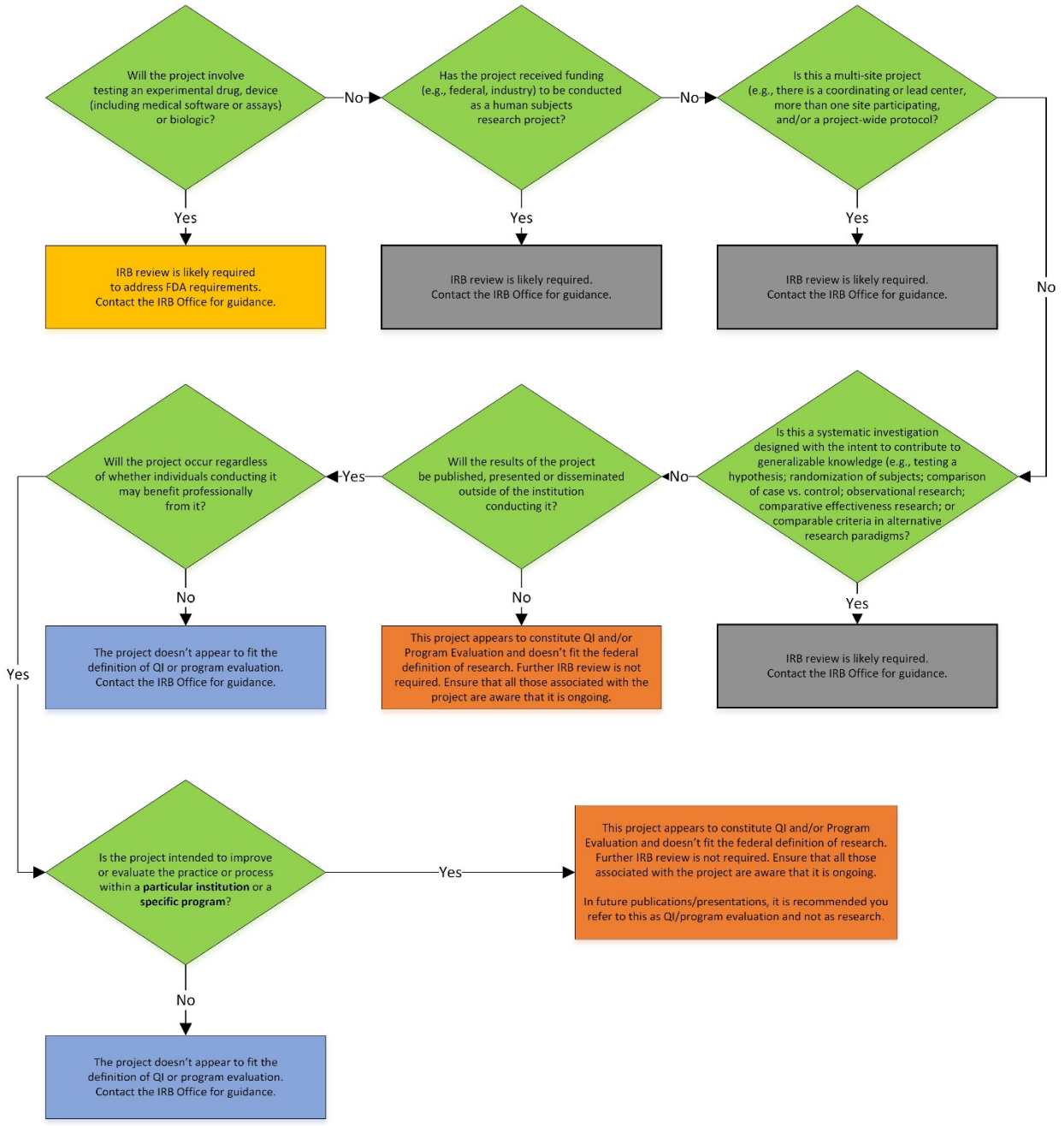
IRB Guidance: Quality Improvement (QI)/Program Evaluation (PE) Decision Tree and Explanation

The purpose of this guidance is to assist researchers in determining if a human subjects research project meets the criteria for Quality Improvement, Quality Assessment, or Program Evaluation, which do not require submission and determination/approval by the Campbell IRB. However, these type of projects do require the investigators to conduct their studies ethically and within any relevant regulation outside of 45CFR46 such as FERPA and HIPAA. This document also provides rationale for asking each question following the decision tree.



Adapted from UW-Madison HS IRBs QI/PE Decision Tree (V4-18-16)

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?
    - The decision tree 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. Please contact the IRB Office for additional guidance.
2. Has the project received funding (e.g., federal, industry) to be conducted as a human subjects research project?
    - The purpose of this question is to determine whether the project has received funding to be conducted as research project or not, for example, quality improvement or program evaluation. 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 decision tree is not a sufficient indicator of whether IRB review is required. If the answer to this question is "Yes," IRB review may be required. Please contact the IRB Office for additional guidance.
3. Is this a multi-site project (e.g., there is a coordinating or lead center, more than one site participating, and/or a project-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. As a result, for multi-site projects, this decision tree is not a sufficient indicator of whether IRB review is required. If the answer to this question is "Yes," IRB review may be required. Note that, in some cases Campbell personnel work with a community partner on a local QI/program evaluation project; in these instances, a "not research" determination may still be applicable. In this case, please contact the IRB Office for additional guidance.
4. Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g., testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?
    - The focus of this question is to evaluate the primary intent and design of the project.
    - Simply publishing or presenting the results of a QI project does not make it research. The key question is what the primary intent of the project is from the outset. If the primary intent of the project is not generalizability (e.g., it is program evaluation/practice improvement related to a specific initiative) 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 design of the project plays a key role in determining intent. If the project is standardized using systematic research methodologies with strong external validity in order to obtain reproducible results, then it would be considered research. If the

intended outcome is simply to report on what happened at the institution/program, this does not indicate research design or intent as it may or may not be generalizable outside of the institution. Note that both research and QI are systematic investigations that may involve human subjects. See IRB Guidance: Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities for details outlining the differences between these types of projects.

- Please be aware that a project can have a double intent: QI as well as research. In that case there is research intent and IRB approval is required.

5. 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. If there is no intention for disseminating results outside of the institution or program conducting the project, the answer should be "No". Lack of dissemination of information is generally a strong indicator that a project does not constitute research. 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 projects.
6. Will the project occur regardless of whether individuals conducting may benefit professionally from it?
    - 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. In contrast, if someone is required to complete a QI 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".
    - 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.
7. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?
    - If the intention upon designing and conducting the project is not to improve or evaluate a specific practice/program, then the answer should be "No" which indicates research intent and IRB review is likely required.
    - This question is also trying to identify the specificity of a project, hence the use of "particular institution' or "specific program". If it is being conducted in a multi-site context with a common protocol across sites, then the results could be be generalizable and thus constitute research. In this case the answer should be "No" which indicates research intent and IRB review is likely required.

What ethical oversight is appropriate for QI projects that are not research?
The IRB provides ethical oversight of human subject research but there isn't at present a system for ethical oversight of QI activities. At a minimum, schools, departments, assessment centers or other relevant parties should review all proposed QI activities to ensure that risks to participants are not greater than minimal (this would require IRB oversight) and that there are appropriate protections for individual's privacy and confidentiality of their identifiable data.