**University at Buffalo Guidance on Quality Assurance and Quality Improvement Projects**

In this document, you will learn the difference between Quality Assurance (QA)/Quality Improvement (QI) projects and research. This information will help you identify which projects are solely QA/QI, which are human subjects research, and which are both QA/QI and research. It will also prepare you to complete the QA/QI Self-Determination Survey.

Federal regulations require human subjects research to be reviewed and approved by the IRB, while activities that are solely QA/ QI do not require IRB oversight. However, some QA/QI activities may also be research and therefore need IRB approval.

If a project is conducted as QA/QI, but it meets Human Research criteria, then the researcher could be conducting human research without approval which would be serious non-compliance. Sometimes even with the guidance provided here, determining if an activity is Research or QA/QI can be challenging. You can reach out to the UB Clinical Research Facilitators (ctsihelp@buffalo.edu, 716-829-4357) with questions.

After reviewing these materials, if you find that your project is human subjects research, you must request review by the IRB as an IRB submission, completing the protocol document (HRP-503), which is available in the Click Library.

**Externally Funded Projects**

If your project has external funding from a federal agency or other organization that indicates the funder views the project as human subjects research, you must submit the project for IRB review and determination. If your project is funded by some other external entity, but not as a RESEARCH grant (e.g., foundation or individual philanthropy), it may be defined as a QA/QI project. You can consult with the IRB about such projects.

## Definitions and Criteria

*Quality Assurance (QA):*

QA is a systematic method of monitoring and evaluating projects, policies and programs, particularly about their effectiveness and efficiency. The purpose of QA is to assess that a program is doing what it is intended to do and that standards of quality are being met.

*Quality Improvement (QI):*

The U. S. Department of Health and Human Services defines quality improvement as " . . . systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups." QI is designed for the purpose of improving the quality of a service, a program, or a process, with particular emphasis on ensuring the needs and expectations of the patients and their community are met.

*Research:*

The IRB regulations define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

*NOTE: The intent to publish findings is an insufficient criterion for determining whether a QI activity constitutes research. Simply because a project intends to publish its findings does not render that project "research" as defined in the IRB regulations.*
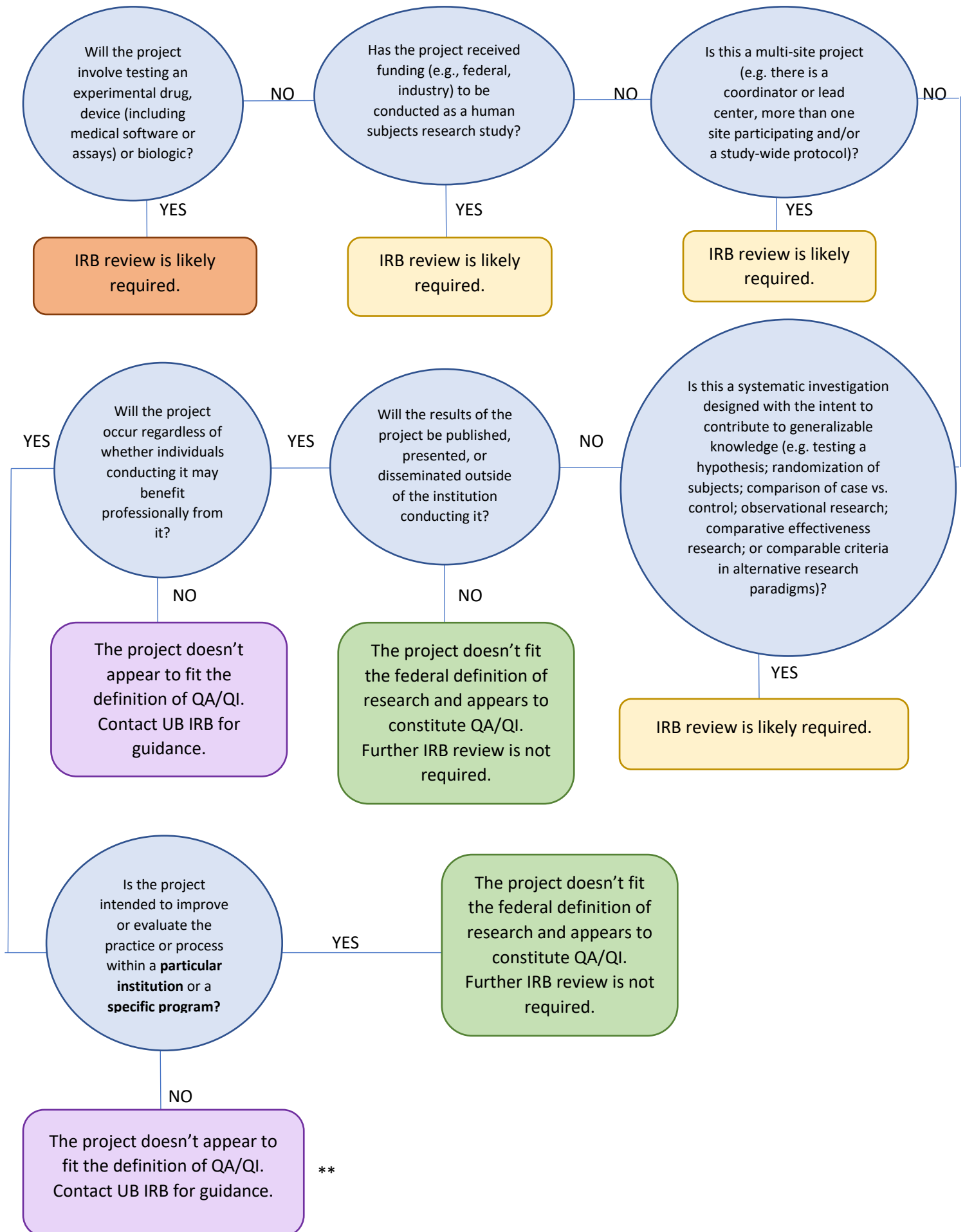
The following table summarizes characteristics of QA/QI and research:

