Ballarat Health Services

&

St John of God Hospital

Human Research Ethics Committee

Standard Operations Manual

January 2021

Contents

SOP Reference BHSSJOG-2020-SOP1

Purpose: To describe the function of the BHSSJOG HREC

1. The primary objective of the BHSSJOG HREC (the "HREC) is to:

- Protect the mental and physical welfare, rights, dignity and safety of participants of research
- To facilitate ethical research through efficient and effective review processes
- To promote ethical standards of human research and;
- To review research in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007) (including subsequent updates) (National Statement and Victorian Health Policy Directive

2. The Terms of Reference for the BHSSJOG HREC can found on the BHS Research website.

3. This operating procedure does not prohibit BHS from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve an expedited review of the project, provided that such other HREC is an accredited lead HREC.

4. Research projects may include, but are not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, access to health information, as well as epidemiological, social, and psychological investigations.

5. The HREC will assess projects submitted to it for review in accordance with the National Statement and any relevant guidelines and legislation in order to determine their ethical acceptability.

SOP Reference BHSSJOG-2020-SOP2

Title: HREC Membership

Purpose: To describe the membership composition of the BHSSJOG HREC

1. The composition of the HREC is in accordance with the NHMRC National Statement.

2. Minimum membership comprises of eight members, men and women as follows:

a) A Chair (and a Deputy Chair, usually SJOG executive nominee);

b) At least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work;

c) At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;

d) At least one person who performs a pastoral care role in a community, for example an Aboriginal elder, a minister of religion

e) At least one member who is a Lawyer;

f) At least two members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC.

3. To ensure the membership equips the HREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

4. Where required, the HREC may seek advice and assistance from appropriate Expert Reviewers to assist with the review of a project. An up-to-date list of Expert Reviewers is kept by the BHS Ethics and Governance Office. However, the HREC must be satisfied that such experts have no conflicts of interest, or have declared any conflicts of interest, in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) is required to provide an undertaking of confidentiality and is not entitled to vote on any matter.

5. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the HREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members, where possible.

SOP Reference BHSSJOG-2020-SOP3

Title: Appointment of HREC Members

Purpose: To describe the process for the appointment of members to the BHSSJOG HREC

1. Members are appointed as individuals rather than in a representative capacity.

2. Prospective members of the HREC are recruited by direct approach, nomination or by advertisement. Prospective members are asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the BHS website.

3. A selection committee, consisting of the Chair, Manager Ethics and Governance and at least one other HREC member review the prospective applicant's Curriculum Vitae and interview the applicant.

4. Members are reference checked, police checked and finally appointed by the Chair. New members receive a formal notice of appointment.

5. The Chair and Deputy Chair are nominated for appointment by the Chief Executive Officers of each hospital: Ballarat Health Services & St John of God Hospital. In the absence of the Chair, the Deputy Chair performs the role and duties of the Chair.

6. The letter of appointment includes:

a) The date of appointment

b) Length of tenure

c) Assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member and the;

d) Conditions of their appointment including:

i. Familiarising themselves with National Statement & other guidelines as provided.

ii. Preparing for & attending scheduled meetings; or if unavailable, providing comments

iii. Attend continuing education or training in research ethics at least every 3 years

iv. An assurance of confidentiality on undertaking their appointment (all matters of which they become aware during the course of their work on the HREC will be kept confidential)

v. Declaration of any conflicts of interest, which exist at the time or may arise during their tenure on the HREC. These may be made to the Manager Research

and Ethics or at a HREC meeting if the PI/CI relates to a specific research project

7. Upon appointment, members are provided with the following documentation:

a) National Statement on Ethical Conduct in Human Research (2018)

b) BHSSJOG HREC Terms of Reference

c) HREC Standard Operating Procedures

d) List of members' names and contact information for the BHS Ethics and Governance team

e) Any other relevant information including web links to HREC processes, state & national guidelines and legislation.

8. Members are appointed for a period of three years and may serve consecutive terms at the discretion of the HREC Chair & Quality of Care Committee. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Quality of Care Committee. Members are advised when his/her term has expired. Reappointment is by application to the HREC Chair who then makes a recommendation to the Quality of Care Committee.

9. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

10. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions are met by BHS.

11. Members shall not be remunerated. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.

12. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy where necessary.

13. Membership lapses if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

14. Members are expected to participate in relevant specialised working groups as required. The Chair and Deputy Chair will be expected to be available between meetings to participate in Research, Research, Ethics and Governance Office meetings where required.

15. A member may resign from the HREC at any time.

SOP Reference BHSSJOG-2020-SOP4

Title: Induction and Training of HREC Members

Purpose: To describe the process for the orientation of new members to the BHSSJOG HREC

1. Induction involves some or all of the following:

a. Introduction to other HREC members prior to the HREC meeting.

b. Informal meeting with Chair and Manager, Ethics and Governance to explain their responsibilities as an HREC member, the HREC processes and procedures.

c. New members will be required to sit in on HREC meetings as an “Observer” before their appointment takes effect.

d. ‘Partnering’ with another HREC member in the same category.

e. Priority given to participate in training sessions.

SOP Reference BHSSJOG-2020-SOP5

Title: Induction and Training of HREC Members

Purpose: To describe the process for the orientation of new members to the BHSSJOG HREC

Training for the full HREC and the Low Risk Review Sub-Committee occurs on a regular basis for all members each year. This training is offered on a one to one basis, by a mentor or by advertised HREC training provided by the DHHS, PRAXIS and the National HREC training providers. The training provides in cites to the following HREC procedures:

1. Research which poses greater than low risk as defined by the National Statement as research which poses a foreseeable risk of harm to the participant, even if unlikely". All research which is greater than low risk is ethically reviewed by the BHSSJOG HREC.

2. The process for the review of Low & Negligible Risk research is ethically reviewed by the Low Risk Review Sub-Committee. (LRRSC)

3. The operation of the HREC Secretariat which is responsible for preparing an agenda for each HREC meeting.

4. All completed applications and relevant documents received by the HREC Secretariat by the relevant HREC closing date are included on the agenda for HREC consideration at its next meeting.

5. The meeting agenda and associated documents are prepared by the HREC Secretariat and circulated to all HREC members at least 10 days prior to the HREC meeting.

6. Documentation received after the closing date can be included on the agenda and/or tabled at the meeting at the discretion of the Manager Research Ethics and Governance and HREC Chair.

7. Agenda items include at least the following items:

a) Apologies
b) HREC Minutes (from the previous meeting)
c) Conflicts of Interest
d) Renewals & Amendments to approved protocols requiring HREC review
e) New Research Applications
f) Approval Notifications
g) Information & Relevant Literature
h) General Business/ Matters Arising

8. The agenda and all documentation are confidential.

SOP Reference BHSSJOG-2020-SOP6

Title: Conduct of HREC Meetings

Purpose: To describe the format of meetings of the BHSSJOG HREC

1. The HREC will meet on a regular basis at least eight (8) times per year. Meeting dates and agenda closing dates are available on the BHS Research website.

