ST JOHN OF GOD
Health Care

Research Handbook

and Useful Forms

Research Governance Framework and
Guidelines for Conducting Human Research
at St John of God Health Care

Last Updated October 2017

PREAMBLE

The *SJGHC Research Handbook* has been compiled to facilitate and streamline the process of conducting human research at St John of God Health Care (SJGHC), from initial approval through to completion. It provides information to researchers on the SJGHC research governance framework, including how to obtain initial and ongoing approval for research at SJGHC. The *SJGHC Research Handbook* contains the Terms of Reference of the SJGHC Human Research Ethics Committee (HREC) and details the guidelines, policies, procedures and other reference material for an understanding and appreciation of the implications of research and research conduct at SJGHC.

The *SJGHC Research Handbook* should be read by all researchers intending to conduct human research at SJGHC. Researchers should also familiarise themselves with the following key documents:

1. *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007)
2. *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* (CHA, 2001).
3. *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007)
4. Section 95(A) of *Privacy Act* (1988)

The *SJGHC Research Handbook* will be revised on a regular basis and is intended to be used as a reference document only. Please do not print it out. Individual forms, checklists and documents may be downloaded from the SJGHC website. Please refer to this website regularly to ensure that the latest versions of forms/documents are used.

Index

This document is hyperlinked. To jump to a section, click on the title from the list below, or use the bookmarks to navigate through the document.

AMENDMENTS

- Research Amendment Submission Process
- Adverse Event Process
- Protocol Deviations and Violations

SJGHC REQUIREMENTS

- Fostering Clinical and Health Service Research at SJGHC
- Time Limits on Research
- Research Data Management and Retention
- Electronic Signatures for Submissions to SJGHC HREC
- Research Conduct
- Statement of Medico-Moral Principles
- Catholic Health Care Philosophy Statement
- Clinical Trial Research Agreements – Legal and Insurance Guidelines
- SJGHC CTRA Templates
    - SJGHC CTRA Template – Phase I-III, Commercial, Employed PI
    - SJGHC CTRA Template – Phase I-III, Commercial, Accredited PI
    - SJGHC CTRA Template – Phase I-III, CRO, Employed PI
    - SJGHC CTRA Template – Phase I-III, CRO, Accredited PI
    - SJGHC CTRA Template – Phase I-III, CRG, Employed PI
    - SJGHC CTRA Template – Phase I-III, CRG, Accredited PI
    - SJGHC CTRA Template – Phase IV, Commercial, Employed PI
    - SJGHC CTRA Template – Phase IV, Commercial, Accredited PI
    - SJGHC CTRA Template – Phase IV, CRO, Employed PI
    - SJGHC CTRA Template – Phase IV, CRO, Accredited PI
    - SJGHC CTRA Template – Investigator Initiated
    - SJGHC CTRA Template – Device (MTAA)
    - SJGHC CTRA Template – Registry, Employed PI
    - SJGHC CTRA Template – Registry, Accredited PI
    - SJGHC Material Transfer Agreement Template

List of Abbreviations

A&TSI	Aboriginal & Torres Strait Islander
ACHS	Australian Council of Health Standards
ACU	Australian Catholic University
AHEC	Australian Health Ethics Committee
ANZCTR	Australian New Zealand Clinical Trials Registry
APP	Australian Privacy Principles
ARC	Australian Research Council
ASR	Annual Safety Report
CAPA	Corrective and preventive actions
CEO	Chief Executive Officer
CHA	Catholic Health Australia
CPI	Co-ordinating Principal Investigator
CRM	Clinical Risk Management
CRG	Collaborative or Cooperative Research Group
CRO	Contract Research Organisation
CT	Computed Tomography
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
CTX	Clinical Trial Exemption
DOHWA	Department of Health Western Australia
EO	Executive Officer
GCP	Good Clinical Practice
GCRP	Good Clinical Research Practice
GST	Goods and Services Tax
HR	Human Resources
HREA	Human Research Ethics Application Form
HREC	Human Research Ethics Committee
IB	Investigator's Brochure
ICH-GCP	International Conference of Harmonisation - Good Clinical Practice
ICMJE	International Committee of Medical Journal Editors
IDMC	Independent Data Safety Monitoring Committee

IP	Intellectual Property
LOD	Learning and Organisation Development
MRI	Magnetic Resonance Imaging
MTA	Material Transfer Agreement
MTAA	Medical Technology Association of Australia
NHMRC	National Health and Medical Research Council
NMAHPSRC	Nursing, Midwifery, Allied Health and Pastoral Services Research Council
PI	Principal Investigator
PICF	Participant Information and Consent Form
PSOA	Participating Site Operational Approval
QI	Quality Improvement
SAE	Serious Adverse Event
SJG	St John of God
SJGHC	St John of God Health Care
SOP	Standard Operating Procedure
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SRC	Scientific Review Sub-committee
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
WHO ICTRP	World Health Organisation International Clinical Trials Registry Platform

Pathways of Ethical Review at SJGHC

The following forms of approval are required before a research project can commence at SJGHC:

PARTICIPATING SITE OPERATIONAL APPROVAL

All submissions, regardless of level of risk, require Participating Site Operational Approval before research can commence at SJGHC. This is obtained by completing a Participating Site Operational Approval Form (PSOA) which should be signed by the head of all relevant departments/services (e.g. health records) to be utilised in the research project and the Divisional CEO/relevant director. The PSOA functions as governance approval for the study.

LEGAL APPROVAL (IF APPLICABLE)

All studies that are "More than Low Risk" also require approval by SJGHC Legal Services of the insurance, indemnity and contractual arrangements for the research. Some "Low Risk" studies may also benefit from a legal agreement prior to commencement, e.g. when there is a possibility that significant new Intellectual Property (IP) will be created by the project. The SJGHC Ethics Office can be contacted in the first instance for further details regarding this process.

ETHICAL APPROVAL

All submissions, regardless of level of risk, require ethical approval before research can commence. Ethical approval is granted in writing by the SJGHC Human Research Ethics Committee (HREC) within approximately a week of the HREC meeting/out of session review, and confirms that the research proposal is ethically viable.

"More than High Risk" projects undergo a full review process: these are first tabled at the Scientific Review Sub-committee (SRC), which review studies for scientific merit, validity and safety. The SRC meets approximately a month prior to the HREC, to allow researchers to reply to any major queries.

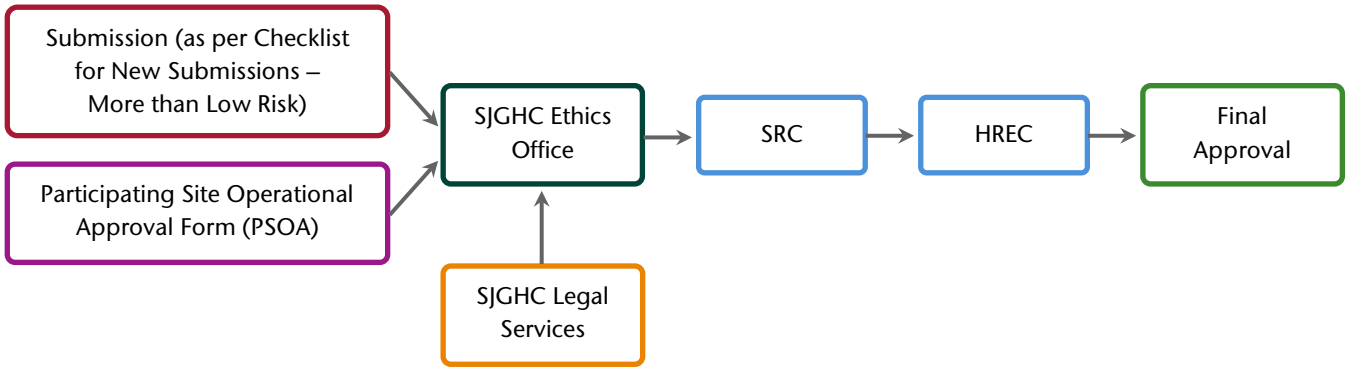
"Low risk" research (broadly defined as research where the only foreseeable risk is discomfort) and "More than High Risk" research previously approved by an NHMRC-accredited HREC (as per the Checklist for New Submissions - Expedited Review) may undergo an expedited review process. Projects are reviewed and granted approval out of session by a sub-group of the HREC and/or SRC, and are then tabled at the next HREC meeting for the information of the Committee only.

"Negligible risk" research (broadly defined as research where there is no foreseeable risk of harm or discomfort) is reviewed for approval out of session by the Chair of the SJGHC HREC, and then tabled at the next HREC meeting for the information of the Committee only.

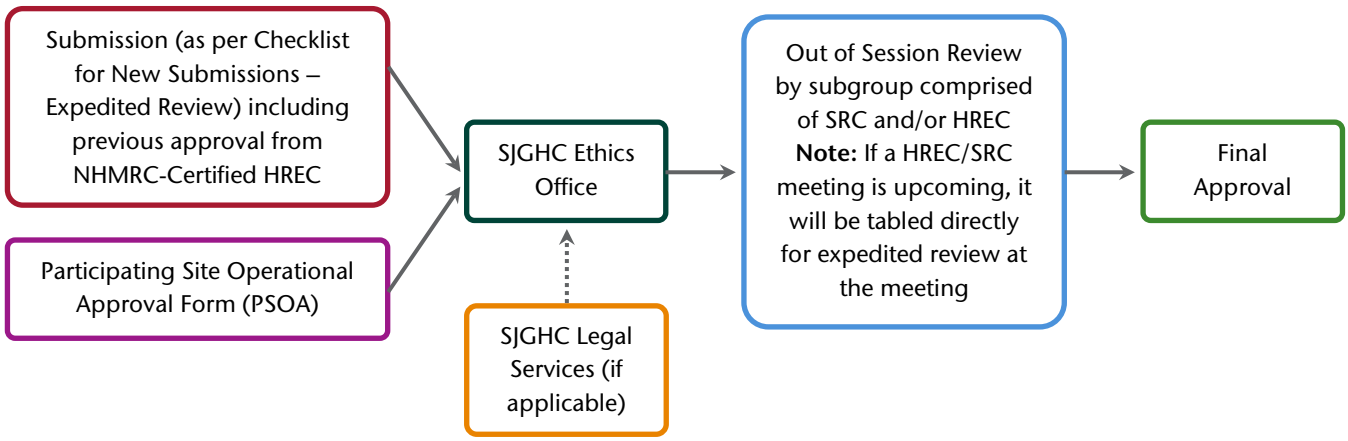
FINAL APPROVAL

All submissions, regardless of level of risk, require final approval before research can commence. The SJGHC Group Director of Medical Services (as the delegate of SJGHC) confirms final study approval in writing once Ethical Approval, Participating Site Operational Approval and Legal Approval (if applicable) have been granted. As the SJGHC Ethics Office keeps a record of all these approvals, it is important that all approvals are communicated to the SJGHC Ethics Office.

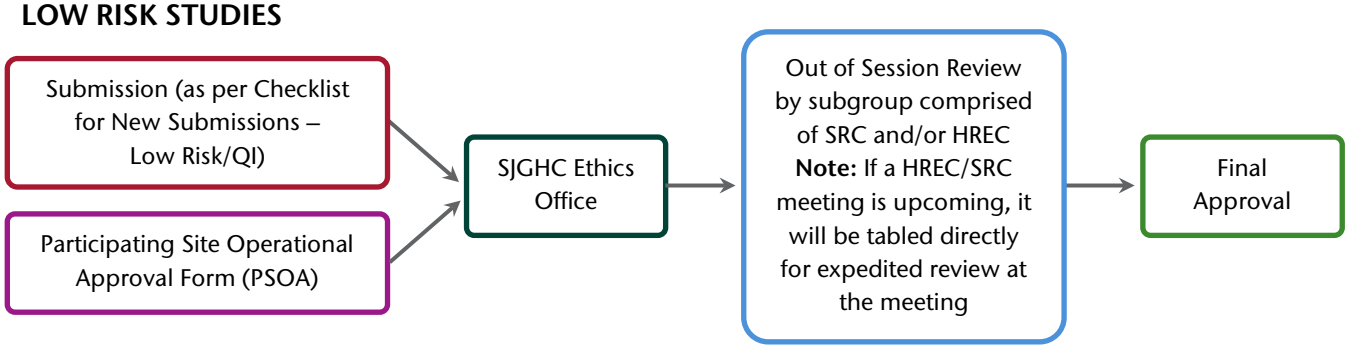
MORE THAN LOW RISK STUDIES



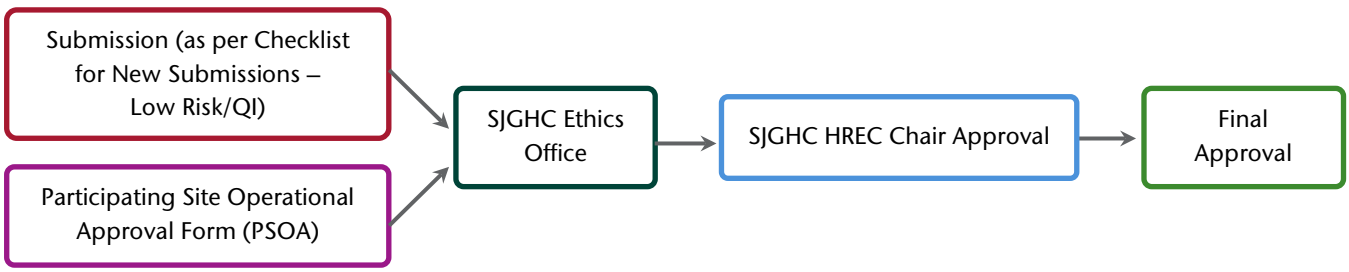
PREVIOUSLY APPROVED STUDIES



LOW RISK STUDIES



NEGLIGIBLE RISK STUDIES



SJGHC Human Research Ethics Committee Terms of Reference

AIM

The St John of God Health Care Human Research Ethics Committee ("the Committee") aims to facilitate and support the development of a strong culture of research ethics within the organisation.

PHILOSOPHY

St. John of God Health Care (SJGHC) is a ministry of the Catholic Church and has the dignity of all human life at the core of its Mission and Values. The Committee is committed to observing the *Statement of Philosophy and Statement of Medico Moral Principles* (Bishops of Western Australia) and the *Code of Ethical Standards* (Catholic Health Australia, 2001) as it applies to human experimentation and human research ("research").

The Committee is an approved Human Research Ethics Committee (HREC) properly constituted and operating in accordance with National Health and Medical Research Council (NHMRC) guidelines. It is guided by the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and subsequent editions ("the National Statement"), the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007) ("the Code") as well as other relevant codes and regulatory requirements.

The Committee and the Scientific Review Sub-Committee (SRC) along with researchers and SJGHC (as the organisation), share the responsibility for the ethical design, review and conduct of research. However, ultimate accountability for research – ethical acceptability and research governance (i.e. scientific quality, safety, privacy, risk management, financial management and operational management) rests with SJGHC. The *SJGHC Research Handbook* (latest edition) details the SJGHC Research Governance Framework.

ACCOUNTABILITY

The Committee is accountable to the SJGHC Governing Board via the Group Chief Executive Officer ("Group CEO").

ROLE

The Committee has two key roles:

1. a research ethics role for SJGHC Divisions; and
2. a national research ethics role as a "reviewing HREC" committed to facilitate the efficient and effective ethical review of (multi-centre) research conducted throughout Australia. Specifically, SJGHC's certification status under the NHMRC National Certification Scheme of Institutional Process Related to the Ethical Review of Multi-centre Human Research, means that the Committee can conduct a single ethical review for other Australian institutions/researchers of their research/multicentre research in the following categories: Clinical Trials Phase 0, I, II, III and IV, clinical trials drugs and devices, clinical trials surgery, clinical trials other, clinical interventional research other than clinical trials, population health and/or public health, qualitative research,

mental health and other health and medical research including genetic, pathology/biobank studies.

PURPOSE

The purposes of the Committee are:

1. To promote ethical decision-making in research within SJGHC that is guided by Catholic moral principles and values, through:
    a. policy and protocol review and development for the whole of SJGHC
    b. addressing issues of research ethics
2. To encourage a culture of research ethics within SJGHC through:
    a. raising awareness and understanding of research ethics issues
    b. providing caregivers and researchers with guidance on the conduct of ethical, high quality research.
    c. encouraging caregivers and researchers with both conducting and participating in research and the translation of research results into improvements in health care and health service management.
3. To formally review for ethical approval research proposals to be conducted at SJGHC and at any other organisation where it has been agreed that the Committee will conduct such review on its behalf.
4. To work as part of the SJGHC Research Governance Framework (as outlined in the *SJGHC Research Handbook*) to ensure all research is reviewed from a scientific/medical, operational, legal and ethical perspective before final study approval is granted.
5. To maintain an electronic database and archived records as per the Code, of all SJGHC approved research.
6. To monitor approved research in unison with the participating site(s).
7. To advise SJGHC and its Divisions as applicable, on any Committee recommendations to revoke a research study on ethical grounds. However, if the Committee or SJGHC through the participating SJGHC Division(s), considers that urgent suspension of research is necessary, the instruction to stop is to come from the participating site (refer to *Research Conduct* in the *SJGHC Research Handbook* for more details).
8. In unison with SJGHC and its Divisions, and as per the *National Safety and Quality Health Service Standards* and the *Australian Council of Health Standards (ACHS) EQuIP National Accreditation Guide* (and subsequent editions), to foster and encourage a SJGHC research program that ideally is driven by clinical needs, and for which research outcomes are implemented throughout the organisation with the aim of ultimately improving the quality of clinical care to SJGHC patients:
    a. Publication of Committee activities and details of SJGHC approved research (with prior permission of the researchers).
    b. Intranet and internet research ethics and research governance information and resources for caregivers and external researchers, respectively.

PRESENTATION OF RESEARCH PROTOCOLS

All research protocols presented to the Committee are to include a completed application form, and to follow the procedures set out in the *SJGHC Research Handbook* distributed to researchers on inquiring about the application process. Details of Committee decision-making and research monitoring processes, as well as the process for addressing complaints about the Committee, are outlined below.

SJGHC HREC APPROVAL AND MONITORING OF RESEARCH

In deliberating on research, the Committee can arrive at any of the following decisions:

1. Ethical approval granted with a recommendation for final study approval;
2. Conditional ethical approval granted (stating each of the conditions on which approval is granted);
3. Ethical approval withheld (stating the reason(s) which are linked to the National Statement);
4. Ethical approval revoked (stating the reason(s) which are linked to the National Statement).

The SJGHC HREC notifies researchers promptly, and in writing, of the Committee's decisions. Final study approval (which is in inclusive of ethical and governance approval, namely operational and any legal approvals) is granted in writing by the SJGHC Group CEO and/or his delegate. In the case that ethical approval is revoked, this is communicated by the SJGHC HREC in writing to the researcher and the SJGHC Group CEO and/or his delegate. The SJGHC Group CEO and/or his delegate will then revoke final approval of the study, and communicate this in writing to the researcher.

As a standard condition of final approval, SJGHC requires that researchers report to the Committee SRC) and the participating SJGHC Division(s) immediately anything that might warrant review of approval of the research protocol:

1. serious, adverse or unexpected effects on participants ("SAEs");
2. proposed changes in the protocol or in key research personnel;
3. Unforeseen events that might affect continued ethical acceptability of the study.

The SRC reviews all SAEs and reports these to the Committee, noting if there is any action required.

