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

Version 1.0

Last Updated July 2025

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, 2025) [latest edition]
2. *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* (CHA, 2001) [latest edition]
3. *Australian Code for the Responsible Conduct of Research* (NHMRC, 2018) [latest edition]
4. Section 95(A) of *Privacy Act* (1988) Cth (2014)

The SJGHC Research Handbook will be revised on a regular basis. Please do not print it out, but check online to ensure you are referencing the latest version of the Handbook.

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List of Abbreviations

A&TSI	Aboriginal & Torres Strait Islander
ACHS	Australian Council of Health Standards
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACT	Adaptive Clinical Trial
ACTA	Australian Clinical Trials Alliance
AHEC	Australian Health Ethics Committee
ANZCTR	Australian New Zealand Clinical Trials Registry
AO	Assessment Officer
APP	Australian Privacy Principles
ARC	Australian Research Council
ARTG	Australian Register of Therapeutic Goods
ASR	Annual Safety Report
CALD	Culturally and Linguistically Diverse
CAPA	Corrective and Preventive Actions
CCI	Consumer and Community Involvement
CEO	Chief Executive Officer
CER	Comparative Effectiveness Research
CET	Comparative Effectiveness Trial
CHA	Catholic Health Australia
CIOMS	Council for International Organizations of Medical Sciences
CIRA	Clinical Investigation Research Agreement
CMO	Chief Medical Officer
CO-I	Co-investigator
CONSORT	Consolidated Standards of Reporting Trials
CPI	Co-ordinating Principal Investigator
CPT	Common Protocol Template
CQR	Clinical Quality Registry
CRM	Clinical Risk Management
CRG	Collaborative or Cooperative Research Group
CRO	Contract Research Organisation
CRT	Cluster Randomised Trial
CSR	Clinical Study Report
CTA	Clinical Trial Approval
CTN	Clinical Trial Notification

CTRA	Clinical Trial Research Agreement
CV	Curriculum vitae; Resume; Bio
DOHWA	Department of Health Western Australia
DMP	Data Management Plan
DMS	Director of Medical Services
DSMB	Data Safety Monitoring Board
EO	Executive Officer
EOI	Expression of Interest
EQUATOR	Enhancing the QUAlity and Transparency Of health Research (Network)
EQUIP	Evaluation and Quality Improvement Program
FDA	Federal Drug Administration
GAA	Guardianship and Administration Act 1990 (WA)
GCP	Good Clinical Practice i.e. ICH GCP E6 (R3)
GCRP	Good Clinical Research Practice
GDR	Group Director of Research
GRO	Group Research Office
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 Council for Harmonisation - Good Clinical Practice
ICMJE	International Committee of Medical Journal Editors
ICT	Information and communication technology
IDMC	Independent Data Safety Monitoring Committee
IP	Intellectual Property
JMO	Junior Medical Officer; considered junior medical staff
LHS	Learning Healthcare System
MRI	Magnetic Resonance Imaging
MTA	Material Transfer Agreement
MTAA	Medical Technology Association of Australia
NCTGF	National Clinical Trial Governance Framework (as per **ACSQHC)**
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance Scheme
NS	National Statement on Ethical Conduct in Human Research

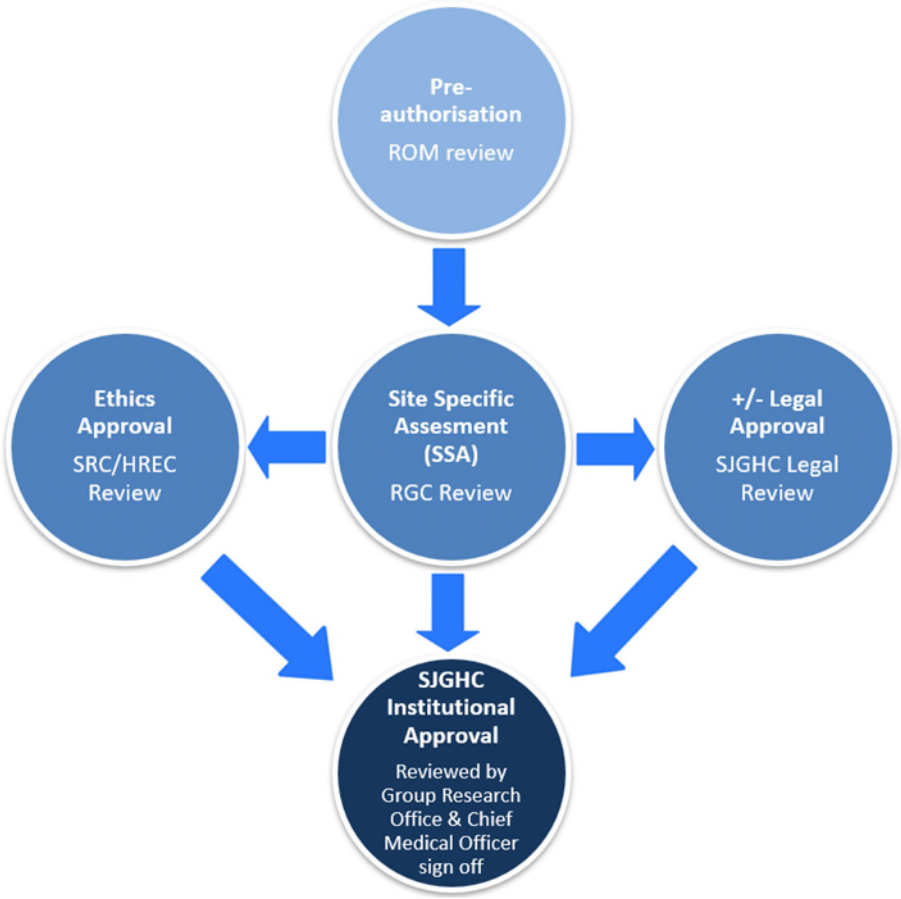
NSQHS	National Safety and Quality Health Service (Standards)
OAIC	Office of the Australian Information Commissioner
OOS	Out of Session
PCT	Pragmatic Clinical Trial
PI	Principal (Site) Investigator or Product Information
PICF	Participant Information and Consent Form
PRE-AUTH	Pre-authorisation
QA	Quality Assurance
QI	Quality Improvement
REG	Registrar/Advanced Trainee; considered junior medical staff
RCA	Root Cause Analysis
RGC	Research Governance Committee
RIA	Research Integrity Advisor
RMO	Resident Medical Officer; considered junior medical staff
ROM	Research Operations Manager
RSC	Research Steering Committee
SAE	Serious Adverse Event
SJG	St John of God
SJGHC	St John of God Health Care
SIA	SJGHC Institutional Approval
SNA	Short Notice Assessment
SOC	Standard of Care
SOP	Standard Operating Procedure
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SRC	Scientific Review Sub-committee
SSA	Site Specific Assessment
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UMRN	Unique Medical Record Number
USADE	Unanticipated Serious Adverse Device Effect
VMO	Visiting Medical Officer; Consultant
VSM	Victorian Specific Module
WAAHEC	Western Australian Aboriginal Health Ethics Committee
WASM	Western Australian Specific Module