2. Members attend HREC meetings in person or via teleconference with preference for in-person attendance.

3. The Chair may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 8). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.

4. Meetings are scheduled for an allocated time. If the business is not completed within the allocated time, the HREC either continues the meeting until all agenda items have been considered or schedules an additional meeting. If an additional meeting is called for, then the meeting is held within 5 working days (where possible).

5. The HREC meeting is conducted in private, to ensure confidentiality and open discussion. Members are advised of the meeting room details in the meeting agenda.

6. Notwithstanding paragraph 5, the HREC may agree to the presence of visitors or observers to a meeting.

7. Members who are unable to attend a meeting contribute prior to the meeting through written submissions to the HREC Secretariat or HREC Chair. Written comments must be received prior to the meeting so that they may be discussed at the meeting by the members present. The minutes record the submission of written comments. If the comments cannot be submitted prior to the meeting then their inclusion in the minutes and/or letter to researchers is at the discretion of the HREC Chair.

8. A quorum shall consist of the eight (8) members required to fulfil the minimum membership requirements as outlined in the National Statement (Sections 5.1.29-5.1.30). If the eight core members are not present the chairperson must be satisfied that these members have received all the relevant papers and have had the Support Officer to contribute their views and that these have been received and considered before a final decision is made (as per Section 5.2.30 of the National Statement).

9. Low Risk Review Sub-Committee (LRRSC) Members.

The HREC must appoint 3 members to serve on the LRRSC until the next scheduled HREC meeting (approximately 6 weeks). One member of the LRRSC is required to be an appointee under Category 5.1.30 (c).

The LRRSC must return their review decision within four business days. The Secretary has delegated authority if after 2 attempts of trying to secure one outstanding review and

the decision of the 2 returning LRRSC reviews is the same; the Secretary can advise the research applicant of the LRRSC decision.

SOP Reference BHSSJOG-2020-SOP7

Title: HREC Categories of Research Applications

Purpose: To describe the handling of research applications

Human research conducted at or under the auspices of Ballarat Health Services is defined by three (3) categories (levels of risk) which determine the process for submission and review. The BHSSJOG HREC ensures that the review of low and negligible risk research activities is expedited, and that such research receives appropriate research governance at all times.

The categories of research are:

- **Negligible risk research**: Research where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk even if unlikely, is more than inconvenience, the research is not negligible risk.
- **Low risk research**: Research where the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.
- **Greater than low risk**: Research where the level of risk is more serious than discomfort i.e. harm; including physical, psychological, devaluation of personal worth, social, economic and legal harm.

The National Statement gives further guidance on potentially vulnerable research participants and the types of research procedures that might involve greater than low risk (see Section 2 and 3, National Statement).

Different 'categories of risk' determine which application process should be followed and the appropriate type of ethical oversight (see the BHS Research website for more information).

Low and Negligible Risk Research

The BHSSJOG HREC delegates authority to the Low Risk Review Sub-Committee (LRRSC) to undertake expedited review of low and negligible risk research application

For information regarding the LNRR sub-committee please see SOP 6

All decisions of the Low Risk Review Sub-Committee (LRRSC) are reported under "Approved by Delegated Authority" at the next BHSSJOG HREC meeting.

Greater than low risk research will undergo a two-step review:

1. Review for scientific merit and validity – HREA Applications

Undertaken by two members of the BHSSJOG HREC - Research Review (RR). RR reviews are conducted and written feedback is provided to HREC members via the Agenda of the next HREC meeting. The RR leads the discussion at HREC on these applications.

2. Ethics Review

All comments from the BHSSJOG RR will be documented and filed. All decisions of the BHS SJOG HREC will be included with the HREA application for review and consideration at the next BHS SJOG HREC meeting

3. Research Governance Review (Refer to NS 5.1)

Research governance is defined as the regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality. All low risk and greater than low risk will also undergo research governance review as outlined on the REGO website.

SOP Reference BHSSJOG-2020-SOP8

Title: HREC Review of Research Applications

Purpose: To describe the process of the HREC's consideration of applications

1. The application is reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance; except for those with a conflict of interest, who will leave the room and not participate in the adjudication.

2. The HREC ethically assesses each application in accordance with the NHMRC National Statement on Ethical Conduct in Human Research and other relevant guidelines and legislation. The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.

3. The HREC may also choose to refer the application to an external expert reviewer(s).

4. The HREC must consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.

5. To facilitate the HREC review of applications at least two reviewers/spokespersons (RR) will be appointed to undertake a thorough review of the proposal submitted and to 'marshal' these projects through the committee review. The process is detailed under SOP9:

a) The two spokespersons will provide an in-depth review from different perspectives and present a discussion of the proposed research to the full committee;

b) After both spokespersons have had the support Officer to discuss the research proposal and any concerns or questions, discussion is opened to the full committee with the expectation that at least one member from each category provides a formal comment on the ethical acceptability of the proposed research.

6. The spokespersons and all committee members are provided with a BHS SJOG HREC Review Guide which serves as a prompt to consider the extent to which the research under review reflects the key principles and values outlined in the National Statement. The use of this review guide is strongly encouraged and completed review guides will be retained by REGO as a supplement to the BHS SJOG HREC meeting minutes.

7. The HREC, after consideration of an application at a meeting makes one of the following decisions:

a) To **approve** the project as being ethically acceptable, with or without conditions.

b) To **provide provisional approval** to the project with requested amendments, this may then be reviewed for final approval by the HREC Chair and/or other delegated authority – refer item 10 below.

c) To **resubmit to HREC** as a decision on the project required clarification of information or the provision of further information to the HREC was not acceptable.

d) To **not approve** the project (at this time the researcher may choose to rewrite the protocol in order to make it ethical)

8. The HREC endeavours to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision is considered to be carried by a majority of the members who examined the project. The vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.

9. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.

10. For projects where the HREC has requested clarification, the provision of further information, or amendment of the project, the HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:

a) Chair or Deputy Chair alone

b) Chair or Deputy Chair, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application

c) A sub-committee of the HREC.

d) Minor amendments the Secretary may be provided with delegated authority

In such circumstances, the HREC is informed at the next appropriate meeting, of the final decision taken on its behalf, when the approval will be ratified. The applicant may commence the project once a decision as been made by the delegated officer.

11. If the HREC decides that further information or responses from the investigator (as in Point 6, c & d above) should be considered at a further meeting of the HREC, the PI (and/or delegate) is invited to attend the HREC meeting in order to provide clarification and answer any further questions raised.

12. The HREC delegates the expedited ethical review of low and negligible risk research projects to the Low and Negligible Risk Review Committee.

Low /Negligible Risks Applications submitted to LRRSC

1. The Low Risk Review Sub-Committee (LRRSC) has delegated authority by the BHSSJOG HREC to provide out of session review and approval to low risk research projects.

