Bolton Clarke 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? see '@' on page 2		
Overlap with research			
6	Do you aim to generate any new generalisable knowledge?		
7	Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the clients/residents?		
8	Does the proposed activity involve randomisation, the use of a control group, a placebo or comparing cohorts?		
9	Does the proposed activity seek to gather information about the clients/residents beyond that collected in routine clinical care?		
10	Does the proposed activity involve testing of non-standard (innovative) protocols or equipment?		
Broader implications			
11	Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?		
12	Do you plan to use data or analysis from the proposed Quality Improvement activity for another purpose?		
Is the Research LOW RISK?			
13	Is the foreseeable risk more than inconvenience or simple discomfort? see '#' on page 2 Yes = **more than Low level of Risk** see '^' on page 2 *See NHMRC National Statement 2.1.6 & 2.1.7 for guidance*		
Does the Research activity target the following PARTICIPANT GROUPS?			
14	Women who are pregnant and the human foetus		
15	Children and young people		
16	People in dependent or unequal relationships		
17	People highly dependent on medical care who may be unable to give consent		
18	People with a cognitive impairment, an intellectual disability, or a mental illness		
19	People who may be involved in illegal activities		
20	Aboriginal and Torres Strait Islander Peoples		

Governance Pathways

1. **If the answer is 'No' to all questions, this is a QI project and no ethical review is required.**
   Please contact research@boltonclarke.com.au for confirmation of this
2. **If the answer is 'Yes' to question 1 and 'No' to all other questions, this is a QI project and no ethical review is required.**
   Please contact research@boltonclarke.com.au for confirmation of this
3. **If the answer is 'Yes' to questions 1 and 2 but 'No' to all other questions, then your project is eligible for a low-risk ethics review which will be undertaken by the Bolton Clarke Research Review & Governance Committee (RRGC).**
   Please contact research@boltonclarke.com.au
4. **If 'Yes' to any question beyond questions 1 and 2 then your project requires a full ethical review by Bolton Clarke Human Research Ethics Committee.**
   Please contact research@boltonclarke.com.au

*@ The **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, it is 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.'*

*# **Discomfort** is defined in the National Statement as less serious than harm and may involve body and/or mind. Examples of discomfort from the National Statement include:*

- *Minor side-effects of medication*
- *The discomforts related to measuring blood pressure*
- *Anxiety induced by an interview*

^ Activities that are considered 'Low Risk' include:

- *Surveys where the research topic and questions will not induce (or have the potential to) distress or cause reputational or professional harms*
- *Secondary use of data where consent at the time of collection was obtained to access, share, and use the data for secondary research purposes*
- *Secondary use of identifiable data where a waiver is requested to access data that does not include personal medical or health information*
- *Interviews or Focus Groups where the research topic and guiding questions will not (or have the potential to) induce distress or cause reputational or professional harms*
- *Interventions – research involving participants undergoing a non-clinical intervention/assessment task (e.g. activity) where the research tasks may induce discomfort but will not (or will not have the potential to) induce distress, cause reputational or professional harms, and/or involve an element of active concealment or planned deception*

Source: ethical-considerations-in-quality-assurance-and-evaluation-activites.pdf (nhmrc.gov.au)