In addition to the above, SJGHC requires as part of its monitoring process, that researchers report on the progress of their research at least annually to both the Committee (via the SRC) and the participating SJGHC Division(s). Specifically, researchers in their study progress reports must address any issue(s) raised by the Committee (or its sub-Committee) with the original research proposal, as well as any of the conditions of approval imposed by the Committee.

Via the SRC, SJGHC may also adopt other processes for monitoring research progress e.g. audits of study documentation processes.

Finally, researchers are advised to make research participants aware that a confidential complaints system is available to them. Any complaints from research participants regarding an approved research project (i.e. complaints about the researchers and/or the conduct of the research) can be notified to the Executive Officer (EO) of the Committee (refer to the SJGHC "Research Conduct Policy" for more details).

COMPLAINTS

All complaints about the conduct of the Committee and SRC in reviewing research proposals, should be made in writing, and follow a process as such:

1. The complainant should initially direct the complaint to the Committee Chair to be resolved through the normal Committee process. The Chair will consider the complaint and propose a course of action in liaison with the complainant, and report the proposed action at the next Committee meeting, before its implementation.
2. Should the complainant remain dissatisfied with the action taken, then the complaint should be directed to the Group CEO or his/her nominee to be dealt through SJGHC's general complaints process.
3. In the event that resolution is not achieved by either of the above processes, the complainant should seek advice external to SJGHC.

REPORTING

Committee Reporting to the Group Director Medical Services

The Committee agendas and minutes are distributed to, and discussed with the Group Director of Medical Services who has the delegated institutional authority to grant final approval of human research conducted at SJGHC.

Committee Reporting to the SJGHC Group CEO

The Committee reports the research ethics activities for the organisation at least annually, to the SJGHC Group CEO, who presents this to the Governing Board. Reports may also include information on ethical issues that are of concern to SJGHC.

Committee Reporting to the NHMRC

The Committee complies with all reporting requirements as set by the NHMRC.

MEMBERSHIP

As the Committee is central to SJGHC's Catholic identity, those serving as members have a strong personal commitment to the faithful application of Catholic moral principles to health care.

The Committee's membership, in accordance with the National Statement, includes as far as possible equal numbers of men and women, at least one-third of who are external to SJGHC. The Committee's core (i.e. minimum) membership includes:

- Chair;
- a member with knowledge of, and current experience in, the professional care, counselling or treatment of people (e.g. nurse or allied health professional);
- a member who performs a pastoral care role in the community (e.g. minister of religion);
- a lawyer who is not engaged to advise the institution;
- a lay man and a lay woman who have no affiliation with the institution or organisation and do not currently engage in medical, scientific, legal or academic work;

- two members with current research experience that is relevant to research proposals considered by the Committee

In addition to this core membership, the Committee may have additional membership as deemed necessary, and at all times with the aim of maintaining a gender balance on the Committee as per NHMRC guidelines

All Committee (and sub-Committee) members have legal protection provided by SJGHC for liabilities that may arise in the course of bona fide conduct of their duties in reviewing research and ethical issues.

Members (and sub-Committee members) undertake appropriate induction and are expected to participate in continuing ethics education. Reasonable costs associated with this will be met by SJGHC.

All SJGHC HREC Members provide their services and expertise on a voluntary basis and receive reimbursement of parking and extraneous costs associated with attending meetings and other business associated with their membership of the Committee. In addition, the Chair of the HREC receives remuneration to compensate for the additional time required to both chair the meeting for the HREC and perform executive duties. This remuneration will be extended to the Deputy/ Acting Chair when they are acting in the capacity of Chair.

PROCESS FOR THE APPOINTMENT OF MEMBERS

Expressions of interest for Committee membership can be forwarded to the EO) of the Committee. At the time a vacancy occurs, the position may be filled from the list/pool of interested persons, open nominations or by community advertisement.

Members are appointed after a process of consultation among the relevant groups: SJGHC Executive and the SJGHC HREC. A potential member should have at least two internal (SJGHC) nominations or otherwise the potential member will be required to cite at least 2 referees on their CV and a reference check will then be conducted by SJGHC. Members are appointed foremost as individuals for their expertise rather than in a representative capacity. Approval of these appointments is given by the Group CEO or his delegate.

Members are appointed for a minimum 2 year term and are eligible for reappointment, with reappointments considered within the 2nd and 3rd year of the current appointment term.

OFFICE BEARERS

The positions of Chair of the HREC, Deputy Chair of HREC and Chair of the SRC are appointed by the Group CEO for a minimum term of 2 years. A previous office bearer can be nominated for more than one term.

In the absence of the Chair, the Deputy Chair performs the duties of the Chair. In the absence of both the Chair and Deputy Chair, the Chair/Deputy Chair may appoint an Acting Chair from the Committee members.

An Executive Officer (EO) provides administrative support to the Committee.

MEETINGS

Meetings are held monthly. Members may also be called to meet on urgent matters, with notice of less than 24 hours.

The minutes and agenda of each meeting are forwarded to Committee members approximately a week prior to the scheduled meeting.

QUORUM

Decisions shall not be reached unless all 8 core members are present at the meeting, or alternatively have given their advice to the Chair. This advice will be recorded in the minutes of the meeting. Committee decisions are reached by consensus.

CONFLICTS OF INTEREST

Conflicts of interest (actual or potential) may compromise the research process itself and/or research governance.

No member of the Committee or sub-Committee, or expert advisors can adjudicate on research in which he/she may be:

1. personally involved or participating in the research;
2. have an affiliation or interest in the research, be it financial, private, professional or institutional;
3. personally involved in competing research.

Members are obliged to declare any actual or potential conflicts of interest in a particular research study at the Committee meeting where that study is to be considered, and will be asked to be excused from discussions of the particular research.

In addition, where there are conflicts of interest involving researchers, the Committee may adopt the following measures to manage these:

1. the information is required to be disclosed to research participants;
2. a person other than the researcher is required to make the initial approach to participants;
3. the information is required to be disclosed in any report of the research;
4. the research is required to be conducted by another researcher;
5. approval is withheld.

PERFORMANCE MONITORING

Oversight of efficient and effective ethical review of research may be demonstrated through the following performance measures:

- An active, well governed, and ethical research program across SJGHC
- HREC member participation in continuing research ethics education
- A sixty (60) day timeframe for ethics review by the Committee
- Monitoring and review of all approved research projects is maintained over the life of the research

- Committee compliance (as a HREC) with NHMRC guidelines including Certification requirements
- SJGHC's Research Governance Framework follows guidelines in the National Statement and the Code for Research
- Number of complaints about research ethics and governance, breaches of the Code and cases of research misconduct

AUTHORISATION

These Terms of Reference are authorised by the SJGHC Group CEO.

REVIEW OF TERMS OF REFERENCE

These Terms of Reference are to be reviewed at a minimum every 3 years or at an earlier date if the need arises.

SJGHC HREC Membership

Name	Qualifications	Sex	Appointment	Position
Clinical Professor Dr Simon Dimmitt *	BMedSc (Hons) MBBS FRACP FCANZ	M	Chair (with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement)	Consultant Physician, General & Cardiovascular Medicine (accredited to St John of God Health Care)
Ms Tracey Piani *	RN BA (Hons)	F	Member with knowledge of and current experience in the professional care, counselling or treatment of humans (i.e. medical practitioner, clinical psychologist, social worker, nurse as appropriate)	Deputy Director of Nursing, St John of God Midland Public & Private Hospitals
Fr Joe Parkinson *	STL PhD	M	Member who performs a pastoral care role in a community for example an Aboriginal Elder, a minister of religion	Minister of Religion; Bioethicist, Director L. J. Goody Bioethics Centre
Mr Eric Heenan *	BLaw (Hons) The Honorarable Q.C.	M	Member who is a lawyer, and where possible who is not engaged to advise the institution	Retired Supreme Court Judge, WA
Dr Janie Brown *	BNurs MEd PhD	F	Member with current research experience that is relevant to research proposals to be considered at the meetings	Senior Lecturer, School of Nursing, Midwifery and Paramedicine, Curtin University
Sr Leonie O'Brien *	BEd MPS	F	Laywoman who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work	Mercy Sister
Dr Ben Carnley *	MBBS FRACP FRCPA	M	Member with current research experience that is relevant to research proposals to be considered at the meetings	Consultant Haematologist, Haematology West
Mr Hamish Milne *	BA (Hons) MPhil MBA GAICD FAIM	M	Layman who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work	Self-employed Consultant, State Manager RACGP
Professor Sally Sandover	BSc MPH	F	Community Member. Member with current research experience that is relevant to research proposals to be considered at the meetings	Associate Dean (Medical Education), Curtin University Medical School
Mr Patrick O'Connor	MPsych (Clinical) MBA	M	Community Member. Clinical Psychologist	Senior Clinical Psychologist, Health Dept WA (mental health services) & Clinical Psychologist: Hillarys Medical Centre
Mr Colin Keogh	BSW MAPP GCLCC	M	Deputy Chair. Hospital Representative. Expert knowledge in Mission and culture	Director of Mission, St John of God Murdoch Hospital
Ms Mary Rigby	BSc (Nurs) MBioethics	F	Community Member. Expert knowledge in nursing, particularly palliative care/oncology.	Clinical Nurse Manager, ICON Cancer Care, Midland

* Core Member

Scientific Review Sub-Committee (SRC) Terms of Reference

BACKGROUND

The Scientific Review Sub-Committee ("the SRC") is a sub-committee of the St. John of God Health Care (SJGHC) Human Research Ethics Committee (HREC). The two Committees work closely together to review all human research proposals to be conducted at any of the SJGHC Divisions.

The principal role of the SJGHC HREC is to consider research proposals from an ethical perspective, whereas the principal role of the SRC is to review proposals for scientific merit ie. scientific validity and safety.

PURPOSE

The purposes of the SRC are:

1. To review for scientific merit ie. scientific validity and safety, all human research proposals to be conducted at any of the SJGHC sites in Australia, including:
    a. New research submissions
    b. Study amendments
    c. Study progress reports, including final reports and publications
2. To review for the appropriate use of SJGHC biospecimens (and related health data) all human research proposals requesting access to these human tissue samples and data.
3. To make recommendations for approval or otherwise of research proposals to the SJGHC HREC.
4. To provide advice to investigators/researchers on research design and process that improves the scientific validity and safety of research proposals.
5. To report the SRC's activities on a regular basis to the SJGHC HREC.
6. To review final study reports including translation of study results.

MEMBERSHIP

There is to be some cross membership of the SRC and the SJGHC HREC.

The SRC membership includes expertise and current research experience that is relevant to the types of research proposals considered by the SRC. The SRC may also seek external advice from relevant experts where deemed necessary, to assist in the consideration of particular research proposals.

Members are nominated by the Chairman of the SJGHC HREC. Members are nominated for a minimum 2 year term and are eligible for reappointment.

OFFICE BEARERS

The position of Chair is nominated by the Chairman of the SJGHC HREC for a term of 2 years. A previous office bearer can be nominated for more than one term. The Executive Officer of the SJGHC HREC also provides administrative support to the SRC.

CONFLICT OF INTEREST

Members are obliged to declare any actual or potential conflicts of interest in a particular research study at the SRC meeting where the research is to be considered. Such conflicts of interest may include:

1. Personal involvement or participation in the research
2. An affiliation or interest in the research – be it financial, private, professional or institutional
3. Personal involvement in competing research.

Where there are any actual or potential conflicts of interest in research, members will be excused from meeting discussions and will not be permitted to adjudicate on such research.

MEETINGS

The SRC meets between meetings of the SJGHC HREC, for a total of 8 meetings per year.

In order to address any outstanding issues prior to SJGHC HREC meetings, members may be requested out of session, to review and comment (via email) on researcher replies to SRC queries. The SRC may also be called to meet more frequently (as required) to address urgent matters.

QUORUM

The quorum for meetings shall be half the total number of members. Alternatively, the quorum can be less than this provided that absent members have provided their advice to the Chairman on agenda items before the meeting. This advice will be recorded in the minutes of the meeting. SRC decisions are reached by consensus.

REMUNERATION

Each member is expected to attend all scheduled meetings per year.

Each member who is not a SJGHC employee is remunerated at $250 (incl. GST) per meeting. This remuneration is partially funded from administrative fees charged on research proposals submitted for approval to the SJGHC HREC.

AUTHORISATION

These Terms of Reference are authorised by the St John of God Health Care Human Research Ethics Committee.

REVIEW OF TERMS OF REFERENCE

These Terms of Reference are to be reviewed at a minimum every 3 years or at an earlier date if the need arises.

Scientific Review Sub-Committee Membership

CURRENT AS OF MAY 2017

Name	Qualifications
Professor Sally Sandover (Chair)	BSc MPH
Clinical Professor Dr Simon Dimmitt	BMedSc (Hons) MBBS FRACP FCANZ
Dr Michael Byrne	BMedSci (Hons) MBBS MRCP FRACP
Prof Kevin Croft	PhD FRSC
Professor Leanne Monterosso	BNurs (Hons) RN RM NNT GCTT PhD FACNA
Mr John Taylor	FRCP FRCS FRCS (Ed) FRACS FRCOG FRANZCOG
Ms Gemma McGrath	BNurs BLaws (Hons) MLaws
Dr Paige Tucker	BSc BMed/BSurg (Hons)
Dr Kylie Russell	MHS (Ed) BNurs PhD
Mr Myles Murphy	BPhysio GCSportsPhysio MClinPhysio

Nursing, Midwifery, Allied Health and Pastoral Services Research Council (NMAHPSR) Terms of Reference

PURPOSE

The purpose of the SJGHC Nursing, Midwifery, Allied Health and Pastoral Services Research Council is to inform and advance clinical practice, influence policy development, improve outcomes for patients, their families and caregivers and actively engage caregivers in the research process at all level of the organization. This will be achieved through relevant enquiry into any sphere relating to patient care and clinician interactions, professional roles and workforce issues.

The Council will work to:

- Provide leadership and assist with the facilitation nursing, midwifery, allied health and pastoral services research within St John of God Health Care, ensuring the integrity of the research process is maintained
- Identify priority areas for nursing, midwifery and allied health and pastoral services research in collaboration with relevant clinical reference groups and Divisions
- Coordinate dissemination of identified potential research opportunities to the Divisions, including Division-based projects, group and multi-site national and/or international research projects
- Explore and review opportunities and proposals for research projects involving university and other research institute collaboration
- Act as a consultative body with an advisory and educational role for issues pertaining to the provision of nursing, midwifery, allied health and pastoral services professional research
- Assist with the development of direct care clinicians' research skills through education and mentoring
- Assist Divisions with identifying/seeking funding opportunities for nursing, midwifery, allied health and pastoral services clinical research
- Provide advice on the ethics approval application process as required
- Facilitate the translation of validated research outcomes into practice within SJGHC and more broadly as appropriate
- Promote and facilitate evidence-based practice

REPORTING RESPONSIBILITY

The Council is responsible to the Group Director of Nursing who will act as the Executive Sponsor and be a member of the Council. The Council will be chaired by a Director of Nursing appointed by the Group Director of Nursing. A written report will be prepared for the Group Nursing Leadership Team on an annual basis.

Members of the Council are to report to their Directors of Nursing/Managers and other relevant Divisional and Executive Management Committee members and internal divisional forums on matters pertaining to nursing, midwifery, allied health and pastoral services research.

MEMBERSHIP

The members of the Nursing, Midwifery and Allied Health Research Council will represent all divisions and include:

1. Group Director of Nursing - Executive Sponsor
2. Chair to be appointed from the membership by Group Director Nursing
3. One divisional representative from each small and medium division
4. Two divisional representatives from each large division
5. Senior Allied Health Professional
6. Group Manager, Clinical Projects
7. Group Coordinator Pastoral Services/Palliative Care
8. Chair in Nursing Research- Murdoch
9. Nursing and Midwifery Research Coordinator
10. Executive officer SJGHC HREC
11. One member SJGHC HREC
12. Other co-opted members as required e.g. CRM, Manager LOD

MEETINGS

Meetings will be held bi-monthly. Special meetings can be convened as required.

QUORUM

A quorum shall be the Chairperson or nominated deputy and a minimum of 50% plus one of the membership.

CIRCULATION OF MEMBERSHIP

The minutes shall be circulated to all Council Members, Divisional Directors of Nursing and Divisional Learning and Development Coordinators.

REVIEW

These terms of reference will be reviewed biennially.

Submission Process – Steps to Approval

Please refer to *Pathways of Ethical Review at SJGHC* in the *SJGHC Research Handbook* for a summary of the approval process at SJGHC for research of different risk levels.

ENQUIRIES AND QUERIES

Initial enquiries and queries about making a research submission to the SJGHC HREC, or any other ethics queries that arise during the course of a research project, should be directed in the first instance to the Executive Officer of the SJGHC HREC.

This is particularly useful in the following cases:

1. to plan ahead a sufficient timeframe in which to obtain study approval,
2. to clarify the process to follow to obtain approval of a study, including who to contact within SJGHC to begin discussions and obtain "operational approval"/"participating site approval" (refer to *Participating Site Operational Approval Form (PSOA)* in *SJGHC Research Handbook*).
3. to determine what, if any documentation needs to be reviewed by SJGHC Legal Services e.g. indemnity and insurance arrangements. Researchers should utilise (as appropriate) the template SJGHC Clinical Trial Research Agreement (CTRA)/SJGHC Deed of Access, Insurance and Indemnity.
4. to ascertain if a particular research study is "negligible risk", "low risk" or "high risk", and the level of corresponding ethical review (i.e. formal or informal review) that is required. For example, clinical audits where there is no intention of publishing results may not require a submission to the SJGHC Human Research Ethics Committee.
5. Where "expedited review" is being requested e.g. a limited timeframe in which to commence a study. Note: SJGHC has both a expedited review process for "low risk" research as well as an expedited review process for "higher risk" research which meets certain criteria (refer to the Expedited Review Checklist for "Higher Risk" Research. Timing constraints alone are not an acceptable reason for seeking expedited review and cannot justify expedited review where the study is high risk.

Upon making contact with the Executive Officer of the SJGHC HREC, researchers will receive a copy of the *SJGHC Research Handbook*. This should be read in full as it is a complete reference guide to obtaining and maintaining the ethical approval of, and meeting the research governance requirements for, research projects.

SUBMITTING A NEW RESEARCH PROPOSAL

Researchers are requested to complete either one of the following application forms as part of their submission:

1. Human Research Ethics Application (HREA) which is particularly useful if the researcher will be submitting their research proposal to multiple Human Research Ethics Committees (HRECs). This is available online at www.hrea.gov.au. Please download a new form each time as the document continues to be updated, OR

2. Another HREC Ethics Application Form (particularly where this has been already completed) may be appropriate in lieu of the HREA.
3. WA-Specific Module addresses additional ethical issues specific to Western Australia that is not addressed in HREA. Researchers intending to conduct research in WA should complete both the HREA & WA-Specific Module. The WA-Specific Module is available online at: www.health.wa.gov.au/healthdata/docs/wa_specific_module.doc)

Please note that whether completing HREA or another Application Form, there is also other documentation that needs to accompany a research submission. Researchers should refer to the *Checklists for New Submissions* in the *SJGHC Research Handbook*, as a quick reference to ensure all necessary documentation has been included before forwarding their submission to the SJGHC HREC.

