How to Conduct Research with Bolton Clarke

This document supports the conduct of research with and at Bolton Clarke and outlines the processes for review and approval of research projects.

Researchers who have any queries regarding conducting research with Bolton Clarke should contact:

The Co-ordinator, Research Review and Governance Committee, Bolton Clarke Research Institute

Email: research@boltonclarke.com.au

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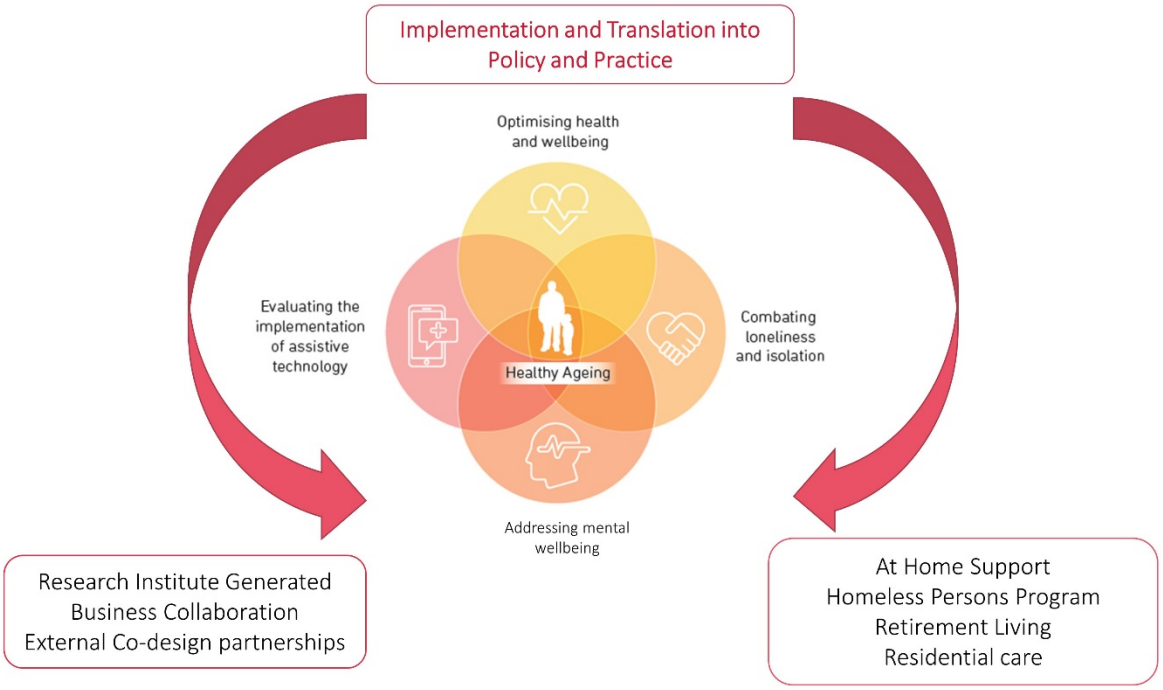
Context

Bolton Clarke is a not-for-profit aged care provider, caring for older community members in their own homes, retirement villages and in residential aged care homes.

The Bolton Clarke Research Institute (BCRI) supports Bolton Clarke staff to provide evidence-based care to our clients and residents, and generates research to support appropriate translation of evidence into Bolton Clarke practice. Bolton Clarke has 4 research priorities:



Underpinning all research at Bolton Clarke is co-design. This involves working with community members, clinicians, clients, residents and researchers, to ensure that we ask the right questions, engage participants and conduct robust research. Bolton Clarke prioritises collaborations with organisations who are interested in co-designing their projects with us. Research projects undertaken at Bolton Clarke must have received ethical approval, under consideration of the NHMRC National Statement and guidelines, from the Bolton Clarke Human Research Ethics Committee (HREC) (an NHMRC registered HREC) which meets bi-monthly.

The BCRI welcomes collaboration with external researchers to undertake research at Bolton Clarke.

For any research to be undertaken at Bolton Clarke, it must meet the following criteria:

1. Relevance	Be relevant to our communities, staff, organisation and the broader aged care industry;
2. Fill a Gap	Fill a gap in existing research/knowledge,
	Aim to lead to positive change in care delivery;
3. Engagement	Have engagement with the BCRI at the early stages of research project development;
4. Approval	Have the approval of the BC HREC and the relevant Bolton Clarke business leader (facilitated by BCRI).

