Research Protocol Application – Exemption Template

Protocol Information

1. Principal Investigator (PI) Name:*

   _____

2. Which of the following are you?

   ◯ Graduate Student (Skip to Question 3)

   ◯ Faculty/Staff Member (Skip to Question 6)

3. Principal Investigator's (PI's) Fairfield Graduate Student e-mail:*

   _____

Note 1
Attention Graduate Students: Do not proceed to submit this form on your own. Either (A) your Faculty Mentor will handle the entire process on your behalf, or (B) your Faculty Mentor will initially create the application from his or her own account, then share it to you for editing. (Protocols submitted from non-faculty accounts are ignored and automatically terminated.)
Full, detailed instructions for submitting Graduate protocols via method (B) can be found on the Fairfield University IRB Reference Materials page.

4. Are you editing an application that has been created from your Faculty Mentor's own account and subsequently shared with you for editing? (The IRB will automatically reject student Protocols if they were not created from a Faculty Mentor's own account. If confused, please refer to the "Graduate Student Submission Process" guide available on the IRB Information Site.)*

   ◯ No. I ignored the text above, did not bother to look at the guide available on the Fairfield University IRB website, am proceeding with a Protocol created from my own account, and am looking forward to it being auto-rejected by the IRB and having to do all the work over again! (See Note 2)

   ◯ Yes, I'm ready to edit the Protocol that my Mentor created on my behalf. (Skip to Question 5)

Note 2
STOP: Graduate student protocols must be submitted from a Faculty Mentor's account. If you submit on your own, the IRB will ignore the Protocol and terminate it. Please consult your Faculty Mentor for help with properly submitting from his or her own account instead of your own.

5. Faculty Mentor Name:*

   _____

   (Skip to Question 7)

6. Principal Investigator (PI) Fairfield Faculty e-mail:*

_____

7. Protocol Title:*

_____

8. Co-PIs: Please list all Co-PIs' Names, Titles, and Affiliations.

9. External PIs: Please list all External PIs' Names, Titles, and Affiliations.

10. Research Associates: Please list all Research Associates' Names, Titles, and Affiliations.

11. Research Start Date:*

_____

12. (Estimated) Research End Date:*

_____

13. Funding Source:

_____

14. For which type of review would you like to submit this research protocol?*

Exemption from IRB Review

Exempt Research

15. With which of the following is your research involved?*

- ◯ Category 1: Educational Research in Established or commonly accepted education settings and normal education practices. (Skip to Category 1)
- ◯ Category 2: Tests, surveys, interviews, or observation of public behavior. (Skip to Category 2)
- ◯ Category 3: Benign Behavioral Interventions (Skip to Category 3)
- ◯ Category 4: Secondary research for which consent is not required (e.g. retrospective chart review) (Skip to Category 4)
- ◯ Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency (Skip to Categories 5-8)
- ◯ Category 6: Taste and food quality evaluation and consumer acceptance studies (Skip to Categories 5-8)
- ◯ Category 7: Storage or maintenance for secondary research for which broad consent is required (Skip to Categories 5-8)
- ◯ Category 8: Secondary research for which broad consent is required (Skip to Categories 5-8)

Category 1

1. What type(s) of activities will be used? (Check all that apply.)*

   ◯ Research on regular and special education instructional strategies.

   ◯ Research on the effectiveness of instructional techniques, curricula, or classroom management methods.

   ◯ Research comparing instructional techniques, curricula, or classroom management methods.

2. Regarding your activities response above, please select one of the following:

   ◯ The research involves (additional) activities other than those listed above. (See Note 3)

   ◯ The research does not involve (additional) activities other than those listed above. (Skip to Question 3)

Note 3
STOP! Because your research involves activities other than those listed, it is not eligible for exemption. Please go back and change your project's application type.

3. Clearly state the purpose of the study, provide a brief rationale for the study, and indicate your main research questions/hypotheses. Be clear on how this study is intended to contribute to generalizable knowledge.*

4. Describe the research procedure and study design.*

5. Describe the intended participants and the recruiting process.*

6. Describe how consent will be obtained from participants.*

7. Describe how you are ensuring the voluntary nature of participation and minimizing coercion or the perception of coercion. If students are the intended research participants, indicate whether the PI is also the instructor whose class participants are being recruited from.*

8. Discuss how you will protect participants' privacy in obtaining and storing information and data collected from them.*

(Skip to Research Ethics Training)

Category 2

1. What type(s) of instruments/activities will be used? (Check all that apply.)*

   ☐ Educational tests (cognitive, diagnostic, aptitude, achievement)

   ☐ Questionnaire/Survey

   ☐ Interviews

   ☐ Observation of public behavior

2. Please review the following conditions and answer accordingly: (Check all that apply)*

   ☐ Information will be recorded in a manner that participants can be identified. (Name, social security number, license number, phone number, e-mail address, photograph.)