WHO	World Health Organisation
WHO ICTRP	World Health Organisation International Clinical Trials Registry Platform
WMA	World Medical Association

SJGHC Approval Process for Research & Pathways of Review

All research proposed to be conducted at a SJG participating site and/or involving SJGHC patients/staff/data requires review and approval by SJGHC. The purpose of this review is to ensure research is governed to a standard that meets multiple legal, regulatory, and ethical requirements. The process at SJGHC commences with a pre-authorisation (pre-auth) stage. Some proposed research may not proceed beyond review at the pre-authorisation stage. Projects that are progressed beyond pre-authorisation commence a process to ensure good governance, comprising of Site Specific Assessment (SSA) from the relevant SJG participating site(s), SJGHC Legal Approval (where applicable), and review of ethical issues. Projects that meet all requirements are then recommended for SJGHC Institutional Approval (SIA). Institutional approval is communicated by a letter from SJGHC, typically issued by the SJGHC Chief Medical Officer. Once SIA has been issued, the researcher can commence their research at the SJG participating site(s).

DIAGRAM OF SJGHC APPROVAL PROCESS FOR RESEARCH



Changes to SJGHC research approval and monitoring will be progressively implemented over a 12 - 18-month period commencing 1 July 2025. As a part of ongoing national reforms in research, the Australian Commission on Safety and Quality in Health Care (ACSQHC) have developed the National Clinical Trials Governance Framework (NCTGF) which is now a component of Short Notice

Assessment (SNA) at all hospitals that undertake clinical trials. A number of changes to research approval and monitoring processes at SJGHC will be implemented to meet accreditation requirements. Whilst the Framework focuses on the quality and safety of conduct of clinical trials, these recommendations are generic and will be applied to **all research activities** at SJGHC.

The following approvals are required before a research project can commence at SJGHC:

PRE-AUTHORISATION (PRE-AUTH)

Applicants should direct new research enquiries/proposals to conduct research at SJGHC to the Research Operations Manager (ROM) (or equivalent) at the participating hospital/service via the contacts as follows:

SJG Site	Contact	Email Address
SJG Accord	Sangeeta Rathi, Research Lead	Accord.Research.Governance@sjog.org.au
SJG Ballarat	Sangeeta Rathi, Research Lead	Ballarat.Research.Governance@sjog.org.au
SJG Bendigo	Sangeeta Rathi, Research Lead	Bendigo.Research.Governance@sjog.org.au
SJG Bunbury	Sangeeta Rathi, Research Lead	Bunbury.Research.Governance@sjog.org.au
SJG Burwood & SJG Richmond	Sangeeta Rathi, Research Lead	NSWMH.Research.Governance@sjog.org.au
SJG Geelong	Sangeeta Rathi, Research Lead	Geelong.Research.Governance@sjog.org.au
SJG Geraldton	Sangeeta Rathi, Research Lead	Geraldton.Research.Governance@sjog.org.au
SJG Healthcare at Home	Sangeeta Rathi, Research Lead	HAH.Research.Governance@sjog.org.au
SJG Mt Lawley	Sangeeta Rathi, Research Lead	MountLawley.Research.Governance@sjog.org.au
SJG Midland	Benjamin Kan, Research Operations Manager	MI.ResearchGovernance@sjog.org.au
SJG Murdoch	Steve Edmonston, Research Operations Manager	MU.MurdochResearchGovernance@sjog.org.au
SJG Social Outreach	Sangeeta Rathi, Research Lead	SocialOutreach.Research.Governance@sjog.org.au
SJG South East Melbourne (Berwick, Frankston, Langmore)	Sangeeta Rathi, Research Lead	SEM.Research.Governance@sjog.org.au
SJG Subiaco	Natalya Beer, Manager Clinical Trials	Research.network@sjog.org.au

SJG Site	Contact	Email Address
SJG Warrnambool	Sangeeta Rathi, Research Lead	Warrnambool.Research.Governance@sjog.org.au
SJGHC Group Research Office (Multi-site enquiries)	GRO Governance Team	Research.Governance@sjog.org.au

New research proposals will be assessed via a pre-authorisation process at site level to evaluate feasibility (including financial viability), as well as completeness and accuracy of the protocol of the proposed project. The relevant ROM will notify the applicants in writing to confirm pre-authorisation to proceed with making a research submission to SJGHC, commencing with site governance approval/Site Specific Assessment (SSA).

For research enquiries involving more than one hospital or service, initial enquiries can be directed to the Group Research Office (GRO) Governance Team via email Research.Governance@sjog.org.au. Please specify which SJGHC sites you propose to involve and the nature of the involvement. One site will be identified by SJGHC as the lead site.