CONDITIONS OF APPROVAL

Research proposals require SJGHC HREC approval before commencement. The following are the standard conditions of approval for all research approved by the SJGHC HREC. In addition to these, with some research projects there may be specific conditions of approval which will be outlined to researchers in their final study approval letters.

Failure of researchers to comply with any of the conditions of approval may result in suspension or withdrawal of study approval. In cases of non-compliance and/or where circumstances warrant that a study should be discontinued, the SJGHC HREC will recommend to the SJGHC Participating Site(s) that approval be rescinded, or otherwise suspended until such a time as specific conditions are met.

1. **Duration of Approval & Requests for Time Extensions:** Ethics approval letters will stipulate the duration for which a study is approved or otherwise approval is as per the timeframe specified by the researcher in the original submission. It is the responsibility of researchers to apply in writing to the SJGHC HREC for any extensions of time to complete research before the timeframe expiry date.
2. **Study Amendments (including Study Extensions):** Study approval is limited to the research proposal as originally submitted. Any subsequent amendments to the study and/or study documentation (e.g. research personnel, protocol, participant information and consent form (PICF), Investigator Brochure, etc.) and any study extensions (e.g. of scope, data analysis, time) must be referred to the SJGHC HREC for approval prior to implementation. If the Committee considers the amendments/ extensions to be significant, researchers may be required to submit a new study application for approval.
3. **Adverse Events, Unforeseen Events, Protocol Deviations/Violations, Withholding/ Withdrawal of Approval, Allegations/Suspicion of Research Misconduct:** Researchers must report immediately to the SJGHC HREC anything which might warrant review of study approval and/or affect continued ethical acceptability of the study:
    a. serious, and suspected unexpected serious adverse events on participants, unforeseen events (e.g. new information about the experimental drug, new potential conflict of interest) and any significant protocol deviations or violations (i.e. this includes "protocol exemptions" granted by the Sponsor, and any deviations/violations as judged by the researcher to materially affect the ongoing safety of participants)
    b. any withholding, or withdrawal of study approval by another HREC or institution,

c. any allegation or suspicion of research misconduct.

4. **Reporting on Study Progress:** SJGHC through its research governance framework, requires that researchers complete regular study progress reports (annually at a minimum) and a final study report at the conclusion of a research project. As part of the final study report, researchers are requested to provide copies of any publications/ presentations of research findings. ***In the particular case where a decision is made by the researcher to cease a research project before the expected completion date, the SJGHC HREC must be advised immediately, with an explanation of the reason(s).*** These reports are to assist in verifying that the conduct of research conforms to the approved research proposal, and that the interests of those who have consented to take part as participants in research, are protected. Failure to meet these report requirements will mean approval of the study will lapse and a new application will need to be submitted.

Information and Advice for Researchers Making New Submissions

APPLICATION FORM

Researchers have the option of completing either the Human Research Ethics Application (HREA) or an alternative institutional Ethics Application form. These have been designed to help researchers appreciate the ethical aspects of their research and enable the Committee to fully understand any ethical implications. As HREA has been developed to be recognised by all Human Research Ethics Committees (HRECs) throughout Australia, researchers are strongly encouraged, particularly if conducting a larger scale, multicentre study, to complete HREA which is available online: www.hrea.gov.au

TRACKING OF STUDY DOCUMENTATION

All study documents submitted to the SJGHC HREC (e.g. protocol, PICF, questionnaires, etc.) must have a version number and date in the footer. This is to ensure that amendments to the documents can be easily tracked and the latest version quickly identified.

RESEARCH PROTOCOL/PROJECT DESCRIPTION

The protocol provides a justification of the study i.e. background/literature review including a listing of any previous publications relevant to the proposed study, study hypothesis(es), study objectives and study methodology. It explains the reasons for choosing the particular research method e.g. why the study is prospective or retrospective, the use or otherwise of controls, the need or otherwise for a blind or double blind study and the rationale for the type of statistical analysis, including power and sample size calculations. A power and sample calculation is required for all prospective quantitative research (except for pilot studies) to facilitate an assessment of the scientific merit of the proposed research. The protocol should include the following:

1. Rationale for the project
    a. Why is it important to conduct the project?
    b. What are the expected benefits of the project?
    c. What are the risks of the project and how will they be managed?
2. Background for the project (literature review)
3. Aim(s)/Objective(s) of the project
4. Description of Participants and Recruitment Process
    a. Inclusion/Exclusion Criteria
    b. Justification for sample size
5. Methodology
    a. Data technique(s) to be used (e.g. retrospective medical record review, interview, etc.)
6. How project results will be analysed

Useful guides for protocol/project description include the SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents. SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) is an international initiative that aims to improve the quality of clinical trial protocols by defining an evidence-based set of items to address in a protocol. Refer: www.spirit-statement.org

Also, the Common Protocol Template Initiative is working with industry stakeholders and regulators to create a model clinical trial protocol template containing a common structure and model language. www.transceleratebiopharmainc.com/assets/common-protocol-template/

NATIONAL SCIENTIFIC REVIEW COMMITTEE

If you are submitting a study that has had prior review by a National Scientific Review Committee, please advise of this on the Submission Cover Page.

The establishment of two National Scientific Committees is part of a pilot project to provide expert advice to researchers and Human Research Ethics Committees (HRECs) on complex genetic studies and clinical trials involving medical devices. For more information, please see the following website: https://www.australianclinicaltrials.gov.au/national-scientific-review-committees

CLINICAL TRIAL

A *"clinical trial"* refers to a trial of an unapproved therapeutic good within Australia (i.e. use of unregistered medicine (drug)/medical device and/or use of medicine/medical device outside its approved indications, doses or duration of treatment. Clinical trials require an application to the Therapeutic Goods Administration (TGA) under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes. A CTN or CTX Form is to be signed by all parties - the investigator, sponsor, HREC and the approving authority (i.e. the participating site where the trial will be conducted). A Certificate of Insurance is essential to ensure adequate compensation/indemnity provisions for trial related injury/mis-adventure and to protect both study participants and researchers. A Clinical Trial Research Agreement (CTRA)/contract is also required to outline respective responsibilities of, and financial arrangements between the parties involved in the trial. For monitoring purposes, researchers must provide the SJGHC HREC with details of the constitution of any Independent Data Safety Monitoring Committee (IDMC) for the trial: names and positions of members, and frequency of meetings.

PRODUCT/PROCEDURE AND DEVICE INFORMATION

Information on all products/procedures/devices to be used in a clinical trial (e.g. drug toxicity, dosage guidelines, indications for use, etc.) enables the HREC to assess the safety of the product/procedure/device, and make a risk-benefit assessment of the proposed trial. This information can also be of practical use to caregivers of the SJGHC participating site(s) who may be called on to administer aspects of the research protocol.

In addition, for trials of implantable devices, researchers must also provide the SJGHC HREC with a copy of the descriptor of the system for tracking participants for the lifetime of the device.

CONSUMER ENGAGEMENT

Researchers are encouraged from the onset to seek consumer and community engagement in their research. Consumer input should influence decisions about what to research, as well as the particular research design. Where consumer representatives have been involved in this process, please advise the names, and what the interests are, of these representatives.

As a way of encouraging consumer and community participation in research, where possible* a plain language summary of the study's findings linked to the final study publication should be sent to all study participants. Newsletters can also be sent to participants throughout the duration of the study to keep participants updated on study progress and preliminary findings.

* With large epidemiology studies, it is acknowledged that it may be difficult to convey results to the large number of participants, many of whom may also be deceased, particularly if the study is a retrospective study.

PARTICIPANT INFORMATION SHEET AND CONSENT FORMS (PICFS)

PICFs need to be in plain language, avoiding jargon, ambiguities and misleading statements and need to be succinct i.e. outlining the additional processes and risks for participants associated with being part of the specific study. This is important as it allows a participant to come to a decision on whether to enter the study and has medico-legal significance in the event of any adverse event. Participants should be given a copy of the signed PICF for their records.

The National PICF Project has developed and issued a suite of standardised PICFs to serve as a starting point for researchers. The PICF has three parts: A) General Information, B) Trial details, C) Consent Form. These forms will be reviewed annually and updated as needed. All of these documents were designed to provide guidance and assist researchers, institutions and HRECs in the conduct of multi-centre ethical review.

These Proformas can be found in the *SJGHC Research Handbook* and accessed online at www.nationalpicf.com.au. The User Guide for the National PICF can be used to help develop a PICF, and can be downloaded at http://www.nationalpicf.com.au/research.html.

PREGNANCY WORDING IN PICFS

There should be no reference made to "artificial contraception"/"birth control" in the PICF(s). When speaking of reproductive risks while participating in research, the following format is to be used in ALL PICFs, in accordance with the teachings of the Catholic Church:

> *"Because of the [known/unknown] effects of the [study medication] women should avoid becoming pregnant [and/or breast-feeding] during the course of this trial."*
>
> *"Because of the [known/unknown] effects of the [study medication], men should avoid fathering a baby during the course of this trial [and should inform their partner about this requirement]."*

PARTICIPANT CONCERNS ABOUT THE STUDY

Researchers should insert the following paragraph in the PICF:

"The St John of God Health Care Human Research Ethics Committee has given ethical approval for the conduct of this study. If you have any concerns or complaints regarding this study, you can contact the Executive Officer of the Committee (telephone number (08) 9382 6940) on a confidential basis. Your concerns will be drawn to the attention of the Committee that is monitoring the study."

STUDY BUDGET

The budget identifies the explicit costs of the research activity/the costs in addition to regular patient intervention as well as in-kind support (i.e. support other than direct cash amounts). Researchers must identify funding source(s) in the budget and itemise all payments to study participants (i.e. financial remuneration, reimbursement, rewards/benefits/ incentives), as well as any expenses. The PICF should also outline these budget details.

USE OF SJGHC LOGO/LETTERHEAD

Only researchers conducting research as part of their employment with SJGHC should use the SJGHC logo/letterhead on PICFs. All other externally-initiated and/or sponsored research should not display the SJGHC logo/letterhead on PICFs. This ensures that study participants can accurately identify who has initiated the study. To differentiate from other participating sites, PICFs can still be identified as a "SJGHC version" on footnotes in these documents.

CLINICAL TRIAL REGISTRATION

Sponsors/researchers are strongly encouraged to register their clinical trial with WHO ICTRP (http://www.who.int/ictrp/en/), ANZCTR (www.anzctr.org.au) or other equivalent public registry before trial commencement and provide these details to the SJGHC HREC.

Trial registration promotes research transparency and ensures the evidence for a new treatment/therapy/drug/medical device/ medical intervention is widely available. It can help researchers identify gaps in their research, prevent unnecessary duplication of trials, and facilitate publishing of results. The International Committee of Medical Journal Editors (ICMJE) will not publish the results of any clinical trial not included on an authorised register at the trial's inception.

PRIVACY DECLARATION

All external researchers (i.e. excluding SJGHC caregivers, accredited practitioners) conducting research at a SJGHC site are required to sign a separate Privacy Declaration Form as part of their study submission to the SJGHC HREC.

RESUMES

Researchers should include an abbreviated, current resume (& publication list) which outlines their academic qualifications, experience and skills to carry out research.

RESEARCHER CONCERNS ABOUT THE ETHICAL REVIEW PROCESS

Should a researcher have any concerns regarding consideration of their study submission by the SJGHC HREC (and/or sub-Committee) this can be discussed in the first instance with the Executive Officer of the Committee. Every effort will be made to explain the ethical review process, and to provide specific submission feedback i.e. how the Committee arrived at its decision and the reason(s)

for its decision. If the matter remains unresolved and the researcher wishes to make a formal complaint, the complaint should be put in writing to the Chair, SJGHC HREC to be resolved through the normal Committee process, and failing this, through the SJGHC complaints process.

RESEARCHER RESPONSIBILITIES

If you remove your research submission or fail to reply to any queries raised in the study review process, you will be required to make a full submission to the SJGHC HREC before further consideration will be given to your proposed study.

You may not embark on, or publicise a study until you receive written approval from SJGHC HREC.

All correspondence to the SJGHC HREC should quote the allocated study SJGHC HREC reference number.

Researchers are welcome to attend meetings of the SRC and/or SJGHC HREC, to present their study submission in person and address any queries directly with Committee members. Please advise the Executive Officer at the time of submission that you would like to attend the meeting(s). Researchers may also be invited by the SRC and/or SJGHC HREC to attend meetings if clarity is needed or there are outstanding issues.

QUALITY IMPROVEMENT (QI) PROJECTS

Quality improvement (QI) projects in health services are about evaluation of clinical practice with the intention of improving health service delivery and health care outcomes. All QI conducted ***with or about people ("Human QI")*** requires ethical consideration: will the people involved – patients, caregivers or community – be exposed to any additional harm, discomfort, inconvenience, or possible breach of their privacy? What is the risk of such exposure: "more than low risk", "low risk" or "negligible risk"? And most importantly, are these risks justified by the potential benefits of the QI?

It is important to identify, minimise and manage any risks/ethical issues that arise in the design and conduct of Human QI and the dissemination/publication of Human QI results, and to justify decisions about these aspects of Human QI before project commencement. Please refer to "Guide for QI Projects" for more information regarding submission of QI projects to the SJGHC HREC.

Guide for QI Projects

Research studies tend to ask ***"What is best practice?"*** and are conducted with the intention to publish results and impact clinical practice. Conversely, quality improvement (QI) projects ask ***"Are we following agreed best practice?"*** and evaluate clinical practice with the intention of improving health service delivery and health care outcomes. QI tends to be conducted for "internal" purposes only. However, increasingly it is sought to publish QI project results and many journals now request prior ethical review and approval of QI as a requirement of publication. The two kinds of QI projects are "Pure QI" and "Human QI".

PURE QI

Pure QI looks solely at processes/systems/programs and does not use data about or samples taken from people. Pure QI does not require ethical review by the SJGHC Ethics Committee (HREC). Pure QI should be registered as per the usual process with the Quality and Risk Department of the relevant SJGHC Division.

HUMAN QI

Human QI involves using data about or samples taken from people (such as a review of patient medical records – traditionally known as an audit, or a survey of caregivers/staff), and needs to be submitted to the SJGHC Ethics Committee (HREC) for ethical consideration. It is important to identify, minimise and manage any risks/ethical issues that arise in the design and conduct of Human QI and the dissemination/publication of Human QI results, and to justify decisions about these aspects of Human QI before project commencement.

ESSENTIAL CRITERIA FOR HUMAN QI PROJECTS

All Human QI projects should be reviewed by the SJGHC HREC and meet the following criteria:

Research Merit and Integrity
✓ A good rationale for undertaking the project
✓ Clear and achievable project aims
✓ Based on a thorough literature review
✓ Person(s) conducting project has appropriate skills, knowledge and experience
Justice
✓ Fair process for collection of information about people with minimal burden
✓ Feedback of results (where possible) to study participants/wider community
Beneficence
✓ Any risks minimised and justified by benefits of undertaking QI
Respect
✓ Voluntary consent of individual study participants obtained if new information sought

ASSESSING THE LEVEL OF RISK OF HUMAN QI PROJECTS

The National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007) ("the National Statement") provides a basis for ethical review of Human QI, which is often "low risk" or "negligible risk" research. Please refer to the following sections of the National Statement ("§ NS") and Privacy Act 1988 (where applicable) to determine the ethical issues involved in your QI project.

Voluntary, Informed Consent (§2.2 NS)

- ✓ Participants freely able to consent
- ✓ All details of QI project clearly communicated to participants
- ✓ No deception of participants e.g. concealment of project aims, covert observation of participants
- ✓ No coercion, pressure or strong inducements to participate

Privacy and Confidentiality (§95A Privacy Act)

- ✓ Collection, use and/or disclosure of personal information has prior participant consent
- ✓ Proposed collection, use and/or disclosure of personal information is consistent with the primary purpose of collecting the data
- ✓ Participants and/or SJGHC Participating Site(s) are neither directly or indirectly identifiable in the presented/published results

Participant Vulnerability/Ethical Considerations Specific to Participants (§4 NS)

- ✓ Pregnant Women & unborn child (§4.1 NS)
- ✓ Children & young people (§4.2 NS)
- ✓ Independent Relationship with Researcher e.g. Doctor with Patient, Manager with Caregiver, etc. (§4.3 NS)
- ✓ Palliative or Intensive Care Patients (§4.4 NS)
- ✓ People with cognitive impairment, intellectual disability, mental illness (§4.5 NS)
- ✓ People involved in illegal activities (§4.6 NS)
- ✓ Aboriginal or Torres Strait Islanders (§4.7 NS)
- ✓ People in other countries (§4.8 NS)

Perceived, Possible or Actual Conflict of Interest (§5.4 NS)

- ✓ No researcher affiliation with any of the external organisations involved in the QI
- ✓ No financial or other benefits researcher receiving from any of the external organisations involved in the QI

Risk of Harm (§2.1 NS)

- ✓ No novel and/or invasive procedures, devices and/or treatments
- ✓ Low probability and severity of any harms:
  - physical (e.g. pain, injury, illness, ionising radiation)
  - psychological harms (e.g. distress, embarrassment, fear)
  - emotional harms (e.g. manipulation, disrespect, injustice

- social harms (e.g. discrimination, damage to relationships)
- economic harms (e.g. out of pocket expenses)
- legal harms (e.g. discovery of illegal activity & prosecution)

✓ No Human tissue samples (including blood)

✓ No genetic material and/or information

Guide for Applications to Become an Authorised Prescriber of an Unapproved Product

Guidelines on how to become an authorised prescriber of an unapproved product (under Section 19(5) or Section 41HC of the Therapeutic Goods Act 1989) can be found in the reference: *Access to unapproved therapeutic goods Authorised prescribers (dated October 2004)* which is available on the Therapeutic Goods Administration (TGA) website:
www.tga.gov.au/sites/default/files/access-authorised-prescriber-guidelines.pdf

It is the responsibility of the applicant to complete the application to become an authorised prescriber of an unapproved product, as outlined in these TGA guidelines. Please note these TGA guidelines include a template Patient Consent Form which should be used along with a detailed Patient Information Sheet about the unapproved product. There is also a template Ethics Committee endorsement letter. This letter includes a section titled "conditions imposed by the HREC." At SJGHC, these conditions are:

1. Informed consent to be obtained from each patient or guardian for the use of the unapproved product.
2. Successful maintenance of your accreditation status/credentialing at the site covered by the endorsement.
3. Immediate reporting of any suspected unexpected serious adverse events (SUSARs) from the use of the unapproved product.
4. Provision of regular audit reports to the SJGHC HREC to outline the number of patients for whom the unapproved product has been used, confirming any SUSARs and demonstrating compliance with the conditions imposed by the TGA on the Authorisation.

There is a 2 step process to obtain SJGHC endorsement of Authorised Prescriber status:

1. Firstly, written endorsement of the local (SJGHC) site Credentialing Committee is required. This is to confirm that the clinician can prescribe the unapproved product within their scope of practice. The Credentialing Committee will also decide if any supervision and/or audit reports may be required as part of the credentialing process. NOTE: A copy of the required documents listed below should also be forwarded to the Credentialing Committee.
2. Secondly, written endorsement from the SJGHC HREC is required.

