

Quality Improvement & Level of Risk Checklist

This Checklist is to be used as a guide to determine if an activity requires ethical review and, if so, what Level of Ethical Review.

		Yes	No
Publication			
1	Do you wish to publish or present your results outside Bolton Clarke?		
Burdens and risks			
2	Does the proposed activity impose a burden on clients/residents beyond that experienced in their routine care e.g. completing a questionnaire or interview?		
3	Does the proposed activity pose any risks for clients/residents beyond those of their routine care e.g. intervention outside of routine care?		
Privacy and confidentiality			
4	Does the proposed activity risk breaching the confidentiality of any individual's personal information beyond that experienced in the provision of routine care e.g. providing identified or potentially identifiable data to a third party not involved in the individual's routine clinical care?		
Waiver of Consent			
5	Will the proposed activity make use of personal / health information for a purpose which is un-related to the original purpose of collection without consent of persons to whom the information relates? *		
Overlap with research			
6	Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the clients/residents?		
7	Does the proposed activity involve randomisation, the use of a control group, a placebo or comparing cohorts?		
8	Does the proposed activity seek to gather information about the clients/residents beyond that collected in routine clinical care?		
9	Does the proposed activity involve testing of non-standard (innovative) protocols or equipment?		
Broader implications			
10	Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?		
11	Does you plan to use data or analysis from the proposed Quality Improvement activity for another purpose?		
Is the Research NEGLIGIBLE or LOW RISK?			
12	Is the foreseeable risk more than inconvenience or simple discomfort?? Yes = more than Negligible or Low Risk. See National Statement 2.1.6 & 2.1.7 for guidance		
Does the Research activity target the following PARTICIPANT GROUPS?			
13	Women who are pregnant and the human foetus		
14	Children and young people		
15	People in dependent or unequal relationships		
16	People highly dependent on medical care who may be unable to give consent		
17	People with a cognitive impairment, an intellectual disability, or a mental illness		
18	People who may be involved in illegal activities		
19	Aboriginal and Torres Strait Islander Peoples		

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If 'No' to all questions, this is a Quality Improvement project and no ethical review is required.**

If 'Yes' to any question, you will need to discuss whether a submission to HREC is needed, please contact research@boltonclarke.com.au

- If Yes to any question from 1-11, but No to questions 12-19, your project may be eligible for expedited review

**National Privacy Principle 2.1(a) states that 'An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless ... both of the following apply:*

- 1. the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;*
- 2. the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose.*

***Please note:* Any Quality Improvement activity still needs to be conducted in a way that adheres to ethical principles and relevant legislation. This should include consideration of whether the people involved will be exposed to any harm as a result of the activity. Participants must be afforded appropriate protections and respect. Considerations should be outlined in a project plan, and include how participant consent will be obtained, how participants' privacy will be protected, and how ethical issues that may arise will be managed. Source: [Ethical Considerations in Quality Assurance and Evaluation Activities](#), NHMRC 2014