Exemption Review Policy

Under certain circumstances, human subject research activities subject to the IRB may be granted exempt status. The significance of exempt status, which may be requested by an investigator when submitting an application to an IRB and may be granted by the IRB Chair or designees, is that the research activity is not monitored by the IRB. Assuming the project does not change, it also is not subject to continuing IRB oversight. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct. Thus, depending on the circumstances, researchers performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

It is the policy of Siena College IRB that to be deemed to be exempt, human subjects research activities must be reviewed and determined to fall within one or more of the explicit exemption categories listed in the federal regulations (see below).

EXEMPT CATEGORIES - Federal

Exemption #1 (45 CFR 46.101(b)(1)): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption #2 (45 CFR 46.101(b)(2)): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption #3 (45 CFR 46.10(b)(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 (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
Exemption #4 (45 CFR 46.101(b)(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.

Exemption #5 (45 CFR 46.101(b)(5)): Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption #6 (45 CFR 46.101(b)(6)): Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.