

## DO I NEED TO SUBMIT TO THE IRB?

### REGULATORY REQUIREMENTS BY RESEARCH TYPE

	Quality Improvement / Non-Human Subjects Research	Exempt	Expedited	Full Board
<b>Initial Application/Request for IRB Determination</b>	MAYBE <sup>1</sup>	YES	YES	YES
<b>Study Modifications<sup>2</sup></b>	MAYBE <sup>3</sup>	YES	YES	YES
<b>Reports of Unanticipated Problems (UAPs) and Noncompliance</b>	NO	NO	YES	YES
<b>Continuing Review</b>	NO	NO	MAYBE <sup>4</sup>	YES
<b>Study Closure</b>	NO	NO	YES	YES

<sup>1</sup> There is no *regulatory* requirement that Quality Improvement (QI) or Non-Human Subjects Research (NHSR) projects be submitted to the IRB for a QI/NHSR determination. Many journals, however, require an IRB letter. The IRB will review and provide determinations for all QI and NSHR studies submitted to the IRB. PLEASE NOTE: The IRB is unable to issue a retroactive QI or NHSR determination. Students or faculty seeking a QI or NHSR determination letter for publication MUST submit to the IRB for that determination before study activities begin.

<sup>2</sup> Changes to exempt, expedited, and Full Board studies must be submitted to and approved by the IRB prior to implementation UNLESS the change is necessary to eliminate apparent immediate hazards to human subjects.

<sup>3</sup> Changes in study activities for QI and NSHR projects for which the IRB has made a QI or NHSR determination are required to be submitted to the IRB. Changes to study personnel for QI or NHSR projects and changes to QI or NHSR projects that were not submitted to the IRB for an initial determination do not require IRB review.

<sup>4</sup> Non-FDA regulated expedited research will ONLY require continuing review if the Full Board (in rare circumstances) makes a determination that there is a compelling reason to maintaining ongoing IRB oversight of the minimal risk research. In these cases, the IRB is required to provide rationale for the determination that continuing review is required and to communicate this rationale to the investigator. IRB approval letters for ALL expedited studies will clearly communicate “Continuing Review REQUIRED” or “Continuing Review NOT REQUIRED.”

Last Revised: 07/31/2024