SUNY Institute of Technology

SUBJECT – Institutional Review Board	**EFFECTIVE DATE –** 8 January 2013
TITLE – Exempt Research	**APPROVED BY –** SUNYIT IRB; Deborah Tyksinski, PhD, Associate Provost

SCOPE – This policy applies to all faculty, staff and students within or under the auspices of SUNYIT conducting research involving human subjects, and to the SUNYIT IRB Committee that oversees the conduct of that research.

PURPOSE – To establish guidelines for the submission of and IRB review of Exempt Research.

POLICY – All research involving human subjects must be reviewed and approved by the Institutional Review Board (IRB) unless the IRB Chair or the designated representative determines that the research falls within one or more of the categories of research exempt from federal regulations governing human subject protection. Exemptions will not be granted if (1) information will be recorded by investigators in such a manner that subjects can be identified directly or through identifiers; *and* (2) disclosure of subjects' responses could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation. Investigators conducting exempt research are responsible to protect the rights and welfare of research participants. Investigators are not authorized to determine exemption status of research.

Definition **- Department or agency head** means the head of any federal department or agency; or any other office or employee of any department or agency to whom authority has been delegated (46.102(a)).

Guidance – Exempt Research

Federal regulations provide for the exemption from IRB review of six categories of research if the research involves no more than minimal risk, *and* certain conditions are met. **The rights and welfare of subjects participating in research that is granted exempt status must be protected.** For this reason, the IRB may still require informed consent of those subjects. Research determined not to qualify for exempt status cannot be conducted until it is formally reviewed and approved by the IRB. **Research that involves the following, by federal regulation, cannot be exempt:**

1. Prisoners.
2. Survey or interview techniques which include children as subjects.
3. Observation of children when the investigator participates in activities being observed.

The following categories of research may be exempt from IRB review as specified in 46.101(b):

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

(Clarification *- Examples of research that* ***should not*** *be exempt include: Research that involves deception or withholding of information from subjects; or research that involves evaluation of radically new instructional strategies.)*

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 subject can be identified, directly or through identifiers linked to the subjects; and
   (b) Disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

***(Clarification** – Research is not exempt if the research data contains any subject identifiers and if disclosure to unauthorized individuals could harm the subject in any way.*

***Example:** Survey research that deals with private aspects of behavior such as sexual preferences and can be linked to the subject.)*

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 2, if:
   (a) The human subjects are elected or appointed public officials or candidates for public office or,
   (b) Federal statutes require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

***(Clarification** – Personal identifiers can be maintained if a federal statute protects confidentiality, or if the subject is a public official or a candidate for public office.)*

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:
   (a) These sources are publicly available, *or*
   (b) The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

***(Clarification** – Research must be totally retrospective in nature (existent). The information derived from the use of data, records or biological specimens must be recorded in such a way that the subjects cannot be identified. No direct or indirect (demographic) subject identifiers can be used or linked back to the subject, including one-way identifiers/codes.)*

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:
   (a) Public benefit or service programs;
   (b) Procedures for obtaining benefits or services under those programs;
   (c) Possible changes in/or alternatives or those programs or procedures; or
   (d) Possible changes in methods or levels of payment for benefits or services under those programs.

***(Clarification** – Permits research on public benefit or service programs such as Medicaid, unemployment, and Social Security. Thorough review is required to ensure protections, as this research could involve vulnerable populations such as economically disadvantaged or elderly, decision-making impaired persons.)*

6. Taste and food quality evaluation and consumer acceptance studies, if

(a) Wholesome foods without additives are consumed or
(b) Food is consumed that contains a food ingredient at or below the level and for a use 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 US Department of Agriculture.

***(Clarification** - Research should not require subjects to consume food of any volume or type that has potential risk to cause indigestion, vitamin deficiency, or allergic reaction (such as with peanuts or latex). Any food consumption requirements should constitute reasonable eating behaviors.)*

Procedures – Exempt Research

1. The Institutional Review Board is responsible for certifying that research meets exemption criteria as specified in ***45 CFR46.101(b)(1-6).*** To effect certification, the IRB Coordinator screens all research applications that may qualify as exempt research and consults with the IRB Chair or designated representative for final determination.

2. For chart review or specimen research to be classified as exempt, all of the following must apply:
   (a) The research must be entirely retrospective (the data exists **prior** to the start of research);
   (b) The data must be collected without identifiers or a link to identifiers so there is no possible way to go back to the records at a later date);
   (c) The chart review must be conducted by an individual who would normally have access to the records as part of the patient's (subject's) routine clinical care.

(Clarification – *If it is necessary to capture identifying patient (subject) information or maintain a link to the data source, then the study should be submitted for expedited or full review, and a waiver of informed consent **might** be granted.)*

3. Investigators may initiate a request for exemption review by completing an *IRB Application for Determination of Research Exemption Status Form* and submitting it electronically to the IRB according to instructions on the form, along with any appropriate documents from, but not limited to the following list, if they believe their research falls within one of the exemption categories:
   (a) Summary of the research
   (b) Research protocol, if applicable
   (c) Consent form or request to waive consent or waive documentation of consent, if applicable
   (d) Data collection forms, if appropriate
   (e) De-identification Form, if appropriate, i.e., chart/specimen review
   (f) Survey and / or other research materials
   (g) Any other written information that will be provided to subjects
   (h) Any other supporting documentation, as appropriate
   (i) Investigator's Brochure, if available
   (j) Advertising or recruitment materials
   (k) Copy of FDA Form 1572, if appropriate

4. If the Chair confirms that exemption is appropriate, the IRB Coordinator will notify the Principal Investigator (PI) in writing, stating the exemption category for which the research qualifies. A copy of the letter will be filed in the IRB records.

5. If it is determined that the research does not qualify for exemption, the IRB Coordinator will notify the PI in writing and request a completed *SUNYIT Application Form for IRB Review of Human Subject Research* be submitted to the IRB through the IRB Office. The IRB Coordinator will submit the form and supporting documents to the Institutional Review Board for expedited or full board review, as appropriate.
6. The IRB Coordinator will notify the full board of all research classified as exempt by including it on the Agenda for the next scheduled IRB meeting and documenting it in the minutes, along with a brief synopsis of the research.

References

45 CFR 46101(b)(1-6)
IRB Guidebook Chapter IV
Bankert, E. & Amdur, A. (2006) Institutional Review Board Management and Function, 2nd Ed.
OHRP Guidance Documents (*FAQS* and *Public Benefit*)
SUNY Upstate University IRB
SUNY Binghamton IRB
University of Kentucky IRB
Northshore IRB