) individuals with questionable capacity to consent; 3) prisoners; 4) fetuses and pregnant women; 5) the terminally ill; 6) students and employees of USD; and 7) comatose patients.
- E. The project targets (not simply includes) a particular religious, racial, ethnic, or sexual-orientation population. (This criterion is included to ensure the equitable distribution of the benefits and burdens of research according to the justice principle of The Belmont Report.)

- F. The project is a type that the responsible University unit has specified to require IRB review and approval.
  - G. The external funding source for the project has required that it be submitted for IRB review and approval.
- II. Institutional Review Board (IRB)
- A. **Composition.** The IRB membership includes at least one faculty member from each of the Schools of Business Administration, Leadership and Education Sciences, Law, and Nursing and Health Science; at least two faculty members from the College of Arts and Sciences; an Associate Provost as the representative of the University Administration; the Director of Sponsored Programs as an ex officio and non-voting member; at least one undergraduate student representative; at least one graduate student representative; and at least one representative from the community, following the guidelines in 45 CFR 46.107.
  - B. **Appointment and Terms.** Faculty members of the IRB will be appointed by the University Senate. All other members will be appointed by the Provost. Members serve three-year terms, except the undergraduate and graduate student representatives and the representative from the community who serve one-year terms. Members typically will be appointed in the Spring to serve terms commencing June 1. An appointment not made by June 1 shall be made as soon as practicable. The term of a member who is appointed after June 1 shall end on the same date as the term would have ended had the appointment commenced June 1. All appointed members may be reappointed to serve additional terms.
  - C. **Vacancy.** When a vacancy occurs on the IRB its chair will immediately notify the Provost or the Chair of the University Senate, as pertinent (See Section I.B), and request the appointment of a new member to fill the vacancy from the same College/School or representative category as the departed IRB member. If the vacancy occurs within an unexpired term, then appointment of the new member will be to the unexpired portion of that term. In the event the Associate Provost's position on the IRB becomes vacant or the Associate Provost is unable to serve, the Provost will appoint a substitute until a new Associate Provost is appointed to the IRB or the Associate Provost resumes the IRB duties.
  - D. **Chair.** The chairperson of the IRB ("IRB chair") will always be a member of the full-time faculty. The IRB chair is elected by the members of the IRB for a two-year term. The members of the IRB also will elect a Chair-Elect to understudy the IRB chair six months before the then current Chair's term expires. If a vacancy occurs in the unexpired term of the IRB member who is its chairperson, the IRB will vote to elect a new chairperson to complete the term. A new member will be appointed by the Provost.

- E. Duties. The IRB will implement this policy in accordance with all relevant laws and regulations. To do so, the IRB will create procedures, forms and other instruments, as it deems necessary. If anything in this policy or in IRB procedures, forms, or other instruments (collectively “policy”) can be construed to conflict with governing law, then the IRB will bring such possible conflicts promptly to the attention of the University Senate and University counsel and, pending amendment of the policy, will implement the policy in a manner that conforms with the IRB’s understanding of the law.
- III. Responsibilities of Researchers, Faculty Advisors, Instructors and Research Sponsors
- A. It is the researcher’s responsibility to comply with all relevant laws and regulations affecting research involving human subjects.
- B. The researcher must submit to the Office of the Provost a research proposal following the guidelines presented on the Cover Sheet, which is to accompany all research proposals.
- C. At the end of the study, the researcher must submit Summary/Continuation Form to the Provost’s Office. If the research will continue beyond the yearly anniversary from the previous approval, a Summary/Continuation Form must be submitted in a timely fashion prior to that date. It is the researcher’s responsibility to determine whether full or expedited review is possible at the one-year anniversary of approval date. Researchers should check the URL <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> for specific the guidelines for determining when expedited review is possible. Should the researcher fail to submit the Summary/Continuation Form in a timely fashion the research *must* stop until the form is completed and acted upon.
- D. If during the research an adverse event occurs, the researcher must stop the research and immediately report the event to the IRB.
- E. Instructors conducting classroom projects and faculty advisors of student projects are responsible for insuring that student research conducted under their direction must conform to the requirements of federal law and regulations on research regarding human subjects. Instructors and advisors must review the current Federal Policy for the Protection of Human Subjects, 45 CFR 46 (1991, as amended) to determine whether the process for IRB review must be initiated and, if so, which level of review is appropriate. In doing so, instructors and advisors should pay particular attention to the definition of “research” [45 CFR 46.102(d)] and the categories of exemption from detailed review [45 CFR 46.101(b)] contained in the Federal Regulations. See generally <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. Evidence of IRB approval of thesis/dissertation research involving human subjects must appear in the bound copy of the project. If unsure how to proceed,

instructors and advisors should contact the appropriate College/School representative on the IRB prior to continuing with the project.

- F. USD sponsors have primary responsibility to ensure that all research conducted by outside agents under their sponsorship is conducted in accordance with all relevant regulations, laws and USD policies.
  
- IV. Administrative Review. The IRB chair will prepare an annual report that includes a listing of all proposals submitted to the IRB and an indication of the action taken. The Associate Provost will keep a record of all actions taken. This report and a copy of each proposal and documentation will be kept in the Provost's Office. A copy of the report will also be forwarded to the President.
  
- V. Violations of Human Subject Policies and Procedures. The IRB will investigate alleged violations of these policies and procedures, and report its findings to government agencies as required by law (See 45 CFR 46.113), to the Provost, and to the President.
  
- VI. Institutional Research. Research (See definition at 45 CFR 102(d)) conducted by the University for the evaluation of its programs or to provide information for planning, policy formation, and decision making, is subject to the same criteria as any other research as defined in 45 CFR 46.

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