

Endicott College Guide for Approval of Human-Subjects Research Form

Please use this form to determine whether your proposed research requires informed consent and review by the Endicott College Institutional Review Board (IRB). Senior thesis or research undertaken as part of a class assignment must be approved by the instructor prior to submission to the IRB.

1. If the proposed research meets one or more of the Federal Categories for Exemption, the research **does not** have to be reviewed by the Endicott College IRB.
Check which exemption the project falls under. (See attached.)
 - Exemption for Educational Settings [45 CFR 46.101(b)(1)]
 - Exemption for Tests, Surveys, Interviews, Public Behavior Observation [45 CFR 46.101(b)(2) or (b)(3)]
 - Exemption for Existing Data, Documents, Records and Specimens [45 CFR 46.101(b)(4)]
 - Exemption for Public benefit or service Programs [45 CFR 46.101(b)(5)]
 - Exemption for Food Taste and Acceptance Studies [45 CFR 46.101(b)(6)]
2. If the proposed research does not meet federal criteria for exemption but involves adults, please submit *Proposal Submission Form* (attached) to IRB for full review. Please also consult *Guidelines for Informed Consent in Research Projects* (attached) for more details.
3. If research involves children, please complete *Guidelines for Research Involving Children* (attached) in addition to the forms listed under item 2.

Categories for Exemption from Human Subject Review

from Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services and Part 46 Protection of Human Subjects, 46.101(b) effective June 23, 2005.

Research activities in which the only involvement of human subjects falls in one or more of the following categories **may be** exempt from Endicott College Human Subject Review. If the faculty supervisor determines that a student's research project meets one of the Federal Categories for Exemption, the research **does not** have to be reviewed by the Endicott College IRB. However, *all undergraduate research proposals must follow the review process established by the School or department under which the research is being conducted.* This process may involve peer review, faculty review and/or committee review.

Exemption 45 CFR 46.101(b)(1) for Educational Settings

(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 45 CFR 46.101(b)(1) or (b)(3) for Tests, Surveys, Interviews, Public Behavior Observation

(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 could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(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 45 CFR 46.101(b)(5) for Existing Data, Documents, Records, and Specimens

(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 45 CFR 46.101(b)(5) for Public Benefit or Service Programs

(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 45 CFR 46.101(b)(6) for Food Taste and Acceptance Studies

(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. *Participants should be screened for food allergies.*

****For Human Subject Regulations Decision Charts that help researchers determine if a research project involving Human Subjects is Exempt, see:**

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>Endicott College

Guidelines for Research Involving Children

Adapted from Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services and Part 46 Protection of Human Subjects, Subpart D sec. 46.401-8 effective June 23, 2005.

Name: _____ Date: _____

Name of Research Proposal: _____

Faculty/Supervisor: _____ Approved Not Approved

When a research project involves the use of children as research subjects or participants, special precautions must be taken. To ensure that your project adheres with Endicott College guidelines for research involving children, please complete the following information and include this form in your application for approval of research.

1. Review by Endicott College Academic School or Department

Research using children as subjects which involves survey or interview procedures or observations of public behavior *must be reviewed by a committee of at least two members of the School or Major under which the research is being conducted.* Please see your faculty/supervisor, dean or chair for guidelines for review in your major.

2. Assessment of Risk.

For all research studies involving children, the student researcher should make an initial determination of the appropriate risk category and the faculty supervisor will either *Approve* or *Not Approve* the project. Please check the category that best describes your research:

<i>Check which applies</i>	<i>Risk Category</i>
<input type="checkbox"/>	Research does not involve greater than minimal risk to children. *** <i>“Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the 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,” 45CFR46.102</i>
<input type="checkbox"/>	Research involves greater than minimal risk to children. If the research involves greater than minimal risk to children it <i>must be reviewed by the Endicott College IRB.</i>

3. Research Involving Children Conducted in a School Setting

Research done in a school setting must abide by the school and/or district research policy. Please attach a description of that policy here with particular attention to the approval process (superintendent, principal, classroom teacher etc).

3. Parental Consent

Parental consent is required for all research directly involving students under the age of 18, including surveys, interviews, and observations. Research involving review of records, curriculum and other school-based inquiry that does not directly involve students does not need parental permission, unless specified by the school/district policy.