The Research Proposal Application Process

All research project applications must be reviewed by the Bolton Clarke Institute Research Review and Governance Committee (RRGC) and approved by the relevant Bolton Clarke Business Stream, and the Bolton Clarke Human Research Ethics Committee (HREC), where appropriate, before commencement.

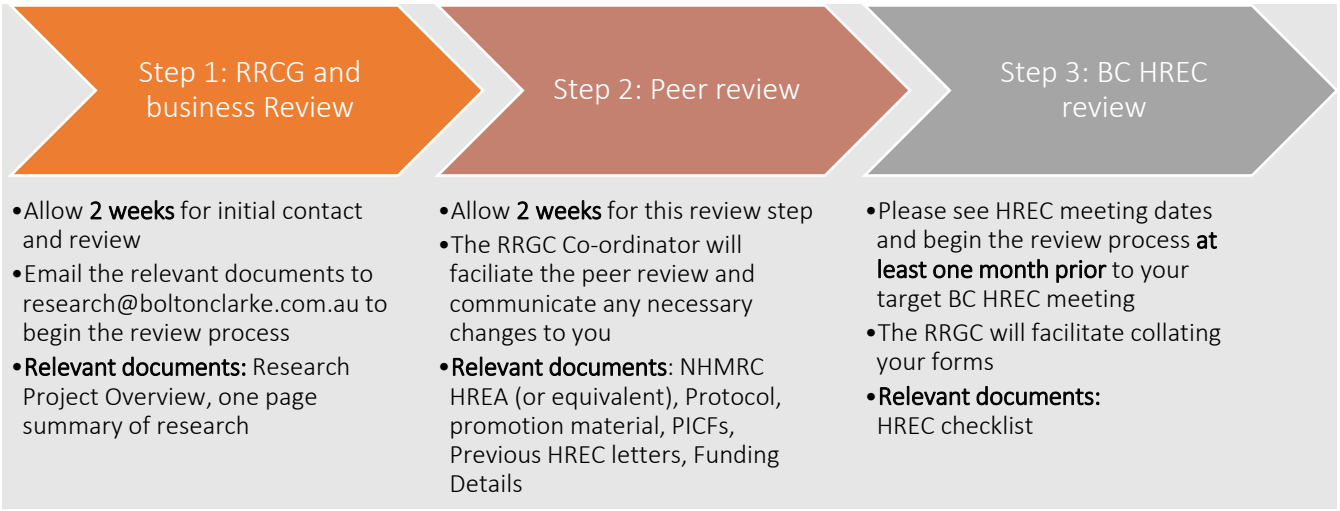
This review process will be undertaken in three steps:

- Step 1: RRGC and Business review;
- Step 2: Peer Review; and
- Step 3: HREC review

The RRGC Co-ordinator will facilitate this process and field any enquiries about Research Governance at Bolton Clarke. Please submit research proposals approximately **4 weeks** prior to HREC meeting dates, preferably earlier to engage in a process of codesign with BCRI.

Submit all proposals to research@boltonclarke.com.au.

The RRGC reviews applications for scientific merit, clinical significance, rigour and timelines. The relevant Business Stream assesses the implications of the proposed study on resources, staffing and other clinical activities; and the relevant Executive General Manager provides approval. The HREC considers the ethical implications of the proposed study.



Considerations for different groups

Researchers external to Bolton Clarke:

Contact the Bolton Clarke Institute Research Review Governance Committee via research@boltonclarke.com.au.

Please initiate contact at least 4 weeks prior to your desired HREC meeting date.

Bolton Clarke and the BCRI encourage co-design of research projects. To facilitate this you may want to contact BCRI early in the project. You may also be put in contact with a member of the BCRI to support your research if appropriate for the project.

Bolton Clarke employees:

We recommend you collaborate with a member of the BCRI. You must contact the RRGC via research@boltonclarke.com.au to have your research reviewed for Governance and Ethics Approval, which is required of all research at Bolton Clarke.

