Clear Form

Protocol #_____

Western Washington University
Office of Research and Sponsored Programs
Human Subject Research Exemption Form

The purpose of this form is first to determine if a project is considered research and if the individuals involved are research subjects. Next, if the project is determined to be research and the individuals to be research subjects, under federal regulations (45 CFR 46) does the project qualify for exemption from full review by the Human Subjects Review Committee (HSRC)? The HSRC must make this determination Please complete and submit this form to the Research and Sponsored Programs, OM 530, MS 9038. Incomplete forms will not be reviewed. **Contact with subjects can not begin until project is approved.**

Project Investigator(s): Michael Murphy Email: Murphy28@students.wwu.ec W#: 00671***

Department: Continuing College Education Mail Stop: 9087 Phone: 509-675-2591

Project Title Disruptions in the Classroom

Proposed Project Start Date: Fall 2012 Project Duration: 4 Months

☐ Faculty ☐ Research Associate ☐ St aff/Admin ☒ Graduate ☐ Undergraduate

1. ☒ YES ☐ NO Is the proposed project a systematic investigation designed to develop or contribute to generalizable knowledge?

2. ☒ YES ☐ NO Are the human subjects in your study living individuals?

If you answered NO to Question 1 or 2, stop here; no review is required, and it is not necessary to submit this form. If you answered YES to both questions, continue.

3. ☒ YES ☐ NO Will you obtain data through intervention or interaction with these individuals? (Note: "Intervention" includes both physical procedures by which data are gathered [for example, measurement of heart rate or venipuncture] and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the investigator and subject [for example, surveying or interviewing].)

4. ☒ YES ☐ NO Will you obtain identifiable private information about these individuals? (Note: "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, or information which the individual can reasonably expect will not be made public [e.g., a medical record]. "Identifiable" means that the identity of the subject may be ascertained by the investigator or associated with the information [e.g., by name, code number, pattern of answers, etc.].)

If you answered NO to Questions 3 and 4, stop here; no review is required, and it is not necessary to submit this form. (However, keep a copy for your records.) If you answered YES to either question, continue.

5. ☒ YES ☐ NO Is the proposed study a student research project, defined as a project which is a normal part of the student's course work; is supervised by a faculty member; has as its primary purpose the development of the student's research skills; does not present more than minimal risk to participants or to the student investigator; does not deal with issues of a sensitive nature; and is not genuine research which is expected to result in publication or some other form of public dissemination? (Note: Independent Study, Bachelor's Essay, and Master's Thesis research projects are considered research projects and must be reviewed by the HSRC.)

If YES, stop here; no review is required, and it is not necessary to submit this form. (However, keep a copy for your records.) If NO, continue.

6. ☐ YES ☒ NO Does the study present more than minimal risk to the subjects? (Note: "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect as well as psychological, emotional, or social risk.)

If YES, stop here and complete a full HSRC application). If NO, continue.

Categories of Research which are Exempt from HSRC

Federal regulations (45 CFR 46) permit the exemption of some types of research from HSRC review. If your research can be described by one or more of the categories listed, check the appropriate category(ies) and answer Questions 7-20 on a separate sheet of paper. (Please number your responses, limit each to one typewritten page, and attach them to this form.). If your research cannot be described by any of the categories listed below, your research does not qualify for exemption, and you must complete a full HSRC form. (Note: Exemption categories cannot be applied to research involving fetuses, pregnant women, children, human in vitro fertilization, or prisoners.)

☐ **Category 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. (46.101[b][1])

☐ **Category 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 the human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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. (46.101[b][2])

(Note: Exemption for survey and interview procedures does not apply to research involving children. Exemption for observation of public behavior does not apply to research involving children except when the investigator does not participate in the activities being observed.)

☐ **Category 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 Category 2 above if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (46.101[b][3])

☐ **Category 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. (46.101[b][4])

❑ **Category 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 to these programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. (46.101[b][5])

❑ **Category 6** - Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) 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. (46.101[b][6])

On separate sheets, please answer in clear, non-technical terms, the following questions regarding your research, and the involvement of human subjects in your research.

7. What is your research question, or the specific hypothesis?

8. What are the potential benefits of the proposed research to the field?

9. What are the potential benefits, if any, of the proposed research to the subjects?

10. Answer a), then answer either b) or c) as appropriate.

    a) Describe the population your research is designed to study, including the number of subjects.

    b) Describe how you will recruit subjects from your population of interest. You should include specific details about your sampling strategy (e.g. selection of cases from telephone or web lists, classes, or clinics). If appropriate, explain how you will contact key individuals who will facilitate access to the sample subjects (e.g. group leaders). Any materials to be used for recruitment (e.g. advertisements, web pages, contact letters or emails) should be included, in addition to a description of any use of compensation.

OR

    c) Describe how you will access preexisting data about the subjects.

11. Briefly describe the research methodology. Attach copies of all test instruments/questionnaires that will be used. Note: All attachments must be in final form; drafts are unacceptable.