Meeting and Submission Dates

NEW MORE THAN LOW RISK STUDIES REQUIRING FULL REVIEW

Submission Dates	SRC Meeting Dates	HREC Meeting Dates
9 October 2017	20 October 2017	8 November 2017
6 November 2017	17 November 2017	13 December 2017
8 January 2018	19 January 2018	14 February 2018
6 March 2018	16 March 2018	11 April 2018
8 May 2018	18 May 2018	13 June 2018
12 June 2018	22 June 2018	11 July 2018
9 July 2018	20 July 2018	8 August 2018
10 September 2018	21 September 2018	10 October 2018
8 October 2018	19 October 2018	14 November 2018
5 November 2018	16 November 2018	12 December 2018

NEW STUDIES FOR EXPEDITED REVIEW, LOW RISK AND NEGLIGIBLE RISK STUDIES*

Submission Dates	HREC Meeting Dates
2 October 2017	11 October 2017
30 October 2017	8 November 2017
4 December 2017	13 December 2017
5 February 2018	14 February 2018
6 March 2018	14 March 2018
3 April 2018	11 April 2018
30 April 2018	9 May 2018
5 June 2018	13 June 2018
2 July 2018	11 July 2018
30 July 2018	8 August 2018
3 September 2018	12 September 2018
2 October 2018	10 October 2018
5 November 2018	14 November 2018
3 December 2018	12 December 2018

* Please note that previously approved studies for expedited review and low or negligible risk studies will be added to the HREC agenda if the date it is received by the SJGHC Ethics Office is close to a submission deadline. In other cases these studies will be circulated for review out of session, and approval is usually granted after a week.

PICF updates due to safety concerns, safety reports, local SAEs and final reports are reviewed at SRC meetings. All other submissions, including amendments and annual reports, are reviewed at HREC meetings as per the dates listed above.

Submission Addresses

SJGHC HREC POSTAL ADDRESS

St John of God Health Care HREC
Suite 304, 25 McCourt Street
SUBIACO WA 6008

SJGHC HREC OFFICE CONTACT DETAILS

Telephone: (08) 9382 6940
Facsimile: (08) 9382 6037

Executive Officer to Committee: Ms Gorette De Jesus
Email: gorette.de.jesus@sjog.org.au or ethics@sjog.org.au

Research Ethics Officer: Ms Karen Roberts
Email: karen.roberts@sjog.org.au or ethics@sjog.org.au

SJGHC DIVISION ADDRESSES AND CEOS

Accord (Greensborough Office)	**Berwick**
St John of God Accord	St John of God Berwick Hospital
PO Box 62	PO Box 101
GREENSBOROUGH VIC 3088	BERWICK VIC 3806
CEO: Tony Hollamby	CEO: Lisa Norman
Accord (Mooroolbark Office)	**Bunbury**
St John of God Accord	St John of God Bunbury Hospital
PO Box 151	PO Box 507
MOOROOLBARK VIC 3138	BUNBURY WA 6231
CEO: Tony Hollamby	CEO: Mark Grime
Ballarat	**Burwood**
St John of God Ballarat Hospital	St John of God Burwood Hospital
PO Box 20	13 Grantham Street
BALLARAT VIC 3353	BURWOOD NSW 2134
CEO: Alex Demidov	CEO: Mark Ayling
Bendigo	**Frankston**
St John of God Bendigo Hospital	St John of God Frankston Hospital
PO Box 478	255 Cranbourne Road
BENDIGO VIC 3806	FRANKSTON VIC 3199
	CEO: Sally Faulkner

Geelong	**Pinelodge Clinic**
St John of God Geelong Hospital	St John of God Pinelodge Clinic
PO Box 1016	1480 Heatherton Road
GEELONG VIC 3220	DANDENONG VIC 3175
CEO: Stephen Roberts	
Geraldton	**Richmond**
St John of God Geraldton Hospital	St John of God Richmond Hospital
PO Box 132	177 Grose Vale Road
GERALDTON WA 6531	NORTH RICHMOND NSW 2754
	CEO: Stephen Brooker
Hawkesbury	**Subiaco**
St John of God Hawkesbury District Health Service	St John of God Subiaco Hospital
Locked Mail Bag No 10	PO Box 14
WINDSOR NSW 2756	SUBIACO WA 6904
Site Contact: Lisa Connell lisa.connell@sjog.org.au	Site Contact: Dino Cercarelli research.network@sjog.org.au
Midland	**Warrnambool**
St John of God Midland Public & Private Hospitals	St John of God Warrnambool Hospital
PO Box 1254	PO Box 316
MIDLAND WA 6936	WARRNAMBOOL VIC 3280
Site Contact: Heather Wootton heather.wootton@sjog.org.au	CEO: Trevor Matheson
Murdoch	**Wembley Day Surgery**
St John of God Murdoch Hospital	St John of God Wembley Day Surgery
100 Murdoch Drive	190 Cambridge Street
MURDOCH WA 6150	WEMBLEY WA 6008
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Mount Lawley	
St John of God Mount Lawley Hospital	
Thirlmere Road	
MT LAWLEY WA 6050	
CEO: Chris Hanna	

Administrative Fee Schedule

Significant SJGHC funding is required to support formal ethical review and research governance activities including record retention and archiving, as required under the recommendations of the National Health and Medical Research Council (NHMRC) and Therapeutic Goods Administration (TGA). In order to alleviate this high resource commitment and achieve some cost recovery, an administrative fee applies to all new research submissions to the SJGHC HREC.*

The administrative fee is a one-off fee to be paid at the time of initial submission of a research proposal to the SJGHC HREC, and covers any and all future amendments and extensions made to that research. This fee is also only charged once regardless of the number of SJGHC sites throughout Australia which are involved in the particular study. The administrative fee schedule is as follows:

Type of Study	Fees
Commercially Sponsored External Studies e.g. Pharmaceutical companies, commercial device companies	$6,000 + GST
Not-For-Profit External Studies (excludes University applications)	$700 + GST (charged on a discretionary basis)
University Studies e.g. Student-initiated	$250 + GST
Internal Studies e.g. SJGHC caregiver-initiated studies	$50 + GST

* In addition to the above, the SJGHC HREC also reserves the right to charge researchers, at its discretion, recovery costs for any significant direct or indirect SJGHC infrastructure costs involved in a research study (e.g. SJGHC staff time, equipment use, facility/room use, etc.).

EXEMPT FROM FEES

Studies conducted under the auspices of competitive state or national research funding bodies (e.g. NHMRC grant-based studies) are exempt from fees. Not-for-profit external studies will be reviewed individually and charged on a discretionary basis. Similarly, any Phase 0 and 1 studies will be reviewed individually and charged on a discretionary basis. The intention of this administrative fee schedule is NOT to hinder research but to offset SJGHC's costs associated with the review and ongoing monitor of approved research.

PROCESS

At the time of initial submission of a research proposal, the researcher should provide the following details to the Executive Officer, SJGHC HREC:

1. Full title of the study
2. Sponsor/researcher's name and postal address details
3. Sponsor/researcher's ABN (if applicable, for GST purposes)

4. Contact person's details (i.e. name, address & telephone) to direct tax invoice to.

SJGHC Finance will then forward a tax invoice directly to the sponsor/investigator for payment. Alternatively, researcher can make a cheque out to "St John of God Health Care" clearly stating that it is for administrative fee for study [state full study title] and forward it to the Executive Officer, SJGHC HREC.

Useful References

Researchers may find these references helpful in conducting research:

1. *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) [Updated 2014] provides guidelines to researchers making submissions to Ethics Committees throughout Australia.
   www.nhmrc.gov.au/guidelines-publications/e72

   The following sections of the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) are commonly referred to by the SJGHC HREC in correspondence to researchers:

   2.2.9 No person should be subject to coercion or pressure in deciding whether to participate. Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes. Here as always, a person should be included as a participant only if his or her consent is voluntary.

   2.3.9: Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.

   2.3.10: Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:
   a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
   b) the benefits from the research justify any risks of harm associated with not seeking consent
   c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
   d) there is no known or likely reason for thinking that participants would not have consented if they had been asked
   e) there is sufficient protection of their privacy
   f) there is an adequate plan to protect the confidentiality of data
   g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
   h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
   i) the waiver is not prohibited by State, federal, or international law.

   5.1.7: For research that carries only low risk (see paragraph 2.1.6) and does not fall under any of the chapters listed in paragraph 5.1.6, institutions may choose to establish other levels of ethical review. These levels are described in paragraphs 5.1.18 to 5.1.21.

   3.5.1: Where research may discover or generate information of potential importance to the future health of participants, or their blood relatives, researchers must prepare and follow an ethically defensible plan to disclose or withhold that information.

   5.5.3: Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies, and take prompt steps to deal with any unexpected risks. For monitoring of approved clinical research, see paragraphs 3.3.19 to 3.3.22.

   3.1.12: Qualitative research that explores sensitive topics in depth may involve emotional and other risks to both participant and researcher. There should be clear protocols for dealing with distress that might be experienced by participants.

2. *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* (CHA, 2001)
   http://www.cha.org.au/code-of-ethical-standards

3. *Guidelines approved under Section 95A of the Privacy Act 1988* (NHMRC, 2014) provides a framework to ensure privacy protection of health information collected, used or disclosed in the conduct of research and the compilation or analysis of statistics, relevant to public health/ safety or health service management.
   https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/pr2_guidelines_under_s95a_of_the_privacy_act_140311.pdf
   https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/flow_chart_s95a_guidelines_150514.pdf
4. *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007) provides guidelines for responsible research practice and management of breaches of the Code and research misconduct. Whilst written for universities and other public sector research institutions, all are encouraged to incorporate these guidelines.
   www.nhmrc.gov.au/publications/synopses/r39syn.htm
5. *World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects* (WMA, 2013)
   https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf
6. *Note for Guidance on Good Clinical Practice* (TGA, 2000). Annotated with Therapeutic Goods Administration (TGA) comments, this indicates which sections of the international research guidelines ICH-GCP have been adopted by TGA to reflect local requirements. Whilst TGA, as the Australian regulatory agency for clinical trials, has adopted ICH-GCP, in some instances the National Statement requirements exceed those of ICH-GCP.
   https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
7. *The Australian Clinical Trial Handbook: A Simple, practical guide to the conduct of clinical trials to International standards of Good Clinical Practice (GCP) in the Australian context* (TGA, 2006)
   https://www.tga.gov.au/sites/default/files/clinical-trials-handbook.pdf
8. *Access to Unapproved Therapeutic Goods: Authorised Prescribers*. This TGA webpage outlines the mechanisms and regulations that allow patients to access unapproved medicines or medical devices in Australia.
   https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers
9. *National PICF Templates* and *User Guide* http://www.nationalpicf.com.au/index.html
10. *Processes for Low Risk and Negligible Risk Ethical Review* (NHMRC, 2007)
    https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/ethics/human_research/NS_low_risk_flow_chart.pdf
11. *NHMRC National Certification Scheme: Institutions with certified ethical review processes* (February 2017) is a current list of all NHMRC-Certified HRECs.
    https://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/ethcial_issues/att_2_-_list_of_institutions_v38-0_feb_2017.pdf
12. Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC November 2016)
    https://www.nhmrc.gov.au/guidelines-publications/eh59

13. *World Health Organisation International Clinical Trials Research Platform* (WHO ICTRP). http://www.who.int/ictrp/en/

14. *The Australian New Zealand Clinical Trials Registry (ANZCTR)*. An online register which covers all clinical trials involving Australian/NZ researchers or participants. www.anzctr.org.au

15. *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (Australian Radiation Protection and Nuclear Safety Agency, 2005) https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/rps/rps8.pdf

16. *NHMRC Policy on Complaints* (NHMRC, 2016) https://www.nhmrc.gov.au/guidelines-publications/po01

17. Statement on Consumer and Community Participation in Health and Medical Research (NHMRC, September 2016) https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16298_nhmrc_-_statement_on_consumer_and_community_involvement_in_health_and_medical_research-accessible.pdf

18. *Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (NHMRC, 2006) including *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC, 2003). These documents guide ethical health research on Aboriginal and Torres Strait Islander (A&TSI) peoples, written on a framework of A&TSI values and principles. https://www.nhmrc.gov.au/guidelines-publications/e65 https://www.nhmrc.gov.au/guidelines-publications/e52

19. *Challenging Ethical Issues in Contemporary Research on Human Beings* (NHMRC, 2007) illustrates challenging issues that arise in considering human research proposals. www.nhmrc.gov.au/publications/synopses/e73syn.htm

20. MJA Supplement: *Clinical Practice Guidelines for communicating prognosis and end-of-life issues with adults in the advanced stages of a life-limiting illness, and their caregivers*. https://www.mja.com.au/system/files/issues/186_12_180607/cla11246_fm.pdf

21. Organ and Tissue Donation by Living Donors: Guidelines for Ethical Practice for Health Care Professionals (NHMRC, 2007) and Making a Decision about Living Organ and Tissue Donation (NHMRC, 2007) outlines ethical practice for health professionals on living organ/tissue donation. https://www.nhmrc.gov.au/guidelines-publications/e71 https://www.nhmrc.gov.au/guidelines-publications/e70

22. *Medicines Australia Guidelines for Compensation for Injury Resulting From Participation in a Company-Sponsored Clinical Trial.* https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/

23. *Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide* http://www.bmj.com/content/348/bmj.g1687

24. *Australian Clinical Trials: Bridging the gap between patients and clinical trials* www.australianclinicaltrials.gov.au

Useful Forms

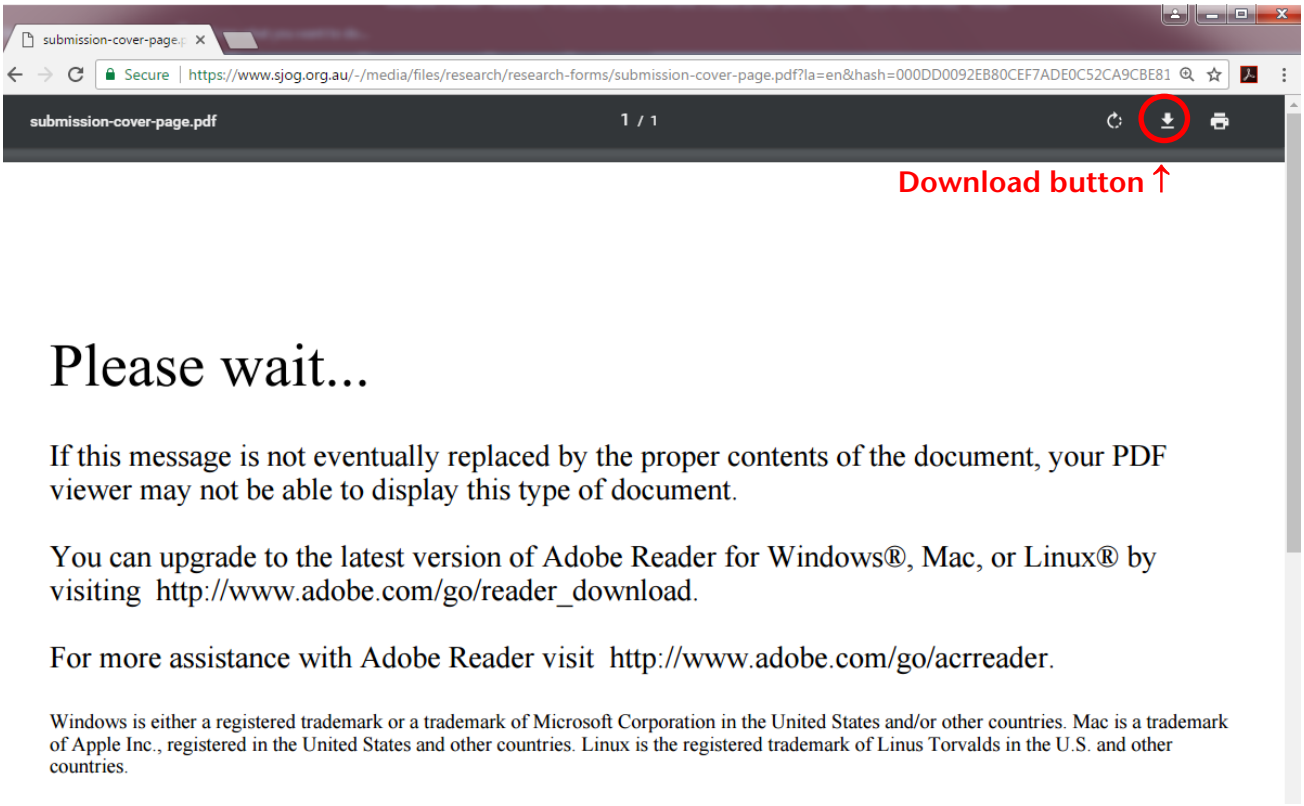
The following forms are used for submissions to the SJGHC HREC. Please click on the links below to download the most current versions of these forms.

Please do not use the saved form as a template, as these forms are regularly updated and submissions will not be accepted on earlier versions of forms.

HOW TO DOWNLOAD FORMS

Please note, the forms may not open in your web browser as they are dynamic PDF documents.

If you attempt to open them in a web browser PDF viewer rather than Adobe Reader, the following error message may appear:



Once you have clicked the links below to download the forms, open them from the Downloads folder on your computer. If the document appears as above, click on the download button in the top right corner to download (as indicated by the red circle).

FORM FOR ALL RESEARCH SUBMISSIONS

- Submission Cover Page

FORMS FOR NEW RESEARCH SUBMISSIONS

- Checklists for New Submissions:
  (Refer to Pathways of Ethical Review at SJGHC to determine which checklist to use)

  - More than Low Risk
  - Expedited Review
  - Low Risk/QI
- Participating Site Operational Approval Form
- Privacy Declaration for External Researchers
- Declaration of Interest

FORMS FOR APPLICATIONS TO BECOME AN AUTHORISED PRESCRIBER

- Submission Cover Page for Authorised Prescribers
- Checklist for HREC Endorsement of Authorised Prescriber Status

FORMS FOR MONITORING RESEARCH

- Local Site SAE and SUSAR Report
- Annual (or Interim) Study Progress Report Proforma
- Final Study Report Proforma

These forms are able to be signed with electronic signatures. Please refer to our policy regarding electronic signatures for submissions.

Research Amendment Submission Process

Research amendments can refer to amendments made to the following:

- Study Protocol
- Participant Information and Consent Form (PICF)
- Investigator Brochure (IB)
- Study questionnaire(s), surveys, psychological scales or inventories, interview questions
- Participant documentation e.g. patient diary
- Study advertisements and other recruitment material
- Change to research personnel i.e. researcher/s added to or removed from the study

Study extensions can refer to the following:

- Extensions of time for completion of the study
- Extensions of the scope of the study e.g. increasing the sample size/participant recruitment numbers
- Extension of data analysis to include additional factors in the analysis

All submissions to the SJGHC HREC should be made using the "SJGHC HREC Submission Cover Page", which is to be used in lieu of a cover letter. All requests for research amendments and study extensions will be placed on the next scheduled SJGHC Scientific Review Sub-Committee meeting agenda unless they are considered "minor"/ "straight-forward" requests, in which case they will be placed directly onto the next scheduled SJGHC Human Research Ethics Committee (HREC) meeting agenda.

If the research amendment or study extension is considerable and represents a significant departure from the study that was originally as currently approved, a new research submission may be required.

The **ORIGINAL request** (complete request which includes each and every document and has original signatures) is to be submitted to the SJGHC Ethics Office:

- Electronic copy sent via email to ethics@sjog.org.au in pdf (Adobe Acrobat) format

This original request must include:

1. SJGHC HREC Submission Cover Page
2. Summary of Changes (and where applicable include abbreviated, current resume and publication list of any new research personnel) / Explanation of Reasons for Extension
3. Clean copy of Amended document(s)
4. Amended document(s) with tracked changes

NOTE: For amendments with resource/implementation implications for SJGHC, an amended Participating Site Operational Approval Form must be completed by the relevant department(s) who will be affected by the proposed change.