Students:

Research students wanting to undertake research within Bolton Clarke must have their Principal Supervisor recorded as the Principal Researcher of the project. Research students must have a BCRI researcher on their supervisory team.

Clinical Trials:

Please note: Bolton Clarke does not act as a participating agent for a trial, including:

- administering a trial drug, treatment or procedure, or
- monitoring the response of a person to a drug, treatment or procedure.

Bolton Clarke does not administer or monitor trial drugs, treatments or procedures on behalf of non-Bolton Clarke research.

Step 1: RRCG and Business Stream Review

The first step to conducting research with Bolton Clarke is to contact the Research Review and Governance Committee Co-ordinator via research@boltonclarke.com.au.

The purpose of the first step of review is to ascertain whether your research is relevant to Bolton Clarke and the BCRI, as well as determining our capacity to accommodate the proposed research. Initial contact, RRGC review and Business Stream review will take approximately **2 weeks**. The RRGC meets weekly, as such you can expect a response to your initial contact within a week of enquiry. This initial stage is the ideal time to inquire about co-designing or collaborating with Bolton Clarke and the BCRI.

Approval for your project to be undertaken at Bolton Clarke will be sought from the relevant Business Stream Leader, Head of Research and RRGC Co-ordinator. The RRGC will facilitate contacting relevant people within the organisation to determine capacity to undertake the research. You may also be put in contact with a member of the BCRI to facilitate your research if appropriate for the project.

RRGC Initial Review

Initial review of your research proposal will be undertaken by the RRGC, which consists of the Head of Research, the HREC secretary, the RRGC Co-ordinator (a Senior Research Fellow) and one rotating Research Fellow/Officer. At this stage a decision whether to pursue a research collaboration will be based on:

- Relevance to communities, staff, organisation and the broader aged care industry
- Whether the research fills a gap in existing knowledge, with the aim of leading to positive change in care delivery
- Engagement with BCRI at early stages of research project development

The RRGC will request the following to undertake Step 1:

- Research Project Overview Form
- A one-page summary of the project

Bolton Clarke Business Stream Review

The RRGC Co-ordinator will facilitate a review of your proposal by the relevant Business Stream Leader. Bolton Clarke has three business streams: At-Home Support, Residential Aged Care and Retirement Living. Details of your proposal will be sent to the relevant Business Stream Leader, including number of participants, required resources, and anticipated involvement of Bolton Clarke. The relevant Business Stream Leader will review your application for:

- Resources, such as use of kitchens, community halls, meeting rooms, equipment
- Impact on clients and/or residents, including how participants will be recruited and considerations for the specific population

- Impacts on staffing including 'back-fill' requirements and potential involvement in research
- Impact on other departments, for example People and Culture or Information Services

Head of Research Approval

Once the RRGC and Business Stream Leader have reviewed your proposal, Bolton Clarke's Head of Research will review the details of the proposal and provide approval to move on to Step 2: Peer Review and Step 3: HREC Review.

If the RRGC, Business Stream Leader or Head of Research identify any resolvable issues with your proposal, the RRGC Co-ordinator will communicate this to you and allow you time to modify your proposal. It is possible that there may not be capacity within the organisation to undertake your proposal due to competing priorities or overlap with other research being undertaken. If the RRGC, the relevant Business Stream Leader and Head of Research all approve the research your proposal will progress to Step 2: Peer Review.

Step 2: Peer Review

After RRGC, Business Stream and Head of Research approvals have been obtained at Step 1, your research proposal will undergo governance and peer review by members of the BCRI and relevant experts within the organisation. The peer review will be facilitated by the RRGC Co-ordinator and requires **2 weeks**.

The peer review will focus on the following issues:

- Significance of the research
- Research quality
- Research team quality and capability
- Readiness Assessment for Pragmatic Trials (RAPT) domains of relevance to implementing projects at Bolton Clarke (risk, feasibility, measurement, cost acceptability, alignment and impact) (Baier, Jutkowitz, Mitchell, McCreedy, & Mor, 2019)
- Timelines, resources/staffing, relevance to Bolton Clarke, and involvement of BCRI

Each issue will be scored based on the below criteria independently, by at least two independent peer reviewers. The scores from each domain and recommendations of the reviewers will be considered by the RRGC.

