Guidelines for conducting research at Bolton Clarke

Researchers who have any queries regarding ethics approval should contact:

The Secretary
Human Research Ethics Committee
Bolton Clarke
Level 1, 347 Burwood Hwy
Forest Hill VIC 3131

Phone: (03) 9814 2736
Email: ethics@boltonclarke.com.au

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This document provides guidance for all researchers who are seeking to conduct research within Bolton Clarke and/or with Bolton Clarke clients, residents, staff or data.

The Policy Context for Research at Bolton Clarke

External Researchers, Research Groups or Research Organisations:

Expressions of interest are invited from researchers and research groups from universities or affiliated research institutes and organisations who wish to conduct research in partnership with Bolton Clarke. Please contact the Institute via ethics@boltonclarke.com.au

Bolton Clarke employees:

As well as the Guidelines for Conducting Research at Bolton Clarke, employees are required to obtain support, in writing, for the conduct of research from their Bolton Clarke line manager.

Research students:

Students, including Bolton Clarke employees, who are undertaking post-graduate study with research project requirements, must have HREC approval to undertake research at Bolton Clarke.

The Research Proposal Application Process

All research projects must be approved by the Bolton Clarke Institute Research Review Advisory Group (RRAG), the Bolton Clarke Business Stream, and the Bolton Clarke Human Research Ethics Committee (HREC), where appropriate, before commencement. This is to ensure protection of research participants, the responsible and ethical conduct of research, clinical support and access to research participants. Each level of review serves a specialised function:

- The RRAG reviews the scientific merit, clinical significance, rigour and time lines of the proposal;
- The Business Stream concerned assesses the implications of the proposed study on resources, staffing and other clinical activities;
- The HREC considers the ethical implications of the proposed research.

Research proposals and applications for review by the RRAG may be submitted to:

Bolton Clarke
The Secretary HREC
Level 1, 347 Burwood Hwy
Forest Hill VIC 3131

Email: ethics@boltonclarke.com.au

How to get started:

- Contact the Institute via ethics@boltonclarke.com.au to discuss your submission. You will be allocated a mentor from Bolton Clarke to assist you with navigating the approval process. Please provide contact details and a brief description of the research proposal in your email.
- Read the Guidelines for Conducting Research at Bolton Clarke. Make a note of any questions to ask your mentor.
- Discuss your proposal with your mentor and provide the information required for the RRAG to consider your proposal – information about the scientific merit, clinical significance, rigour and times lines of the proposal and the HREC application type (low risk or other) that you are requesting to submit.
- If your application requires ethical approval, once the RRAG has approved your submission ready for review, submit the NH&MRC Human Research Ethics Application (HREA) form and required attachments for HREC consideration.
- Commence your research once written approval has been obtained from the HREC.

The Role of Bolton Clarke Human Research Ethics Committee

The Bolton Clarke Human Research Ethics Committee (HREC) operates within:

- The guidelines set out in the National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007);
- The Commonwealth Privacy Act (1988);
- The Health Records Act (2001) Victoria and similar legislation in other states
- The Victorian Health Commissioner's (2002) Statutory Guidelines on Research for the Purposes of Health Privacy Principles 1.1 (e) (iii) and 2.2 (g) (iii) and similar legislation in other states; and
- Any relevant amendments made to the above documents.

Submission of Applications to the Bolton Clarke HREC:

Proposals must be submitted on the NH&MRC Human Research Ethics Application (HREA) Form. A link to this form is available on the Bolton Clarke website. The Bolton Clarke HREC has a separate process for considering low risk applications. Full details of the low risk application process and guides to determine if an application is low risk are also available on the Bolton Clarke website.

Applications must be complete and use plain English throughout. Applications that fail to answer all questions or do not provide all requested attachments may be delayed or rejected by the HREC.

The HREC will only communicate with one designated applicant.

Timing of Submission of Proposal:

The HREC usually meets on the second Tuesday of every second month commencing in February of each year. Proposals should be submitted at least twelve (12) working days before the meeting date.

HREC meeting dates and dates for submission are available on the Bolton Clarke website.

Student Submission:

In the case of a student of research applying for project work within Bolton Clarke, the principal supervisor of the student must take responsibility as the Principal Researcher of the project.

Ethical Assurances:

Participation in the research project should not interfere with client care or cause harm to clients, residents, carers or staff.

All invited participants must receive the following information:

- Title of research project;
- Name of researcher(s);
- Research funding details;
- Explanation of what research is about and what will be expected of participants during the project in a plain language statement in their preferred language;
- Approval of Bolton Clarke Human Research Ethics Committee and the institutional Human Research Ethics Committee of any other participating university/agency (if applicable);
- Assurance of anonymity and confidentiality of research participants;
- Assurance of the right of participant(s) to refuse to participate in a research project or to withdraw from a project without jeopardising the service they receive from Bolton Clarke, or their employment status;
- Avenue for complaints about the project or the researchers; and
- The method(s) of dissemination of research results.

