Resources to determine if a project is Human Subject Research (HSR) or a Quality Activity (QA)* and if it requires Institutional Review Board (IRB) Approval

*Quality Activity (QA) is a general term that includes quality improvement and quality assurance projects.

**Note #1:** If the self-reported responses to the HRP-309 Worksheet indicate that the project is QA, a formal submission to the IRB is not required and you may continue by notifying the appropriate Department of your proposed QA project. However, it is still recommended that you complete the Rutgers Non-Human Subject Research Self-Certification Tool.

**Note #2:** If the self-reported responses to the HRP-309 Worksheet indicate that the project is not QA, or if they are inconclusive, submit to the IRB for determination via eIRB using the Non-Human Subjects Research form.

**Note #3:** The Rutgers Non-Human Subject Self-Certification tool yields an unofficial assessment. If a formal determination of QA is required (e.g., journal publication requirement), submit to the IRB via eIRB. If no formal determination of QA is required, you may continue by notifying the appropriate Department of your proposed QA project.

---

*Links embedded within boxes. Ctrl click to follow link.

**Start**

Review Rutgers “Identifying HSR” website

Check federal govt OHRP Decision Chart
01: Is an activity HSR covered by CFR Part 64?

My proposed project is considered Human Subject Research as per my review of OHRP Decision Chart 01.

I think my project is QA and NOT HSR, or I am not sure

Complete Rutgers HRP-309 Worksheet for QA Determination (See Quality Activities)

Submit to IRB as a research protocol / study for approval

Notify the appropriate Department of your proposed QA project to ensure that all department and/or local facility requirements and policies are met.

 FOR QA PUBLICATION: As per the tools above, if you know your project is QA/Non-Human Subjects Research and you intend to publish, then submitting to the IRB via eIRB is recommended, as journals may require IRB review & a formal determination of non-human subjects research by the IRB.

Continue project as approved