Please refrain from submitting new research enquiries to the GRO Ethics Team. The Ethics Team is available to provide support in relation to ethical review enquiries, and can be contacted using the generic email address ethics@sjog.org.au

SITE SPECIFIC ASSESSMENT (SSA)

All submissions involving SJG sites (except for case studies**), require site governance approval before the research can be considered for SIA. The Site Specific Assessment Form (SSA) documents this site governance approval process.

Once applicants have pre-auth, they should immediately proceed with completion of a SSA Form and submission of any other site-required supporting documentation e.g. CVs, GCP Certificates, evidence of compliance with SJGHC ICT and Privacy Policies, evidence of consumer engagement in the development of the protocol, etc. The Applicant's SSA submission will then be reviewed by the SJG Participating Site Research Governance Committee (RGC) which will either approve or not approve the submission or make further recommendations.

The SSA Form should be signed by the head of all relevant departments/services to be utilised in the research project (e.g. health records) and the Chair of the RGC or other relevant Site CEO/Director.

The SSA Form (either fully signed or in draft) must also accompany all submissions to the SJGHC HREC as a record of site governance.

Wherever possible the SSA/site governance approval process and ethics review process will occur concurrently. However, it will often be necessary for completion of SSA and RGC approval **before** a project can be submitted for ethical review. Applicants will be informed when submission for ethical review can occur.

**For case studies, a SSA is not required. Instead, please provide written confirmation of the site Director of Medical Services endorsement for publication of the case study.

PLEASE NOTE: Before making an ethics submission to the SJGHC HREC for *changes* to existing approved research, researchers should first seek SJG participating site governance approval (by contacting the relevant SJG site ROM) for the following types of study changes:

- Protocol Amendments
- Investigator (PI and co-investigator) changes
- Extension requests

The SJG site(s) may require corresponding updates to the SSA Form and/or legal agreement before endorsing these changes from a site governance perspective.

LEGAL APPROVAL (IF APPLICABLE)

All clinical trials with an external sponsor (irrespective of risk level) that involve any direct research activity at SJGHC require approval by SJGHC Legal Services of the insurance, indemnity and contractual arrangements for the research. Legal review will generally not be required if SJGHC involvement in a trial involves only provision of information on behalf of a clinical trial that is being conducted by another organisation and there are no direct research activities at SJGHC.

Some non-trial studies may also require a legal agreement prior to commencement e.g. where data or material are being transferred to an external party/researcher or when there is a possibility that significant new Intellectual Property (IP) will be created by the project;.

Where members of the research team who are not SJGHC caregivers or accredited Visiting Medical Officers, and the project requires those researchers to have access to SJGHC facilities, a site-access agreement will be required.

The relevant SJG site ROM can be contacted for any initial queries regarding legal agreements, insurance and indemnity requirements as well as queries about the legal approval process.

ETHICAL REVIEW AND APPROVAL

As an independent review process, the SJGHC HREC, in conducting ethical review of research, observes the *Code of Ethical Standards (Catholic Health Australia, latest edition)* as it applies to human experimentation and human research, the *National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (latest edition) (NS)* as well as other relevant codes and regulatory requirements.

Ethics approval is granted in writing by the SJGHC HREC within approximately a week of the HREC meeting/out of session (OOS) review and confirms that the research proposal is ethically acceptable as per the requirements set out in the NS.

SJGHC INSTITUTIONAL APPROVAL (SIA)

All proposed projects require SJGHC institutional approval (SIA) before commencement. This applies irrespective of approval at other health services and level of risk. Ethical approval alone, by the SJGHC HREC or another HREC, is never sufficient to commence research activities.

Once SSA/site governance approval, ethics approval and any legal approval have been granted, the SJGHC Group Research Office (GRO) will review new study submissions to provide assurance to the SJGHC Chief Medical Officer (CMO) that all research governance requirements have been adequately addressed. Following this GRO review, the SIA letter will be issued by the CMO, as the delegate of SJGHC.

Once applicants have received the SIA letter, the research can commence at SJGHC.

As the SJGHC GRO coordinates the issuing of SIA letters and maintains a complete central record of each study, it is important that all SSA and legal approvals are communicated to the GRO in a timely and prompt manner.

PATHWAYS OF ETHICAL REVIEW

There are different pathways for ethical review depending on the risks and burdens associated with a given research proposal and what prior approval a research proposal already has. When completing submissions to the SJGHC HREC, researchers should refer to the appropriate Checklist, which is integrated into the online Ethics Submission Form.

SJGHC is certified under the NHMRC Certification Scheme to review multicentre research and ***the research proposed for external, non-SJG sites which do not have access to a local HREC.*** Thus, SJGHC HREC as an NHMRC "Certified HREC" can provide ethics review and oversight for multicentre research which other institutions can choose to accept without the need for further ethical review. A researcher intending to conduct research in an external, non-SJGHC site without access to a HREC can also apply for "***SJGHC HREC review only***." In both of these scenarios, the institutional responsibility i.e. research governance approval for final study commencement lies with the relevant external, non-SJG party as the responsible legal entity. The SJGHC HREC letter of ethics approval can be used as evidence of ethical review and approval of the research.

This NHMRC Certification Scheme is to be differentiated from the National Mutual Acceptance (NMA) Scheme whereby Australian state/territory health departments mutually accept the ethics and scientific review of multicentre research proposals undertaken in the public health sector. SJGHC as a private institution is not a party to the NMA.

The following types of research require both SJGHC HREC approval and approval from another specialised HREC before commencement:

1. Research proposals that explicitly involve Aboriginal and Torres Strait Islander Peoples or where Aboriginality is a key determinant must be reviewed by the Western Australian Aboriginal Health Ethics Committee (WAAHEC) or other equivalent specialised HREC.
2. All research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage must be reviewed by the Department of Health WA HREC.
3. Research that involves veterans must also be approved by the Department of Veteran's Affairs HREC.

