**Submission to the IRB is not required for quality /performance improvement activities.** If a formal determination by the IRB is desired, please email the completed form to PROVOST-IRB-QUALITY@pobox.upenn.edu. The IRB will contact you with the results of their review and may request additional information to assist with their determination. **Please allow 5 business days for initial review.**

Activities that meet the definition of human research will require submission to the IRB via [HS-ERA](https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do).

QI/PI activities that do not meet the definition of human research will be reviewed and acknowledgement from the IRB will be given. If there is interest in disseminating or publishing the results of the QI/PI activity, this correspondence can be submitted to a peer-reviewed journal or other publication as evidence of IRB review.

**Prior to completing this form, please review the IRB’s guidance document on QI/PI projects**: <https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/qiqa-project-guidance>.

**NOTE: IRB forms are protected for quality control purposes. Unprotected /altered IRB forms will not be accepted.**

|  |  |
| --- | --- |
| **Project Title:** |       |
| **Project Leader** |
| Name: |       |
| Department:  |       |
| **Who should the IRB contact with questions?**  |
| Name:  |
| Penn Email:   |

|  |
| --- |
| **Key Personnel**  |
| **Name** | **Department (and Institutional Affiliation if other than Penn)** |
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| **Section A: Project Description** |
| 1. Provide a *brief* background that supports the need for this project to improve the quality of the program, process, etc. under study.

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| 1. Identify the project question or goal.

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| 1. Describe the project design, methods, and procedures.

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| * 1. Does the project involve the administration of an FDA regulated product (i.e., drug, device, specimen test, etc.) or change the usage of an FDA regulated product?

[ ]  No [ ]  Yes, please explain:       |
| * 1. Are any of the above methods or procedures untested, experimental, or do they involve blinding, random selection, randomization to interventions, control groups, etc.?

[ ]  No [ ]  Yes, please explain:       |
| 1. Describe any interaction or intervention with humans, as part of the initiative.

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| 1. Will identifiable data from individuals be used, collected, and/or disclosed?

[ ]  No [ ]  Yes* 1. If yes, please identify the source of the data and describe how the data will be accessed and stored securely. Penn Medicine /Penn Dental personnel should confirm adherence to the [IRB’s guidance](https://irb.upenn.edu/sites/default/files/Protection%20of%20Electronic%20Data%20and%20Protected%20Health%20Information-Combined.pdf) when ePHI is used, collected, or disclosed.

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| 1. Is this project funded?

[ ]  No [ ]  Yes, please provide the funding source:       |
| 1. Is this project being conducted to fulfill any educational program requirements (e.g., Capstone project, Master’s thesis, etc.)

[ ]  No [ ]  Yes, please explain:       |
| 1. Please describe how the collected data will be used (e.g., prepare a report for operational leaders, publish the findings, etc.).

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| **Section B: Project Approval** |
| 1. If the primary purpose of your project is for quality or performance improvement, please obtain approval from the operational leader within your department or health system [Please refer to FAQ item 1 of the QI/PI Project Guidance Document].

[ ]  No – Contact the appropriate operational leader for approval. [ ]  Yes – Please specify whom:      [Examples of operational leaders include a medical director of a unit or clinical area, division/ department chief, nurse manager, Dean, other health system or institutional leader that can approve the implementation of a quality /performance improvement project].  |

**Please Note:** By submitting your proposed project for a QI/PI determination you are certifying that if the project is established to qualify as QI/PI, you and your Department would be comfortable with the following statement in any publications regarding this project: ***“This project was reviewed and determined to qualify as quality improvement by the University of Pennsylvania’s Institutional Review Board.”*** Likewise, language in publications or presentations should not reference research terminology.