# Research Protocol Application – Quality Improvement Template

## Protocol Information

1. _____

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. 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:*

   _____

   (Skip to Question 7)

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?*

    Quality Improvement

## Quality Improvement

15. For your application to be submitted as a Quality Improvement Project, your research must involve healthcare and meet all seven of the below criteria:

    **1) Purpose**- The project is intended to improve the process/delivery of care while decreasing inefficiencies.

    **2) Project Staff-** The project will be conducted by the clinicians and staff who provide care or are responsible for the performance quality in the institutions where the project will take place.

    **3) Project Design-** The project is flexible, allowing ongoing change, evaluation, and revision.

    **4) Recruitment-** The project will involve a sample population (staff or patients) ordinarily seen in the institution where the project will take place.

    **5) Consent-** The planned activity will only require consent that is normally sought in clinical practice and could be considered part of usual care.

    **6) Benefits-** Most of the current patients involved in this project (at the institution where the planned activity will take place) could potentially benefit from the project.

    **7a) Risk-** The risk to participants is no greater than that involved in the care they are already receiving.
    OR
    **7b) Risk-** The burden of participating in the activity could be considered acceptable or ordinarily expected when reforms are being introduces to the way care is provided.

    Does your research involve healthcare and meet all seven of the above criteria?*

    ◯ Yes

    ◯ No (See Note 3)

**Note 3**
**STOP!** Because your research does not meet the above criteria, it cannot be submitted as a Quality Improvement Project. Please go back and change your application type.

16. Clearly state the purpose of the project.*

17. Describe the procedures to be followed and how data will be collected.*

18. Explain who the participants are (e.g., nurses, supervisors, etc.) and how they will be asked to participate.*

19. Provide the location where the study will be run. (Institution, city, state, and specific location.)*

20. Provide any other additional information you believe is pertinent for the IRB to verify that your research is a Quality Improvement Project.

## 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 4**
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.