Based on the outcome of the peer review your proposal will either be accepted, accepted with minor revisions, require major revisions, or be rejected. The outcome of the peer review will be communicated with you by the RRGC Co-ordinator, and if your proposal requires minor revisions, the RRGC will endeavour to submit your proposal to the HREC at your desired meeting. To facilitate this, please respond quickly to the revisions. if the required revisions are significant it may need to be delayed until the next HREC meeting date.

Peer review criteria

Peer review criteria a)-c) below are based on NHMRC Clinical Trials and Cohort Studies Peer Review Guidelines (2020, Version 3).

a) Significance

Significance for this research proposal/project is the extent to which the findings will substantially advance knowledge to improve the prevention, diagnosis or treatment of medical conditions, or to improve health and wellbeing. To assess significance, consider the following:

Criteria:
Relevance of the research proposal to the objectives and desired outcomes of the project:
Does the project address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health, particularly older people?
Does the project address improvements as a result of providing reliable evidence of the effects of health-related interventions on health outcomes (or appropriate surrogates), particularly for older people?
Does the project address improvements as a result of reliable evidence on the relation of important risk factors and other exposures to health-related outcomes, particularly for older people?
Rationale for the proposed research strongly supported by evidence:
Has an outline of what previous research has occurred been provided?
Has the applicant referred to or conducted a systematic review or a thorough literature review? Do the points of difference between these studies and the proposed research provide strong justification for the proposed research?
Does the research question(s) meet the needs of research end-users, such as consumers, community members, policy makers and clinical practitioners?
If the research objectives are achieved, would the research have a significant impact on the health issue in question? This may include contributing to knowledge, health, economic and social impacts?

b) Research quality

Research quality encompasses the quality and feasibility of the proposed research, incorporating theoretical concepts, hypothesis, research design and robustness. Research quality will be assessed in terms of, but is not limited to, the following considerations:

Criteria
Is there a clear research question(s)?
Appropriateness of study design and methodologies for the research question(s)
Have any major pitfalls been addressed?
Have the risks associated with the study been identified and strategies employed to mitigate them (e.g. recruitment shortfalls, participant attrition, legal-ethical barriers, political issues)?
Are the proposed inclusion and exclusion criteria appropriate and justified? This includes appropriate consideration of sex and gender, and other factors such as ethnicity, culture and language.

Are the proposed methodological approaches appropriate and clearly specified? Are data collection, management and statistical analyses described?
Were relevant research end-users, such as consumers, community members, policy makers and clinical practitioners, engaged during development of the research plan? Will they be involved in the conduct of the study? Will they be informed of the outcomes?
Have barriers and enablers associated with implementation been thoroughly considered and managed?
Study feasibility
Are the required techniques established? Are the required expertise and resources available, including infrastructure, equipment and facilities?
Are targets for the recruitment of participants realistic? Is the sample size achievable and sufficient to detect meaningful effect differences?
Does the proposal include appropriate and realistic milestones and performance indicators and timeframes? Can the end-points be measured?
If the proposal is a retrospective cohort study, are the data available of high quality, with low confounding factors and of sufficient volume to be informative, in relation to the health-related questions being asked?

c) Research team quality and capability

This criterion is used to assess whether the research team named has the appropriate mix of research skills and experience to undertake the study and achieve the stated objectives of the proposed research. Team quality will be assessed in terms of, but not limited to, the following considerations:

Criteria
Does the research team collectively provide an appropriate mix of research skills and experience to successfully undertake this clinical trial and/or cohort study?
Does the research team have sufficient expertise to anticipate and solve potential obstacles (e.g. higher than anticipated non-compliance rates or new competing therapies) to the success of the proposal?
Do they have expertise in all aspects of the research proposal?
Does the expertise include the methodological and scientific underpinnings (e.g. statistics, bioinformatics and health economics) of the research proposal?
Does the research team have the networks, influence and experience to manage all aspects of the study?
Do the researchers have expertise in this or related area of research? Does the team have capability to undertake the study?
Does the research team reflect the contribution of students, early- and mid-career researcher/s to the study?

d) The Readiness Assessment for Pragmatic Trials (RAPT) - domains of relevance to implementing projects at Bolton Clarke

To complement the above criteria, these domains, taken from the RAPT model (2019), aim to ascertain the likelihood of interventions becoming 'business as usual'. These relate to the ability to undertake the research, and whether it will be effectively implemented at Bolton Clarke. Further information about each of these domains can be found here.