Adverse Event Process

As per Section 3.3.22 of the National Statement, *"For any trial site under the HREC's responsibility, the researcher must notify in the manner and form specified by the HREC any serious adverse events at any of those trial sites."* Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), annual trial safety updates and other related safety information are reviewed by the Scientific Review Sub-committee and then tabled at meetings of the SJGHC HREC.

Researchers should forward to the SJGHC Ethics Office:

- Electronic copy sent via email to ethics@sjog.org.au in pdf (Adobe Acrobat) format

of all reports from the Independent Data Safety Monitoring Committee (IDMC) (or equivalent), SJGHC Local Site/SAE SUSAR Forms, and the trial SUSAR listings/annual trial safety updates and other related safety information. All safety submissions (with the exception of Local SAEs/SUSARs) should be accompanied by a completed SJGHC HREC Submission Cover Page signed by the Principal Investigator in lieu of a cover letter.

This Protocol is a SJGHC requirement for a clinical trial's continued ethical approval. It is based on the NHMRC *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (November 2016). Researchers who do not meet the following requirements may have the SJGHC HREC approval withdrawn. Please note, the guidelines refer to safety reports being provided directly from the sponsor to the HREC. For practical reasons, it is preferred that these reports are provided to the SJGHC HREC by the Site Investigators.

LOCAL SITE EVENTS (SAES AND SUSARS OCCURRING ON A SJGHC SITE)

1. Researcher is required to report local site SUSARS immediately to the SJGHC HREC on the designated SJGHC SAE/SUSAR Form, and all other local site SAEs promptly as and when these are resolved.
2. To allow the SJGHC HREC to monitor both local and other site SAEs/SUSARs with perspective and ensure that any changes in the benefit/risk balance of a clinical trial are compatible with continued ethical approval, the researcher is also required to provide the following:
    a. Their own opinion in regard to potential impact of SAEs/SUSARs on need for action and continued ethical acceptability of a clinical trial. There are specific questions within the SJGHC Local Site SAE/SUSAR Forms which address these safety issues.
    b. Copies of reports from the Independent Data Safety Monitoring Committee (IDMC) (or equivalent), as and when these are received. This will provide further advice as to whether the safety information requires or indicates the need for a change in the trial protocol including changed safety monitoring.

SAES AND SUSARS OCCURRING IN ALL OTHER AUSTRALIAN AND INTERNATIONAL SITES

1. Researchers are NOT required to complete the designated SJGHC Local Site SAE/SUSAR Form.
2. Researchers are NOT required (unless the researcher, sponsor or SJGHC HREC considers it necessary for a specific clinical trial due to its risk, size or complexity, or as required for other

purposes e.g. insurance arrangements) to report individual SAEs and SUSARs from all other Australian and international sites.

SIX MONTHLY LINE LISTINGS/SUSARS

1. As per the most recent Safety and Monitoring Guidelines published by the NHMRC in November 2016, researchers are NOT required to provide to the SJGHC HREC a six monthly listing of all SUSARs.

ANNUAL TRIAL SAFETY UPDATES

1. Researchers are required at least annually, to provide to the SJGHC HREC a trial safety update that appropriately reviews safety information in the previous 12 months. Depending on whether the trial is commercially sponsored, investigator or collaborative group sponsored, this trial safety update may take one or more of the following formats:
    a. updated investigator brochure (IB);
    b. current, approved Product Information (PI);
    c. an European Union Annual Safety Report (ASR);
    d. other trial update reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA).

Protocol Deviations and Violations

PROTOCOL VIOLATIONS

A protocol violation is a failure to comply with the study protocol as approved by the Human Research Ethics Committee (HREC). A violation is a serious non-compliance with the protocol that can result in the exclusion of a participant or their results in the study, participant refusal to be part of the study, and in some cases a charge of research misconduct.

PROTOCOL DEVIATIONS

A protocol deviation is a less serious non-compliance with the approved study protocol.

Note: Some protocol violations and deviations may be considered as a "breach of the Code" (*The Australian Code for the Responsible Conduct of Research,* NHMRC 2007) or constitute research misconduct. There is a separate reporting process for allegations of "breaches of the Code" and "research misconduct" as detailed in the *SJGHC Research Handbook*.

REPORTING PROTOCOL DEVIATIONS AND VIOLATIONS TO THE SJGHC HREC

> "Researchers have a significant responsibility in monitoring as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies, and take prompt steps to deal with any unexpected risks (section 5.5.3, *National Statement on Ethical Conduct in Human Research*, NHMRC, 2007).
>
> "An HREC must receive from any investigator(s), in an expedited manner, any deviations from the trial protocol that were undertaken by investigators to prevent imminent harm to subjects; any change significantly affecting the risk/benefit of the trial…" (pg 19 of *Australian Clinical Trial Handbook*, March 2006, TGA)

Researchers should provide written reports to the SJGHC HREC of all significant protocol violations and deviations occurring at any SJGHC participating site as soon as practicable. Minor protocol violations/deviations as well as any occurring at other Australian or overseas sites do not require reporting to the Committee.

Significance is to be determined by the researcher, but for sponsored trials this does ALSO include any protocol deviations/violations which the Study Sponsor may require to be reported to the Committee. Significance refers principally to the degree to which the protocol deviation/ violation produces imminent harm to research participants and/or alters the risk/benefit ratio of the study – thus potentially affecting the continued ethical acceptability of the research:

- There are substantive safety or ethical implications for the participant(s)
- The scientific integrity of the study is compromised (i.e. completeness, accuracy & reliability of study data is affected)

Consideration should be given to the degree to which the following are contributing factors:

- Researcher misconduct (or "breaches of the Code")

- Non-compliance with legislative requirements (e.g. privacy legislation)
- Major flaws in the study design/methodology (e.g. exclusion criteria too strict)

Researchers should report the following to the SJGHC HREC:

- Nature of the deviation/violation and reason(s) for occurrence.
- Impact of the deviation/violation on patient safety and/or scientific integrity.
- Any recommended action (e.g. participant withdrawal). Note: If any changes to the study are required as a result of the deviation/violation, an amendment should be submitted.
- Include documentation of contact with the Study Sponsor regarding the deviation/ violation and any recommended action (where applicable).
- What steps/safeguards have been/are to be taken to avoid a recurrence.

All Protocol Deviation/Violations with corrective and preventive actions (CAPA) should be submitted to the HREC with a completed SJGHC Submission Cover Page.

Fostering Clinical and Health Service Research at SJGHC

PREAMBLE

Research is pivotal to the acquisition of new knowledge, the continuous quality improvement in healthcare and the delivery of health service excellence. SJGHC acknowledges the importance of research and encourages clinical and health service research of a high ethical and scientific standard, with the ultimate regard for participant welfare.

SJGHC's Vision, Mission and Values promote a holistic and comprehensive approach to health care which respects the intrinsic and unique dignity of each human person and endeavours to nurture the whole person: their physical, intellectual, social and spiritual wellbeing. This Catholic ethical basis for SJGHC's activities extends to research: research is not merely a scientific pursuit and a good end in itself. Research is about continuing the healing ministry of Jesus Christ and promoting a culture of life.

PURPOSE

The purpose of this document is to provide an overview of how SJGHC fosters clinical and health service research of a high ethical and scientific standard with the ultimate regard for participant welfare. This overview is also a means of demonstrating SJGHC's performance against the *Australian Council on Healthcare Standards (ACHS) EQuIP National Accreditation* (and subsequent editions) standards on research governance: Standard 15.10 and Standard 15.11.

SCOPE

"Research" refers to all research including human quality improvement projects, clinical audits and undergraduate student projects which occur on SJGHC premises (including tenancies/private consultancy rooms situated within SJGHC), and/or involves SJGHC patients, caregivers or facilities/services, and is conducted by SJGHC caregivers, accredited practitioners or external researchers. It also includes SJGHC collaborative research.

THE SJGHC RESEARCH GOVERNANCE FRAMEWORK

Research governance must be of a high standard and researchers must conduct research in a manner which minimises the risks to SJGHC as an organisation, as well as the risks to its key stakeholders e.g. research participants, researchers. The SJGHC Research Governance Framework supports the conduct of research to improve the safety and quality of health care in the following ways:

1. SJGHC abides by the *Code of Ethical Standards for Catholic Health and Aged Care Services* (Catholic Health Australia, 2001) ("the Catholic Code"), the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) ("the National Statement"), the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007) ("the Research Code"), other applicable guidelines/statements and relevant state/territory and federal legislation.
2. At an organisational level, SJGHC has an overarching, group policy *Research Involving Humans* which governs the quality of research in the organisation: providing guidelines for the research

process at SJGHC and also outlines principles for the disclosure and management of conflicts of interest in the specific context of research.

3. The SJGHC Ethics Office has the role of central coordination, overseeing the review and approval of new research proposals, and under its leadership, overseeing the ongoing monitoring of approved research to the point of study completion. As the central repository for the organisation's research records, the SJGHC Ethics Office is responsible for the management and maintenance of these research data records. The office also has a key role in providing educational resources, guidance on and/or coordination of training in ethics and research matters as part of induction and continuing education for members of the SJGHC Human Research Ethics Committee (HREC) and Scientific Review Sub-committee (SRC), SJGHC caregivers and researchers. However, each SJGHC Division participating in a particular study ("the SJGHC Participating Site") is ultimately responsible for final study approval, monitoring of approved research at its site, its research data management and retention (including databanks), and the provision of ethics and research training for its caregivers.

RESEARCH DESIGN, REVIEW AND APPROVAL

The research design, review and approval process is open and transparent, well communicated, timely and effective.

1. This *SJGHC Research Handbook* is widely available to the public. It is the standard operating procedures (SOP) manual detailing the guidelines, protocols and resource information to assist in the design of an "ethical" research study, outlining the process of how to make a research submission to the Committee and the requirements to maintain ethical approval throughout the duration of a study, and including the forms and documentation required to obtain and maintain ethical approval. The *SJGHC Research Handbook* can be downloaded from the SJGHC website and is also available to SJGHC caregivers on the SJGHC Intranet (i.e. COMPASS) site.
2. SJGHC publicises its meeting and submission dates a year in advance.
3. Researchers are advised of the outcome of meetings within approximately a week - often by email as well as a posted hardcopy.
4. The SJGHC Research Governance Framework allows researchers to respond to queries and to have these reviewed promptly. Researchers are welcome to attend scheduled meetings to outline their research and address outstanding queries. Queries can also be reviewed out of session to avoid a wait until the next scheduled meeting(s).
5. The Terms of Reference for the SJGHC HREC and SRC, which are reviewed annually, are available to the public as part of the *SJGHC Research Handbook*.
6. The SJGHC HREC is accountable to and reports to the SJGHC Governing Board via the Group Chief Executive Officer.

PROJECT MANAGEMENT, DEDICATED RESOURCES AND INFRASTRUCTURE

SJGHC promotes sound research project management and ensures appropriate and sufficient resourcing of research.

1. There is a dedicated budget for the SJGHC Ethics Office. SJGHC Divisions also dedicate budget components towards research governance.

2. There are funding monies made available for SJGHC research infrastructure and research project sponsorship e.g. the Jean and John Tonkinson Research Foundation, which has been funding colorectal cancer research at SJG Subiaco Hospital.
3. There are funding monies allocated for research and ethics training of SJGHC caregivers, researchers and members of the SJGHC HREC and SRC to support them in their respective roles and ensure they can perform their duties.
4. There are dedicated personnel and infrastructure (i.e. clinical trial units, clinical trial administrators/research assistants) throughout the organisation e.g. oncology clinical trials at SJG Hospitals in Subiaco, Murdoch and Bunbury.
5. Many SJGHC Divisions have caregivers whose role it is to promote, support and coordinate research in a particular specialty e.g. Research Coordinator, Emergency Dept., SJG Murdoch Hospital, and Research Coordinator, Dept. of Anaesthesia, SJG Subiaco Hospital.

RISK MANAGEMENT

The ultimate consideration in research is participant welfare and the potential benefits which can be derived from the research for participants (as individuals or a group). Ethical research requires a thorough assessment of the risks against the benefits, and ultimately a judgment on whether the potential benefits of the research justify the risks.

1. Risk management is commensurate with the type of research and its inherent risk (i.e. potential for harm, discomfort or inconvenience) and with due consideration for the categories of study participants involved (i.e. their vulnerabilities, choices, experience, perceptions and values). With the above considerations, research submitted to SJGHC is categorised as either "negligible risk", "low risk" or "high risk."
2. There are various layers of review of new research proposals and ongoing monitoring of approved research at SJGHC, including the following:
    a. SJGHC SRC – reviews research for scientific merit and validity including major protocol amendments. The SRC also reviews serious adverse events (SAEs) that occur in the context of clinical trials, in particular suspected unexpected serious adverse events (SUSARs).
    b. SJGHC HREC – reviews research for ethical approval and monitors research progress (via annual and final study reports) including any trial SAEs/SUSARs.
    c. SJGHC Participating Site – reviews site research from an operational/logistical perspective and monitors study progress including any local SAEs/SUSARs.
    d. SJGHC Legal Services – reviews research from a legal perspective e.g. indemnity and insurance coverage, Clinical Trial Research Agreements (CTRAs) and other contractual arrangements to cover particulars e.g. intellectual property and publication rights.
    e. SJGHC Nursing & Midwifery Allied Health and Pastoral Services Research Council (NMAHPSR) – identifies priority areas for nursing, midwifery, allied health and pastoral services research, including SJGHC Division-based projects, group, multi-site studies or participation in national or international research projects. NMAHPSR explores opportunities for research involving university and other collaboration, and identifies research funding opportunities and other "non-financial" means of support for research. Ultimately, NMAHPSR aims to promote and facilitate the integration of validated research outcomes into clinical practice within SJGHC and more broadly as appropriate.

3. Depending on the "risk" of the research, there are 3 basic pathways of ethical review and approval:

    a. **Formal/Full Review:** This pathway is for studies which are "More than Low Risk" e.g. clinical trials. The SRC will firstly review the research for scientific merit, validity and safety. The researcher will be given the opportunity to reply to any scientific queries and may attend the SRC meeting to outline their study and address any queries in person, before the study then proceeds to the SJGHC HREC. Approximately within a week of the meeting, the researcher will receive written confirmation of the outcome of ethical review and provided all other approvals have been granted, final study approval from SJGHC.

    b. **Expedited Review:** This pathway is for "low risk" studies that include many of the Quality Improvement (QI) projects with a human component, or studies that are more than low risk which have already been approved by an NHMRC-certified HREC. QI Projects in Health Services (refer to *Information and Advice for Researchers Making New Submissions* in the *SJGHC Research Handbook*) details the QI that requires ethical consideration (i.e. QI conducted with or about people) and the pathway of ethical review and approval for human QI.

    Ethical review of "low risk" studies is conducted out of session by select members of the SRC/SJGHC HREC and the studies approved by the Chairman of the HREC (as delegated authority), with reporting to the SJGHC HREC at its next scheduled meeting. Other "low risk" studies may be tabled directly at the next scheduled meeting of the SJGHC HREC for ethical review only. Researchers conducting "low risk" studies complete the SJGHC Ethics Application-Low Risk Projects.

    Studies which are "More than Low Risk" but have been approved by an NHMRC-Accredited hospital-based HREC may also be approved via an Expedited Review pathway as per the *Checklist for New Submissions – Expedited Review* in the *SJGHC Research Handbook.*

    c. **Exempt from Review:** For "negligible risk" studies, there is no formal review but notification is made to the Chairman/Executive Officer of the HREC e.g. research using existing collections of data/records that contain only non-identifiable data. A record of these studies will be kept as with all other research.

4. SJGHC has an established system for research adverse event reporting and review. Refer to *Adverse Event Process* in the *SJGHC Research Handbook*.

5. SJGHC protocols on research conduct and research data management and retention (refer to *Research Conduct* and *Research Data Management and Retention* in the *SJGHC Research Handbook*) attempt to minimise risks to researchers conducting research, risks to the organisation and risks to research participants.

PRIVACY AND CONFIDENTIALITY

Privacy and confidentiality of participants in research is safeguarded:

1. External researchers are required to sign a Privacy Declaration Form.
2. Members of the SJGHC HREC and SRC are required to sign a Privacy Declaration Form.
3. Research is reviewed by the SJGHC HREC to ensure it addresses requirements of the *Privacy Act* 1988, the *Australian Privacy Principles* (APPs), and the *NHMRC Guidelines approved under Section 95(A) of the Privacy Act*.

RESEARCH INTEGRITY

Research integrity is maintained through management of potential and actual conflicts of interest, as well as appropriate complaint processes:

1. Researchers are required to sign a Declaration of Interest Form.
2. Members of the SJGHC HREC (and the SRC), as well as any others (e.g. invited experts) in attendance at these Committee meetings are required to sign a Conflict of Interest Declaration Form.
3. Research participants are alerted to the fact that they can make confidential contact with the SJGHC HREC through the Committee Executive Officer, should they have any concerns about a research study or researcher.
4. Researchers are made aware, through the *SJGHC Research Handbook*, that there is an organisational process to address any concerns they may have with the review and approval process of their research.
5. SJGHC has a separate, confidential process to review and manage breaches of the Research Code and more serious allegations of research misconduct (refer to *Research Conduct* in the *SJGHC Research Handbook*).

TARGETED RESEARCH AND CONTINUOUS QUALITY IMPROVEMENT

Decisions about research priorities and practices take into consideration the specific needs of SJGHC's patients/caregivers participating in the research:

1. A significant proportion of Australian cancer patients are cared for in the private health sector but are limited in their access to the latest oncology clinical trials. Many SJGHC Divisions are able to provide to their privately insured cancer patients, the opportunity to participate in the latest oncology clinical trials.
2. A Professorial Chair of Perinatal and Women's Mental Health (a first in Australia), established by SJGHC in partnership with the University of NSW, is able to conduct leading research into perinatal health, which in turn is contributing to improving the quality and effectiveness of SJGHC's perinatal mental health services. Similarly, SJGHC in partnership with the University of New South Wales has the only Professional Chair in Trauma and Mental Health in Australia, conducting post-traumatic stress disorder (PTSD) research and providing much needed support for our many war veterans and crisis service personnel.

3. At SJG Subiaco Hospital there are various established biobanks (e.g. Colorectal Cancer Biobank) which is being accessed for the latest human genetic research – by internal and external researchers. Human genetics is the "new frontier" in research. It has the potential to offer significant breakthroughs in diagnosis and treatment for many diseases and conditions with a genetic component, by tailoring pharmaceuticals and other therapies to an individual patient's genetic makeup.
4. A focus of SJGHC's research efforts has been in the relatively new discipline of Palliative Care – of particular relevance to Catholic teaching. Palliative care research aims to improve both the clinical management of SJGHC palliative care patients and the support provided to patients' families. This is an under-researched area in which, as per its Mission, Vision and Values, SJGHC can potentially make significant improvements towards holistic and comprehensive care to patients and their families.

INTERNAL PROMOTION OF RESEARCH

The SJGHC Research Program promotes the development of knowledge and its application throughout the organisation and wider community. As a leading Australian private health care provider, research at SJGHC is being integrated into its services and conducted as part of routine clinical practice. Thus, the focus and priorities for SJGHC research reflects the profile of, and is centred on the needs of, its patients, their families and communities, and/or its caregivers.

