The purpose of this document is to provide guidance to individuals who are deciding whether to submit QI/QA activities to the IRB. This document is based on IRB policies for when submission is required.

Traditional QI/QA projects are typically designed, or intended, to:

* improve patient care;
* compare a program/process/system to an established set of standards such as standard of care, recommended practice guidelines, or other benchmarks;
* improve the performance of institutional practice or local systems;
* bring about improvements in health care delivery.

By comparison, Human Subjects Research, which requires IRB review, is defined by the Department of Health and Human Services (DHHS) as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If any QI project meets the criteria for research *and* involves human subjects, prior IRB review is needed. For further information, see [DHHS regulations under 45 CFR 46.102](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102) **and** [BMC/BU Medical Campus HRPP Policies and Procedures](http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/)**.**

Methodology, publication of findings, or the systematic collection of data, do not by themselves delineate QI/QA initiatives that are also considered human subjects research because such activities can occur in both research *and* non-research projects. According to [DHHS guidance](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html), “the intent to publish is an insufficient criterion for determining whether a QI activity involves research.” Activities that start out as QI/QA non-research projects (because they are not designed with the intent to generalize the findings) can evolve into human subjects research when a decision is made to use *previously collected* QI/QA data for research purposes. Use of previously-collected QI/QA data for research purposes requires IRB submission and review.

Boston Medical Center (BMC) has created two checklists based on IRB policies to help faculty and staff determine when they must submit QI/QA projects to the IRB. For assistance with this checklist, you may contact Nicholas Cordella, MD, Medical Director Quality and Patient Safety, at nicholas.cordella@bmc.org or the IRB at 617-358-5372 or medirb@bu.edu. If there is any uncertainty, err on the side of IRB submission. Please see the [IRB website](https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/) for instructions on how to submit to the IRB.

**Please complete BOTH checklists below and note**:

* If you answer “yes” to all the questions in Checklist One, IRB review is not required.
* If you answer “yes” to any of the questions in Checklist Two, IRB review is required.
* QI/QA findings (that are not considered research) may be published but should not be described as research. The project must be described as “quality improvement” or “quality assurance” in public presentations, academic curriculum vitae, publications, and/or other representations to any third party audience, with a planned statement similar to: “This project was undertaken as a Quality Improvement Initiative at Boston Medical Center, and as such, was not formally supervised by the Institutional Review Board per their policies.”
* ***Regardless of whether IRB review is needed*,** all Protected Health Information must be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant BMC-controlled electronic systems that meet BMC’s security standards for protection of PHI.

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|  | **Checklist 1** | YES | NO |
| 1. | If the intervention involves patients, are all patients who get the intervention expected to benefit? |  |  |
| 2. | Is the purpose of measurement related to your project to determine the effect of process change, measure performance, or for submission to an authorized national or state registry and/or database that has the intent to improve the delivery of clinical care?  |  |  |
| 3. | Is the purpose of this project to improve institutional processes or delivery of care consistent with established quality standards?  |  |  |
| 4. | If the initiative involves patients, will all patients involved in the initiative receive standard of care at a minimum? |  |  |
| 5. | Does the project involve systemic data collection to monitor and compare performance to defined standards?  |  |  |
| 6. | Will the project be described as “quality improvement” in public presentations, academic curriculum vitae, publications, and/or other representations to any third party audience, with a planned statement similar to: *“This project was undertaken as a Quality Improvement Initiative at Boston Medical Center, and as such was not formally supervised by the Institutional Review Board per their policies.”*? |  |  |
| 7. | Is there an agreement with the leadership of the clinical practice unit in which the project will take place (the unit in the hospital, clinic, division, or care group) that this is a Quality Improvement project that will be undertaken to improve institutional processes or delivery of care? |  |  |
| 8. | Is the project conducted by clinicians and staff where the project will take place, and does it involve staff and/or patients of Boston Medical Center and/or Boston University School of Dental Medicine? |  |  |

**AND**

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|  | **Checklist 2** | YES | NO |
| 1. | Is the intent of the project either to test a novel hypothesis, answer a research question or replicate another researcher’s original study? |  |  |
| 2. | Does the project seek to test interventions, treatments or practices that are not currently considered standard of care in any existing practice (neither consensus-based, nor evidence-based)? |  |  |
| 3. | Does the project involve withholding any aspect of standard of care?  |  |  |
| 4. | Is the intent of the project to design or develop a new standard of care or benchmark? |  |  |
| 5. | Will the physician and/or staff be blinded to any aspect of the patient’s care? |  |  |
| 6. | Will persons (including patients and investigators) be exposed to greater than minimal risks beyond standard of care? |  |  |
| 7. | Will the project involve a research design (e.g., randomization) that over-rides clinical decision-making? |  |  |
| 8. | Does the project involve using a medication or medical device or procedure outside of usual medical practice? |  |  |
| 9. | Does the project involve funding from a research grant or other research agreement? |  |  |
| 10. | Will the project be described as research in representations such as publications, presentations, or academic dossier?  |  |  |
| 11. | Are chart reviews the ONLY activities in the entire QI/QA project? |  |  |

Please direct any questions to Nicholas Cordella, MD, Medical Director Quality and Patient Safety, at nicholas.cordella@bmc.org.

**References**

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