Low Risk research applications are exempt from full committee review and may be submitted on any date (no applicable deadline) for review by the REGO Office. Applications must be submitted by researchers in the appropriate format and must include all required documentation including:

- LNR Application Form – completed via ERM online forms (required to be signed by the principal investigator, research team)
- Study Protocol
- Research Data Management Plan
- Curriculum Vitae of all members of the research team
- GCP Certificate Mandatory 1 July 2021
- Peer Review Form

Closing dates for receipt of LNR applications as well as guidelines to assist applicants in the preparation of their applications are available to applicants on the REGO website

2. **Negligible risk** research is reviewed out of session by the RGO and members of the LRRSC committee Negligible risk research is exempt from full committee review and maybe submitted on any date (no applicable deadline) for review by the REGO.

3. LRRSC members are provided with an approved template for the review comments. The template reminds the LRRSC of the NS requirements and the agreed time frame for the completion of Low/Negligible applications which is **4 business days.**

The LRRSC decisions are recorded via the following:

a. Approved

b. Approved subject to minor amendments detailed below (Delegated authority to approve amendments – HREC Secretary)

c. **Further Information Requested** (Comments within this section relate to the applicant not satisfying the National Standards for LNR application) – Approval will be delayed until the LRRSC has confirmed all amendments requested on the original "Further Information" request have been completed to their satisfaction. The LRRSC will return their decision within 24 hours.

d. Referred to the next BHHSJOG HREC (LRRSC are required to provide a list of their concerns which align to the NS on why they are referring to HREC)

e. LRRSC Reviews - 3 Reviews no common opinion- Referred to HREC Chair and delegated officer (Member of the Research Office) for review and authority to approve.

The Secretary will refer the LNR application and all supporting documentation to the Chair for review and decision. The HREC chair has delegated authority after considering all documentation to either:

- **Approve**
- **Approve subject to amendments**
- **Recommendation that the application requires resubmission via the HREA form due to risks and submission to the full committee**
- **Not approved as not meeting the National Statement Guidelines - Chair to confirm the NS sections that were not met when confirming this outcome**.

4. Low-/Negligible Risk review is approval in accordance with the National Health and Medical Research Council Act 1992 and the National Statement on Ethical Conduct in Human Research (2007) (Updated 2018). Please refer to the links: for the National Statement : A User Guide: National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 | NHMRC. NS: **Section 2.0;2.1,2.1.1-2.1.8**, **5.1.3, 5.1.5,5.1.18, 5.1.23, 5.1.28 -5.1.33, 5.2.1 (these include 5.1.37 and paragraphs 5.2.6 to 5.2.29.**

SOP Reference BHSJOG-2020-SOP9

Title: HREC Review of Research Applications

Purpose: To describe the process of the HREC's consideration of applications

1. The application is reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance; except for those with a conflict of interest, who will leave the room and not participate in the adjudication.

2. The HREC ethically assesses each application in accordance with the NHMRC National Statement on Ethical Conduct in Human Research and other relevant guidelines and legislation. The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.

3. The HREC may also choose to refer the application to an external expert reviewer(s).

4. The HREC must consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.

5. To facilitate the HREC review of applications at least two reviewers/spokespersons will be appointed to undertake a thorough review of the proposal submitted and to 'marshal' these projects through the committee review. The process is:

a) The two spokespersons will provide an in-depth review from different perspectives and present a discussion of the proposed research to the full committee;
b) After both spokespersons have had the opportunity to discuss the research proposal and any concerns or questions, discussion is opened to the full committee with the expectation that at least one member from each category provides a formal comment on the ethical acceptability of the proposed research.

6. The spokespersons and all committee members are provided with a BHS SJOG HREC Review Guide which serves as a prompt to consider the extent to which the research under review reflects the key principles and values outlined in the National Statement. The use of this review guide is strongly encouraged and completed review guides will be retained by REGO as a supplement to the BHS SJOG HREC meeting minutes.

7. The HREC, after consideration of an application at a meeting makes one of the following decisions:

a) To approve the project as being ethically acceptable, with or without conditions.
b) To provide provisional approval to the project with requested amendments, this may then be reviewed for final approval by the HREC Chair and/or HREC subcommittee.
c) To defer making a decision on the project until the clarification of information or the provision of further information to the HREC.
d) To not approve the project (at this time the researcher may choose to rewrite the protocol in order to make it ethical)

8. The HREC endeavours to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision is considered to be carried by a majority of the members who examined the project. The vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.
9. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.

Submission of Review Template
HREC appointed members will receive the Approved BHSSJOG HREC Review Template to complete. The completion of this form is mandatory and must be provided to the HREC Secretary prior to the scheduled meeting.

SOP Reference BHSSJOG-2020-SOP10

Title: Preparation of HREC Minutes

Purpose: To describe the process and format for minutes of a meeting of the HREC

1. The HREC Secretariat is responsible for preparing and maintaining minutes of all HREC meetings.

2. The minutes include the recording of decisions taken by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.

3. In relation to the review of new applications or amendments, the minutes record a summary of the main ethical issues considered, including any requests for additional information, clarification or amendment of the project.

4. In recording a decision made by the HREC, any vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.

5. To encourage free and open discussion and to emphasis the collegiate character of the HREC, particular views are not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

6. Declarations of conflicts of interest by any member of the HREC and the absence of the member concerned during the HREC consideration of the relevant application are minuted (refer to SOP17: Conflicts of Interest).

7. The minutes are finalised within 5 working days following the relevant meeting including review by the HREC Chair or delegate officer (The Secretary) for accuracy.

8. The minutes are circulated to all members of the HREC once finalised and also as an agenda item for the next meeting. All members will be given the support by the Secretary to seek amendments to the minutes prior to their finalisation. The minutes will be formally approved and signed by the HREC Chair at the next HREC meeting.

9. The signed final copy of each meeting's minutes is retained in an electronic, secure and confidential 'HREC Minutes' file.

SOP Reference BHSSJOG-2020-SOP11

Title: Notification of HREC decisions

Purpose: To describe the procedure for notification of decisions of the HREC concerning the review of new applications

1. The HREC Secretariat reports the HREC decision in writing to the PI (and study contact) within 5 working days of the meeting, unless otherwise notified.

2. If the HREC determines that further information, clarification or amendment is required for the consideration of a project, the correspondence to the PI clearly articulates the reasons for this determination and outlines the information that is required. Where possible, requests for additional information, clarification and/or amendment refer to the National Statement or relevant pieces of legislation.

3. If the requested information is not received from the applicant within 60 days of the letter being sent the project may be dismissed and the applicant may be required to re-submit the project at a later date.

4. The HREC endeavours to openly communicate with researchers to resolve outstanding requests for further information, clarification or amendment of projects relating to ethical issues. The HREC may nominate one (or more) of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.