   ☐ The disclosure of information obtained would put participants at risk for civil or criminal liability or damage to their financial standing, employability, or reputation. (Drug or alcohol use, criminal or other illegal activity.)

   ☐ Participants include those under the age of 18 years old.

   ☐ None of the above are true.

3. Clearly state the purpose of the study, provide a brief rationale for the study, and indicate your main research questions/hypotheses. Be clear on how this study is intended to contribute to generalizable knowledge.*

4. Describe the research procedure and study design.*

5. Describe the intended participants and the recruiting process.*

6. Describe how consent will be obtained from participants.*

7. Describe how you are ensuring the voluntary nature of participation and minimizing coercion or the perception of coercion. If students are the intended research participants, indicate if the PI is also the instructor whose class participants are being recruited from.*

8. Discuss how you will protect participants' privacy in obtaining and storing information and data collected from them.*

9. For studies using questionnaires, surveys, and/or interviews: Provide a description, sample questions, and/or file uploads for the documentation you plan to use.

(Skip to Research Ethics Training)

Category 3

10. Clearly state the purpose of the study, provide a brief rationale for the study, and indicate your main research questions/hypotheses.*

11. Describe the research procedure and study design.*

12. Describe the intended participants and the recruiting process.*

13. Describe how consent will be obtained from participants.*

14. Describe how you are ensuring the voluntary nature of participation and minimizing coercion or the perception of coercion. If students are the intended research participants, indicate if the PI is also the instructor whose class participants are being recruited from.*

15. Discuss how you will protect participants' privacy in obtaining and storing information and data collected from them as research participants.*

16. For studies using questionnaires, surveys, and/or interviews: Provide a description, example questions, and/or file uploads for the documentation you plan to use.

Note 4:
Explicitly address how your research meets the definition and qualifications for the exemption category by answering the questions below.*

17. Will subjects be adults 18 years or older?

- ◯ Yes (Skip to Question 9)
- ◯ No (see Note 5)

Note 5:
Stop! This research does not qualify for this exemption category. Please go back and select the appropriate category.

18. Discuss how the study meets the definition of a benign behavioral intervention:*
    It must be brief in duration (not exceeding a few hours in its entirety), harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

19. The data collected must be through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met. (Select all that apply)*

- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ☐ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make a determination of exemption

20. Is deception involved?

- ◯ Yes
- ◯ No (Skip to Question 13)

21. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is applicable only if the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
Indicate what subjects are told in this regard when they provide their consent to participate in the study, and how they will be debriefed after.

22. Please upload your consent document or consent script.
(Skip to Research Ethics Training)

Category 4

1. Clearly state the purpose of the study.*

2. Where are you collecting the information/biospecimens from? How do you have access to this information?*

3. Describe the research procedures and what data will be collected.*

4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met. Select all that apply.

   ☐ Use of publicly available identifiable private information or identifiable biospecimens.

   ☐ Information recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

   ☐ Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined by HIPAA.

   ☐ Analysis of data on behalf of a federal agency or department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

5. Discuss how you will record information in a way so that the identity of the subjects cannot be readily ascertained.

(Skip to Research Ethics Training)

Categories 5 – 8

6. Clearly state the purpose of the study.*

7. Describe the research procedures and who will be included in the study as participants.*

8. Explain how your study meets [CFR 45 46.104(d)(5,6,7,8)] exemption criteria.*

(Skip to Research Ethics Training)

Research Ethics Training

1. Have you completed a certificate program for research ethics program (e.g. CITI, NIH)?*

   - (●) Yes
   - ( ) No

2. What date did you complete the certificate program?

   asfjklfs

3. Please upload a copy of the most recent certificate.

General Upload/Information

1. If you would like to include a message to the Chair with your initial application submission, please type it here:

2. Please use this box to respond to any application comments and/or requests from the IRB:

3. Please upload any additional documentation having to do with this protocol application here:

Note 10
If the PI is a graduate student, faculty mentors will need to digitally sign the application before it can be submitted.
Any information completed on this document must be entered into a digital application using Fairfield University's IRB system, Infonetica.

4. **Faculty Mentors:** By digitally signing and submitting this Protocol, you are taking responsibility for your student's work, much like a Co-PI. You are confirming that you've read and reviewed all Protocol materials and collaborated with the student to make necessary changes. You are agreeing to oversee/update the Protocol over the study's full duration, taking ultimate responsibility over it, especially if the student leaves the Institution.