1. The brochure *St John of God Health Care Human Research Ethics Committee* and the ethics tool kit for managers *Role of SJGHC Human Research Ethics Committee* (both downloadable on the SJGHC intranet), the *SJGHC By-laws for Medical and Dental Practitioners* (latest edition), and the protocol on research conduct (refer to *Research Conduct* in the *SJGHC Research Handbook*) outline the specific role and responsibilities of the SJGHC HREC, SJGHC researchers, and SJGHC participating sites (managers) in the review and conduct of ethical research. The protocol on research conduct also covers the process for review and management of breaches of the Research Code as well as more serious allegations of research misconduct.
2. The SJGHC NMAHPSR, through its identification and support of nursing, midwifery, allied health and pastoral services research in priority areas, plays a key role in promoting and facilitating evidence-based practice.

EXTERNAL PROMOTION OF RESEARCH

SJGHC promotes itself as a centre for research and actively protects its reputation and relationships with external entities in the conduct of research:

1. SJGHC caregivers, clinicians, SJGHC patients and their families are provided with support and opportunities to participate in various levels of research (i.e. from human quality improvement (QI) projects and small, local pilot studies to multicentre phase II, III and IV clinical trials of new drugs/medical devices), with differing degrees of risk (i.e. negligible risk, low risk, through to higher risk research), from a variety of internal and external sources (i.e. commercially sponsored clinical trials, studies from research institutes, universities, grant-awarded research, student studies, investigator-initiated studies, etc.), in different types of research both qualitative and quantitative (e.g. interviews, observational, focus group studies, epidemiological research and/or genetic research which may use biobanks/databanks, clinical drug/device trials, innovative

therapy or other intervention studies), and covering a wide variety of both clinical and non-clinical specialties/sciences (e.g. medical, nursing, allied health, social sciences, humanities and management). SJGHC caregivers receive support to engage in research e.g. research funding, study leave, sponsorship, mentoring, access to local specialised resources and facilities.

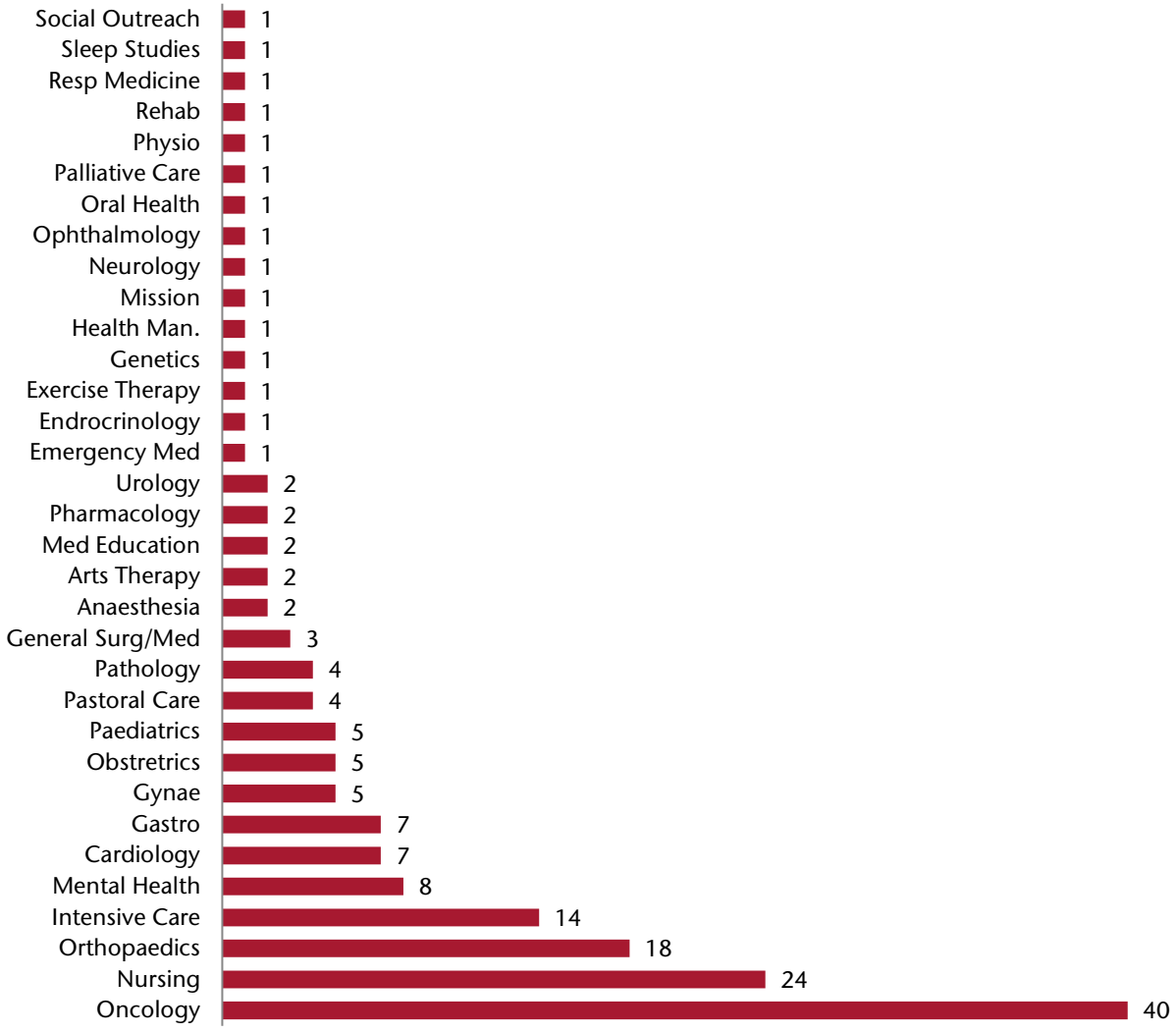
2. SJGHC caregivers and clinicians are encouraged to conduct and engage in internal quality improvement/audits as well as more formal research that has the potential to benefit their immediate workplace practice.
3. Formal collaborative research endeavours are actively sought with other organisations such as universities, other health care providers and cooperative research groups. Within nursing, there are various collaborative arrangements to develop nursing research that has the potential to contribute to improvements in nursing practice at SJGHC. SJG Murdoch Hospital and Notre Dame University have a joint appointment: a Professorial Chair of Nursing Research. There is also a Professorial Chair of Nursing, SJGHC Eastern Region, in collaboration with the Australian Catholic University based at SJG Ballarat Hospital. Research collaborations in other clinical specialities include the St John of God and Barwon Health Chair Orthopaedic Surgery in partnership with Deakin University. This position is based at SJG Geelong Hospital and aims to develop the regions academic, clinical and research capability in orthopaedic surgery.
4. SJGHC research and research outcomes are publicised to both caregivers and the broader community through SJGHC's annual report, internal management reports (e.g. trends in research activity), through the SJGHC intranet and website, and through published papers in professional journals, and presentations at conferences/seminars.
5. Formal deeds/clinical trial agreements which cover intellectual property rights and publication practices ensure that research results/findings are appropriately translated into SJGHC clinical practice to improve its service delivery and clinical outcomes.
6. SJGHC has a close working relationship with the LJ Goody Bioethics Centre and the Caroline Chisholm Centre for Health Ethics which both provide ongoing advice on clinical and research ethics issues and to reflect the CHA Code and Catholic medico-moral principles. The Director of the LJ Bioethics Centre is currently a core member of the SJGHC HREC. In these ways, SJGHC guards against clinical and research situations which may bring it into disrepute with the Catholic Church. SJGHC is thereby able to maintain its relationship with the Catholic Church, and operate as a ministry of the Catholic Church.
7. Agreements with the Barwon Health HREC to conduct ethical review and monitoring of research proposals that are conducted across both the local public and private hospitals (i.e. at SJG Hospitals in Geelong and Warrnambool), and the SJGHC membership included in the local Ballarat HREC (i.e. for SJG Ballarat Hospital), ensure that Catholic ethics is part of the HREC ethical review and deliberations for local SJGHC research.

KEY PERFORMANCE INDICATORS/RESEARCH OUTCOMES

Number of New Research Submissions per Site in 2015-2016*							
Subiaco	100	Bunbury	12	External	4	Pinelodge	1
Murdoch	38	Bendigo	5	Burwood	3	Hawkesbury	2
Midland	11	Geelong	5	Berwick	3	Pathology	3
Ballarat	9	Social Outreach	1	Warrnambool	3	Richmond	1
Mt Lawley	7	Frankston	3	Geraldton	4		

* Some research is done under more than one SJGHC site. These figures represent the number of new research projects being conducted at each site.

New Research Submissions to the SJGHC HREC in 2015-2016 by Speciality**



** This is the absolute number of new research submissions to the SJGHC HREC. In 2015-2016, the total number of new research submissions was 169.

STRATEGIC PLAN FOR RESEARCH

Active participation in research and education is a key element of our SJGHC Strategic Priorities 2015-2019 and is specifically identified as a means: to be a recognised leader in the Australian health sector for the provision of high quality health care. Research excellence is an investment in the future health of the community SJGHC serves.

It is important that new research opportunities are encouraged which continue to have regard for the SJGHC Mission and focus on areas of clinical importance, strength and organisational relevance – and in particular with greater emphasis on translational research i.e. research conducted with the input of multidisciplinary teams and thus informed by evidence from the various sciences/ specialties so as to move "from bench to bedside": from laboratory experiments and clinical trials to actual point-of-care patient applications.

The strategic focus on research incorporates an increasing research commitment as follows:

1. Facilitation of the delivery of "Excellence in Care" - safe, appropriate, and effective health - to improve outcomes for our patients/clients, by promoting continuous evaluation and learning.
2. Fostering an engaged workforce that is motivated to deliver "Excellence in Care", by providing opportunities for caregivers and accredited health professionals to engage in research activities, and actively supporting these efforts.
3. Attracting the highest quality caregivers and accredited health professionals, by enhancing SJGHC's reputation as a centre of research excellence.
4. Supporting efficient provision of healthcare and demonstrating value for money and sound stewardship of scarce resources, by evaluating current practices and introducing innovative solutions to eliminate wasteful activities.
5. Assistance in addressing areas of community need, by actively engaging with consumers and external agencies to define these priorities, and evaluating outcomes of SJGHC initiatives.

Time Limits on Research

A patient cannot give indefinite consent to access personal health data (e.g. from health records). When they consent to participate in a study, patients must be made aware of, and consent to, a specified time period for which their health data will be available to the researcher. The following Protocol is a requirement for the St John of God Health Care (SJGHC) Human Research Ethics Committee (HREC) approval.

SPECIFIC TIME PERIODS

1. For each new research application submitted for review to the SJGHC HREC, the researcher must specify:
    a. The time period for which access is required to a patient's health data/health records ("data collection phase"). The precedent for the data collection phase is no longer than 3 years.
    b. The time period for the study as a whole ("study time period). The study time period will normally be longer than the data collection phase, and will vary with the complexity of the research.
    c. In the case of Registries and Biobanks (with an indefinite finish date) the SJGHC HREC may approve the study with no stated finish date.
2. Both the data collection phase and the study time period must be defined in the research application and in the Patient Information and Consent Form (PICF) by specific commencement and completion dates.
3. The researcher may not access data after the data collection phase has expired, unless an extension has been granted by the SJGHC HREC.

EXTENSIONS

4. The researcher wishing to extend the specified time periods (either the data collection phase or the study time period), is required to make application to the SJGHC HREC. The relevant periods are noted in 1.a and 1.b above.
    a. If this application is made before the expiry of the relevant period, the researcher need seek only an amendment to the existing approved study.
    b. If this application is made after the expiry of the relevant period, the Committee will deem this to constitute an entirely new study, for which a new research proposal must be lodged.
5. The researcher wishing to extend the range of data collected is also required to make application to the SJGHC HREC.
    a. The Committee will first determine whether a proposed extension substantially alters the aim or scope of the original study.

b. If this application is made before the expiry of the relevant period, and does not substantially alter the aim or scope of the original study, the researcher need only seek an amendment to the existing approved study.
c. If this application is made after the expiry of the relevant period, or substantially alters the aim or scope of the original proposal, the Committee will deem this to constitute an entirely new study for which the researcher must lodge a new research proposal

6. All requests for study extensions should be made to the SJGHC HREC using the SJGHC Submission Cover Page.

Research Data Management and Retention

PREAMBLE

The *Australian Code for the Responsible Conduct of Research* (2007) ("the Code") describes the role and responsibilities of researchers and institutions in the appropriate collection, use, disclosure, storage and destruction of research data, and the important contribution this makes towards the responsible conduct of research.

Research data must be managed to ensure confidentiality and security of personal information of a sensitive nature, and so comply with relevant privacy legislation.

Ultimately, researchers must ensure the integrity and scientific rigour of their research. Research data must be accurate, complete, authentic, reliable, and in a durable and retrievable format to allow verification of results. Determining what research materials to retain should be considered in terms of the potential future value of the data, and whether the research can be replicated.

PURPOSE

This protocol provides guidelines for the effective management and retention of research data at St John of God Health Care (SJGHC). It should be read in conjunction with the Code and the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007), chapter 3.2: Databanks.

Researchers conducting research involving SJGHC, their research units/SJGHC Division(s) involved in the research and the SJGHC Ethics Office (the personnel providing administrative support to the SJGHC HREC), are all obliged to follow this protocol.

DEFINITIONS

Research data refers to information and records obtained and used for research purposes at SJGHC including source documents/primary materials and person-identifying research material:

1. Information obtained from the person in interview, questionnaires, focus groups, audiotape, audiovisual records, photographs, personal and medical histories, biographies, and demographic information.
2. Clinical, social or observational information from a source other than directly from the person, e.g. medical notes, information from a person's carer or relative.
3. Information derived from human tissue e.g. blood, bone, muscle, organ and waste products, including genetic and radiological information – unless this information forms part of a human tissue bank. Research data collected in association with a human biobank is NOT covered by this protocol. For guidelines on the establishment, governance, management and use of human biobanks, genetic research databases and associated data used for research purposes, refer to the OECD Guidelines on Human Biobanks and Genetic Research Databases (2009). Another useful resource document is the Biobanks Information Paper (NHMRC, 2010).

For the purposes of this protocol, research data also refers to records of research studies and records of research ethical review processes maintained by the SJGHC Ethics Office.

Databank refers to a systematic collection of data or information, whether individually identifiable, re-identifiable or non-identifiable.

Human Biobank refers to an organised collection of human biological material (e.g. blood, urine, tissue samples or material collected e.g. DNA extracted) and any related information stored for more than one or more purposes. It includes human and population genetic research databases and collections, otherwise known as bio-repositories or gene-banks. Related information refers to information collected in the establishment of the database and information that is obtained through research on the material held (e.g. personal, clinical, genetic, biochemical or phenotypic information).

Individually identifiable data refers to data with individual identifiers such as individual's name, image, date of birth, address.

Re-identifiable data refers to data where individual identifiers have been removed and replaced with a code. By using the code or linking different data sets, individuals can be re-identified. The term 'de-identified information' is not used in the National Statement as it can be misinterpreted ie de-identified information may be re-identifiable or non-identifiable, depending on the process used to de-identify the information and depending on the point of reference.

Non-identifiable data refers to data with no individual identifiers.

Databank custodian refers to the individual researcher or research unit/SJGHC Division who collected the data, or an intermediary such as a data warehouse that manages data coming from a number of sources.

SCOPE

This protocol applies to research data covering various data sources including databanks. Whilst databanks may be initially created and used for reasons other than research such as disease surveillance and quality assurance, they have potential use in future research.

GUIDELINES

5.1 Research data should be accurate, complete and in sufficient detail to enable the published research results and methods to be open to scrutiny by colleagues and the research community at large. Secrecy of research data should only be necessary for a limited period in the case of contracted research or in specialised areas where the cooperation of research subjects will not otherwise be attainable.

5.2 Research data should be recorded in:

5.2.1 a durable form (preferably electronic with a backup system),

5.2.2 a secure form to ensure confidentiality and privacy of identifiable, sensitive data,

5.2.3 an appropriately referenced and retrievable/accessible form.

5.3 During the course of a study, researchers are responsible for ensuring their research data is held in a secure place with access limited to only those involved in the study. To protect privacy and confidentiality, once information is collected, any identifying records of individual persons should be held separately from the research data.

5.4 The minimum period of research data retention is determined by the specific type of research. As per the Code, section 2.1.1, generally all research data is to be retained for a minimum of 5 years from the date of publication or 5 years following the completion of the research if publication is not intended. The exceptions are:

5.4.1 student projects that are for assessment purposes only, need only be kept for 1 year after completion.

5.4.2 clinical trial research data must be retained for at least 15 years from the completion of the trial, and may need to be kept indefinitely depending on whether there is persistence of interest and discussion in the research, and/or the research work continues to have community or heritage value.

5.4.3 If a research study has community or heritage value, it must be retained permanently.

5.4.4 If a research study is relevant to a known or anticipated legal action then the research data must be kept until legal proceedings are complete.

5.4.5 If a research study is relevant to an allegation(s) of research misconduct, it must be retained permanently.

5.5 There is a need to be cognisant of any differing obligations for research data retention within contractual arrangements, professional standards, legal requirements or award conditions. These may specify longer research data retention periods e.g. trial sponsors may have specific requirements for research data retention stated in Clinical Trial Agreements.

5.6 Researchers should factor into their initial study budgets the cost of research data retention, and ensure through their department/SJGHC Division where the research is conducted that there are adequate arrangements for research data storage and for later secure destruction.

5.7 The research unit/SJGHC Division where the research is conducted should normally be responsible for maintaining specific registers of:

5.7.1 their research data and their location, and have procedures for retention of the research data.

5.7.2 their databanks (even if not currently used for research).

5.8 All new databanks that are created at SJGHC – even if not for the initial intention of research, should be submitted for approval to the SJGHC HREC. The collection, use, disclosure and storage of data for research purposes requires participant consent or otherwise a waiver of consent granted by the SJGHC HREC.

5.9 Researchers cannot access identifiable data in a databank without prior ethical review.

5.10 For databanks, participant consent should specify:

5.10.1 whether data will be stored in identifiable/re-identifiable/non-identifiable form.

5.10.2 the purposes for which the data will be stored, used and/or disclosed.

5.10.3 whether specific, extended or unspecified consent for future research is being sought or otherwise a waiver of consent by the SJGHC HREC.

5.11 Databank custodians are responsible for insuring that databank information is used responsibly and respectfully, and that the privacy of participants is safeguarded.

5.12 Whenever research using re-identifiable data reveals information that bears on the wellbeing of participants, researches have an obligation to consider how to make that information available to participants and the databank custodian must take all necessary steps to re-identify those data.

5.13 Separate to registers maintained by the research unit/SJGHC Division, the SJGHC Ethics Office will maintain a central database on the SJGHC computer network, of all research applications made to SJGHC. The database, which will have secure and limited access available to key personnel, will record summary details about each research study, including when the study has been completed/published and the retention/ archival details period. The database will also act as a management tool to track each component of approval (i.e. ethical, legal, operational, final approval) and study progress i.e. from submission, to final destruction (OR permanent archive) of the research record.