5. The BHS Research, Research, Ethics and Governance Office notifies the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or amendment have been satisfactorily resolved. Notification of ethical approval is in writing, and contains the following information:

a) Title of project

b) Name of the Principal Investigator

c) Unique HREC project identification number

d) The version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets and Consent Forms, Advertisements, Questionnaires etc.

e) Date of HREC approval.

f) Conditions of HREC approval.

6. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the National Statement or other relevant pieces of legislation. HREC member(s) or BHS Research Office staff may be nominated to work with the researcher to assist in re-submission.

SOP Reference BHSSJOG-2020-SOP12

Title: Submission of Amendments and Renewals

Purpose: To describe the procedure for the submission and HREC review of requests for amendment and renewal (extension) of HREC approval for approved protocols

1. Proposed changes to approved research projects or conduct of the research (amendments) and requests for extensions to HREC approval (renewals) must be submitted by the PI (or study contact) to the Research, Research, Ethics and Governance Office for review.

2. Requests must outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must have the changes highlighted and contain revised version numbers and dates.

3. Requests for amendments and renewals undergo a two-tier review;

Scientific Review:

- Firstly, a scientific review is undertaken by an expert reviewer (or member of REGO).
- For minor amendments and renewals will be processed in 3 days by the HREC Secretary all major amendments will be processed within 10 working days.
- REGO collates the comments, queries and requests for clarification into a letter and reports in writing to the PI (or study contact) within 5 working days. This letter contains instructions for submission for ethical review.
- The PI (or study contact) is responsible for responding to these queries (updating documents where necessary) and submits the amendment via ERM or renewal to the REGO for ethical review.

Ethical review:

An ethical review is conducted by the HREC Chair or delegate (within 3 working days) who is responsible for providing final sign off as per delegation from the BHSSJOG HREC.

REGO reports in writing to the PI and/ or nominated contact person, advising of the ethical approval outcome of the proposed amendment and/or request for extension, within 3 working days of the ethical review.

If ethical comments, queries or requests for clarification are raised these are forwarded to the PI (or study contact) by REG. The PI (or study contact) is responsible for replying to these queries (updating documents where necessary) before final approval can be granted by the HREC Chair.

The HREC Chair reserves the right to escalate any amendment or renewal to the full HREC if it contains major ethical implications.

Renewals to HREC Approval which are more than 6 months expired require full HREC review.

4. If the HREC (or HREC Chair) determines that further information, clarification or amendment is required for the consideration of the request for amendment or extension, the correspondence to the investigator clearly articulates the reasons for this determination and outlines the information that is required. Where possible, requests for additional information, clarification and/or amendment refer to the National Statement or relevant pieces of legislation.

5. Amendment and renewal requests approved by the HREC Chair are ratified by the HREC at a subsequent meeting. Researchers do not need to wait for the HREC ratification to occur before proceeding.

6. Where an urgent protocol amendment is required for safety reasons, the Chair may review and approve the request (with the help of an expert reviewer if necessary). In such circumstances, the amendment or renewal information is tabled at the next HREC meeting.

7. All reviewed and approved requests for amendments and extensions are recorded, and the status of the project is updated by REGO on the ERM database.

SOP Reference BHSSJOG-2020-SOP13

Title: Monitoring of Approved Research

Purpose: To describe the procedure for monitoring research projects approved by the BHSSJOG HREC

The HREC monitors approved projects to ensure compliance with the protocol and relevant legislation and guidelines as per HREC approval. The BHSSJOG HREC mechanisms for monitoring are as follows:

1. Annual Reports (including DSMB reports)

An annual report must be submitted to the Research, Ethics and Governance Office by the PI (or delegate) in April each year. The annual report is submitted via ERM and the deadline for receipt of annual reports is published on the BHS Research Website – 30 April, each calendar year.

The Annual Reports are reviewed by the Research, Ethics and Governance Office within 15 working days of receipt. The Office corresponds with the PI (or delegate) with any queries, comments or clarification required. Once the Annual Report is complete and correct it is listed on the agenda for the next HREC meeting. The HREC may request to review the report and any queries, comments or clarifications raised are sent to the PI by the HREC secretariat within 5 working days. If no queries are raised the Annual Report is accepted and filed.

2. Final Reports

A final report must be submitted to the Research, Ethics and Governance Office by the PI (or delegate) at the completion of a research project or if the project is discontinued or abandoned. The final report is submitted on the ERM Final Report Form. The final reports are reviewed by the Research, Ethics and Governance Office within 5 working days of receipt. The Research, Ethics and Governance Office corresponds with the PI (or delegate) with any queries, comments or clarification required. Once the final report is complete and correct it is listed on the agenda for the next HREC meeting. The HREC may request to review the report and any queries, comments or clarifications raised are sent to the PI by the HREC secretariat within 5 working days following the meeting. If no queries are raised the Final Report is accepted and filed.

3. Serious Adverse Event (and other adverse event) reports. A serious unexpected suspected Adverse Event must be reported in a timely fashion Please refer to the NHMRC guidelines for Reporting & Handling of information.

4. Monitoring & Auditing visits

The BHS Research, Ethics and Governance Office conducts on site monitoring and auditing. The purpose of the auditing program is to review how research is conducted, and to detect, correct and prevent potential and existing problems. The objectives of the auditing program are:

i. To ensure research is conducted ethically, safely, legally and in compliance with the protocol, conditions of HREC approval and institutional policies & procedures.

ii. To raise awareness of requirements and promote researchers' accountability.

iii. To ensure that the conduct of research does not compromise the integrity of the results. All ongoing human research projects with ethics approval granted by the BHSSJOG HREC are eligible to be audited, including clinical trials, observational studies, clinical audit activities and public health research projects. Studies from all tiers of risk (negligible risk, low risk and greater-than-low risk) will be audited, however higher risk studies will be the focus of more audits than those considered to be lower risk.

Projects may be selected for auditing for a variety of reasons:

- Human Research Ethics Committee request
- Following approval of a new protocol;
- As part of the approval process; or
- Due to the classification of risk.
- Random selection
- A complaint i.e. from a participant, parent, fellow researcher
- Annual report verification

SOP Reference BHSSJOG-2020-SOP14

Title: Complaints from Research Participants (Management & Resolution)

Purpose: To describe the mechanism for receiving, handling and responding to complaints from participants concerning the conduct of a project approved by the BHSSJOG HREC

1. Role of the Principal Investigator (PI):

PIs have a responsibility to ensure that their research protocol conforms to the national ethical guidelines and any relevant regulations and has full ethics approval from the relevant HREC.

In doing so the information statements must state that:

- The research participant can contact a member of the study team to obtain further information about a research project or to discuss any concerns or complaints about the project.
- If the participant wishes to speak to an independent person regarding concerns and complaints about the research project then the Manager, Research Ethics & Governance may be contacted directly.

If a member of the study team receives a complaint, the PI should be notified. The PI must act appropriately, impartially and in proportion to the complaint. In most cases, this person will be able to resolve the complaint by addressing the concerns of the complainant.

