

# Guidelines to identify research versus quality improvement/assurance studies

This document is intended to aid investigators when assessing whether a study is a research study or a quality improvement/assurance study.

For questions about research versus quality improvement/assurance, contact [CBSREB@blood.ca](mailto:CBSREB@blood.ca).

	<b>Research</b>	<b>Quality Improvement/Assurance</b>
<i>Purpose</i>	<ul style="list-style-type: none"> <li>To test a hypothesis OR establish clinical practice standards where none are accepted</li> <li>Generate new knowledge</li> <li>Results intended to be published in a peer-reviewed journal</li> </ul>	<ul style="list-style-type: none"> <li>To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards</li> <li>Adapting existing knowledge</li> <li>Results may be published, but primary focus is within the organization</li> </ul>
<i>Starting point</i>	<ul style="list-style-type: none"> <li>To answer a question or test a hypothesis</li> </ul>	<ul style="list-style-type: none"> <li>To improve performance</li> </ul>
<i>Benefits</i>	<ul style="list-style-type: none"> <li>Designed to contribute to generalizable knowledge and may or may not benefit subjects</li> </ul>	<ul style="list-style-type: none"> <li>Designed to promptly benefit a process, program, or system and may or may not benefit patients</li> </ul>
<i>Risks</i>	<ul style="list-style-type: none"> <li>May place subjects at risk and stated as such</li> <li>May infringe the privacy or professional reputation of participants, providers or organizations</li> </ul>	<ul style="list-style-type: none"> <li>By design, does not increase patient's risk, except for possible privacy/confidentiality concerns</li> </ul>
<i>Data collection</i>	<ul style="list-style-type: none"> <li>Systematic data collection</li> <li>Gathering information about the participant beyond that which is collected routinely</li> </ul>	<ul style="list-style-type: none"> <li>Systematic data collection</li> <li>Usually using routinely collected data</li> </ul>
<i>End point</i>	<ul style="list-style-type: none"> <li>Answer a research question</li> </ul>	<ul style="list-style-type: none"> <li>Promptly improve a program, process or system</li> </ul>
<i>Testing/analysis</i>	<ul style="list-style-type: none"> <li>Statistically prove or disprove a hypothesis</li> <li>Comparison of cohorts; randomization or the use of control groups or placebos</li> </ul>	<ul style="list-style-type: none"> <li>Compare a program/ process/ system to an established set of standards</li> </ul>

Note: table approved by Canadian Blood Services REB February 2019