

Quality Assurance (QA) and Quality Improvement (QI) Screening Checklist

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The sometimes-subtle differences and frequent overlap in attributes can make it challenging to differentiate between QA/QI and Human Subjects Research (HSR). The purpose of the *QA/QI Screening Checklist* is to help investigators distinguish QA/QI activities from HSR that requires IRB review.

Instructions:

- Prior to starting the screening checklist, review [OHRE SOP 0501: Human Subject Research Determination](#) and the [Quality Assurance and Quality Improvement \(QA/QI\) FAQs](#).
- Open the downloaded checklist with Acrobat Adobe Reader directly from the saved file location.
- Consider each statement and indicate Yes or No by marking the respective check box.
- If the project is not funded, the last statement is not considered in the screening.
- If you indicated 'Yes' to all of the statements, the project is likely QA/QI and NOT human subjects research.
- If you are unsure after completing the screening checklist, consult the IRB at irb_questions@unc.edu or 919-966-3113.
- Investigators are encouraged to request a formal determination of Not Human Subjects Research (NHSR) by the UNC-Chapel Hill IRB by submitting an NHSR request in [IRBIS](#).
IMPORTANT: The IRB is unable to grant retroactive IRB approval for a QA/QI project that is later determined to be HSR.

Component	Statement	Yes	No
Intent	The project intends to describe and close a specific, local performance gap. Its focus is to continuously assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards. <i>HSR intends to address a gap in scientific knowledge, often through the test of specific hypotheses, with implications beyond the local setting.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Methods	The methods are flexible and include approaches to evaluate rapid and incremental changes. <i>HSR follows a fixed research plan that typically remains unchanged throughout the research.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Intended Benefit	The project may benefit a local process, program, or system and may or may not benefit patients directly. <i>HSR provides potential societal benefit in developing new or advancing existing generalizable knowledge. Direct benefit to participants is not typically the intent of HSR or is not certain.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Risk	The risk to patients is no greater than that of usual care. <i>HSR may place participants at increased risk of physical, psychological, emotional, social, legal, and/or financial harm.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Applicability of results	The intent of the project is to produce immediate and continuous results that can be implemented directly into local practices and care delivery. <i>Results of HSR are not expected to immediately affect or change local practice.</i>	<input type="checkbox"/>	<input type="checkbox"/>

Component	Statement	Yes	No
Funding	<p>The project is funded by internal clinical/operations funds or a program that offers clinical reimbursement incentives. The project is not receiving funding for implementation of research.</p> <p><i>Funding sources for HSR may include an outside organization with an interest in the results, a manufacturer with an interest in the outcome of the project relevant to its products, or a non-profit foundation that typically funds research, or by internal research accounts.</i></p> <p><i>If the project is not funded, leave blank.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>
Sharing and disseminating	<p>The project <u>may or may not</u> share results through peer-reviewed publication and presentation outside the institution.</p> <p><i>HSR results are <u>expected</u> to be published or presented to others through a peer-reviewed process.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>If there is an intent to, or possibility of publishing your work, you and your Department/Unit are comfortable stating in the methods section that the project was undertaken as a QA/QI initiative at [location], and as such the IRB did not provide oversight for the project under their policies.</p> <p><i>HSR publications generally include a statement about IRB oversight.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>
Resources			
<p>OHRE SOP 0501: Human Subject Research Determination</p> <p>OHRE SOP 6001: Definitions</p> <p>Quality Assurance and Quality Improvement (QA/QI) FAQs</p> <p>Baily MA, Bottrell M, Lynn J, Jennings B, Hastings Center. The ethics of using QI methods to improve health care quality and safety. <i>Hastings Cent Rep.</i> 2006;36(4):S1-S40. doi:10.1353/hcr.2006.0054</p> <p>Ogrinc G, Nelson WA, Adams SM, O'Hara AE. An instrument to differentiate between clinical research and quality improvement. <i>IRB.</i> 2013;35(5):1-8.</p>			