

Determination of Human Subjects Research Form for Quality Improvement/Quality Assessment Activities

Project Description:

1. Submit a summary (one page or less) within IRBNet describing the project goals. The abstract must:

- 1) describe the reasons for conducting the proposed project,
- 2) provide a brief description of the project including objectives, and
- 3) describe the proposed activities for the project.

2. What organization or department will be reviewed during the quality improvement or quality assessment project? (If the organization or department is unaffiliated with Regis University, a site approval letter is required.)

3. Answer the questions below in **either** the Quality Improvement/Professional Development Projects section or the Program Evaluation Projects section to determine if your project is actually quality improvement or if it is program evaluation. ALL questions must be answered TRUE to be considered a Quality Improvement Project or a Program Evaluation Project.

Quality Improvement/Professional Development Projects	Program Evaluation Projects
<p>The project is intended to improve or evaluate a practice or process within a particular institution, classroom, or specific program.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>	<p>The evaluation is being initiated based on the request and needs of a partner organization or department for internal purposes only.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>
<p>The primary intent of the project is not designed to expand knowledge of a scientific discipline or scholarly field of study.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>	<p>The intent of the evaluation is to improve a specific program and/or to meet funding agency requirements.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>
<p>All activities are “best practices”, “routine care”, or “standard practice” and conducted by staff where the project will take place.</p>	<p>The program or intervention being</p>

<p>Untested methods and/or interventions are not being evaluated.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>	<p>evaluated has been tested and is evidence based (already shown to be effective).</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>
<p>The project does not involve a control group or randomization of subjects or blinded interventions.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>	<p>The evaluation does not involve randomization of participants, but may involve comparison of variations in programs.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>
<p>The project is not funded externally (outside Regis) as a human subjects research project.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>	<p>The project is not funded externally (outside Regis) as a human subjects research project.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>
<p>The project will not involve testing of an experimental intervention, methodology, drug, device (including medical software or assays), or biologic.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>	<p>The project will not involve testing of an experimental drug, device (including medical software or assays), or biologic.</p> <p><input type="checkbox"/> True <input type="checkbox"/> False</p>