**DIRECTIONS:** Please use this worksheet to assist in determining if your project is Quality/Process Improvement (QI/PI) versus Human Subjects Research. If you tally the higher number of ‘yes’ marks under the **QI header**, submit an application to the IRB requesting **Not Human Subjects Research (NSHR)/Quality Improvement (QI)** review type in Section 1, Question 7 and indicate ‘yes’ to Question 13, “Is this a quality improvement project?”

If the higher number of ‘yes’ marks, indicate the project is more than likely **Human Subjects Research**, please submit an application to the IRB requesting another review type in Section 1, Question 7.

**You may contact the IRB for further assistance with determining the review type for your project**.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Human Subjects Research** | Y | **N** | **Quality Improvement (QI)** | **Y** | **N** |
| **Purpose** | designed to develop or contribute to generalizable knowledge  reanalyze data from a previous research or QI activity |  |  | Identified local Hopkins/affiliate problem designed to implement knowledge, assess a process, improve a program or delivery of care with consideration of established/accepted standards |  |  |
| **Starting Point** | knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis |  |  | knowledge-seeking is integral to ongoing management of a program or system, including a health-care delivery system |  |  |
| **Design** | follows a specific protocol designed to answer discrete research questions  May be single or multicenter  Funding may be external or internal  Intends to develop and evaluate/validate a concept or process which can then be generalized to other settings.  Studies which develop or evaluate a device (predictive model, algorithm, toolkit, etc.).[[1]](#footnote-1)  Research on educational instructional strategies or curriculum evaluation. |  |  | adaptive, iterative  Generally single center only  Generally not externally funded |  |  |
| **Benefits** | might or might not benefit current participant intended to benefit future patients/individuals |  |  | has the potential to directly benefit a process, system or program; might or might not benefit patients or individuals |  |  |
| **Risks** | may put participant at risk |  |  | does not increase risk to patients/individuals, with exception of possible risks to privacy or confidentiality of data |  |  |
| **Endpoint** | answer a research question |  |  | improve an existing program, process or system |  |  |
| **Analysis** | statistically prove or disprove hypothesis |  |  | compare program, process or system to established standards/best practices |  |  |
| **Adoption of Results** | intent to contribute to generalizable knowledge  avenues for dissemination could include scientific presentation/publication |  |  | intent to utilize results locally [e.g. for system enhancement]  Insights from initiatives may be shared [e.g. in a QI journal][[2]](#footnote-2) |  |  |
| **Publication/Presentation** | investigator obliged to share results |  |  | QI practitioners/investigators encouraged to share systematic reporting of insights |  |  |

\*Adapted from Children’s Hospital of Pennsylvania: <https://irb.research.chop.edu/quality-improvement-vs-research>

1. Projects designed to develop and test a device (algorithm, predictive model, etc.) often are by their nature designed to build and contribute a solution that could be generalizable. The development of these tools may also be FDA regulated requiring IRB oversight. Investigators conducting this work should to submit to the IRB as research or seek consult prior to initiating their work if they believe the project may qualify as QI.

2. Examples of QI journals: The Joint Commission Journal on Quality and Patient Safety, Journal for Healthcare Quality, Journal of Nursing Care Quality, BMJ Quality and Safety, BMC Health Services Research, Journal of Patient Safety

\*Doctorate of Nursing Practice (DNP) students seeking a QI determination should submit their scholarly project proposals to the DNP Project Ethical Review Committee (PERC). Additional information about the DNP PERC may be accessed [here](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/jhson_project_ethical_review_committee.html).

**Please check the IRB website for updates to QI policies and guidelines:**

<https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_2a.html>

1. [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)