It is recommended that the above information is provided through the NH&MRC National Participant Information and Consent Form (PICF) templates available via the Bolton Clarke website. Ensure that all relevant sections of the PICF are utilised and include the section headings.

Informed Consent:

Research participants must be fully informed regarding the intent, nature, purpose and scope of the research when deciding if they will participate. This includes advice to participants on whether personal or identifying information will be provided to any third parties, which must be identified. Participation in the research project must be voluntary and participants should be fully aware that they are free to withdraw at any time.

Researchers must pay particular attention to the issue of 'informed consent' and demonstrate that every attempt has been made to use an accessible medium and to appropriately attend to levels of comprehension in the presentation of all relevant information pertaining to the research project. Where individual participants are unable to comprehend sufficiently to give consent, this must be sought from the person or body who has the legal authority to make decisions on behalf of the person.

Should client(s), resident(s), carer(s) or staff member(s) decide to participate in the research, researchers must obtain their written consent on a form that reflects participant's understanding of their rights and expected level of input into the research.

In cases where consent is indicated by response, the requirement for a signed form may be waived. However, this would be assessed on an individual basis and must be explained in the HREA.

Protection of Research Participants:

Bolton Clarke has a responsibility to ensure that our employees and all clients in our care that participate in research are not exposed to undue risk, unnecessary or unwarranted intrusion, that their consent to participate is ethically obtained and their privacy and confidentiality is protected. To this end, no research project can commence until the written permission of the HREC has been received. Breach of the specific and standard conditions of approval may, by discretion of the organisation, result in the withdrawal of permission to undertake research with Bolton Clarke, our employees and clients.

The privacy and confidentiality of participants' personal details/information must be ensured at all times, including in the publication of any data, papers or reports. The anonymity of participants, including Bolton Clarke employees, must be ensured throughout the research process. For example, if the research project uses surveys, information should be stored so that it is not possible to link the data provided to individuals participating in the project.

Bolton Clarke recognises its responsibility to our clients and residents who may be aged, frail or living with a disability and so reserves the right to withdraw access to or vary the conditions applying to research conducted at Bolton Clarke.

Sponsorship and Funding:

It will not be assumed by the HREC that any proposal containing a request for outside funding will be funded through the nominated channel. The HREC will not consider unfunded applications.

Researchers must declare any affiliation with funding source/s or whether they have any financial interest in the outcome of the research project.

If subcontractors are to be used for any part of the project, this must be written into the ethics application.

Benefit/Relevance of Project to Bolton Clarke Clients and/or Staff:

The objectives and potential findings of the project must demonstrate relevance and benefit in relationship to national health priorities and the strategic direction of Bolton Clarke.

Bolton Clarke Resource Implications:

The proposed research must be able to be accommodated within Bolton Clarke without causing overload or saturation related to:

- service delivery,
- demand on staff,
- other current research projects and the potential for overlap or contamination, and
- the topic to be examined.

An estimate of Bolton Clarke client, resident and/or staff involvement plus details of other Bolton Clarke support sought must be provided to the HREC in the application.

Research Methods:

Evidence should be given that the target population is accessed most appropriately through Bolton Clarke and, where possible, that other avenues have also been explored/utilised.

The sampling technique must be appropriate in terms of:

- selection
- recruitment
- maintenance of anonymity
- accessing of clients/staff
- causing minimal disruption to clients/staff
- size

Bolton Clarke is unable to divulge client contact details without client consent to non Bolton Clarke staff and this needs to be considered in the development of the recruitment plan. In situations in which access to specific participants from the Bolton Clarke client/resident population is sought, their consent is required for the provision of their name to the researcher.

The data collection technique and instruments must satisfy the following requirements:

- content and format are non-intrusive
- design
- sensitivity to the topic/issue being researched
- reliability and validity of instruments

The proposed project design and data analysis must also satisfy the HREC in terms of:

- research rigor
- the potential value and clinical application of the findings

Data Management:

All projects must ensure that participant confidentiality is ensured at all times regardless of the type of data collection instruments used (e.g. questionnaires, audio or video recordings). This condition also applies to research projects that involve longitudinal studies. Persons other than the researcher must not be able to link the information collected to individual participants. Researchers must provide details of the procedures they will use to ensure this protection in their research application, for example, strategies for information storage, access and disposal of data.

The amount of personal data available to any researcher including access to participants will be dependent upon the type and extent of the research and the potential benefits of the research. This will be mutually agreed on at the outset of the project.