The PI must also consider that they have a responsibility to determine whether to suspend/modify the research procedure should there be reasonable suggestion of harm to a participant(s) and must report these concerns to the HREC and may seek their assistance.

PI's must inform the Manager, Research Ethics & Governance of all relevant concerns and complaints received or ethical issues raised during the course of their research in a timely fashion. The HREC may impose a penalty on applicants for not reporting relevant concerns and complaints received from participants.

2. Role of the Manager, Research Ethics & Governance

Should the response not satisfy the complainant, the PI should advise the complainant of their right to contact the Manager, Research Ethics and Governance who is responsible for receiving complaints relating to research activity at BHS.

At any-time the PI and/or Manager, Research Ethics and Governance may request assistance from the Consumer Liaison Officer.

The PI must ensure that privacy legislation is adhered to by asking the complainant to directly contact the Manager, Research Ethics and Governance, or seeking written permission to refer a complaint to the complaints officer with any identifying information, as in some cases it could preclude a comprehensive investigation of a complaint.

Complainants can contact the Manager, Research Ethics and Governance to discuss the complaints procedure; however, in most cases only a formal written complaint can be investigated (Exclusion would be if physical disability prevents this and a written record will be taken by the investigator or complaints officer). The complaint and the identity of the complainant will be treated confidentially.

The Manager, Research Ethics and Governance must handle the complaint in a co-operative and sensitive way and in most cases will be able to resolve the matter.

If the complaint cannot be resolved or if the Manager, Research Ethics and Governance determines that further investigation is required (i.e. if the complaint relates to the ethical conduct of a research study) then the HREC Chair will be informed of the complaint.

3. Role of the HREC & HREC Chair

Should the complaint not be resolved (or require further investigation as detailed above), the HREC Chair and Manager, Research and Partnerships will conduct a preliminary investigation into the complaint and determine the appropriate course of action.

If urgent action is deemed to be required, the HREC Chair may take appropriate steps to ensure that the rights and welfare of participants are protected. Such action may include suspending the approval for a research project whilst an investigation is conducted.

Following the initial review of a complaint, possible outcomes are that

1. No further action is required; or

2. There are sufficient grounds to investigate the complaint further.

If a further investigation is warranted, a meeting may be required between the HREC Chairperson or full HREC and the researcher/s. The following procedures which are recommended in the National Statement, may occur:

- Invite the PI to explain the situation to the committee and to demonstrate why the project should not be discontinued and ethical approval withdrawn.
- Advise the PI that they may be accompanied by one or more colleagues including their line manager.
- Reconsider the original research proposal and seek additional information from the PI in relation to the conduct of the study, or any other relevant factors, before making a final decision whether to revise or reconfirm the original decision to approve the project.
- Having considered the matter, the committee may:
    - Withdraw approval and stop the project; or
    - Require amendments to the original research proposal or to the conduct of the research; or
    - Allow the project to continue without amendment; and/or
    - Choose to inform the Researcher’s line manager of their discussion and/or decision.

The HREC should provide the PI and the complainant with an explanation of the outcome. In some cases (e.g. if approval is withdrawn) it may be necessary to notify the other research participants.

In some circumstances, it is recommended that the complainant address the HREC or meet with members of the HREC, depending on whether the complainant would be comfortable in this situation and nature of the complaint, to discuss the concerns.

SOP Reference BHSSJOG-2020-SOP15

Title: Complaints from Researchers (Management & Resolution)

Purpose: To describe the mechanism for receiving, handling and responding to complaints from researchers regarding the HREC review process

1. Any concern or complaint about the HREC review process is to be submitted to the Research Ethics & Governance Manager. This is done in writing and must detail the grounds of the concern or complaint.

2. The Manager, Reserch Ethics & Governance will ask the secretariat of the relevant subcommittee of the HREC to prepare all the material relating to the project (If necessary) and the complaint will be considered by the HREC Chair.

3. If the complaint is in regard to an application which has not been approved by either Committee there are further support offices to negotiate the details involved in the research which will assure compliance with ethical issues. If an application has had conditions placed upon it which the researcher feels adversely affects the quality of the project, the researcher may request that the HREC reconsider its decision. This may involve the researchers being asked to attend a meeting to discuss the project. The Committee may wish to co-opt expert advice at this stage. If the outcome is still considered unsatisfactory, the Chief Executive Officer will be contacted and may review the procedures by which the HREC came to its decision.

4. The National Statement advises that if the matter is not thereby resolved to the satisfaction of the complainant, they may take further steps, including an appeal against the decision. These steps may include the following.

a) The HREC or the researcher may contact the Australian Health Ethics Committee (AHEC) for advice on interpreting NHMRC Guidelines in order to reach an appropriate decision or to help a complainant understand the reasons for the HREC decision.

b) If the complainant(s) are still not satisfied, they may seek a meeting with the HREC Chair (or approved delegated officer), for further clarification. The complainant(s) may be accompanied by one or more support persons, or, in the case of researchers, one or more colleagues. A record of any such meeting should be kept.

c) The institution and the complainant(s) may agree on a person who can take the role of mediator, not necessarily a professional mediator, in an attempt to resolve the dispute. The institution should bear the costs of such mediation.

d) The mediator should consider the complaint, the reason(s) for the committee's original decision (from the minutes of the relevant meeting), the advice, if any, provided by AHEC and the record of the meeting above. Having considered this material, the mediator should then meet with the parties, attempt to facilitate a

resolution of outstanding issues and provide a report of the results of that meeting to the institution.

5. If the matter remains unresolved despite such steps being taken, the final decision rests with the relevant institution. In some circumstances it may be open to a complainant to seek judicial review.

6.The Committee will make every effort to resolve complaints promptly and within a reasonable timeframe as circumstances dictate

SOP Reference BHSSJOG-2020-SOP16

Title: Suspension or Withdrawal of HREC Approval

Purpose: To describe the procedure for suspension or withdrawal of ethical approval by the HREC

1. Where the HREC (or HREC Chair) finds reason to believe that continuance of a research project will compromise participants' welfare, or that a research project is not being or cannot be conducted in accordance with its ethical approval, it should immediately seek to establish whether ethical approval for the project should be suspended or withdrawn.

2. In such circumstances, the Research Ethics & Governance Office/HREC must immediately notify the PI (and study contact) of the suspension of the HREC Approval.

3. An investigator cannot continue with the research if ethical approval has been suspended and must comply with any special conditions imposed by the HREC. The research may not be resumed unless either:

- The investigator subsequently establishes to the HREC that continuance will not compromise participants' welfare and/or is to be conducted in accordance with its ethical approval;
- The research is modified to provide sufficient protection for participants, the amendment is ethically reviewed, and the modified research is approved by the HREC.

4. The HREC, after consideration at a meeting, makes the final decision with regards to reinstatement or withdrawal of ethical approval. The PI (and study contact) is notified in writing of the HREC decision within 5 working days.

