*Quality assurance or quality improvement (QA/QI), or program evaluation projects sometimes seem like human subjects research that the IRB needs to review, particularly when they involve conducting surveys, reviewing identifiable data, drawing conclusions about problems, and suggesting methods for improvement. The key, however, is determining whether the proposed project is designed to be generalizable to the extent of meeting the federal definition of research.*

*QA/QI projects are typically focused on* ***improving the performance of an institutional practice in comparison with an established standard or goal****, are focused on a local practice and consequently limit their scope to the specific institution, the* ***results are not intended to apply to anyone beyond the scope of the project****, and conclusions are drawn only in relation to the particular institutional setting/practice. Publication is not sufficient criterion for determining whether a project is research. In QI activities, if the results of the project are shared outside the institution (i.e. published or presented), it would only be intended to share a successful improvement in practice from which other institutions could interpret the results and draw their own conclusions. The key is whether the institution conducting the QA/QI project intends to draw broad conclusions and consider their participants as a representative sample (generalizable results).*

*The important question to consider is not whether something is QA/QI or research, but* ***whether the QA/QI activity also includes human subjects research****. Many activities can be both (for example, a quality improvement project that uses research methods). If a component of a proposal is clinical research, IRB review is required to ensure compliance with human research regulations. This tool is designed to help investigators determine whether such projects meet the federal definition of research requiring IRB review.*

Considerations in determining whether the project is QI or research:

|  |  |  |  |
| --- | --- | --- | --- |
| **Consideration** | **Question** | **Yes ✓** | **No ✓** |
| PURPOSE / INTENT | Is the primary aim or motive of the project either to:   * Improve / strengthen patient care?   OR   * Improve / strengthen operations, performance or efficiency? |  |  |
|  | Is the objective to implement a specific aspect of health or healthcare delivery and not to generate new knowledge that can be applied to larger groups of people or that is generalizable beyond the institution or program? |  |  |
| RATIONALE | Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on:   * literature, * consensus statements, or * consensus among clinician team? |  |  |
|  | Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes? |  |  |
| METHODS | Are the measures an accepted standard of care (i.e., not novel, unproven methods)? |  |  |
|  | Do the methods include any of the following?   * Control Group * Randomization * Fixed protocol |  |  |
| RISK | Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)? |  |  |
| BENEFIT | Is the intervention considered within the usual clinician-patient therapeutic relationship? Or is a direct benefit to participants indicated or a potential local institutional benefit specified? |  |  |
| PARTICIPANTS | Will the activity only involve participants (patients, parents, or UConn Health staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place? |  |  |
| FUNDING | Is the project funded by any of the following? *(Funding alone does not determine whether it is research but may require closer look.)*   * An outside organization with an interest in the results * A manufacturer with an interest in the outcome of the project relevant to its products * A non-profit foundation that typically funds research, or by internal research accounts |  |  |

*If all checkmarks are inside the gray boxes, the project is likely QI and not human subjects research. Projects that are not HSR, do not need review by the IRB. If there are any checkmarks in white boxes, contact the IRB for a determination.*

**Characteristics of a QI project that do not determine the need for IRB Review:**

* Intent to publish – both QI and research may be published.
* Process of data collection – both QI and research may include prospective or retrospective data collection. For IRB purposes, only projects involving living individuals are considered human subjects research; projects using only decedent data are outside this definition but may still need to follow HIPAA rules.

**Clarifications for publishing QI work:**

* Do not refer to QI projects as research in publications or presentations.
* If the project was not submitted to the IRB for determination, the following statement may be included in the manuscript:
* *“This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research.”*
* If the project was reviewed by the IRB and was determined not to be human subjects research, the following statement can be included in the manuscript:
* *“This Quality Improvement Initiative was reviewed and determined to not meet the criteria for human subjects research by the UConn Health Institutional Review Board.”*

**Key points:**

* A request for a Human Subjects Research Determination by the IRB must be submitted **prior** to beginning the project; determinations cannot be made retrospectively.
* For more information on the Human Subjects Research Determination form and how to submit, please visit the [HSPP website](https://ovpr.uchc.edu/services/rics/hspp/irb/irb-instructions-forms-and-samples/).
* If IRB review is required, the IRB must review and approve the project **prior** to implementing any aspect of the project.

***Resource Links:***

* [*OHRP Quality Improvement Activities FAQs*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html)
* [*What needs to be reviewed by the IRB (CHOP resources on Quality Improvement*](https://www.research.chop.edu/services/what-needs-to-be-reviewed-by-the-irb)*)*
* [*Standards for Quality Improvement Reporting Excellence (SQUIRE) Guidelines*](https://www.squire-statement.org/index.cfm?fuseaction=page.viewpage&pageid=525)
* [*A Hastings Center Special Report: The Ethics of Using QI Methods to Improve Health Care Quality and Safety*](https://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/using_qi_methods_to_improve_health_care_quality_safety.pdf)
* *UConn Health HSPP Website:* [*Quality Improvement vs Research*](https://ovpr.uchc.edu/services/rics/hspp/resources/quality-assurance-quality-improvement-and-research/)
* *Ogrinc, G., Nelson, W.A., Adam, S.M. and O’Hara, A.E. An Instrument to Differentiate between Clinical Research and Quality Improvement. IRB: Ethics & Human Research, Vol. 35, No. 5 ( 2013): 1-8.*