12. Give specific examples (with literature citations) for the use of your test instruments/questionnaires, or similar ones, in previous similar studies in your field.

13. Describe how your study design is appropriate to examine your question or specific hypothesis. Include a description of controls used, if any.

14. Give specific examples (with literature citations) for the use of your study design, or similar ones, in previous similar studies in your field.

15. Describe how you will address privacy and/or confidentiality.

16. If your research involves the use of schools (pre-kindergarten to university level) or other organizations (e.g., community clubs, companies), please attach a clearance letter from an administrator from your research site indicating that you have been given permission to conduct this research. For pre-kindergarten to grade 12 level schools, an administrator (e.g. principal or higher)

should issue the permission. For post-secondary level schools permission may be granted by the class instructor. **For Western Washington University, this requirement of a clearance letter is waived if you are recruiting subjects from a scheduled class**. If you are recruiting subjects from a campus group (not a class) at Western Washington University, you are required to obtain a clearance letter from a leader or coordinator of the group.

17. If your research involves the use of schools (pre-kindergarten to university level) or other organizations (e.g., community clubs, companies), and you plan to take still or video pictures as part of your research, please complete a) to d) below:

    a) Who have you contacted at the school district or organization involved, to determine the policy on the use of photography in the school or organization?
    b) Explain how your research plan conforms to the policy on the use of photography in the school or organization.
    c) Attach a copy of the school district or organization policy on the use of photography at the school or organization.
    d) Explain how you will ensure that the only people recorded in your pictures will be the ones that have signed a consent form.

18. Attach a copy of your informed consent form. (A checklist is attached for you to use as a guide.)

19. Attach a copy of your curriculum vitae.

20. Attach a copy of the Certificate of Completion for Human Subjects Training from the online human subjects training module, for each person involved in the research who will have any contact with the subjects or their data. See "Training" at http://www.wwu.edu/depts/rsp/human.html. Human subject certification is valid for five years. After five years, researchers must complete the certification again.

Principal Investigator: Michael Murphy

Signature: _____ **Date:** _____

Name of Faculty Advisor (if student) _____

Signature: _____ **Date:** _____

Department Chair: _____

Signature: _____ **Date:** _____

For RSP use only: **Date Received:** _____ **Exemption:** ☐ **Yes** ☐ **No**

RSP/HSRC Signature: _____ **Date Reviewed:** _____ **Category:** _____

Informed Consent Requirements Checklist

Informed consent is required from any subjects put at risk. A copy of the informed consent form to be used on the project must be submitted to the Human Subjects Review Committee with the Human Subjects Activity Review Form and the Human Subjects Research Exemption Request. The consent form should include the following:

- ☐ A statement that the study involves research and an explanation of the purposes of the research.
- ☐ A brief, clear explanation of the research procedures to be followed (in non-technical terms, or where necessary, with technical terms defined), including the expected duration of the subject's participation.
- ☐ A description of discomforts or risks to be expected.
- ☐ A description of the benefits of the research (to the individual, to the field, etc.).
- ☐ An offer to answer inquiries from participants concerning the procedures (provide contact information for the primary research or, for student research, faculty advisor). Instructions that questions about subject's rights as a research subject should be directed to: Janai Symons, Research Compliance Officer (RCO), (360) 650-3082. Directions that in the event the subject suffers any research related injuries or adverse effects as a result of participation in the study the primary researcher and/or RCO should be contacted.
- ☐ A statement that participation is voluntary and that the subject is free to withdraw his/her consent and to discontinue participation without penalty or loss of benefits to which the subject is otherwise entitled.
- ☐ A statement describing the extent, if any, to which confidentiality of records and data identifying the subject will be maintained.
- ☐ A reference to any age restrictions or associated permissions for the subject population. If minors are to be excluded from your study, include a line on the consent form which reads “I am at least 18 years of age.” If the subjects are or can be minors, include a line for the required parental signature.
- ☐ A statement saying that a copy of the consent form will be given to the person signing the form. (Give the subject two copies of the form-one marked "Researcher" and one marked "Participant"-have them sign both copies and retain the copy marked "Participant.")
- ☐ Oral Consent: Only in special and/or unusual circumstances can consent of the subjects be obtained orally. The Committee must approve a waiver of the requirement to document informed consent. A waiver of written consent might be granted in the case where: (a) the risk to the subject is minimal; (b) use of primary procedures for obtaining consent would invalidate important research objectives; or (c) where alternative means would be less advantageous to the subjects.

For further guidance on preparing your consent form, see the samples given on the RSP website at http://www.wwu.edu/depts/rsp/stdconsent.pdf for a standard consent form and http://www.wwu.edu/depts/rsp/childconsent.pdf for a parental consent/child assent form (used when your subjects are under 18 years of age). The numbers in parentheses at the end of statements on the templates refer to the numbered listing above.