5. In the case of withdrawal of ethical approval the HREC will notify the Quality of Care Committee.

SOP Reference BHSSJOG-2020-SOP17

Title: Record Keeping

Purpose: To describe the procedure for the preparation and maintenance of records of the HREC activities

1. The Research Ethics & Governance Office prepares and maintains electronic records of the BHSSJOG HREC activities, including agendas and minutes of all meetings of the HREC.

2. The Research Ethics & Governance Office prepares and maintains a confidential electronic record for each application received and reviewed and records the following information:

- Unique project identification number
- Principal Investigator(s)
- Title of the project
- Ethical approval or non-approval with date
- Approval or non-approval of any changes to the project
- Terms and conditions, if any, of approval of the project
- Whether approval was by expedited review
- Action taken by the HREC to monitor the conduct of the research.

3. The file contains a copy of the application, including signatures (scanned or electronic), relevant correspondence (including that between the applicant and the HREC), all approved documents and other material used to inform potential research participants.

4. All relevant records of the HREC, including applications, membership, minutes and correspondence, will be kept as secure confidential electronic files in accordance with the requirements of the Health Records and Information Privacy Act 2002 (HRIPA).

5. To ensure confidentiality, any documents provided to HREC members, which are no longer, required, are disposed of in a secure manner, such as shredding or placed in confidential bins. HREC Members & Expert reviewers who do not have access to secure disposal give their documents to the Research, Research, Ethics and Governance Office for disposal.

6. Data pertaining to research projects is held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 7 years following the completion of the research or termination of the study. For clinical research, records will be retained for 15 years following the completion of the research

7. The database of all the applications received and reviewed is maintained in accordance with the NHMRC National Statement on Ethical Conduct in Human Research.

SOP Reference BHSSJOG-2020-SOP18

Title: Conflicts of Interest

Purpose: To describe the procedure for the disclosure and management of potential conflicts of interest in research

1. The following process outlines the procedure for the disclosure and management of potential conflicts of interests in research within the BHSSJOG HREC. In all cases committee members are not required to detail the conflict of interest if they choose not to, but must state they have one. Conflicts of interest which are not detailed will be assumed as 'actual' conflicts of interest (in lieu of an explanation otherwise).

2. The process for the disclosure and handling of potential conflicts of interest of HREC members is as follows:

a) HREC Members are asked to declare any conflicts of interest at the time of their appointment or as they arise during their appointment.

b) Conflicts of interest that do not relate to a specific research project must be notified to the HREC Secretariat (Research Ethics & Governance Office) by the member.

c) For conflicts of interest that relate specific research projects the HREC Chair calls for members to declare these at the beginning of the HREC meeting.

d) A HREC member must, as soon as practicable during the HREC meeting, inform the Chair if he/she has a potential conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.

e) If the member details the perceived conflict of interest then it is the responsibility of the HREC to determine if the declaration is an actual conflict of interest for the member. If so, the member will withdraw from the meeting until the HREC consideration of the relevant matter has been completed. The member is not permitted to adjudicate on the research.

f) Written reviews/comments from (absent) HREC members are to include a full disclosure of any potential conflict of interest, financial or otherwise, in a project or other related matter(s) under consideration by the HREC. The HREC will determine if the conflict of interest renders the review/comments unacceptable.

g) The existence of all conflicts of interest which are declared (and details where given) and the absence of member(s) during the consideration of relevant matters are recorded.

3. Expert Reviewers who review projects make a full disclosure of any potential conflicts of interest, financial or otherwise, prior to reviewing a project. The process for handling the conflicts of interest of expert reviewers is as follows:

a. If the Manager, Research and Partnerships deems these to be actual conflicts of interest then the reviewer is not chosen to conduct the review and another reviewer is found.

b. If the Manager, Research and Partnerships determines that the conflict of interest is a perceived conflict but not an actual one then the reviewer conducts the review and records the perceived conflict of interest on the Reviewer Template.

c. If a review has already been submitted and a declared or known conflict of interest becomes apparent then the conflict of interest is documented. It is the responsibility of the Manager, Research and Partnerships and/or HREC Chair to determine if the conflict of interest renders the review unacceptable. If so, another reviewer is found.

4. The process for handling potential conflicts of interest from researchers involved in research is as follows:

a) Researchers are required to make a full disclosure of any potential conflicts of interest, financial or otherwise, when applying for BHSSJOG HREC approval (in the ERM coversheet)

b) Strategies for addressing the perceived, actual or potential conflicts of interest are to be discussed, agreed and documented between the researcher and the BHSSJOG HREC.

This may include, but is not limited to the following:

a. Public disclosure of the researcher's financial or other interest in the research.
b. Public disclosure of the researcher's financial interest in the commercial success of any therapeutic outcome or product resulting from the research.
c. Independent monitoring of the research project.
d. Amendment of the researcher responsibilities as per the protocol.
e. Exclusion of the Researcher from participating in all or a portion of the research.

SOP Reference BHSSJOG-2020-SOP19

Title: Research which is exempt from BHSSJOG HREC Review

Purpose: To describe the procedures for determining which projects are exempt from HREC review

1. A research project may be exempt from review if the research falls out of the BHSSJOG HREC jurisdiction (or simply does not require HREC review) such as:

a) The project is a collaboration to share non-identifiable data collected from an approved research project (please note this is subject to the informed consent conditions, if applicable).

b) The project proposes to use BHS as a recruitment tool (i.e. through a currently established database, or posting flyers in the hospital) however the research is being conducted by a separate institution.

2. In these cases the PI must email (or mail) the Research Ethics & Governance Office providing an explanation on the project and why it falls into one of the above categories and include necessary documentation as follows:

a) Approval certificate from reviewing HREC

b) Protocol

c) Information letter or flyer to be used at BHS (if applicable)

d) Material Transfer or Collaboration Agreement (if applicable)

3. The PI will be notified via email from REGO within 5 working days as to whether their application has been exempted from review or whether clarification is required.

4. If the application is exempt from review, an Exemption Letter will be provided to the PI (or study contact) by the REGO Manager. The PI may then conduct their research without BHSSJOG HREC Approval.

5. REGO will include the project on the Exempt from Review database

SOP Reference BHSSJOG-2020-SOP20

Title: Quality Assurance Process for HREC Information

Purpose: To describe the procedure for the submission of QA applications.

Quality Assurance - All projects including Quality Assurance (QA), quality improvement, or audit activities, where there is an intention to publish or otherwise present the data beyond the hospital staff, must be submitted prospectively to the RGO Unit for review.

The National Statement on Ethical Conduct in Human Research (NS), Section 5.1, states that research that involves no more than low risk research (including QA and negligible risk research) 'must be reviewed by people who are familiar with the NS and have an understanding of the ethical issues that can arise; and have due regard to privacy regulations (laws) and is reviewed to ensure that it does not require review by the Human Research Ethics Committee (HREC).