For research conducted by students as part of a higher tertiary degree ("student research"), students should ensure that their Supervisor(s) have signed off on the submission paperwork to the SJGHC HREC and that ethics approval is also obtained from the relevant University/tertiary educational institution before research commencement (i.e. either prior or following SJGHC HREC approval). A copy of the University/tertiary educational institution HREC approval should be provided to the SJGHC Ethics Team for completion of records.

All student (undergraduate and postgraduate) research projects as well as research proposed by Junior Medical Staff (JMO/RMO/REG) should be presented as follows:

- Co-ordinating Principal Investigator (CPI): must be a Senior Caregiver, Visiting Medical Officer and/or Prof/Lecturer/Supervisor to supervise the research
- Principal (Site) Investigator (PI): needs to be an onsite Senior Caregiver or Visiting Medical Officer. It cannot be a Student or JMO/RMO/REG

- Co-Investigator (Co-I): is the Student or JMO/RMO/REG.

In summary, as outlined below, the pathways for ethical review of research (which are based on risk and burden of the research and what prior approval the research already has), ensure a high quality, efficient ethics review process to support the timely start-up of research:

HIGHER RISK PATHWAY

"Higher risk" research (which includes "Greater than low risk" research where there is risk of harm and/or foreseeable burden, and "High risk" research where there is risk of significant harm and/or foreseeable burden) must undergo a full ethics review process. This type of research is first evaluated by the SJGHC Scientific Review Sub-Committee (SRC), which reviews studies for scientific merit, validity and safety, prior to proceeding to SJGHC HREC review.

The SRC meets approximately a month prior to the HREC, to allow time for researchers to reply to any major queries and for researcher replies to be circulated to the SRC for out of session review, before being tabled at the HREC meeting.

EXPEDITED REVIEW PATHWAY

Certain "higher risk" research previously approved by an NHMRC-Certified hospital-based HREC does not require a full ethics review. This research can undergo an expedited review process and be tabled directly at the HREC (or SRC) meeting only, whichever meeting is scheduled first.

There are circumstances where SJGHC will accept the prior scientific and/or ethics review of a NHMRC-Certified hospital-based HREC, so that a previously approved study will undergo review via the Expedited Review pathway, acknowledging the prior HREC approval. However, as with all other research proposals, SJGHC HREC will consider and approve these studies from a Catholic bioethical perspective and will be responsible for continuing to directly monitor progress of these studies until completion.

"Higher risk" research may be approved at SJGHC via the Expedited Review pathway when the following criteria are met:

- Research is not investigator-initiated research
- Research does not specifically involve pregnant women, children or device implants
- Research is not a Phase I/II pharmaceutical or device clinical trial i.e. 'first-in-human' or early phase trial
- Documentation of approval is provided from at least one other NHMRC-Certified hospital-based HREC (please refer to list available here) or by the DOHWA HREC (in the case of WA Data Linkage Branch studies only)
- Evidence is provided of Peer/Scientific Review Process and Support for the research (defined as independent, expert and formal review of the study that occurs prior to HREC submission as per question 1.9.1.1 and 1.9.1.2 of the HREA. For commercially sponsored research, peer review should be conducted outside of the Sponsor and their partners in research)

It is not a strict requirement that all of the above criteria are fulfilled. For further advice, researchers should discuss their research proposal directly with the SJGHC Ethics Team before making a submission.

LOW RISK PATHWAY

"Low risk" research (where there is no risk of harm and the only foreseeable risk is discomfort and/or foreseeable burden) does not require full review by both the SJGHC SRC and SJGHC HREC. "Lower risk" research can be tabled directly at either a HREC or SRC meeting (whichever is scheduled to meet first) – with the exception being lower risk research where the researcher is directly accessing or otherwise using identifiable personal information in medical research or personal health information which is seeking a waiver of the requirement for consent. These proposals must be approved by the SJGHC HREC to meet the requirements of both the NS and Privacy Act 1988 (i.e. S95 and S95A guidelines) which require that waivers of consent are approved by a HREC: "Only a HREC may grant a waiver of the requirement for consent for research using personal information in medical research, or personal health information. Other review bodies may grant a waiver of the requirement for consent for other research." All other lower risk research seeking only a waiver of consent under NS 2.3.10 may be approved by the SRC.

Likewise, where researchers need approval to use an opt-out approach for consent in their research to which the Privacy Act 1988 (i.e. S95 or S95A guidelines) apply, only a HREC may grant this approval. All other lower risk research using an opt-out approach for consent, may be approved by the SRC.

NOTE: "Low risk" research can include some types of clinical trials e.g. comparative effectiveness trials (CETs). The Ethics Team will conduct an initial submission review of all CETs to determine if it will benefit from a full review or if it can undergo expedited review.

Researchers submitting under the "expedited review" or "low risk" pathways (and not the higher risk pathway), also have the option to request out of session (OOS) review by a subgroup of the SRC and/or HREC if there are extenuating circumstances e.g. student course requirements have a tight timeframe, grant funding timeline requirements, etc. The researcher should discuss this directly with the SJGHC Ethics Team before completing their online ethics submission.

