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IRB FORM 2

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD
REQUEST FOR IRB EXEMPTION

The following information must be submitted in typed or word processed format. Fill in all information lines. If information is not applicable, indicate by answering "N/A."

Principal Investigator:
Project Title:
Today's Date:

Policy and Procedures

In general, research that does not propose to disrupt or manipulate subjects' normal life experiences, or incorporate any form of intrusive procedures, may be declared exempted from expedited or full IRB review. Major considerations when determining if an exempted level of review is appropriate include level of risk and the presence or absence of deceptive procedures. 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 examination or tests. Any degree of deception disqualifies a research protocol from exempted review. Research that is judged to involve more than minimal risk, intentional deception, or a protected population and does not meet the categories for exempt or expedited review, must be presented to the entire review board for discussion and consideration of approval or non-approval.

Informed Consent. Some exempt research projects ethically require informed consent. If, in the investigator's opinion, the study requires informed consent, the method used to obtain informed consent should be described and the proposed consent form submitted as per FORM 1. If the study does not require consent, it should be so stated and justified.

Complete FORM 2, Part A and indicate the appropriate *Exemption Category (categories)* in FORM 2, Part B. Submit FORM 2 along with the IRB Application and Research Protocol (FORM 1) when the investigator considers that the proposal may qualify for an exemption from Federal Regulations as noted in **45 CFR §46.101(b),** exempt from full board or expedited review. If a project meets any of the six exemption categories found in **45 CFR §46.101(b),** and is not excluded by the limitations for the specific categories, it may be exempt from full review. The IRB reserves the right to request the investigator to provide additional information concerning the proposal. After review, the IRB will send the applicant formal notification of whether or not the proposal qualifies for exempt status.

FORM 2, Part A. Checklist for Exempted Review (Limitations) Check responses to the seven items.

1.	It is clear that the nature of the proposed research fits one of the categories listed in FORM 2, Part B (Research Activities Eligible for Exempted Review CFR 45 §46.101(b).)	Yes ☐ No ☐
2.	No implications for criminal or civil liability, employability, or damage to subject's financial standing or reputation would exist if data were known outside the study.	Yes ☐ No ☐
3.	The research does not use a protected group as subjects (e.g., e.g. fetuses, pregnant women, prisoners, mentally handicapped, or minors.	Yes ☐ No ☐
4.	The study does not present more than a MINIMAL RISK to subjects	Yes ☐ No ☐
5.	The study does not involve DECEPTION.	Yes ☐ No ☐
6.	Appropriate informed consent procedures will be followed.	Yes ☐ No ☐
7.	The study will not be conducted in another country.	Yes ☐ No ☐

"Yes" answers to all of the above are required to qualify for a recommendation for exempted review. If the answer to any one of these questions is "no," then expedited or full IRB review is required.

FORM 2 Part B. Research Activities Eligible for Exempted Review CFR 45 §46.101(b).
Please indicate into which of the Exemption Categories your research falls by checking all that apply.

☐ (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.

☐ (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations 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 (2) of this section if:
- ☐ (i) The human subjects are elected or appointed public officials or candidates for public office; or
- ☐ (ii) Federal statues(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (No child subjects)

☐ (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. (Retrospective)

☐ (5) Research and demonstration projects which are conducted by or subject to the approval of any [Federal] 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.

☐ (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.

On an attached page, please explain how your project fits into the indicated category(s) CFR 45 §46.101(b). Typed response.

SIGNATURES (To sign the document, click on the pink tab below and follow the computer prompts)

_____

Signature of Sponsor (required for students) Date

_____

Name Position Academic Unit/Department

_____

Signature of Sponsor (for non-doctoral employees) Date

_____

Name Position Academic Unit/Department

_____

Signature of Vice President (for staff employee) Date

_____

Name Position Academic Unit/Department

_____

Signature of College Dean (for faculty) Date

_____

Name Position Academic Unit/Department

NOTE: Applications without all requested information will be returned without IRB review.

Last revision: March 2010.