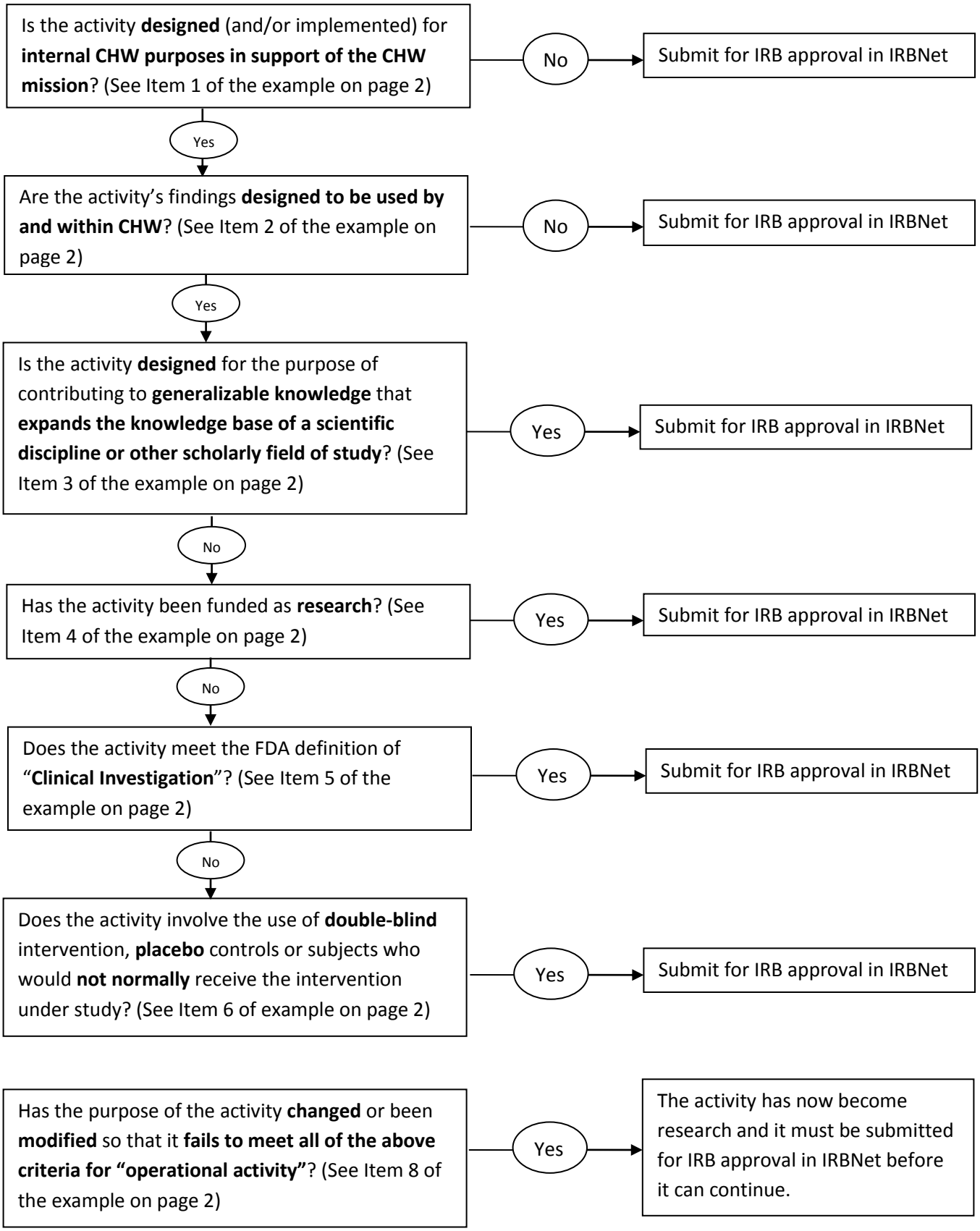
Is My Project a Quality Improvement/Operational Activity or Research Activity?



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Example:

It has been shown that careful control of blood glucose in diabetic patients recovering from surgery is associated with fewer complications and shorter recovery times. The ICU at an adult hospital ("AH") uses a tracking program to monitor blood glucose levels in diabetic patients recovering from surgery, but has become aware of certain limitations. A newly developed program package in use at other medical centers is gaining wide acceptance.

1. The ICU staff has designed an activity to compare the two monitoring programs using the AH diabetic patients recovering from surgery in the ICU. The activity is **consistent with the AH mission** that their patients deserve the best care and has been **designed/implemented for internal purposes- the AH ICU**. At this point it is an operational activity and not research. Operational activities do not need to undergo any sort of review by the IRB nor does the AH HRPP need to be contacted in advance.

2. It is decided to broaden the scope of the activity by including patient data from other ICUs outside the AH and perhaps include children with juvenile onset diabetes. In other words, the activity is no longer designed for **internal AH purposes** and findings obtained from child subjects are not **designed to be used by and within AH**. The activity is no longer considered an operational activity. It now must be registered as research.

3. It is decided to include only diabetic patients in the AH ICU with the aim of determining if the new program package provides more reliable information and leads to better patient outcomes at the AH facility. The activity as designed is operational in nature and, as designed, would not be of general interest to the scientific community. Even if other facilities might find the results interesting or applicable, the activity is NOT **designed to expand the knowledge base of a scientific discipline or other scholarly field of study**. Therefore, it is considered an operational activity and not research.

4. The staff is told that the there is research funding for studies of this type. The staff applies for and receives research funds to support the study. Despite the fact that the design is the same, because it is **funded as research**, it must be submitted for AH IRB review and approval or formal determination.

5. Suppose the new program package includes a blood sampling device that is subject to requirements for prior submission to the FDA. Or suppose the results are to be submitted as part of an FDA application for a research or marketing permit in the future. The activity now becomes a **clinical investigation** as defined by the FDA and must be submitted for AH IRB review and approval or formal determination.

6. Suppose the activity is designed to include use of **placebo controls** or **double-blind interventions**. Suppose patients who normally would not be monitored for blood glucose were also included. Techniques such as these are normally associated with research designs and suggest that this is no longer an operational activity but is designed as a research project. It now must be submitted for AH IRB review and approval or formal determination.

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7. The activity is completed and the evidence suggests the new program package is associated with better glucose control, fewer complications and shorter recovery times when used at our medical center. And so, the new program package is adopted for use. A nursing student wants to use the findings to write a paper as part of a degree requirement. The student wants to present the results at a national convention of ICU nurses. The staff wants to publish the results in a journal that focuses on ICU nursing care. Because the activity does not meet the definition of research, no approvals are required to present or publish the findings. If the journal to which the paper is submitted requires **peer-review** prior to publication, then the investigator(s) may want a formal determination from the AH IRB attesting to the fact that the activity does not meet the definition of research. If this could be anticipated, the request for the formal determination may be made at the outset of the project. If it was not anticipated, the request for formal determination should be made prior to analyzing the data. It should be noted that the nursing student's educational institution may have additional requirements for IRB review and approval. The AH IRB and the nursing student's college or university can be connected to discuss the details of the project.

8. Following up on the data, an investigator notices that the improved tracking software has revealed an apparent correlation between blood glucose levels and a particularly problematic post-operative complication about which little is known. The investigator wants to design a study to systematically reevaluate the data in hopes of demonstrating that the hypothesized correlation is real. The study is now designed to **expand the knowledge base of a scientific discipline or scholarly field of study**. The study is now research and must be reviewed and approved by the appropriate IRB before it can continue.