5.14 The SJGHC Ethics Office will maintain a complete record of every research study application (i.e. including all correspondence relating to the study approval process) in electronic form: Adobe Acrobat (pdf/a.) which is an archival format designed for long terms storage, on CD-ROM/USB, with a back-up on the SJGHC computer network. The computer back-up will be password protected so as to prevent unauthorised access, and only accessible by the SJGHC Ethics Office personnel. This computer back-up ensures that research records are never tampered with or lost. Individual CD-ROM records will be archived under lock and key in the SJGHC Ethics Office or otherwise in a secure, retrievable off-site location.

5.15 Research data forming the basis of publications must be available for discussion with peers/other researchers. Thus, where possible it is preferred that all research data be kept in a re-identifiable form that allows reference by third parties without breaching confidentiality and privacy.

5.16 For the protection of participant privacy and confidentiality, the key to the code for re-identifiable data must be kept separately to the databank.

5.17 In general, identifiable research data must not be transferred outside of SJGHC. Exemptions may apply if participants have given explicit informed consent or if relevant law provides for a transfer or disclosure.

5.18 SJGHC Legal Services will review all Clinical Trial Agreements (CTRAs) to ensure they cover specific requirements for research data ownership and storage during and following research study completion, including in the situations when researchers move between institutions or employers, or data is held outside of Australia. SJGHC Legal Services will also review CTRAs for confidentiality clauses aimed at protecting intellectual property rights, so as to reach explicit agreement on any limitation of free publication and discussion of research results and any restrictions on the use of the research data.

5.19 Generally, research data generated at SJGHC will remain the property of SJGHC. However, for collaborative research conducted across institutions, ownership of data may be negotiated. SJGHC Legal Services should be approached to develop a formal, written agreement between the relevant parties.

5.20 At the end of the research data retention period, research data must be securely and safely disposed of in a confidential manner as per the most effective method at the time, for example:

5.20.1 Research data in paper format should be destroyed by shredding or placing it in the secure SJGHC blue coloured, “confidentiality” bins.

5.20.2 Research data stored in electronic format should be destroyed by rewriting, reformatting or deletion of files.

Electronic Signatures for Submissions to SJGHC HREC

The forms used for submissions to the SJGHC HREC include signature fields where the image of a signature can be uploaded and saved in the form. This is in lieu of wet ink signatures and aids in the transfer of data to the SJGHC Ethics Database. If the signatory is not the person sending the submission electronically to the SJGHC Ethics Office, they must be copied in on the submission email.

The SJGHC Ethics Office allows for the delegation of the role of adding the Principal Investigator's electronic signature to submissions, ***providing the following conditions are met:***

1. The Principal Investigator must complete a Delegation of Authority Log (see below for example), sign this with ink and send the original copy to the SJGHC Ethics Office. This must be received by the SJGHC Ethics Office prior to any submissions where the signature has been added by the delegated individual.
2. The Principal Investigator must be copied in on any correspondence where their electronic signature has been used.

If the forms are printed off for a wet signature, please note that the original is not required by the SJGHC HREC. Please scan the signed forms and email this to the SJGHC Ethics Office.

EXAMPLE DELEGATION OF AUTHORITY LOG

I, [Principal Investigator Name], delegate [Study Coordinator/Other Representative Name] to add my signature to any correspondence to the SJGHC HREC regarding the following study/studies:

- [Study Name]

This delegation is granted with the understanding that I will be copied in on all correspondence which contains my signature. My nominated email address for this purpose is: [Principal Investigator Email]

Signed:

Date:

Research Conduct

PREAMBLE

Researchers should be aware of and comply with the ethical framework governing clinical practice and research at St John of God Health Care (SJGHC):

1. *Statement of Philosophy and Statement of Medico-Moral Principles*, and *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* (2001),
2. *The National Statement on Ethical Conduct in Human Research* (2007) ("the National Statement"),
3. broader legislative requirements and guidelines governing research (refer to the *Useful References* list of this *SJGHC Research Handbook*),
4. *The Australian Code for the Responsible Conduct of Research* (2007) ("the Code").

The Code jointly issued by National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) and Universities Australia, describes the principles of responsible/good clinical research practice (GCRP), and identifies the respective responsibilities of institutions and researchers in e.g. research data management, conflict of interest, researcher training/mentoring, publication and authorship, and handling of breaches of the Code and research misconduct.

PURPOSE

The purpose of this protocol is to describe the standards for research conduct at SJGHC, and to outline the procedures for dealing with complaints about research conduct - assessed as either breaches of the Code or research misconduct.

SCOPE

This protocol applies to research in its broadest sense and includes quality assurance/audit. It refers to research on SJGHC premises (including tenancies/private consultancy rooms situated within SJGHC), and/or involving SJGHC patients, caregivers or facilities/services, and conducted by caregivers, accredited practitioners or external researchers. It includes collaborative research involving SJGHC.

The focus is on research conduct beyond initial approval granted by the SJGHC HREC and the associated conditions of approval. The protocol is based on the Code- being a prerequisite for receipt of NHMRC funding - and should be read in conjunction with the Code.

STANDARDS

1. Integrity

Researchers should demonstrate integrity, professionalism and commitment to excellence. Peer review and consumer/community input into research are extremely valuable. Whilst some degree of secrecy to protect one's own research interests may be warranted, particularly for commercial reasons, researchers should engage in peer review and be as open as possible in discussing their

work with other researchers, consumers and the public at every stage of the research process. Researchers should make both their research methods and study results open to scrutiny and debate.

2. Safety and Risk Management

Underlying the consideration of safety in research is the ethical obligation of researchers to inflict no harm on research subjects, and to minimise potential risk of harm: burden, discomfort or inconvenience to study participants, the research team, the participating SJGHC site and the wider community. Risk may be physical (e.g. pain, infection, adverse drug reactions), psychological (e.g. depression, confusion, guilt), social (e.g. invasion of privacy, loss of community standing), legal (e.g. criminal prosecution) or economic (e.g. loss of employment).

An example of how researchers can minimise risk, is to consider (where relevant) adding a patient specific research alert system to their study e.g. a system of flagging to caregivers in an individual patient's medical record that they are a study participant.

Another example is for researchers/departments involved in regular research to consider maintaining a register of study participants to ensure that individuals have not been "overused" in research. This register should be made available to the SJGHC HREC for scrutiny on request.

3. Respect for Research Participants

Where possible and appropriate, study participants should have the opportunity to receive their individual results/feedback about the outcome of the study in which they have participated. Researchers should consider the possibility for individual participant feedback at the initial stage of study design.

4. Conflicts of Interest

A conflict of interest frequently occurs in the context of research - where researchers have competing obligations and a real, perceived or potential opportunity to prefer their own personal interests to that of the research. A conflict may relate to financial interests, private, professional or institutional benefits that depend significantly on the research outcome. A conflict of interest can potentially compromise researcher integrity and the reputation of SJGHC, and be detrimental to the well-being of research subjects, research governance, and/or the actual research outcomes.

The responsibility for managing a conflict of interest in research rests firstly with researchers. Researchers are required to avoid conflict of interest, and to openly declare, and manage appropriately all actual and potential conflicts of interest. Full disclosure should occur at the initial stage of submitting a research proposal to the SJGHC HREC. Refer to the *Declaration of Interest* in the *SJGHC Research Handbook* which must be completed as part of all new research submissions.

Any conflicts of interest that subsequently arise during the course of a study, must be reported as soon as reasonably practicable to both the SJGHC participating site(s) in the study, and to the SJGHC HREC, with a proposal from the researcher for management or elimination of the conflict of interest. This proposal will be reviewed by the SJGHC participating site and the SJGHC HREC and a finalised version of the proposal will then be agreed in writing between the parties.

The above process will also apply to conflicts of interest declared by institutions involved in multicentre trials.

5. Training and Mentoring

All researchers should have the skill and expertise to undertake a particular research project appropriately or otherwise undergo prerequisite training before engaging in the research. In support of this, SJGHC provides the opportunity for internal researchers to access relevant induction and training courses in research and seek guidance from professional bodies in developing their research expertise.

Access to educational resources in research ethics is also available through the SJGHC Ethics Office and the LJ Goody Bioethics Centre (Mt Hawthorn, Western Australia). A wide range of needs for education in research ethics can be met:

1. Clinicians/Caregivers (i.e. who spend the least amount of their time on research)
2. Students/Junior Researchers (i.e. completing undergraduate/postgraduate studies)
3. Researchers (those who spend most of their time doing research)

The Principal Investigator, and in turn the senior associate researcher(s) should act as research mentors and provide at every stage of the research process, adequate and appropriate direction and supervision to new/trainee researchers, junior researchers and/or students assisting with a research study. For example, as research mentors, they can provide guidance in the complexity of scientific methods and advanced statistical analysis, interpretation of ambiguous data, data management and storage, meeting ethical, operational and regulatory requirements for conduct of research, etc.

6. Publication and Authorship

Researchers are encouraged to publish all research findings in refereed journals as soon as possible after study completion and regardless of outcome (i.e. including negative findings and results contrary to study hypotheses). Any publication delays should not exceed the time needed to protect intellectual property and other relevant interests.

Anyone listed as an author on a publication should accept responsibility for ensuring content familiarity and can identify their contribution to it.

Researchers are encouraged to communicate their research findings through SJGHC media, namely the SJGHC website. Specific permission from researchers is requested as part of the SJGHC annual study progress/final report proformas.

7. Collaborative Research

For collaborative research involving SJGHC, researchers are required to approach SJGHC Legal Services to assist with the establishment of a prior written agreement between the parties. This agreement will cover intellectual property, confidentiality and copyright issues, sharing commercial returns, management of conflict of interest, responsibility for ethics and safety clearances and reporting requirements, dissemination of research results, and the management and retention of primary research materials/research data after study completion.

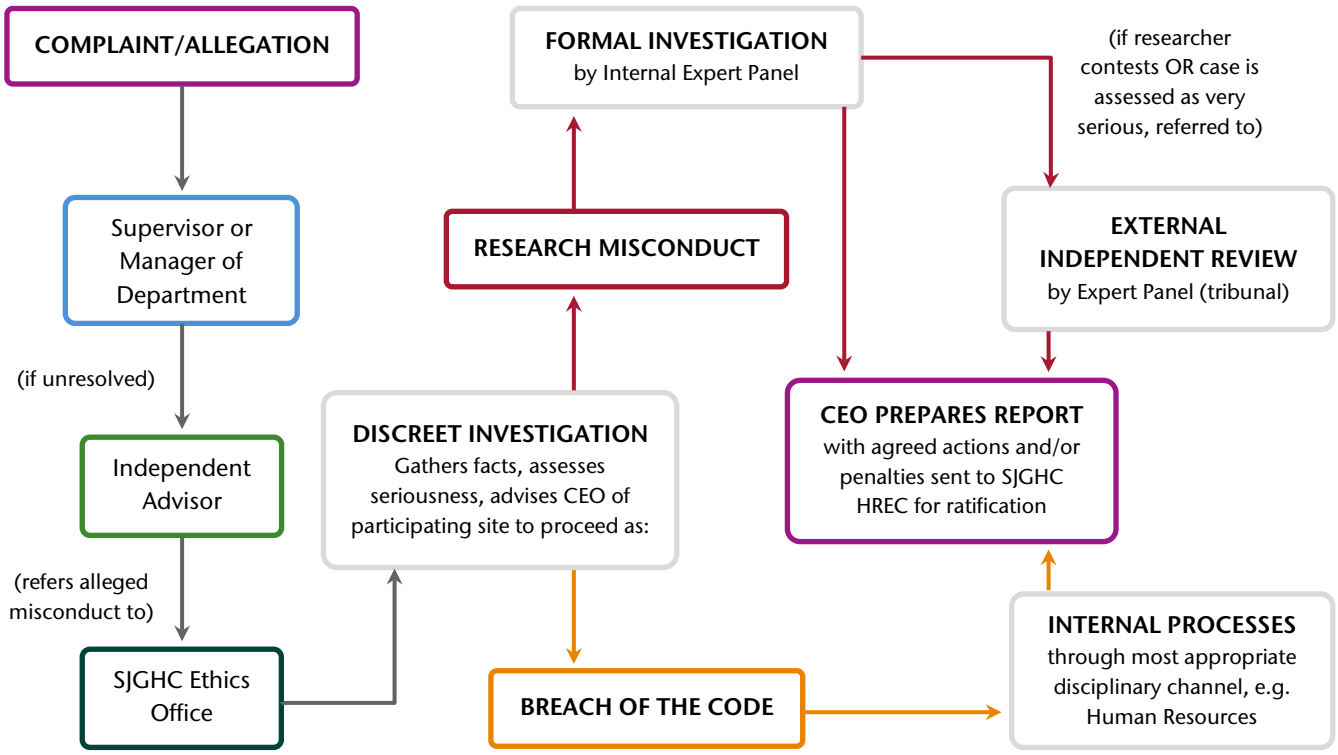
8. Breaches of the Code and Research Misconduct

All researchers, SJGHC caregivers and accredited practitioners are obliged to report suspected or actual research misconduct in a timely manner. “Breaches of the Code” (i.e. minor deviations from the Code) may include honest errors in design or execution of research or interpretation of results, and may occur through research inexperience. “Research misconduct” (i.e. serious, deliberate,

persistent deviations from the Code) may include falsification, plagiarism, deception in proposing, carrying out or reporting research results, failure to declare or manage conflicts of interest, failure to observe the National Statement or the Code, including this SJGHC Protocol, concealment or facilitation of research misconduct, of failure to carry out research as approved by the SJGHC HREC especially where there is unreasonable risk or harm to research subjects.

All official complaints of research misconduct will be investigated and acted upon promptly. Every effort will be made to treat parties fairly, to remedy the situation, and to maintain public confidence in research.

PROTOCOL TO ADDRESS COMPLAINS ABOUT RESEARCH CONDUCT



1. Wherever possible, supervisors/department managers should be the first point of contact when concerns arise. Any breaches of the Code may be addressed and remedied at the departmental level. It is the responsibility of supervisors/department managers to address these appropriately and maintain full records of the process.
2. If a complaint (i.e. which is no more than a breach of the Code), cannot be resolved to everyone's satisfaction at the departmental level, then an independent, confidential advisor should be contacted. This may be the CEO (or a delegate) of the SJGHC Participating Site involved in the research. The role of an advisor is to provide advice only. It is NOT an advisor's role to contact the person who is the subject of the allegation, to conduct investigations or to make assessments of any allegations.
3. Official complaints should be put in writing to the Executive Officer, SJGHC HREC. A discreet investigation will be coordinated by the Chair, SJGHC HREC (or other senior SJGHC delegate experienced in research) in collaboration with the relevant Director of the SJGHC participating

site(s) involved in the research. The purpose of this investigation is to gather facts and recommend how to proceed:

   a. dismiss the allegation,
   b. the complaint assessed as unrelated to research conduct, be dealt with through existing internal SJGHC provisions/disciplinary channels unrelated to the Code e.g. Human Resources (HR),
   c. the complaint assessed as a breach of the Code be dealt with through existing internal SJGHC channels,
   d. the complaint assessed as research misconduct undergo a formal investigation.

4. If the complaint is considered to be a breach of the Code, written advice will be given to the Chief Executive Officer (CEO) of the SJGHC participating site involved in the research with the recommendation that it proceed through the most appropriate organisational channel (e.g. a case of harassment will proceed through HR processes).
5. The CEO will then prepare a written report with recommendations of actions agreed to amongst the parties (i.e. SJGHC participating site, researcher, sponsor, principal investigator, supervisor, publisher, etc.) to remedy the situation. This report will be sent to the SJGHC HREC for ratification before implementation.
6. If the complaint is considered possible research misconduct, written advice will be given to the CEO with the recommendation that the complaint proceed to a formal investigation.
7. The CEO will convene an expert panel to conduct the inquiry and report on fact.
8. The CEO is then responsible for providing the researcher who is the subject of the allegation, a written statement of the allegations and the suggested actions to follow.
9. The researcher has fourteen (14) days in which to respond in writing to this statement.
10. The CEO will then prepare a written report with recommendations of actions including any penalties agreed to amongst the parties (i.e. SJGHC participating site, researcher, sponsor, principal investigator, supervisor, publisher, etc.) to remedy the situation.
11. This report will be sent to the SJGHC HREC for ratification before implementation.
12. Imposition of penalties for research misconduct (such as termination of employment, removal of accreditation privileges, etc.) will be guided by SJGHC policies for employment, accreditation, collaborative research agreements, etc.
13. Should the researcher contest the formal investigation findings or should the complaint be assessed from the onset as very serious, it will be referred for independent, external review: the CEO will convene a panel of external experts to act in the capacity of a tribunal and to report on fact. The panel will have access to legal counsel to assist in the inquiry and the researcher facing the allegations will be entitled to legal representation.
14. Should the researcher under inquiry contest the external panel findings, they may appeal to a higher authority, most usually the courts.
15. Upon expiry of an appeal period to be determined by the SJGHC HREC, the CEO will then prepare a written report with recommendations of actions including any penalties agreed to amongst the

parties (i.e. SJGHC participating site, researcher, sponsor, principal investigator, supervisor, publisher, etc.) to remedy the situation.

16. The report will be referred to both the SJGHC Governing Board and the SJGHC HREC for ratification before implementation.

17. Should research misconduct be found, the finding will also be reported to all relevant parties such as the sponsor and publishers. Action may include correcting the public record of the research. SJGHC will also forward to the NHMRC copies of reports from formal investigations of research misconduct associated with NHMRC funding. NHMRC may act to recover Commonwealth monies, impose sanctions or undertake compliance audit. Refer to the *NHMRC Policy on Complaints* (2008).

Statement of Medico-Moral Principles

1. The statement of the Medico-Moral Principles set out in following paragraphs 3.1 to 3.20 together with the philosophy statement of Catholic health care attached ("Philosophy Statement") comprise the guidelines for all who serve in Catholic health care institutions.

2. This statement:

   (i) deals with aspects of this Christian witness where they touch on medical ethics, the moral teaching of the Catholic Church, and the pastoral care of the sick; and

   (ii) is a directive to every medical and dental practitioner (the "Practitioner") who practises at a Division ("Division") conducted by St. John of God Health Care.

   (iii) is to be read in conjunction with the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (Catholic Health Australia, 2001) and subsequent editions ("the Code of Ethical Standards").

3.1 Those that accept appointments in, or are accredited to Catholic health care institutions, facilities or programs are required to respect the moral teaching of the Catholic Church in respect to present day medicine.

3.2 Catholic health services should care for all patients conscientiously and devotedly. The total good of the patient is the primary concern of the Catholic health care ministry. It is therefore required that the highest standards of medical competence and nursing care be employed in the treatment of patients.

3.3 The spiritual welfare of a person is an integral part of a patient's care. Therefore chaplains and pastoral practitioners are considered members of the health team and must be given every assistance in ministering to the welfare of the patient. Every patient has the right to request that the Minister of his or her choice be asked to visit him or her.

3.4 The patient has the right to be adequately informed of his or her condition by the physician or some other person.

3.5 (a) All patients are entitled to ordinary medicine and nursing care which promised to be beneficial in treating their condition, which is reasonably available, and which is not judged to be unreasonably burdensome. Such treatments are judged "ordinary" and are obligatory.

   (b) Treatments may be judged "extraordinary" and optional if, in view of the patient's actual condition, they do not promise reasonable benefit, and not reasonably available, or are considered to be unreasonably burdensome. Depending on the patient's condition such means may sometimes include the use of respirators, dialysis machines, organ transplants, repeated blood transfusions, prolonged use of drugs such as antibiotics, cardiac stimulants, etc.

