It can be challenging to decide if a project represents Quality Assurance (QA)/Quality Improvement (QI) or qualifies as Human Subjects Research (HSR). To mitigate this challenge, we have developed a QA/QI frequently asked questions document and a screening checklist.

**QA/QI FAQs and Screening Checklist**

QA/QI consists of systematic, data-guided activities to bring about prompt, positive changes to the delivery of health care and involves deliberate actions to improve care, typically at the institutional level. Most QA/QI projects do not require IRB review or oversight; however, in some cases these activities may constitute Human Subjects Research (HSR).

The SOM CRSO has partnered with the NC TraCS Regulatory Program and the UNC Office of Human Research Ethics (OHRE) to develop companion resources to help investigators distinguish between QA/QI and HSR projects. The resources consist of an FAQ document that provides nuanced explanations of the differences and similarities between QA/QI and HSR, as well as a simple screening tool to assist investigators in determining if a proposed project is QA/QI.

Take a moment to explore the QA/QI FAQs and Screening Checklist.

[q/a/i faq](#)  [QA/QI Screening Checklist](#)

These resources may not answer all your questions. If you are unsure after reviewing the FAQs and completing the screening checklist, consult the IRB at irb_questions@unc.edu or 919-966-3113 and/or request a formal determination of Not Human Subjects Research (NHSR) by the UNC-Chapel Hill IRB by submitting a New Study:NHSR submission in IRBIS.

**Your feedback is important!**

If you have additional suggestions for improvements or new resources, please [let us know](#).