Domain		
i)	Risk	Is it known how safe the intervention is?
ii)	Feasibility	To what extent can the intervention be implemented under existing conditions?
iii)	Measurement	To what extent can outcomes be captured during the conduct of the study?
iv)	Acceptability	How likely is the intervention to be economically viable?
v)	Alignment	How willing are providers likely to be to adopt the intervention?
vi)	Impact	How useful will the results be?

Additional criteria

Peer reviewers will also assess your proposal for any other relevant governance elements including; whether your timelines are clearly presented, related to the methodology and allow for completion of project in timeframe specified; practicality of required resources and staffing access requirements from a research methodology perspective; relevance to Bolton Clarke's research priorities and benefits to our population; as well as involvement of the BCRI team on the project.

Relevant Documents

The RRGC Co-ordinator will request documents relevant to the HREC submission for peer review. The following documents will be requested:

- NHMRC Human Research Ethics Application (HREA) (or equivalent)
- Protocol
- Any promotion material
- PICFs (refer to Informed Consent for guidance on creating PICFs relevant to Bolton Clarke's population)
- Previous HREC letters
- Funding Details

You can find further detail about these documents in Step 3: HREC Review or direct enquiries to the RRGC Coordinator.

HREA form

As part of your Proposal please submit a Human Research Ethics Application (HREA), or equivalent. The HREA will assist you to consider the ethical principles of the National Statement on Ethical Conduct in Human Research (2018) in relation to your research.

When completing the HREA, the nominated HREC for review is the Royal District Nursing Service HREC.

Access the form: Welcome - NHMRC Portal (hrea.gov.au)

Please consider the Research Proposal Requirements relevant to the Bolton Clarke HREC and our population when completing your HREA.

Step 3: Bolton Clarke HREC Review

The Bolton Clarke Human Research Ethics Committee (HREC) is an accredited HREC (NHMRC register: EC00349) and will perform an Ethics review of the research proposal.

Any application to the Bolton Clarke HREC must have first been reviewed by the Bolton Clarke Research Review and Governance Committee (RRGC) (See Steps 1 and 2 above for more information). The RRGC will facilitate your submission to the HREC and ensure all the required documentation is provided. All documents listed in the HREC Checklist will need to be completed.

The HREC usually meets on the second Tuesday of every second month commencing in February of each year. HREC meeting dates and dates for submission are available here.

The Role of the 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 (Updated 2018);
- 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.

For more information about the HRECs constitution and operating processes please refer to the Terms of Reference.

Review Pathways /Levels of Review

All research project applications are "triaged" by the Bolton Clarke RRGC and allocated to review by the full HREC or by a low risk review process.

Quality Improvement (QI) or Assurance studies are exempt from the ethical approval process. Researchers may seek acknowledgement from the Bolton Clarke HREC that an activity is QI. If requested, a letter of exemption can be provided by the HREC related to the activity. Any QI study must still be conducted using good ethical principles, and receive approval from Bolton Clarke Business Stream Leaders.

The Levels of Review Checklist can help researchers determine whether their activity is QI or needs to undergo HREC review, and via what pathway. Researchers can also contact the RRGC via email (research@boltonclarke.com.au) for guidance.

There is one set of application procedures and submission deadlines for all levels of review.

1) Negligible and Low Risk

In accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2018), the Bolton Clarke HREC has established a process for the review of research involving no greater than low risk. This expedited review process is outlined in the Bolton Clarke HREC Terms of Reference, Section 11.

As defined in the National Statement, Chapters 2.1.6 & 2.1.7,

Negligible Risk - describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience e.g. filling in a form, participating in a survey or giving up time to participate in research.

Low Risk - research in which the only foreseeable risk is one of discomfort e.g. minor side effects of medication, anxiety induced by an interview or previous trauma. Research in which the risk for participants is more serious than discomfort is not low risk

2) Greater than Low Risk – Full HREC Review

All research that involves more than low risk, or involves individuals in one of the following cohorts (Women who are pregnant and the human fetus; People highly dependent on medical care who may be unable to give consent; People with a cognitive impairment, an intellectual disability, or a mental illness; Aboriginal and Torres Strait Islander Peoples; People who may be involved in illegal activities) must undergo Full HREC Review, as outlined in the National Statement. Given Bolton Clarke is a care provider, any research where participants are people in dependant or unequal relationships must also undergo Full HREC Review.