| | Research | QA/QI |
|---|---|---|
| **Purpose** | To contribute to generalizable knowledge (e.g., testing hypothesis). The aim is to build an evidence base to support established or new treatment, including methods like replication studies, clinical trials, outcomes research, etc. | To evaluate a *specific* program or service with the goal of producing immediate improvements in how standard treatments/services are delivered locally or ensuring it confirms with expected norms |
| **Dissemination of results** | Dissemination is usually planned at the outset of the project. Presentation and publication as a means of sharing generalizable knowledge, filling in gaps in knowledge, or refuting results from other research | Shared with the service providers/program administrators (ie. stakeholders) involved in the evaluated program/service. It can also include public posting of results. Presentation/publication is allowed provided the goal is only to share a unique strategy or model, not to contribute to generalizable knowledge |
| **Analysis** | Statistically test a hypothesis. Quality and importance of results are judged by peer review | Compare program/service to established standards. Quality and importance of results are judged by stakeholders |
| **Data collection methods** | Static:  A systematic data collection in order to fulfill a scientifically valid research design. | Fluid:  As improvements are made to the program/service based on the collected data, the data collection methods and contents may change too |
| **Types of procedures** | *May* include administration of extensive diagnostics and outcomes test batteries and significant deviation from standard practice | Involves no more data collection than what is needed to answer the immediate question with little to no deviation from standard practice |

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**Graphics adapted from University of Wisconsin -Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities materials

# Research vs. QA/QI Decision Tree

**Will the project involve testing an experimental drug, device (including medical software or assays) or biologic?**

— NO →

**Has the project received funding (e.g., federal, industry) to be conducted as a human subjects research study?**

— NO →

**Is this a multi-site project (e.g. there is a coordinator or lead center, more than one site participating and/or a study-wide protocol)?**

— NO →

**YES** ↓

IRB review is likely required.

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YES ←

**Will the project occur regardless of whether individuals conducting it may benefit professionally from it?**

— YES →

**Will the results of the project be published, presented, or disseminated outside of the institution conducting it?**

— NO →

**Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?**

**NO** ↓

The project doesn't appear to fit the definition of QA/QI. Contact UB IRB for guidance.

**NO** ↓

The project doesn't fit the federal definition of research and appears to constitute QA/QI. Further IRB review is not required.

**YES** ↓

IRB review is likely required.

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**Is the project intended to improve or evaluate the practice or process within a **particular institution** or a **specific program?****

— YES →

The project doesn't fit the federal definition of research and appears to constitute QA/QI. Further IRB review is not required.

**NO** ↓

The project doesn't appear to fit the definition of QA/QI. Contact UB IRB for guidance.

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**Processing of the QA/QI Self-assessment tool**

Researcher completes the QA/QI Self-Assessment Tool (redcap.link/UB-QI-determination). Is the project determined QA/QI?

YES

NO

The project doesn't fit the federal definition of research and appears to constitute QA/QI. Further IRB review is not required. REDCap will automatically email the PI a certification/letter indicating this.

IRB review may be required. Does the PI believe that this is correct?

YES

Submit as a research project in Click for UBIRB review.

NO

NO

Contact a Clinical Research Facilitator (CRF) and they will look over your project and advise you. Does the CRF determine the project is QA/QI?

YES

The project doesn't fit the federal definition of research and appears to constitute QA/QI. Further IRB review is not required. CRF will email the PI a certification/letter indicating this.