

Examples of Projects Conducted for Quality Assurance/Quality Improvement Purposes

Below are some examples of projects conducted for quality assurance or quality improvement purposes. Some of them were deemed to be Not Human Subject Research at Tufts Medical Center/ Tufts University because they were purely QA/QI, while others were deemed to be Human Subject Research because they did not meet the criteria for QA/QI.

The list below is not intended to be exhaustive, but rather to help give some concrete examples as researchers consider whether their own project might be considered to be purely QA/QI project, and therefore Not Human Subjects Research.

As a reminder, for projects involving QA/QI to be considered Not Human Subjects Research at Tufts, the following conditions must be met:

Quality assurance/quality improvement initiatives:

- Are intended to improve or assess internal practices, programs, or systems **and**
- Are not designed to contribute to generalizable knowledge

Examples that are considered QA/QI **and NOT** research:

1. The department of Pediatrics at Tufts decides to do a retrospective chart review of all patients seen in their clinic in the past 2 years to determine which conditions are being seen most frequently. They want to use this information to ensure that they are meeting the needs of their clients and may adjust intake forms used based on this information. The products of this project are intended to assess and eventually improve internal practices systems and are not designed to contribute to generalizable knowledge. Therefore, in this example, Tufts would not be considered to be involved in human subject research.
2. A Tufts medical student works with a local non-profit on a project which involves surveys and a literature review. The goal of the project is for the organization to evaluate their ongoing after-school program and adjust the services provided based on this information. This project will serve the local non-profit but also be used to fulfill the student's educational requirements. The project is intended to assess and eventually improve on a program and is not designed to contribute to generalizable knowledge. Therefore, in this example, Tufts would not be considered to be involved in human subject research.

Examples that are considered QA/QI and research:

1. The department of Pediatrics at Tufts decides to do another retrospective chart review of patients seen in their clinic in the past 2 years who presented with the flu. They want to use this information to ensure that they are meeting the needs of their clients when planning for next flu season, but also may use this information to contribute to a larger study with various hospitals about the prevalence of the flu in the Boston area. Although the products of this project are intended to assess and eventually improve internal practices and systems, they are also designed to contribute to generalizable knowledge. Therefore, in this example, the Tufts researchers are conducting both a QA/QI project and Human Subject Research.
2. Another Tufts medical student works with another local non-profit on a similar project which also involves surveys and a literature review. The goal of this project is for the organization to evaluate their ongoing after-school program and adjust the services provided based on this information. This project will serve the local non-profit and will be used to fulfill the student's educational requirements. However, this non-profit also anticipates analyzing the data to determine whether their program works and to make claims about whether the program could work if applied in other settings or be more broadly applicable. The project is intended to assess and improve on a program but is also designed to contribute to generalizable knowledge. Therefore, in this example, the Tufts researchers are conducting both a QA/QI project and Human Subject Research.
3. Tufts is implementing a new hand washing initiative and a researcher plans to track expected improvements in compliance across different areas of the hospital. The researcher plans to link the compliance data to nosocomial (hospital-acquired) infection rates. The researcher will present a report to the medical board on the effectiveness of the hand washing initiative at Tufts. The investigator also plans to publish an article describing the implementation of this hand washing initiative and describing the quality assurance process. The intent of this project is also to publish on the outcome of the implementation to show how infection rates were decreased. The investigator is hoping to contribute to generalizable knowledge about the effect of hand washing on infection rates. Therefore, in this example, the Tufts researchers are conducting both a QA/QI project and Human Subject Research.

Please call the IRB office if you are planning to conduct international research and someone will help guide you, as the requirements for this type of research differ. Please also refer to the information on our website regarding [international research](#).