Recognition of Prior Ethical Approval

The Bolton Clarke HREC will recognise the ethical approval of HRECs that are constituted in accordance with the National Statement on Ethical Conduct in Human Research and appropriately certified by the NHMRC. However, this does not mean all previously approved HREC-approved studies will be deemed suitable to be undertaken at Bolton Clarke. All research undertaken at or with Bolton Clarke needs to undergo review by the RRGC to ensure it is relevant to Bolton Clarke and meets the needs of our cohort.

Research Proposal Requirements

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 2007 (Updated 2018) and the Australian Code for the Responsible Conduct of Research (NHMRC 2018) and any relevant amendments made to these documents.

Ethical Considerations Specific to Participants

Bolton Clarke recognises the potential vulnerability of its client and resident group. Researchers need to be acutely aware of the ethical considerations around people in dependent or unequal relationships (Chapter 4.3, National Statement), people with a cognitive impairment, intellectual disability, or mental illness (Chapter 4.5, National Statement), and people from culturally and linguistically diverse cultural groups. Every effort is to be made to enable inclusion of diverse groups. For example, to enable inclusion of individuals for whom English is not their first language, documents may require translation and/or access to an interpreter may be necessary.

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.

Guidance and templates for completing a Participant Information and Consent Form (PICF) is located here.

It is important to note that the provision of a PICF is not necessarily sufficient to claim consent; rather, it is part of the consent process. It is recommended that researchers verbally explain the study to the potential participant, giving the participant opportunity to ask and have any questions answered. Researchers should permit time for the potential participant to review the PICF and encourage them to discuss their involvement in this project with someone who is able to support them in making their decision, if they desire. This is likely to be a family member (partner/spouse, adult child/grandchild) but this person could be a doctor, friend, neighbour or spiritual elder.

In cases where consent is indicated by response, including verbally, or return of a survey, 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; depending on the nature, complexity and level of risk of the research; and the participant's personal and cultural circumstances

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.

Processes and means for withdrawal or removal of consent by the participant must also be articulated and documented.

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 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.

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.

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.

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. For any projects undertaken in collaboration with Bolton

Clarke, Intellectual Property must be addressed in the associated Collaborative Agreement, approved by all parties.

Reimbursement of Participants

The Bolton Clarke HREC considers it appropriate to offer participants reimbursement for direct out-of-pocket expenses (such as travel expenses), or provide means to facilitate attendance at research activities (such as taxi vouchers). Researchers should consider how this supports equitable participation when planning studies, although should take care not to provide reimbursement in a way that persuades people to participate. A lack of reimbursement should not exclude individuals from participating in a research study.

Submission and Approval

Proposals to be reviewed by the Bolton Clarke HREC must be submitted on the NHMRC Human Research Ethics Application (HREA) Form.

The Principal Researcher, or nominee, may be invited to attend an HREC meeting (either in person or virtually) if committee members require clarification of any aspects of the research project. Researchers may be requested to amend an application before final approval is given.

Researchers can expect written notification of the outcome (approval, conditional approval or non-approval) of their application within fourteen (14) clear working days after the HREC meeting at which the application was discussed.

Research must not commence until written notification of approval is received.

Post-approval requirements

In accordance with the NHRMC National Statement, the Bolton Clarke HREC is required to monitor all projects approved to ensure they are conducted within ethical guidelines.

Annual and Final Reports

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. Failure to do so may result in withdrawal of ethical approval.

Researchers must submit annual progress reports about the project to the HREC. The template for doing so can be accessed here.

At the completion of a project, a Final Report must be submitted using the template. A project is considered complete once data collection is complete, there is no further contact with participants or access to sources of personal health information **and** the data have been analysed.

Completed Progress and Final Reports should be submitted to the HREC secretariat (ethics@boltonclarke.com.au).

Additional Monitoring Requirements

The HREC will monitor proposals approved in accordance with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018).

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.

