Ascension Wisconsin IRB Guidance

QI Self-Certification Decision Tool

The QI Self-Certification Decision Tool allows the user to determine if a project is considered Quality Improvement (QI) or Program Evaluation (PE) that is not subject to IRB review, without requiring submission to and review by the IRB office.

The QI Self-Certification Decision Tool is available online for the Ascension Wisconsin community to use. If a project is deemed to be QI or PE based on the decision tool, the certification can be printed and used as documentation that the project does not constitute research. At Ascension Wisconsin, further IRB review is not required in this case, because the certification takes the place of a formal submission and subsequent notice from the IRB.

If completion of the tool indicates the project may require IRB review, the certification is considered invalid. In this case, the tool refers the user to contact the IRB for further guidance on submission requirements for the project.

The guidance document below is intended to assist users in completing the online Ascension Wisconsin IRB QI Self-Certification Decision Tool.

Topics included in this document:

When to Use the Tool

Projects that do not meet the federal definition of research do not require IRB review. This tool was developed to assist the Ascension Wisconsin community in determining when a project falls outside of the IRB's purview because it does not constitute research, but does qualify as a Quality Improvement (QI) or Program Evaluation project.

This tool **is not** designed to determine all cases when a project falls outside of the IRB's purview. This tool is only for determining if a project is QI/Program Evaluation, rather than research. The Ascension Wisconsin IRB Office has additional resources that can help determine the need for IRB review and guidance on types of review and IRB submissions.

FOR RESIDENTS and STUDENTS: If you are a Resident at Ascension Wisconsin, check with your Resident Program Director before using this tool. Many programs require submission directly to the IRB as a training exercise. Additionally, colleges or universities may have additional requirements for students, check with your school to ensure you meet all applicable requirements.

How to Access the Tool

The IRB QI Self-Certification Decision Tool is available on the IRB website at:
https://redcap.ascension.org/ahnat/surveys/index.php?s=KPEDKN3KDM

This is a public site, available from any device at any time. You do not need an account or log in.

Instructions for Using the Tool and Results

Go to the website above to access the tool. Provide the requested project information and questions. Select the appropriate answers to each question in the order they appear, additional questions may appear based on your answers.

If you receive a STOP HERE message, the project will not qualify for the Self- Certification, follow the provided direction to contact the AW IRB for additional information and guidance.

If you do not receive a STOP HERE message, the completed questionnaire may be printed as certification that the project is "not research", and does not require IRB review. The AW IRB Office will not review your responses as part of the self-certification process. Responses are, however, maintained for quality assurance/improvement purposes.

Explanation of Questions

Project Details:

Enter the general information about the project and lead person conducting the project.

Question 1: Will the project involve testing an experimental drug, biologic, or device (including medical software or assay)?

The Research Decision Tool is based on the definition of research pursuant to the Common Rule (45 CFR 46.102(d)). The purpose of this question is to determine whether federal regulations beyond the Common Rule, such as FDA regulations, need to be applied to a project.

If the answer to this question is “Yes,” IRB review is likely required. Contact the IRB Office for additional guidance.

Question 2: Has the project received funding (e.g. industry or federal) to be conducted as a human subject research study?

The purpose of this question is to determine whether the project has received funding to be conducted as a research study. If you are unsure, consider contacting your program officer for the funding or funding entity to determine whether the funding source requires a specific level of IRB review and oversight.

If the funding source considers the project to constitute human subjects research, this IRB QI/Program Evaluation Self-Certification Tool is not a sufficient indicator of whether IRB review is required. If the answer to this question is “Yes,” IRB review may be required. Contact the IRB Office for additional guidance.

Question 3: Is this a multi-site project (e.g. there is a coordinating site, more than one site participating, and/or a study wide protocol)?

This question is intended to determine whether the project is limited to local activities or whether multiple sites are conducting the same activities. The latter is an indication that the results may be generalizable. If multiple institutions are conducting the activities, it’s less likely that the outcomes will be used for quality improvement or program evaluation at the local institution.

For multi-site projects, this IRB QI/Program Evaluation Self-Certification Tool is usually not a sufficient indicator of whether IRB review is required. If the answer to this question is “Yes,” IRB review may be required. Contact the IRB Office for additional guidance.

Question 4: Does the project involve living embryos or fetus', fetal tissue or the use or study of any birth control methods?

As a Catholic Health Care Institution, there are additional considerations when projects involve these topics, based on the Ethical and Religious Directives for Catholic Health Care Services. If the answer to this question is “Yes,” IRB review may be required. Contact the IRB Office for additional guidance.

Question 5: Is this a systematic investigation designed with the intent to contribute to generalizable knowledge? For example, does the project include: a hypothesis, randomization of subjects, comparison of case vs. control, observational research, comparative effectiveness research, etc.

The focus of this question is to evaluate the primary intent and design of the project. If the primary intent of the project is not generalizability OR the project is not designed in a way that the findings would be generalizable (i.e., limitations to project design), then the answer to this question is "No".

The key question is what the primary intent of the project is from the outset. The design of the project plays a key role in determining intent. If the project is standardized using systematic research methodologies with strong external validity to obtain reproducible results, then it would be considered research. If the intended outcome is simply to report on what happened at the institution/department/hospital, this does not indicate research design or intent as it may or may not be generalizable outside of the institution. Simply publishing or presenting the results of a QI project does not make it research.

Question 6: Will the results of the project be published, presented, or disseminated outside of the institution conducting it?

The purpose of this question is to determine whether, at the outset of the project, the intention is to disseminate results outside of the institution or program conducting the project. Lack of dissemination of information is generally a strong indicator that a project does not constitute research. So, if there is no intention for disseminating results outside of the institution or program conducting the project, the answer should be “No”.

If there is a potential for results to be disseminated outside of the institution or program conducting the project, then the answer is “Yes”. Note that program evaluation and QI projects can be published or presented, but they should not be described as research studies.

Question 7: Will the project occur regardless of whether individuals conducting it may benefit professionally from it?

The question is not focusing solely on whether an individual *will* professionally benefit, but rather whether they would conduct the project *regardless of the potential* for professional benefit.

If the project is being done primarily to bolster one’s own scientific career path and advance his/her program of research, then “No” should be selected in response to this question.

However, if someone is required to complete a project for their medical residency or mandated to conduct a program evaluation by a funding agency, this indicates that the project would have to be conducted regardless of any professional benefit and in this case, the answer to this question would be, "Yes".

Question 8: Is the project intended to improve or evaluate the practice or process within an institution or a specific program?

This question is also trying to identify the specificity of a project, hence the use of “particular institution” or “specific program”.

If the intention upon designing and conducting the project is not to improve or evaluate a specific local process/program, then the answer should be "No" which indicates research intent and IRB review is likely required.