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IRB FORM 2 A

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD
REQUEST FOR IRB EXEMPTION - PROGRAM EVALUATION

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:
Area being evaluated:
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. The Code of Federal Regulations defines research as a *"systematic investigations...designed to develop or contribute to generalized knowledge."* Many activities that involve collection of data from or about people are excluded from this definition, including for example evaluation of a social program under contract with the sponsor, for purposes of assessing and improving the program; psychological studies created by students in a research methods class; or surveys of patient satisfaction with healthcare providers. One broad category concerns evaluation of "normal educational practices," instructional techniques or classroom management methods. In some cases, the IRB has exempted such educational research from review. More commonly, there are other components to the research (for example, examination of student personality characteristics and how this influences their response to lessons, teacher profiles, etc.) that need review, so the IRB tends to be conservative in granting this exemption. This form is to be used specifically when research regarding program evaluation does not identify unique personality variables that influence response to lesson but rather looks at the effects of a specific educational intervention on the population of students as a whole. This form is to be used specifically when it is the intent of a program to continuously monitor/evaluate its practices and wishes the IRB to have a record of this activity.

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 *Checklist for Exempted Review in (Limitations*) and indicate the appropriate *Exemption Category (categories)* in FORM 2, Part B. Submit FORM 2. Ongoing program evaluation meeting any of the six exemption categories found in **45 CFR §46.101(b),** and is not excluded by the limitations for the specific categories, may be exempt from full review. The IRB reserves the right to request the investigator to provide additional information concerning the ongoing program evaluation. 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)

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. fetuses, pregnant women, prisoners, mentally handicapped, minors in a survey or interview study, or minors in a participant observation study).	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).
Check 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 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)

☐ (4) 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.

In the space below (or 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: Submitting this form electronically is acknowledgement that all indicated signatories approve this submission. Applications without all requested information will be returned without IRB review.