DO I NEED TO SUBMIT TO THE IRB?

REGULATORY REQUIREMENTS BY RESEARCH TYPE

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

[1] 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.

[2] 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.

[3] 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.

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