Quality Assessment & Evaluation

The BHSSJOG HREC will be advised of all applications approved under this category by the RGO. The National Health and Medical Research Council (NHMRC) recognises the important contributions that quality assurance (QA) and evaluation activities make to better outcomes, and more efficient and effective work processes. However, there can be uncertainty about what level of oversight QA and evaluation activities require and there can be confusion about whether an activity is research or evaluation or QA. This can be because QA and evaluation activities may include the use of methods or approaches also used in research such as surveys and observation.

Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as ‘peer review’, ‘quality assurance’, ‘quality improvement’, ‘quality activities’, ‘quality studies’ and ‘audit’ are often used interchangeably. In this document the term ‘quality assurance’ is used to include all of these terms. The RGO has prepared a QA application form and an evaluation checklist for use within the RGO for assessment.

To be eligible for Quality Assurance, the project **MUST NOT:**

Aim to generate new generalizable knowledge

Involve any significant departure from the routine clinical care provided to patients

Involve randomisation, control groups, or use of placebo

Seek to gather information about the participant beyond that collected as part of routine care

Involve additional testing, blood or tissue collection

Involve the assessment of safety/efficacy of a new intervention/device

Impose any additional burden, harm or risk, beyond those associated with routine care

Evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives.

SOP Reference BHSSJOG-2020-SOP 21

Title: HREC For Information

Purpose: To describe the procedure for Insurance, Indemnity, Research Agreements and the Victorian Managed Insurance Authority

Statement of Intent and Outcomes

The Ballarat Health Services & St John of God Hospital Human Research Ethics Committee is committed to fulfilling the Australian Code for the Responsible Conduct of Research (2007) and all updates, The National Statement on Ethical Conduct in Human Research (2007) and all updates, and the requirements of the Victorian Managed Insurance (VMIA) by providing a framework for the review of insurance, indemnity and research agreements.

Procedure

As the Hospital's insurer, VMIA has released specific guidelines to guide the process of review for sponsored and collaborative clinical research, which involve clinical trials notification.

Clinical Trials Notification Form

Clinical trials which involve the use of unapproved drugs and devices, including those being used outside of their approved indications, must be notified to the Therapeutic Goods Administration in accordance with all statutory and regulatory requirements. This must be signed by the reviewing HREC and the responsible institution.

Indemnity

All clinical trials involving a commercial Sponsor must provide indemnity in a form no less favourable than the current version Medicines Australia Form of Indemnity for Clinical Trials.

Both commercial Sponsorship and the indemnity must be provided by an Australian corporate entity. The reason for this is both legal and practical. If an indemnity is provided from an overseas-based corporation, with no assets or other presence in Australia, there are major (sometimes insurmountable) problems to be faced, particularly in relation to a corporation based in the USA, if the VMIA or a hospital has to enforce the indemnity. In many cases, enforcement proceedings would have to be instituted, at vast cost, in a foreign jurisdiction.

Where there is no Australian related corporate entity of the relevant overseas corporation, the services of an Australian corporate research organisation may be utilised to conduct the Trial in Australia. In that case, the research organisation is the Commercial Sponsor and must provide an indemnity. Any indemnity provided by a corporate research organisation must be provided by it in its own right. It is not acceptable for the corporate research organisation to provide the indemnity as agent of the overseas company.

Where the involvement of a hospital is limited to ethical review by its HREC Clinical trials are sometimes conducted by private hospitals or practitioners in private practice. Some of these clinical trials are reviewed (for the purposes of obtaining any requisite ethical approval) by a public Hospital's HREC. The Commercial Sponsor's indemnity must name and fully indemnify the public hospital and its agents and servants for their participation and possible legal exposure in providing ethical review of a trial. An indemnity must be provided by the Commercial Sponsor in a form no less favourable than the "Form of Indemnity for Clinical Trials HREC Review Only"

Insurance

For all Sponsored clinical trials, a current Public/Products Liability (or its equivalent) Certificate of Insurance from the Commercial Sponsor must be obtained.

To comply with the minimum insurance requirements, sponsored research must provide a copy of the certificate of currency (or insurance certificate) which contains the following information:

- The type of insurance – Public and Product Liability – or equivalent such as General Liability or Clinical Trials Insurance
- The full legal name of the Australian entity acting as the sponsor

The full legal name of the insurer (which must be approved by the Australian Prudential Regulation Authority or a foreign equivalent). All insurers are required to hold Standard & Poor's financial rating of not less than 'A-'.

- The period of insurance
- That the insurance coverage allows for a minimum of A$10 million for any one occurrence and in the annual aggregate
- That the insurance coverage contains an excess/deductible, or self-insured retention amount greater than A$25,000 for each and every claim or series of claims arising out of one original cause.

Additional information regarding the level of insurance and indemnity required can be obtained from the Victorian Managed Insurance Authority (VMIA) Clinical Trials Guidelineshttp://www.vmia.vic.gov.au/Risk-Management/Clinical-trials/clinical-trial-notification-guidelines.aspx

Clinical Trial Research Agreements

The Sponsor of the trial is the company, institution or organisation that takes overall responsibility for the conduct of the Trial and usually initiates, organises and supports a clinical study of an investigational product in human subjects. The Sponsor must be an Australian company or entity.

A written agreement between Ballarat Health Services and the Sponsor must always accompany a clinical trial; including, where relevant, a Commercial Sponsor which sets out the responsibilities of each party.

Medicines Australia Clinical Trial Research Agreements must be used for clinical trials. The use of the CTRAs should, in most cases, obviate the need for Institution to obtain extensive legal advice in relation to a Clinical Trial Research Agreement.

Commercially Sponsored CTRA

The Commercially Sponsored CTRA is to be used when an Australian pharmaceutical company or an Australian subsidiary of an international pharmaceutical company acts as the Sponsor for the purposes of the clinical trial.

The parties to the Commercially Sponsored CTRA are the Sponsor and the investigating institute.

The Principal Investigator is not a party to the CTRA. However, the Principal Investigator may sign the CTRA to acknowledge the obligations it imposes. The substantive provisions of the Commercially Sponsored CTRA must not be amended. Any minor amendments that may be required to accommodate any operational requirements of either party can be made through Schedule 7.

Corporate Research Organisation (CRO) CTRA

The CRO CTRA is to be used where an entity/ company that is not an Australian resident wishes to initiate a clinical trial and engages a CRO (that is an Australian entity) to act as the Sponsor for the purposes of the CTN application. The CRO becomes, and assumes all responsibilities and obligations that attach to, a Sponsor.

As Sponsor, the CRO must: Provide a Medicines Australia Form of Indemnity in favour of the Institution. Provide evidence of insurance arrangements that meet the minimum requirements of VMIA. It is acceptable for the CRO to be a named additional insured under an insurance policy of an organisation that is not an Australian entity/company.