   (c) The provision of nutrition and hydration even by artificial means is, in principle, ordinary care and as such is morally obligatory, unless or until they cease to be

metabolised adequately or their mode of delivery becomes unreasonably burdensome.

(d) A decision not to use extraordinary means to prolong life should always involve the participation of the competent patient, and also the patient's close relatives. When such a decision is made, medical and nursing staff are to continue to provide the patient with dignified care.

3.6 Everyone has the right and the duty to prepare for the solemn moment of death, and to be well prepared for death as regards both spiritual and temporal affairs. It is the physician's duty to inform the patient of his or her critical condition, or to have some other responsible person impart the information.

3.7 After death the body is attended with respect of dignity.

3.8 The next of kin, spouse and parents of the patient, with the patient's consent, should be kept promptly, reliably and courteously informed regarding the patient's condition.

3.9 The obligation of professional secrecy must be carefully maintained not only as to the information on the patient's charts and records but also as to confidential matters learned in the exercise of professional duties.

3.10 No doctor, nurse or other health care personnel may participate in any procedure of reproductive technology that is not consistent with Catholic moral teaching.

3.11 Abortion, that is the directly intended killing of the foetus before viability, is never permitted.

3.12 Operations, treatments and medications, which do not directly intend or effect termination of pregnancy but which have as their purpose the necessary treatment of a pathological condition of the mother, are permitted when they cannot be safely postponed until the foetus is viable, even though they may or will result in the death of the foetus.

3.13 Euthanasia refers to any act or omission which of itself and by intention causes death, with the purpose of eliminating suffering. Euthanasia in all its forms is forbidden.

3.14 In proper palliative care the primary need is to strive to keep the patient pain free. When such a measure is judged necessary, it is morally justifiable to give a dying person, sedatives and analgesics for the alleviation of pain even though they may deprive the person of consciousness, the use of reason or may unintentionally shorten life.

3.15 Sterilisation procedures, whether permanent or temporary, for men or women, are not to be performed as a means of contraception. Treatments or medication for recognized pathologies which have a secondary unintended effect of producing temporary or permanent sterility may be prescribed when they are medically indicated.

3.16 The transplant of organs from living donors is morally permissible provided the loss of such organs does not deprive the donor of life itself, or of the functional integrity of the body. All such procedures require appropriate free and informed consent, referable to both donor and recipient.

3.17 When there is a difficulty in deciding the moral principles involved in a particular procedure, a medical moral ethics committee or a moral consultant approved by the local Bishop, will be available for consultation.

3.18 In all forms of research wherein the identity of the patient is included in the data, the informed and free consent of the patient is to be obtained. All research procedures are subject to the rulings of the relevant medical, scientific, ethics and other decision-making bodies of the institution.

3.19 The Catholic health ministry, with the approval of the local Bishop, may issue additional principle requirements in relation to medico-moral matters, or may take any action appropriate to the maintenance and preservation of the principles it upholds.

3.20 This statement of Medico-Moral Principles is based on current knowledge and understanding. Particular applications may be modified as scientific investigations and theological developments present new problems or cast light on current ones.

4. In addition and to give effect to the Principles, each Practitioner shall, while practicing at the Division or in premises leased or sub-leased to him by St John of God Health Care Inc:

(a) in the treatment of his or her patients, respect the moral teaching of the Catholic Church and the principles set out in paragraphs 3.1 to 3.20 above and the Philosophy Statement and not do or neglect to do any act or thing which conflicts with those principles or statement;

(b) use his or her best endeavours to provide quality care for patients including their physical and psychological well-being;

(c) provide to his or her patients such medical and nursing care as may be necessary to treat those patients and use his or her best endeavours to relieve those patients of physical and mental distress and pain;

(d) provide his or her patients with information regarding counselling and other services as directed by St John of God Health Care from time to time;

(e) not be obliged to use extraordinary means to prolong a patient's life;

(f) keep secret and confidential all medical information relating to the patient and all other information of a confidential nature acquired in the exercise of his or her professional practice and not disclose such information without having first received the patient's prior informed written consent;

(g) not conduct any practice that intentionally results in abortion, that is the direct killing of the foetus. However, a practitioner shall be entitled to conduct operations, and to provide treatment and medications which do not and are not intended directly to or effect termination of pregnancies but which have as their purpose the necessary treatment of a pathological condition of the mother, when such operations, treatment and medications cannot be postponed safely until the foetus is viable, even though they may or will result in the death of the foetus;

(h) not engage in or practice euthanasia that is any act or omission which of itself and by intention causes death, with the purpose of eliminating all suffering;

(i) be entitled to administer to patients sedatives and analgesics even though the unintended effect of so doing may be to deprive the person of consciousness or the use of reason or unintentionally shorten life, where the Practitioner is of the opinion

which is properly arrived at, that such administration is necessary for the alleviation of pain; and

(j) be entitled to transplant organs from living donors provided that the loss of such organs does not deprive the donor of life or deprive the body of its functional integrity and provided further that prior to performing such procedures the Practitioner shall obtain the free and informed consent of both the donor and recipient.

5. Each Practitioner must:

(a) at all times conduct his or her practice in a way which respects and does not offend the Code of the Canon Law and the teachings and traditions of the Catholic Church in relation to health care as set out in the Code of Ethical Standards;

(b) at all times abide by the Philosophy Statement and the Mission and Values of St. John of God Health Care as set out in the publication "Well Springs", a copy of which the Practitioner acknowledges having received; and

(c) if any doubt arises as to what the Canon Law or those teachings or traditions are or as to the manner in which the same apply or be construed in a particular case or as to the construction or interpretation of anything contained in this Statement or in the Philosophy Statement, consult the Medical Advisory Committee of the Division and abide by every decision made by it.

6. Each Practitioner acknowledges and agrees that:

(a) this Statement of Principles is not intended to be a complete and exhaustive statement of the principles which are to apply to him or her and by which he or she is to be bound in the conduct of his or her practice at the Division; and

(b) this Statement of Principles may be added to, amended or varied by St. John of God Health Care consistent with the Principles of Catholic Health Australia in light of current scientific and medical knowledge and that any such additions, amendments or variations will take effect from the date of such addition, amendment or variation but will not have any retrospective application.

7. Each Practitioner acknowledges and agrees that by applying for accreditation or renewal of accreditation or by continuing to practice at or from the Division after the receipt of these By-Laws he or she agrees to be bound by and to comply with this Statement and the By-Laws as amended from time to time.

Catholic Health Care Philosophy Statement

The church's mission is to proclaim and mediate the healing redemptive love of Jesus Christ in the world.

Catholic health care institutions exist to be a visible expression of their mission. They witness, through the Health Services entrusted to them:

- By testifying to the transcendent spiritual values concerning life, suffering and death;
- By service to all humanity and especially the poor;
- By fostering medical competence and leadership;
- By providing spiritual assistance to the sick;
- By fidelity to the Church's teachings while ministering to the good of the whole person, regardless of sex, status, race, colour or creed.

We collectively embrace and are committed to the Statement of Philosophy as hereafter described:

- Ensuring reverence and respect for all persons regardless of race, creed, sex or economic status from the moment of inception of life to death.
- Providing services with compassion, a caring attitude and positive moral support to every person, especially the spiritually and economically poor and the dying.
- Fostering and promoting competence and excellence among the Medical, Nursing, other allied health professionals and colleagues involved in providing services to people within the Catholic health ministry.
- Encouraging positive communication, working relationships, co-operation and collaboration among colleagues in rendering care to persons based on Gospel values, and Christ, the Divine Physician, as the model.
- Promoting responsible stewardship of human, material, physical and financial resources which are made available for use in the provision of health care services.
- Striving to understand and respect the rights and responsibilities of persons, whether caregivers, patients, visitors, doctors or volunteers, in a sensitive, truthful and ethical manner.

Clinical Trial Research Agreements – Legal and Insurance Guidelines

Topic: Clinical Trial Agreements – Legal and Insurance Guidelines

Contact Dept: SJGHC Ethics Office **Compiled:** September 2008

Person Responsible: Ethics Executive Officer **Last Reviewed:** May 2013

1. PURPOSE

Clinical trials play an important role in the health sector and provide significant benefits to trial participants and the medical community. St John of God Health Care (SJGHC) supports the conduct of clinical trials at its premises subject to the highest standards of care.

This procedure is to assist with the review of clinical trial research agreements (CTRAs) for research conducted at SJGHC by establishing the legal and insurance prerequisites for SJGHC, as a private health care organisation, to be a party to a clinical trial.

Adherence to this procedure will assist with an efficient approval process. SJGHC aims for a 2 week turnaround time for review of CTRAs (and where applicable an Insurance Certificate of Currency) from the date of submission. This 2 week timeframe is on a "stop-the-clock" basis and is on the proviso that the CTRAs accord with the requirements set out in these Guidelines. CTRAs which do not accord with the requirements set out in these Guidelines, will take significantly more time to review and may not be accepted.

2. TYPES OF CLINICAL TRIALS

For the purposes of these Guidelines, a clinical trial has a broad meaning and includes clinical interventional studies*.

There are several different structures of clinical trials depending on the body retaining "sponsorship" of the trial. The table: Attachment A will assist in determining the appropriate type of trial proposed.

Unless SJGHC determines that a clinical trial is "low risk", a suitable CTRA will be required. This assessment will be made by SJGHC based on the details of the nature of the trial and takes into account factors other than just clinical risk.

(* Studies where there is any form of clinical intervention and not solely a clinical trial of an unapproved therapeutic good within Australia that requires an application to the Therapeutic Goods Administration (TGA) under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes).

3. CLINICAL TRIAL RESEARCH AGREEMENTS

3.1 Is a CTRA Required?

Unless SJGHC determines that a clinical trial is "low risk", a suitable CTRA will be required. This assessment will be made by SJGHC based on the details of the nature of the trial and takes into account factors other than just clinical risk.

A trial cannot be considered a low risk trial if it:

a. involves pregnant women; children; device implants; any risk of causing significant harm, or ongoing loss of function to study participants, or
b. is an Investigator-Initiated trial.

If there is uncertainty about whether a CTRA is required, researchers should discuss this with the Executive Officer, SJGHC Human Research Ethics Committee (HREC) before submission of their research proposal to the SJGHC HREC.

The use of a CTRA is an effective way for the parties involved in the conduct of a clinical trial to define and allocate their respective roles and responsibilities.

In order to obtain final approval for a clinical trial to be conducted at SJGHC, SJGHC Legal must approve the indemnity and insurance arrangements and other terms of the CTRA.

3.2 Form of the CTRA

The form of CTRA to be used depends upon the sponsor of the trial:

- Trials conducted by commercial sponsors require the SJGHC CTRA – Commercial Sponsor;
- Trials where there is a Contract Research Organisation (CRO) acting as the Local Commercial Sponsor, require the SJGHC CTRA-CRO;
- Trials conducted by non-commercial sponsors (i.e. universities, research institutes/clinical research group (CRG) or public hospitals, etc.) require the SJGHC CTRA –CRG.

These SJGHC CTRA proformas are all based on the relevant Medicines Australia Standard CTRAs published in November 2012. Please note unedited versions of the Medicines Australia documents will not be acceptable. Also, as per Medicine Australia's own requirements, no amendments may be made to the body of the agreements. Instead, all amendments must be contained in the final schedule of each agreement. Should any amendments be proposed by Sponsors to the SJGHC CTRA proformas, these amendments should be tracked and the CTRAs submitted as tracked documents.

NOTE: Investigator-Initiated Trials. For a number of reasons, these trials can create particular legal issues and should be discussed with the Executive Officer of the SJGHC HREC before submission.

4. SJGHC REQUIREMENTS FOR CTRAS

4.1 Scope of SJGHC's Involvement in the Clinical Trial

Due to the limits of SJGHC's insurance policy and its employed expertise (see 4.2 below), SJGHC's obligations under CTRAs will generally be limited to the following services:

- access to premises, equipment and nursing care under the direction of the accredited doctor conducting the trial; and
- Ethics Committee approval of the trial.

Unless specific and appropriate insurance cover is prearranged and SJGHC has demonstrated a capacity to assume additional tasks, SJGHC must not be contractually bound to organise the trial, obtain consent from patients or evaluate the results of the trial. Any such obligations are outside the scope of SJGHC's existing insurance cover and may not be accepted.

4.2 Principal Investigators

CTRAs must accurately reflect the relationship between SJGHC and the Principal Investigator (PI) ie doctors practising at SJGHC premises are usually not employees of SJGHC, act independently of SJGHC and are not subject to direction from or control by SJGHC outside of the accreditation process.

Accordingly, the CTRA must:

- reflect each party's role and responsibilities in relation to the clinical trial;
- require the PI to be accredited at SJGHC premises; and
- include the PI as a party to the CTRA so that the obligations and responsibilities set out in the CTRA are binding.

4.3 Indemnity

SJGHC will not provide an indemnity under any CTRA.

1. Commercial Sponsors and CROs

   For commercially sponsored trials and trials with local commercial sponsors, the relevant SJGHC CTRA sets out the indemnity requirements, which is for the contracting party (either the commercial sponsor or the CRO) to indemnify SJGHC and the PI.

2. CRGs

   For clinical trials that are sponsored by a university, research institute/CRG or public hospital, etc., SJGHC takes into account the non-commercial, collaborative nature of the research and therefore does not require an indemnity from the CRG.

4.4 Insurance

1. Commercial Sponsors, CROs and CRGs

   A commercial sponsor, CRO or CRG must ensure that it has appropriate and adequate insurance with respect to its responsibilities for a clinical trial and its indemnity obligations during the entire period of the trial. This means that in addition to insurance for its legal liabilities (e.g. its negligence), the commercial sponsor, CRO or CRG must have insurance that provides "No fault" cover to compensate trial participants suffering any loss.

   The commercial sponsor, CRO or CRG must provide SJGHC with an Insurance Certificate of Currency that covers those items set out in Schedule 4 of the SJGHC CTRA-Commercial Sponsor and the SJGHC CTRA-CRO, and clause 11 of the SJGHC CTRA-CRG (refer Attachment B: Insurance cover required by SJGHC to be evidenced by a Certificate of Currency).

   The Insurance Certificate of Currency should be provided with the CTRA to allow its review.

2. Investigator-Initiated Trials

   For clinical trials initiated by PIs, in the absence of a third party sponsor, the majority of the sponsor's obligations fall on the PI who maintains the ultimate control of the clinical trial protocol and the conduct of the clinical trial. Thus, SJGHC requires the PI to maintain adequate insurance to cover liabilities arising under the CTRA as per Schedule 4 of the SJGHC CTRA-Investigator-initiated Trials). This includes both a clinical trials insurance policy with "No fault" compensation, as well as professional indemnity cover that covers the delivery by the PI of health care services contrary to the clinical trial protocol.

The PI should provide SJGHC with an Insurance Certificate of Currency in a form that is acceptable to SJGHC (refer Attachment B: Insurance cover required by SJGHC to be evidenced by a Certificate of Currency). If the PI does not hold this insurance, the PI may still request on a case-by-case basis that SJGHC review the associated risks versus benefits of the specific clinical trial proposal and determine whether the trial may proceed.

4.5 Exclusion of Liability

SJGHC requires any commercial sponsor, CRO or CRG to agree that SJGHC and the PI will not be liable for any incidental, indirect, special or consequential damages arising out of the trial. For example, SJGHC will not be held liable if a product is delayed in being released to the market because of SJGHC's conduct.

APPENDIX A: CHARACTERISTICS OF SPONSORSHIP OF CLINICAL TRIALS

(A) Commercially Sponsored Clinical Trials
- The trial is initiated by a pharmaceutical/device company or other commercial entity and not by an investigator. - The trial is conducted to investigator a drug/device/biological for commercial exploitation by its manufacturer/sponsor. - The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity. - Intellectual property developed as a result of the clinical trial is owned by the relevant pharmaceutical/device company.
(B) CRO Sponsored Clinical Trials
- All of the characteristics set out in this table at (A) above, but an Australian-based contract research organisation is engaged by an international pharmaceutical device/company to manage the trial. This is because the contracting entity should be an Australian corporate entity for ease of enforcing rights in a domestic jurisdiction and accessing Australian-based assets in the event of a dispute.
(C) Collaborative/Cooperative Research Group Clinical Trials
- The trial is initiated by a CRG. - The CRG is the primary author and custodian of the clinical trial protocol. - The research addresses relevant clinical questions and not pharmaceutical/device industry or commercial needs. - The CRG has declared the nature of any sponsorship from a pharmaceutical entity or any other entity that may directly benefit commercially from the research outcomes.
(D) Investigator-Initiated Clinical Trials
- There is no CRG or pharmaceutical/device company sponsoring the trial (although they may contribute to funds or the study drug(s)/device(s). - The clinical trial addresses relevant clinical questions. - The Principal Investigator is the primary author and custodian of the clinical trial protocol. - In some situations there may be an Organisation who employs the Investigator and has obligations under the CTRA.

APPENDIX B: INSURANCE COVER REQUIRED BY SJGHC TO BE EVIDENCED BY A CERTIFICATE OF CURRENCY

- Name and address of the insurer, including its Internet website address.
- Name and address of the insured. If the insurance extends to other parties relevant to the agreement, details should be provided. The institution needs to be satisfied that the Sponsor is actually an insured under the policy.
- Policy number ([ ])
- Period of insurance ([ ]-[ ])
- Class of insurance.
- Sum insured per event including any sub limits ($[ ])
- Aggregate sum insured ($[ ])
- If applicable, any excess of loss/umbrella policy information.
- Deductibles/excesses.
- In the case of a Clinical Trial Policy, confirmation that it provides both cover for No Fault compensation to be paid in accordance with the Medicines Australia Guidelines for Compensation and cover for legal liability.
- Whether the policy is constructed on an "occurrence" or "claims made" wording and in the case of a ''claims made'' policy that cover extends for at least a period of 7 years from the end of the trial.
- Scope of cover.
- Territorial limits of the policy. It is essential that the policy respond to claims lodged and processed in an Australian jurisdiction. Notwithstanding that the cover may apply anywhere in the World, if there are any restrictions on claims in an Australian jurisdiction, these must be detailed.
- Relevant policy exclusions and conditions should be listed and detailed if appropriate. Exclusions relating to specific drug use or implements may be important.

SJGHC CTRA Templates

The following templates are used for Clinical Trial Research Agreements at SJGHC. Please click on the links below to download the most current Word versions of these templates.

- SJGHC CTRA Template – Phase 0-III, Commercial, Employed PI
- SJGHC CTRA Template – Phase 0-III, Commercial, Accredited PI
- SJGHC CTRA Template – Phase 0-III, CRO, Employed PI
- SJGHC CTRA Template – Phase 0-III, CRO, Accredited PI
- SJGHC CTRA Template – Phase 0-III, CRG, Employed PI
- SJGHC CTRA Template – Phase 0-III, CRG, Accredited PI
- SJGHC CTRA Template – Phase IV, Commercial, Employed PI
- SJGHC CTRA Template – Phase IV, Commercial, Accredited PI
- SJGHC CTRA Template – Phase IV, CRO, Employed PI
- SJGHC CTRA Template – Phase IV, CRO, Accredited PI
- SJGHC CTRA Template – Investigator Initiated
- SJGHC CTRA Template – Device (MTAA)
- SJGHC CTRA Template – Registry, Employed PI
- SJGHC CTRA Template – Registry, Accredited PI
- SJGHC Material Transfer Agreement Template