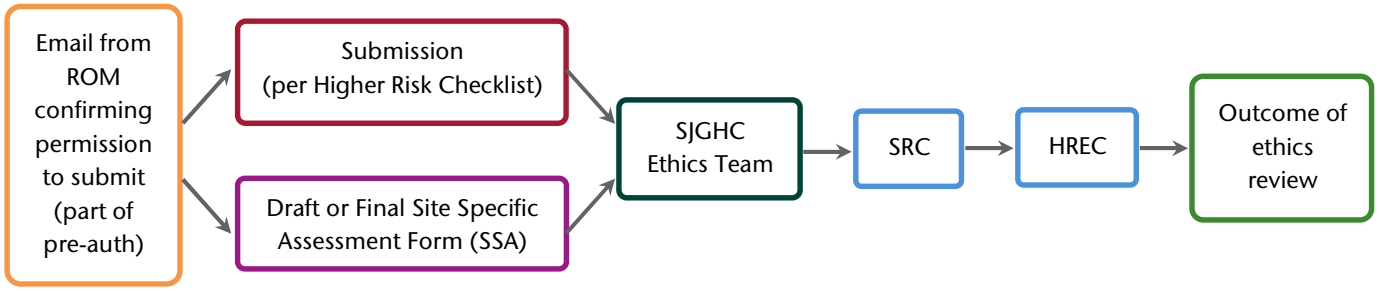
MINIMAL RISK PATHWAY

Research which is specifically only "minimal risk" (where there is no foreseeable risk of harm or discomfort and only potential for minor burden or inconvenience) can undergo expedited review OOS by the Chair of the SJGHC HREC, and then be tabled at the next scheduled Committee meeting for information only e.g. non-interventional research which involves the collection of unidentifiable data only.

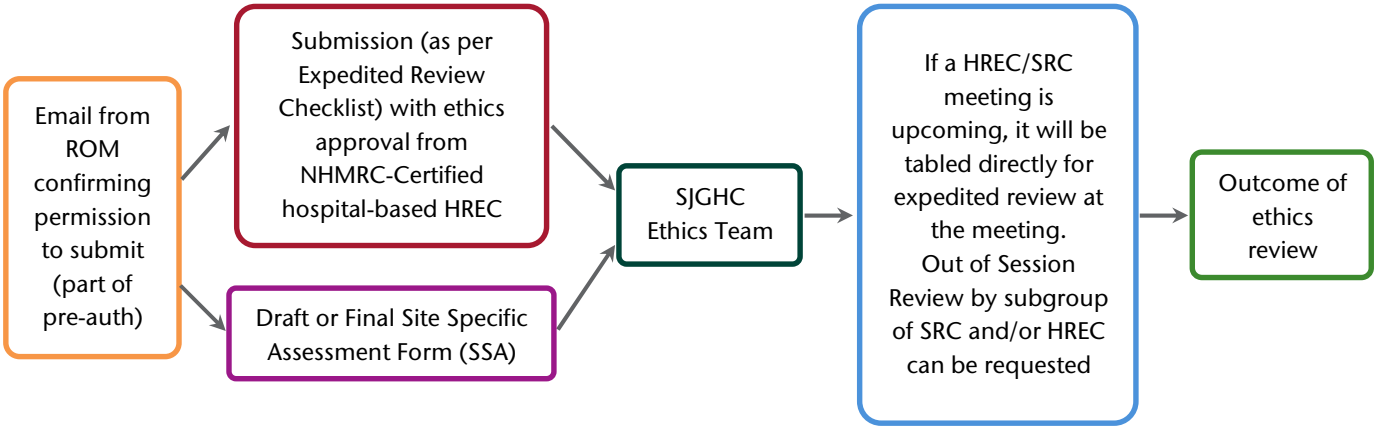
CASE STUDIES

For case studies, researchers should submit their written up case study along with any participant information and consent form (PICF) and SJG participating site DMS written endorsement to publish the case study. This will be reviewed and approved OOS by the Chair of the SJGHC HREC (as delegated authority), and then tabled at the next HREC meeting for the information of the Committee.