Ethics Clearance and Ethical Standards:

Bolton Clarke recognises the vulnerability of its client / resident group. Research proposals must reflect contemporary knowledge of and commitment to proper ethical standards and measures, with due regard to issues of privacy, consent, power relations, accountability and transparency.

Research applications must be consistent with the National Statement on Ethical Conduct in Human Research (NHMRC 2007) and the Australian Code for the Responsible Conduct of Research (NHMRC 2007) and any relevant amendments made to these documents.

Conflict of Interest:

Researchers must disclose any affiliation or financial involvement with any organisation or entity with direct interest in the subject matter of the research.

If, during the Research Project, a participant discloses confidential information to the researcher regarding their safety and well being or issues that place a participant at risk, the researcher is required to disclose this information to the relevant authority with the consent of the participant.

Intellectual Property:

In approving proposals for students to conduct research, Bolton Clarke places no claim on the researcher regarding new intellectual property created by the researcher. The researcher grants to Bolton Clarke a non-transferable, irrevocable license to use the research product or publication for the non-commercial purposes of Bolton Clarke.

Publication of Research Findings:

Bolton Clarke retains the copyright in the records, data, etc that may be made available to researchers. Unauthorised copying or publication of these records, data, film, etc is in breach of Commonwealth copyright law.

At the completion of the project, copies of all publications arising from the research are to be provided to Bolton Clarke via the HREC Secretariat. This includes the research report which may be a copy of the student's thesis.

In the event of publication, the researcher will acknowledge the assistance of Bolton Clarke.

Bolton Clarke recognises that, on occasion, research results that have implications for sensitive policy and/or political issues will be of interest to the media. Researchers will advise Bolton Clarke any anticipated media coverage or publication from the results of research conducted in Bolton Clarke sites/facilities.

Project Approval:

The Principal Researcher, or his or her nominee, may be invited to a HREC meeting if Members require clarification of various aspects of the research. Researchers may be requested to amend an application before final approval is given.

Researchers can expect written notification of the outcome of their application within seven (7) clear working days after the HREC meeting at which the application was discussed.

Monitoring of Research Projects:

Approval to proceed with a project is contingent on researchers submitting an annual progress report about the project to HREC, and as requested from time to time by the HREC. HREC Research Progress and Final Report forms are available on the Bolton Clarke website.

Additional Monitoring Requirements:

The HREC may recommend and/or adopt any additional appropriate mechanisms for monitoring HREC approved research projects, including random inspections of research sites, data, signed consent forms, and/or interviews with prior consent of research participants.

The HREC will monitor proposals approved in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC 2007).

Reporting Adverse Events:

Researchers are required to immediately report to the HREC in writing anything which might warrant a review of ethical approval of the project including:

- serious or adverse effects on participants
- proposed changes in the project methods
- unforeseen events that might affect continued ethical acceptability of the project

Advising Researchers to Discontinue a Research Project:

The HREC may withdraw approval for a research project if it is satisfied that it is not being or cannot be conducted in accordance with the approved proposal.

The HREC will inform the Chief Investigator and appropriate institutions/organisations that the research project be discontinued.

Researchers must not continue with the research if ethical approval has been withdrawn and must comply with any special conditions required by the HREC.

Handling Complaints:

Complaints in writing about the conduct of the research project from research participants, researchers or other interested persons are made to the Chair of the Bolton Clarke HREC for resolution.

Complaints that cannot be resolved in this manner will be referred to the CEO of Bolton Clarke for resolution.

Complaints from researchers about the conduct of the HREC will be referred to the Bolton Clarke CEO in writing, acknowledged and investigated by a third party as directed by the CEO. Complainants will be given the opportunity to present the complaint in person.

Complaints about an activity approved under Commonwealth or State privacy guidelines may be made directly to the relevant federal or state Privacy Commissioner.

Full details of the Complaints Procedure are available on the Bolton Clarke website.

Final Reports:

The HREC requires that the HREC Research Progress and Final Report Forms are completed and submitted as required. These forms are located on the Bolton Clarke website.

On completion of the research, the researcher should send a letter to participants acknowledging participation and advising of the completion of the project. The planned method of feedback of results of the project to participants must be appropriate to the research project. A copy of the letter should be forwarded to the HREC Secretariat.

Guiding Documents and Legislation

Commonwealth Privacy Act 1988

Commonwealth Copyright Act 1968

General retention & disposal authority for the records for higher and further education institutions (2002) Public Records Office Victoria and similar authorities in other states

International Committee of Medical Journal Editors (2008) *Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publications,* International Committee of Medical Journal Editors

NHMRC (2007a) Australian Code for the Responsible Conduct of Research, Commonwealth of Australia, Canberra

NHMRC (2007b) National Statement on Ethical Conduct in Human Research, Commonwealth of Australia, Canberra

Victorian Health Records Act 2001 and similar legislation in other states