

Checklist to determine if a QA / QI study requires DSRB review (Version 30 June 2020)

Where the response to all these questions is “No”, the QA/QI study is unlikely to require an IRB review. If you require a formal IRB letter of waiver from review, fill in and submit the DSRB exempt application form for review.

Where the response to any of these questions is “Yes”, the QA / QI study may need an IRB review. Fill in the appropriate application form on ROAM and submit for DSRB review.

S/N	Questions	Yes	No
1.	Does the proposed quality assurance activity require additional consent from subjects, beyond what is already obtained for clinical practice?		
2.	Does the proposed quality assurance activity pose any risks for subjects beyond those of their routine care?		
3.	Does the proposed quality assurance activity impose a burden on subjects beyond that experienced in their routine care?		
4.	Is the proposed quality assurance activity to be conducted by a person who does not normally have access to the subjects' records for clinical care?		
5.	Does the proposed quality assurance activity risk breaching the confidentiality of any individuals' personal information, beyond that experienced in the provision of routine care?		
6.	Does the proposed quality assurance activity involve any clinically significant departure from the routine clinical care provided to the subjects?		
7.	Does the proposed quality assurance activity involve randomization?		
8.	Does the proposed quality assurance activity involve the use of a control group or a placebo?		
9.	Does the proposed quality assurance activity seek to gather information about the participant beyond that collected in routine clinical care?		
10.	Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of health care providers or the institution(s)?		

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