The substantive provisions of the CRO CTRA must not be amended. Any minor amendments that may be required to accommodate any operational requirements of either party can be made through Schedule 7.

Collaborative Research Group (CRG) CTRA

The CRG CTRA is to be used when a collaborative/ cooperative research group is the Sponsor of the clinical trial. The substantive provisions of the CRG CTRA must not be amended. Any minor amendments that may be required to accommodate any operational requirements of either party can be made through Schedule 4.

Schedule 7 (Commercially Sponsored and CRO CTRA) and Schedule 4 (CRG CTRA)

Schedule 7 of the Commercially Sponsored CTRA and Schedule 4of the CRG CTRA may be used to incorporate into a CTRA any unique operational requirements that are required by a party to allow the conduct of the clinical trial.

Schedules 7 and 4are not to be used to substantially amend the CTRA or to introduce provisions that contradict or otherwise undermine the substantive provisions or intent of the CTRA.

The VMIA has approved a number of Schedule 7provisions submitted by individual commercial sponsors for the Commercially Sponsored CTRA. The approved Schedule 7clauses have been issued to both the health services and the respective commercial sponsor. There will be commercial sponsors that have not submitted Schedule 7provisions for review by the VMIA. Given the substantial collection of Schedule **7** approved clauses, it is reasonable for an Institution to assess the acceptability of any request by such commercial sponsor against the existing approved Schedule 7database provided by VMIA.

Subcontracting Commercially Sponsored and CRO CTRA

If a Commercial Sponsor or a CRO intends to subcontract any of its functions under a CTRA, the following clause can be used by way of Schedule 7:

"The Local Sponsor/CRO may subcontract any of its obligations under this Agreement, save for the obligations set out in clauses 5.1(8), 5.1(9) and 5.1(10) of the Agreement. The Local Sponsor remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the Local Sponsor's acts and omissions. No subcontractor will have any rights under this Agreement against the Institution or be entitled to receive any payment from the Institution."

CRG CTRA

If a CRG intends to subcontract any of its functions under a CTRA, the following clause can be used by way of Schedule 4:

"The CRG may subcontract any of its obligations under this Agreement, save for the obligations set out in clause 10 of the Agreement. The CRG remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the CRG's acts and omissions. No subcontractor will have any rights under this Agreement against the Institution or be entitled to receive any payment from the Institution."

Associated Procedures/Instructions

Nil

Reference Documents

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 (Cth) and all updates
- Australian Code for the Responsible Conduct of Research (2007) and all updates
- VMIA Research Governance Toolkit; VMIA Guidelines for Clinical Trials

SOP Reference BHSSJOG-2020-SOP 22

Title: HREC - For Information

Purpose: Streamlining Ethical Review of Research Projects in Victoria and as part of the National Mutual Acceptance

BHS is a signatory to this agreement

These Standard Operating Procedures (SOPs) describe the procedures and processes in place for the system of streamlined ethical review of multi-site research projects in Victoria and under the National Mutual Acceptance (NMA) initiative.

These SOPs describe the regulatory aspects of a clinical trial or health/medical research project. For guidance on the conduct of research, contact your organisation's research office or visit http://ichgcp.net.

These SOPs provide guidance only; they do not describe research processes in their entirety, and should not be relied upon as a sole source of information for conduct of a research project.

These SOPs provide general guidance for investigators, trial coordinators, sponsors, CROs and other parties in all sectors of clinical, health and medical research. Specific SOPs are also available for *Coordinators of Reviewing HRECs* and *Research Governance Officers*.

Research on humans must be conducted in a safe and ethically responsible manner. Ethical and scientific review should be in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007).

For detailed guidance on research governance and site-specific assessment (SSA), refer to *Research Governance and Site-Specific Assessment – Process and Practice* (available to download from the websites below).

For queries regarding these SOPs, or the ethics and governance processes for research projects in

Victoria and NMA, please contact the Coordinating Office. Tel. 039096 7398 or email multisite.ethics@dhhs.vic.gov.au.

Clinical Trials and Researchwebsite:www2.health.vic.gov.au/about/clinical-trials-and-research/clinical- trial-research

SOP Reference BHSSJOG-2020-SOP 23

Title: HREC for Information

Purpose: The appointment of Honorary (Affiliate) Researcher

Rationale

Ballarat Health Service recognises the importance of working in partnership with representatives from other organisations to undertake research activities to support the accomplishment of its mission, vision and values.

The BHS board and executive support and encourage the participation and interest of honorary appointments in BHS research activities

Ensuring a formal pathway exists for the onboarding of external unpaid researchers is essential to good research practice and minimises organisational risk

Expected Objectives / Outcome

- To provide a mechanism whereby external individuals undertaking research activities with BHS staff can be granted appropriate access to BHS systems and information
- To facilitate monitoring and reporting of the BHS research activities underway
- To manage the risk associated with external individuals undertaking research activities within or for BHS.

Definitions

Honorary (Affiliate) Researcher: Honorary (Affiliate) Researcher appointments are made to the following individuals:

- Individuals who wish to perform research at Ballarat Health Services at the recommendation of an approved Affiliate; A copy of the current MOU or Research Collaboration agreement will be required as evidence of the affiliation agreement to conduct research activities in a non-clinical capacity.

Issues to Consider

This guide in conjunction with the related documents listed below have been developed with the aim of ensuring the right appointment and balance of staff in terms of skills and experience are appointed in an honorary affiliate research capacity. These appointments are to enhance BHS and their individual research performance.

A copy of a current contract that details will be required. The signed agreement must detail such appointees with BHS. These appointments as honorary affiliates research staff will participate only in approved ethics research activities.

These appointments will normally be targeted via an approved Human Research Ethics Application which requires access to patient records.

Detailed Steps, Procedures and Actions

The selection process is concerned with eliminating unsuitable applicants and ultimately offering research honorary appointments to a single applicant.
A comprehensive selection processes requires each applicant completes the approved application form which will include written evidence of the following elements:

- reviewing resumes
- Copy of the approval to conduct research approved by the BHHSSJOG HREC
- evidence of research training; completion of the following degrees, Honours degree, Masters by research and Doctor of Philosophy.
- Completion of training for Good Clinical Practice (GCP)- copy of certificate
- reference checking (mandatory)
- "**Statutory Declaration**" for applicants/staff that have worked or lived in another country other than Australia since turning 16 years of age.
- Valid Research Contract either Memorandum of Understanding or Research Collaboration Agreement
- Term to be confirmed eg. Either 12 months or for the term of the approved Ethics Research Project.

It is essential that all decisions throughout the selection process are research related, valid and non-discriminatory, with adequate record keeping maintained to justify each decision.

The Research (Affiliate) Honorary Appointment Committee will comprise of the following members:

Principal Investigator at BHS

Secretary Ballarat Health Services & St John of God Human Research Ethics Committee or Governance Officer for the Research Ethics and Governance Department.

Manager, Research & Partnerships Chair

Final Approval: Manager, Research & Partnerships