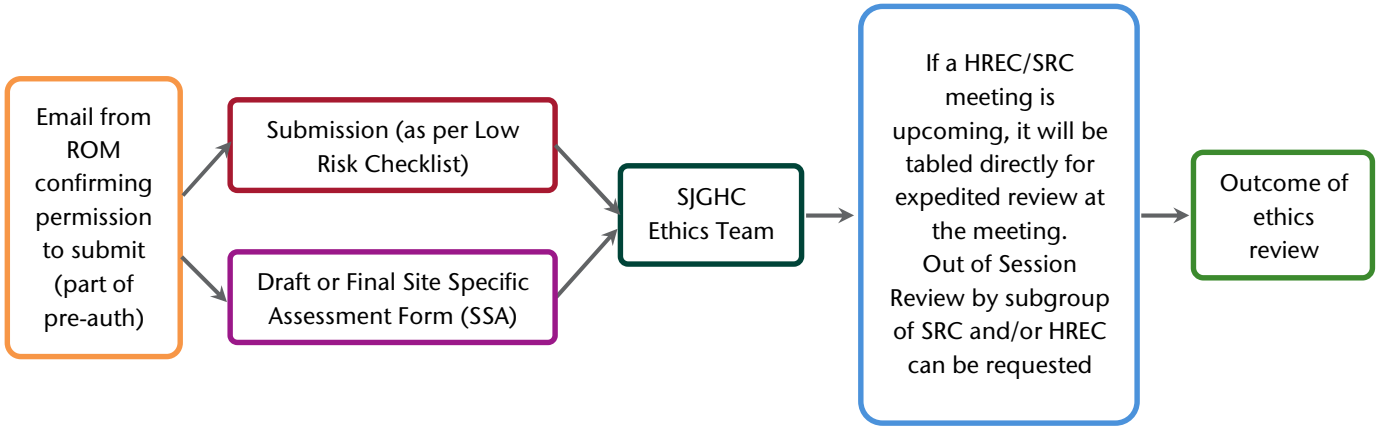
ETHICS REVIEW PATHWAY FOR HIGHER RISK RESEARCH



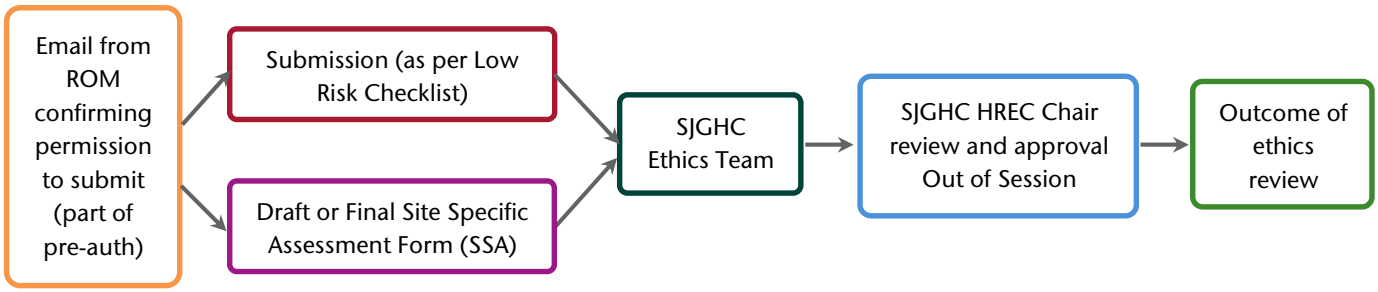
ETHICS REVIEW PATHWAY FOR EXPEDITED REVIEW



ETHICS REVIEW PATHWAY FOR LOW RISK RESEARCH



ETHICS REVIEW PATHWAY FOR MINIMAL RISK RESEARCH



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, 2025) [latest version] and subsequent editions ("the National Statement"), the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2018) ("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:

2. a research ethics role for SJGHC Divisions; and
3. a national research ethics role as a "reviewing HREC" committed to facilitate the efficient and effective ethics 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 ethics 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 ethics 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 of all SJGHC approved research as per the Code.
6. To monitor approved research in partnership 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 for more details).
8. In partnership with SJGHC and its Divisions, and as per the *National Safety and Quality Health Service Standards* (2017 and subsequent editions), *National Clinical Trials Governance Framework* (2022) 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 (preferably the Human Research Ethics Application Form (HREA) or other similar application form), and to follow the procedures set out in the *SJGHC Research Handbook (latest edition)* 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. Ethics approval granted;
2. Conditional ethics approval granted (stating each of the conditions on which approval is granted);
3. Ethics approval withheld (stating the reason(s) which are linked to the National Statement);
4. Ethics 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. SJGHC Institutional Approval (which is in inclusive of ethics and governance approval, and any legal approvals) is granted in writing by the SJGHC Group CEO typically delegated to the CMO. In the case that ethics 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 withdraw SJGHC Institutional 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. Local serious adverse events (SAEs)/suspected unexpected serious adverse reactions (SUSARs)/unanticipated serious adverse device effects (USADEs), annual safety reports, independent data and monitoring committee (IDMC) reports and any significant safety issues (SSIs) (collectively "safety reports");
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 safety reports noting if there is any action required. Safety reports are also tabled at Committee meetings.

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 (six monthly for phase 1 trials) to both the Committee (or its sub-Committee) 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 Chief Medical Officer

The Committee agendas and minutes are distributed to and discussed with the Chief Medical Officer who has the delegated institutional authority to grant institutional 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:

- a chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement

- two people who bring a broad community or consumer perspective and who have no paid affiliation with the institution
- a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional
- a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader
- a qualified lawyer, who may or may not be currently practising and, where possible, is not engaged to advise the institution on research-related or any other matters
- two people with current research experience that is relevant to research proposals to be considered at the meetings they attend

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 non-core Committee members.

The Executive Officer (EO) and Research Ethics Officers provide 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 of the previous meeting and agenda of the current 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.

CODE OF CONDUCT

Members including pool members are expected to abide by the SJGHC HREC/SRC Code of Conduct which forms part of all appointments and is distributed to members with every meeting agenda. Those attending meetings as expert advisors will also be made aware of the SJGHC HREC/SRC Code of Conduct.

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 ethics 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

CURRENT AS OF JULY 2025

Name	Qualifications	Sex	Appointment	Position
Clin Prof 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)
Dr Ben Carnley *	MBBS FRACP FRCPA	M	Member with knowledge of and current experience in the professional care, counselling or treatment of people	Consultant Haematologist
Ms Priscilla Singh *	RM RN MScIPC	F	Member with knowledge of and current experience in the professional care, counselling or treatment of people	Clinical Nurse Consultant (Infection Prevention & Control)
Ms Wendy Meggison*	LLB (Hons) MA RN RM	M	Member who is a qualified lawyer, who may or may not be currently practicing and where possible is not engaged to advise the institution	Principal Lawyer
A/Prof Dr Janie Brown *	BNurs MEd PhD	F	Member with current research experience that is relevant to research proposals to be considered at the meetings	A/Professor, Curtin School of Nursing; Senior Research Fellow, SJG Midland Public & Private Hospitals
Ms Suzanne Lawrence *	BA(Psych)	F	Member who brings a broader community or consumer perspective and who has no paid affiliation with the institution	Senior Lecturer, Social Sciences, ECU
Mr Hamish Milne *	BA (Hons) MPhil MBA GAICD FAIM	M	Member who brings a broader community or consumer perspective and who has no paid affiliation with the institution	WA Faculty and Training Operations Manager RACGP
Dr Myles Murphy*	BPhysio, GCSportsPhysio MClinPhysio, PhD	F	Member with current research experience that is relevant to research proposals to be considered at the meetings	Sports Physiotherapist; Postdoctoral Research Fellow, ECU
Mr Richie Perera *	DipTh BCoun GCertMedHlthLead	M	Member who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader	Manager of Pastoral Services, Catholic Homes; Chair of SJG Midland Hospital Mental Health Consumer and Carer Advisory Group
Prof Sally Sandover	BSc MPH	F	Community Member. Expert knowledge in medical education.	Retired, previously Associate Dean (Medical Education), Curtin University Medical School
Dr Vivian Chiu	PhD BPsych BSc BComm	F	Community Member. Clinical Psychologist	Research Fellow, School of Population Health, Curtin University
Dr Evan Bayliss	MBBS FRACP	M	Community Member. Expert knowledge in oncology	Retired Oncologist

Name	Qualifications	Sex	Appointment	Position
Rev. Dr Joseph Parkinson	STL PhD	M	Pool Member who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader	Minister of Religion; Bioethicist, Director Catholic Bioethics Perth; SJGHC Trustee

***** Core Member

SJGHC Scientific Review Sub-Committee 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 i.e. scientific validity and safety.