Amending approved research

In the event that an already ethically approved research project requires amendment, researchers are asked to complete the Project Amendment Template and submit to ethics@boltonclarke.com.au

Amendments may include (but are not limited to): changes of research personnel, changes to protocols, PICFs, study populations, new collaborations or sites. Researchers are asked to provide a clear description of rationale behind the changes.

If there are changes to any of the study documents, tracked and clean copies of these documents must be submitted as part of the amendment.

Most amendments will be reviewed out of session and will not require full HREC reviews. The HREC secretariat will determine whether amendments are substantial enough to require additional review, or a new study submission.

Once the amendment has been approved, an updated copy of the approval certificate will be provided to the Principal Investigator. It will list the approved documents and changes to the study. Investigators should review the approval certificate to ensure the updated documents are listed correctly. Any amendments must not be implemented until a copy of the approval certificate is received.

To make sure your approval certificates are correct, please take the time to carefully and accurately list the documents submitted on the amendment template. We will use this form to generate your approval certificate.

Withdrawal or Suspension of Approval

The HREC may withdraw or suspend approval for a research project if:

- It is satisfied that it is not being or cannot be conducted in accordance with the approved proposal;
- Serious misconduct by a researcher is suspected or proven;
- The researchers fails to inform the HREC of adverse effects; or
- The wellbeing of any participant is compromised.

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.

If the HREC Chair receives information that suggests and considers that any of the above circumstances may have occurred or are occurring, they will send a letter to the investigator requesting more information and responses to any questions. The Chair will ask for a response within a specified time frame.

The investigator's response will be considered by the Bolton Clarke HREC (out of session if necessary) and if the HREC recommends withdrawal or suspension of ethical approval of the study, the Chair will write to the researcher clearly stating the reasons for the decision. Recommendations for further action and any necessary steps will be explained in the letter.

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.

Reporting Adverse Events

Researchers are required to immediately report to the HREC in writing, via the HREC Secretariat (ethics@boltonclarke.com.au) 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, and
- unforeseen events that might affect continued ethical acceptability of the project.

A serious or adverse event is an incident that results in harm to the research participant.

Protection of Research Participants

Bolton Clarke has a responsibility to ensure that our employees and all 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.

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.

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

Project Closure

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 and feedback should be forwarded to the HREC Secretariat. At the completion of a research project, copies of all publications arising from the research must be provided to Bolton Clarke via the HREC Secretariat (ethics@boltonclarke.com.au). 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 of any anticipated media coverage or publication from the results of research conducted in Bolton Clarke sites/facilities through the HREC secretariat and Bolton Clarke RRGC.

Research Complaints Procedures

This Research Complaints Procedure applies to all staff and students conducting research at Bolton Clarke as well as the individual research institutes and groups for whom Bolton Clarke provides research governance services.

This procedure for handling research related complaints has been developed to clearly set out the roles and responsibilities of Bolton Clarke and its research-related committees and the processes in place in relation to managing any complaints that may be received about research undertaken at and / or by Bolton Clarke.

Complaints may be made about researchers, the conduct of research, or the conduct of a research-related committee. Complaints may be made by research participants, researchers, staff or others.

All complaints will be handled promptly and sensitively.

All complaints will be dealt with in accordance with the principles of natural justice.

This Research Complaints Procedure requires that all research in which Bolton Clarke is involved complies with all relevant codes of practice, ethical guidelines and legislation including:

- The guidelines set out in the National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (Updated 2018);
- 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.

A complaint includes:

- A verbal expression of dissatisfaction that can be dealt with promptly and to the reporter's / complainant's satisfaction at the point of service.
- All written incident reports or complaints.
- Any verbal complaints that cannot be dealt with at the point of service.
- All complaints or allegations relating to research misconduct.

The Australian Code for the Responsible Conduct of Research 2018 defines research misconduct as follows:

Research misconduct is a serious breach of the Code which is also intentional or reckless or negligent.

Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. It

includes avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

Procedures

The following procedures relate to all research related complaints:

- Complaints in writing about the conduct of a research project from research participants, researchers or other interested persons are made to the Chair of the Bolton Clarke HREC for resolution via the HREC Secretariat (ethics@boltonclarke.com.au).
- It is preferred that complaints are made in writing. Where a verbal complaint has been made, a request to put the complaint in writing will be made. Regardless of whether a complaint is verbal or written, the procedure will be the same.
- All complaints will be recorded on the Research Complaints Register. The register includes information to track the progress of the complaint and provide a history of all referrals and action taken, as well as dates of receipt and resolution of the complaint.
  A written file note of the complaint (including actions taken and outcomes) will also be placed in the relevant research project file. All research related complaints will be reported to the Chair of the Bolton Clarke HREC.
- Complaints will be reported to the Bolton Clarke HREC and an update provided on each subsequent committee meeting agenda.
- All complaints related to human research are also reported to the NHMRC's Australian Health Ethics Committee (AHEC) as part of the HREC Annual Report.
- Complaints 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 about an activity approved under Commonwealth or State privacy guidelines may be made directly to the relevant federal or state Privacy Commissioner.

Complaints from Research Participants

Information regarding the contact person for complaints should be included in Participant Information Sheets and Consent Forms, for example:

- If you have any complaints about any aspect of the study or the way in which it is being conducted, you may contact the Principal Investigator on Tel. (0*) **** ****.
- If you have any questions about your rights as a research participant, then you may contact the Bolton Clarke HREC Chair via the secretary of the Bolton Clarke HREC on 03 9814 2736 or ethics@boltonclarke.com.au. Complaints which highlight problems warranting amendments to

the research protocol will be reviewed by the Chair of the Bolton Clarke HREC who will provide written advice to the principal researcher.

Complaints from Researchers

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 from HREC Members and other Interested Parties

Complaints from Bolton Clarke HREC members and other interested persons should be directed in the first instance to the Chair of the Bolton Clarke HREC, via the secretariat (ethics@boltonclarke.com.au). Other interested persons may include heads of departments whose services are required by researchers to support their research project and staff whose assistance or support is required to facilitate the research. The Chair of the Bolton Clarke HREC will endeavour to resolve the problem directly with the complainant and/or the principal researcher (as applicable) and, where necessary (and if appropriate), with the CEO. Where it is not appropriate to refer the complaint to the HREC Chair, the complaint should be forwarded to the CEO who will identify an independent investigator.

Seriousness of Complaints

Complaints will be rated on a scale for seriousness when they are first received by the HREC Secretariat or their delegate and again when they are closed, in order to help with more accurate assessment of seriousness. The level of seriousness does not reflect the amount of resources that may go into the management of a particular complaint. It is not uncommon for less serious complaints to consume large amounts of time and other resources and for more serious incidents to be resolved comparatively quickly.

A complaint can often raise several issues with different levels of seriousness:

- Low rated complaints: are those that ought to be easily resolved by a telephone call or letter and an explanation. These may include misunderstandings or misconceptions where a detailed investigation is unwarranted.
- Medium rated complaints: are those involving incidents such as misunderstandings, access to records, disputes about costs, discourtesy, protocol violations, breaches of privacy without serious consequences, and diagnostic or treatment errors without serious consequences.
- High rated complaints: are those involving significant quality assurance implications, practices that need changing to avoid recurrence of the event, such as amendments to the study protocol, or development of new policy or procedures. In addition, they may include complaints about protocol violations, breaches of privacy, personal injury, professional misconduct, fraud, unlawful or unethical acts, lack of informed consent and diagnostic or treatment errors with

serious adverse outcomes. Complaints that involve research misconduct by Bolton Clarke researchers will be dealt with as detailed in Bolton Clarke Research Institute Governance Manual (Chapter 10: Alleged Research Misconduct)

Guiding Documents and Legislation

Baier, R. R., Jutkowitz, E., Mitchell, S. L., McCreedy, E., & Mor, V. (2019). Risk, Feasibility, Measurement, Cost, Acceptability, Alignment and Impact. *BMC Medical Research Methodology, 19*(156). doi:10.1186/s12874-019-0794-9

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 (2018a) Australian Code for the Responsible Conduct of Research, Commonwealth of Australia, Canberra

NHMRC Clinical Trials and Cohort Studies Peer Review Guidelines (2020, Version 3)

NHMRC 2007(Updated 2018) National Statement on Ethical Conduct in Human Research, Commonwealth of Australia, Canberra

Victorian Health Records Act 2001 and similar legislation in other states