Research Protocol Application – Expedited and Full Board Review Template

Protocol Information

1. Principal Investigator (PI) Name:*

   _____

2. Which of the following are you?

   ◯ Graduate Student

   ◯ 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?*

- ◯ Expedited Review (Skip to Expedited/Full Board Review Question 1)
- ◯ Full Board Review (Skip to Expedited/Full Board Review Question 2)

Note 3
If you are submitting this protocol under Expedited Review, answer question one. Otherwise, continue on to Question 2.

1. Which of the following most closely aligns with your study? (Please use the information icon to view option details and referenced material for each of the options.)*

- ◯ Category 1: Clinical studies of drugs and medical devices
- ◯ Category 2: Collection of blood samples
- ◯ Category 3: Prospective collection of biological specimens by noninvasive means
- ◯ Category 4: Collection of data through noninvasive clinical tests
- ◯ Category 5: Research on data previously collected for nonresearch purposes
- ◯ Category 6: Collection of data from recordings made for research purposes
- ◯ Category 7: Research on individual or group characteristics or behavior
- ◯ Category 8: Continuing review of certain non-exempt research
- ◯ Category 9: Continuing review of other certain non-exempt research

2. Clearly state the purpose of the study. (Usually this will include the research hypothesis.)*

3. Background (Describe past studies and any relevant experimental or clinical findings that led to the plan for this project.)*

4. Research Plan (Provide an orderly, scientific description of the intended methodology and procedures as the directly affects the subjects.)*

5. At what location(s) will the study take place? Please be as specific as possible.*

6. Duration of the project:*

   _____

7. Describe who will be included in the study as participants and any inclusion/exclusion criteria.*

8. What is the intended age range of the study's participants?*

   _____

9. Describe how participant recruitment will be performed.*

10. The IRB must review advertisements for participant recruitment if they contain more than: the study title, purpose, summary, basic eligibility criteria, study site location(s), and site contact information. Please upload your Advertisement(s) for IRB review if it contains more than the information listed.

11. What are the benefits to participants of this study?*

12. What are the risks (physical, social, psychological, legal, economic, etc.) to participants of this study?*

13. If deception is involved, please explain.

14. Indicate the degree of risk (physical, social, psychological, legal, economic, etc.) you believe the research poses to human subjects?*

- ◯ Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the proposed research is 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. (Skip to Question 16)
- ◯ Greater Than Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the proposed research is greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

15. Research presents a Greater Than Minimal Risk: Please provide a statement about the statistical power of the study based on intended sample size, design, etc. to test the major hypothesis.*

16. Are participants to be financially compensated for the study?*

- ◯ Yes
- ◯ No (Skip to Question 20)

17. Compensation Amount:*

_____

18. Compensation Source:*

_____

19. Compensation Type (Gift Card, Cash, etc.):*

_____

20. Will participants who are students be offered class credit?*

- ◯ Yes
- ◯ No/Not Applicable (Skip to Question 22)

21. If course credit is being offered to student participants, please describe any alternative assignment(s) non-participating students may complete to receive an equal amount of credit.

22. If necessary, please describe any additional recruitment inducements:

23. Will personal identifiers (name, social security number, license number, phone number, email address, photograph) be collected?*

- ◯ Yes
- ◯ No (Skip to Question 25)

24. Will personal identifiers be translated to a code?*

- ◯ Yes
- ◯ No

25. Describe how you will protect participant confidentiality and secure research documents, recordings (audio, video, photos), specimens, and other records.*

26. Do you plan to use a written consent form that each participant must read and sign?*

- ◯ Yes
- ◯ No (Skip to Question 28)

27. Please describe how consent will be obtained and by whom:*

28. If the participants are minors under the age of 18 years, will assent forms be used?*

- ◯ Yes (Skip to Question 30)
- ◯ No
- ◯ Not Applicable (Skip to Question 30)

29. Please explain why assent forms are not being used for participating minors:*

Note 4
If you plan to use written consent from that each participant must read and sign, continue onto Question 30. If you do not plan to use a written consent form that each participant must read and sign, skip to Question 32.

30. Please upload any consent and/or assent forms that participants and/or parents/guardians will be required to sign. (If you have obtained a Waiver of Informer Consent from the Fairfield IRB, you may skip this step.)

31. Which of the following waivers are you requesting?
Waiver of Consent:
The IRB can approve a waiver, or an alteration, of the requirement for informed consent to the research if the proposed protocol meets the following criteria:
The research involves no more than minimal risk to the subjects.
The research could not practicably be conducted without the requested waiver or alteration.
The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Waiver of Documentation of Consent:
The IRB may waive the requirement for the investigator to obtain a signed consent form if: (a) the research presents no more than minimal risk, and (b) the research involves procedures that do not require written consent when performed outside of a research setting.
See the IRB information page for detailed information about requirements. You will find specific information on the Submitting Your Research Protocol page under Additional Information > Waivers and Alterations of Informed Consent For Expedited and Full Board Review Protocols.

- ◯ Waiver of Consent (the subjects do not have to agree to take part of the study)
- ◯ Waiver of Documentation of Consent (the subjects do not have to sign a consent form but they do agree to participate in the study) (Skip to Question 33)

32. Explain how your project meets the requirements for a waiver of informed consent, as outlined above.*

33. Are both of the following statements true?*
1) The only record linking the participant to the research would be a consent form, and the principal risk to the participant would be a breach of confidentiality.

2) The research is of minimal risk and involves no procedures for which written consent wouldn't be normally required outside of research.

- ◯ Yes, and I'd like to request a waiver of informed consent.
- ◯ No (Skip to Note 5)

Note 5
STOP! Sorry, your research is not eligible for a waiver of informed consent. You will have to go back and upload the appropriate Consent Forms

34. Explain why you are requesting waiver (or modification) of informed consent (written) and how you instead plan to obtain consent.*

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?

   _____

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 6
Any information completed on this document must be entered into a digital application using Fairfield University's IRB system, Infonetica.

4. **Faculty Mentors:** By 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.