

80.7 Human Subjects in Research

Policy Name:	Human Subjects in Research
Approval Authority:	President
Responsible Officials:	Provost and University Vice President Executive Director of the Office of Sponsored Research
Responsible Office:	Office of Sponsored Research
Effective Date:	1 March 2010

1. Policy Statement

The protection of human subjects is a matter of the utmost commitment for the federal government and the university. To the extent that research uses human subjects, even in the most seemingly benign manner, it will be reviewed in accordance with directives that are codified and reside in the Code of Federal Regulations [at 45 CFR 46](#). Human subject Institutional Review Boards (IRB) are considered to be institutional-level committees; thus they report to the President of the university.

2. Reason/Purpose for Policy

This Statement provides comprehensive information about the organization, scope, authority and responsibilities associated with Stevens' program for the protection of human research subjects.

3. Policy Scope

All faculty, staff, students and any other persons at Stevens involved in the design, conduct or reporting of research at or under the auspices of Stevens that involves the use of human subjects. Additionally, it shall apply to all research projects on which those individuals work, regardless of the source of funding for the project.

4. Related Documents

- [Office of Sponsored Research - Human Subjects/IRB website](#)
- ["SIT Guidelines for the Use of Human Subjects"](#)
- ["SIT IRB Application Forms"](#)

5. Contacts

- Provost and University Vice President
- Executive Director, Office of Sponsored Research

6. The Policy

All Stevens' faculty, staff or students who propose to engage in any research activity involving the use of human subjects must have approval from the Stevens' Institutional Review Board (SIRB), prior to the initiation of the project. The SIRB is responsible for safeguarding the rights and welfare of all persons participating in research projects, whether funded or non-funded. This includes all undergraduate and graduate student research projects. It is important to understand that the regulation that defines human subject protections ([45 CFR 46](#)) describes categories of exempt research; however, this does *not* mean that a researcher is exempt from applying to the SIRB. The term refers to a category of research to which the applicant may apply but the SIRB is the sole determining body regarding the final approval and designation of the appropriate category.

7. Related Resource Documents

- [Belmont Report](#)
- [Code of Federal Regulations - 45 CFR 46](#)
- [Human Subjects Protections Training](#)
- [The Declaration of Helsinki](#)