PURPOSE

The purposes of the SRC are:

1. To review for scientific merit i.e. scientific validity and safety, human research proposals to be conducted at any of the SJGHC sites in Australia, including:
    a. New research submissions
    b. Study amendments due to safety concerns
    c. Study progress reports, including final reports and publications
2. To review for the appropriate use of SJGHC biospecimens (and related health data) 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 and Research Ethics Officers also provide administrative support to the SRC.

CODE OF CONDUCT

Members including pool members are expected to abide by the SJGHC HREC/SRC Code of Conduct which forms part of all appointments and is distributed to members with every meeting agenda. Those attending meetings as expert advisors will also be made aware of the SJGHC HREC/SRC Code of Conduct.

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 6 meetings per year. In order to address any outstanding issues prior to SJGHC HREC meetings, members may be requested out of session (OOS) 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 Chair 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.

SJGHC SRC Membership

CURRENT AS OF JULY 2025

Name	Qualifications
Prof Sally Sandover (Chair)	BSc MPH
Clin Prof Dr Simon Dimmitt	BMedSc (Hons) MBBS FRACP FCANZ
Prof Kevin Croft	PhD FRSC
Prof Leanne Monterosso	BNurs (Hons) RN RM NNT GCTT PhD FACNA
Dr Myles Murphy	BPhysio GCSportsPhysio MClinPhysio PhD
Dr Evan Bayliss	MBBS FRACP
Mr Steven Blyth	BJuris LLB

Submission Process – Steps to Approval

Please refer to SJGHC Approval Process for Research & Pathways of Review for a summary of the approval process at SJGHC for research of different risk levels.

ENQUIRIES AND QUERIES

New Research Enquiries/ Proposed Projects:

Those considering undertaking a research project (or a clinical audit with the primary intention to publish) at any SJG hospital or service must first contact the respective site via the ROM (or equivalent) for advice/pre-authorisation PRIOR to commencing the new research project, seeking funding, or making an ethics submission.

Existing Research Enquiries:

For proposed protocol amendments, changes to Investigators or extension requests for an existing research project, please contact the respective site via the ROM (or equivalent) for advice PRIOR to submitting your request to the SJGHC HREC.

Ethics Enquiries:

Initial ethics enquiries, queries about making a research ethics 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 SJGHC Ethics Team (ethics@sjog.org.au). The Ethics Team will provide support in addressing ethics queries and where necessary consult the HREC or SRC Chair to assist with the reply to ethics queries.

This is particularly useful in the following cases:

1. to confirm submission and meeting dates and plan ahead a sufficient timeframe in which to obtain ethics approval;
2. to coordinate the ethics submission with the progress of the SSA. Please note that pre-authorisation from the SJG Participating Site is required in the first instance, and then the SSA Form can be completed as part of the site governance process. In the interests of the timely start-up of research, please include the draft unsigned SSA Form with the ethics submission (provided that the SSA in progress and you have site permission to progress with the ethics submission);
3. Researchers may only submit for ethical review when informed by a ROM or RGC that a project is ready for ethical review;
4. to ascertain if a particular research study is “minimal risk”, “lower risk” or “higher risk”, and the pathway/level of corresponding ethics review that is required. (For example, clinical audits which are more for internal quality improvement (QI) purposes and for which there is no intention of disseminating generalisable knowledge (i.e. publishing or presenting results externally) may not require a submission to the SJGHC HREC. For further information refer to the Guide for QI Projects within this Research Handbook);
5. Where “expedited review” of a “higher risk” study is being requested. Note: SJGHC has both a expedited review process for “lower risk” research as well as an expedited review process for

"higher risk" research which meets certain criteria (please refer to the SJGHC Approval Process for Research & Pathways of Review) Timing constraints alone are not an acceptable reason to justify expedited review where the study is higher risk.

As well as contacting the Ethics Team, the *SJGHC Research Handbook* (available online), should be read in full by researchers, as it is a complete reference guide to obtaining and maintaining the ethics approval of research projects, and meeting the necessary research governance requirements

SUBMISSION DOCUMENTION FOR A NEW RESEARCH PROPOSAL

All submissions are to be submitted to the SJGHC Ethics Team via the Ethics Submission Form.

Please contact the Ethics Team if you do not receive an acknowledgement of your submission within two - three working days.

Researchers are requested to complete the following ethics 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 HRECs. This is available online at https://hrea.gov.au/. Please download a new form each time you submit a new study 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, AND
3. Jurisdictional specific application forms that address additional ethical issues specific to said jurisdiction. Researchers intending to conduct research in a specific jurisdiction should complete the relevant module(s)/form below along with the HREA/other HREC ethics application form:
    a. WA-Specific Module (WASM) is available to complete online on the WA Research Governance Service (RGS) website: https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx For applications to WA HRECs not using RGS and not involved in the NMA (e.g. SJGHC HREC), a hard copy of the WASM is available on request from RGS Support.
    b. Victorian Specific Module (VSM) is no longer available for download but can be generated and completed within the ERM system.

Please note that whether completing the HREA or another HREC Ethics Application Form, there is also other documentation that needs to accompany a research submission. At minimum, new study submissions should also include a protocol and Site Specific Assessment Form.

Researchers should refer to the Checklists for New Submissions in the *SJGHC Research Handbook* as a quick reference to ensure all necessary documentation is readily available and included before forwarding their submission to the SJGHC HREC. (The Checklists are now incorporated into the Ethics Submission Form, but have been reproduced for reference under Useful Forms.)

