



Introduction

Research Not Requiring IRB Review

Determining whether a project constitutes human subjects research rather than quality improvement or program evaluation involves multiple factors. The **federal definition of research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”**

In contrast, **quality improvement projects or program evaluation projects systematically collect data for administrative, clinical, or reporting purposes, but are not designed to contribute to, or to advance generalizable knowledge.** Instead, they are designed to develop or contribute to knowledge relevant to the organization.

Notes:

1. The researcher may make the determination themselves utilizing this self-determination tool. The determination is only valid if the questions are answered truthfully. It is important

that if you need clarification on any survey question, that you consult with your department's IRB Analyst.

(<https://www.uvm.edu/rpo/human-subjects-research>)

2. Upon completion of this tool, you will receive an email determination that may be provided to journals, conference managers, funding sources and others as necessary to document exemption from IRB review.
3. For projects that are determined exempt from IRB review, utilizing this tool, it is required that any public presentations, academic curriculum vitae, publications, etc., include this statement *"According to the policy defining activities which constitute research at the University of Vermont/University of Vermont Health Network, this work met criteria for operational improvement activities exempt from IRB review."*
4. Please review the Research Not Requiring IRB Review (PDF) in its entirety to prepare yourself for the questions that will be posed to you.

Demographics

Demographic Information

Provide the title of the project.

Provide a summary of the project.

Type your name and credentials as you would like them to show on the email certification.

Provide the sponsor name and the funding proposal (FP) number as assigned by Sponsored Projects. If not sponsored, enter departmental funding.

Provide your email to receive a record of self-determination of Research Not Requiring Prior IRB Review.

Survey Questions

1. What is the primary intent of this project?

- ☐ To improve a practice or process in the delivery of care or improve or assess a specific program; OR
- ☐ To test a hypothesis, answer a research question, or replicate a previous research finding.

If you are testing a hypothesis, answering a research question, or replicating a previous research finding, **this is research that requires IRB review and approval**. Click next to exit the survey.

2. Does the project aim to improve delivery of care, services, or educational practices for **all** persons involved in the project?

- ☐ Yes
- ☐ No

If you have selected no, **this is research that requires IRB review and approval.** Click next to exit the survey.

3. Does the project test interventions, treatments, or practices that are not currently considered standard of medical care or standard educational/curricular practice?

- ☐ Yes
- ☐ No

If you have selected yes, **this is research that requires IRB review and approval.** Click next to exit the survey.

4. Is the intent of the project to design or develop a new standard of medical care or new educational/curricular standard?

- ☐ Yes
- ☐ No

If you have selected yes, **this is research that requires IRB review and approval.** Click next to exit the survey.

5. Does the project involve suppressing any aspect of medical care or withholding standard educational resources?

☐ Yes

☐ No

If you have selected yes, **this is research that requires IRB review and approval.** Click next to exit the survey.

6. Will the project team be blinded to any aspect of the intervention?

☐ Yes

☐ No

If you have selected yes, **this is research that requires IRB review and approval.** Click next to exit the survey.

7. Will persons (including patients, investigators, students, faculty or staff) be exposed to risks beyond standard medical care or standard educational activities?

☐ Yes

☐ No

If you have selected yes, **this is research that requires IRB review and approval**. Click next to exit the survey.

8. Will the project involve a research design (i.e. randomization) that overrides clinical or educational decision making?

☐ Yes

☐ No

If you have selected yes, **this is research that requires IRB review and approval**. Click next to exit the survey.

9. Is the project funded by an entity that requires IRB review and approval and that will not accept a determination of research not requiring IRB review? (*this has occurred with NIH*)

- ☐ Yes
- ☐ No

If you have selected yes, **this tool cannot be used as an official determination. The IRB will need to review and approve your research through a UVM click submission to meet the sponsor's requirement.** Click next to exit the survey.

If you have selected no, this project is considered **Research that does not Require IRB** review. You will receive an email with this determination. Click next to exit the survey.

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