NOTE: Case studies are the exception. Researchers are not required to complete a HREA or another HREC Ethics Application Form for case studies. In terms of submission documentation, researchers are required to only submit:

a. the written case study,
b. the Participant Information and Consent Form (PICF)
c. the written endorsement of the site DMS supporting the publication of the case study.

As "lower risk" research, case studies will undergo expedited review out of session (OOS) by a select member(s) of the SJGHC SRC/HREC and approved by the Chair of the SJGHC HREC (as delegated authority), and then tabled at the next HREC meeting for the information of the Committee.

OBTAINING SITE GOVERNANCE APPROVAL

New Study Submissions:

A complete Site Specific Assessment Form (SSA) must be included in any new study submission to the SJGHC HREC. This form documents governance approval from all departments that will be affected by proposed research at the participating site/s (NOTE: for research that is occurring only at sites external to SJGHC, the form will automatically exclude questions specifically related to SJGHC research governance). SJGHC Institutional approval (SIA) for research to commence will not be granted by the SJGHC CMO until the SSA Form has been signed by the relevant Director/CEO of the participating site/s, and any legal approval (where appropriate) and ethics approval confirmed.

- It is important that the researcher direct all new research enquiries to the relevant SJG site ROM. The ROM will review the study for feasibility before confirming with the researcher that they can then start completing the SSA Form. All ROM contacts are listed here.

The SSA Form is to be filled out by the researcher in discussion with all key stakeholders from departments that will be affected by the proposed research (for example, the Patient Health Information Service will be affected if hospital medical records will be reviewed.)

Changes to existing approved research:

Before making an ethics submission to the SJGHC HREC for changes to existing approved research, researchers should first seek SJG participating site governance approval (by contacting the relevant SJG site ROM) for the following types of study changes:

- Protocol Amendments,
- Investigator (PI and co-investigator) changes
- Extension requests

The SJG site(s) in reviewing these changes to existing approved research may require corresponding updates to the SSA Form and/or legal agreement before endorsing these changes from a site governance perspective.

Once researchers have the SJG site(s) governance approval for these changes to existing approved research, these changes can then be submitted to the SJGHC HREC for ethical approval.

Steps for Completing the SSA Form

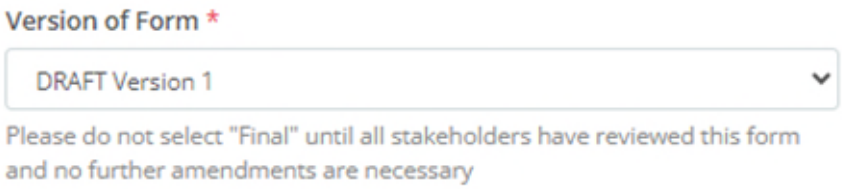
Please make use of the **"Save and Complete Later"** link to save the SSA Form as a draft, and ensure that you click this to generate a new URL ***each time*** you would like to save your progress. You can have the URL sent to your own email address so that you can return to it at any time. You will be required to save the most recent "Save and Complete Later" link in the form before submitting.

Once the form has been submitted, you will be automatically emailed a PDF copy of the completed form and responses can no longer be amended (unless you use the "Save and Complete Later" URL to return to the online form and submit it again.) For this reason, the Final version of the form should not be submitted until it has been discussed with all affected stakeholders and any queries from

affected stakeholders have been addressed in the responses of the form. It is the researcher's responsibility to complete the form in discussion with all key stakeholders, and in doing so to obtain email addresses of these stakeholders for electronic signoff of the form.

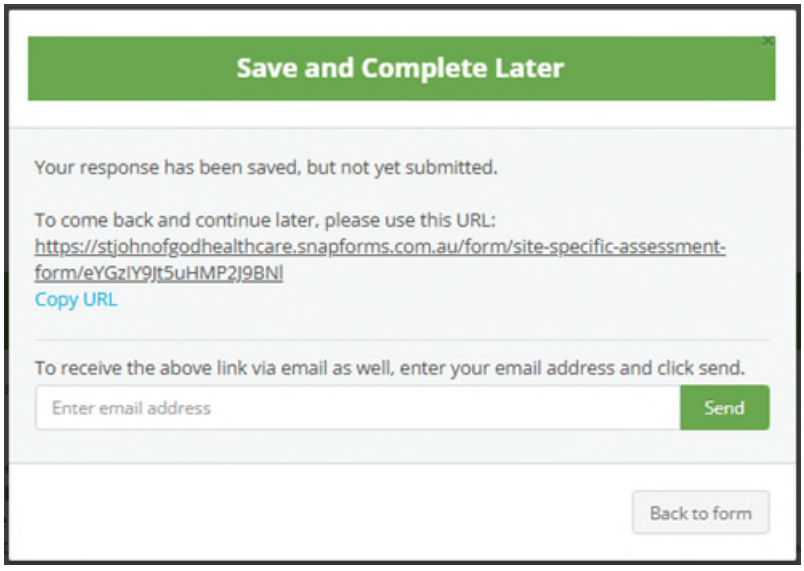
The process for obtaining research governance approval is as follows:

1. Discuss the proposed study directly with the SJG participating site ROM to obtain pre-auth to proceed with the SSA submission.
2. Complete the SSA Form online. On the first page, there is a "Version of Form" field which by default will be set to DRAFT Version 1:

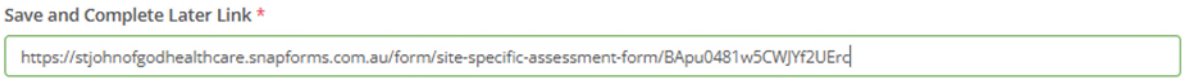


3. At the bottom of each page, there is a **"Save and Complete Later"** link .

Once clicked, this will generate a unique URL which you can copy or email to yourself. Click to generate a new unique link ***each time*** you would like to save your progress.



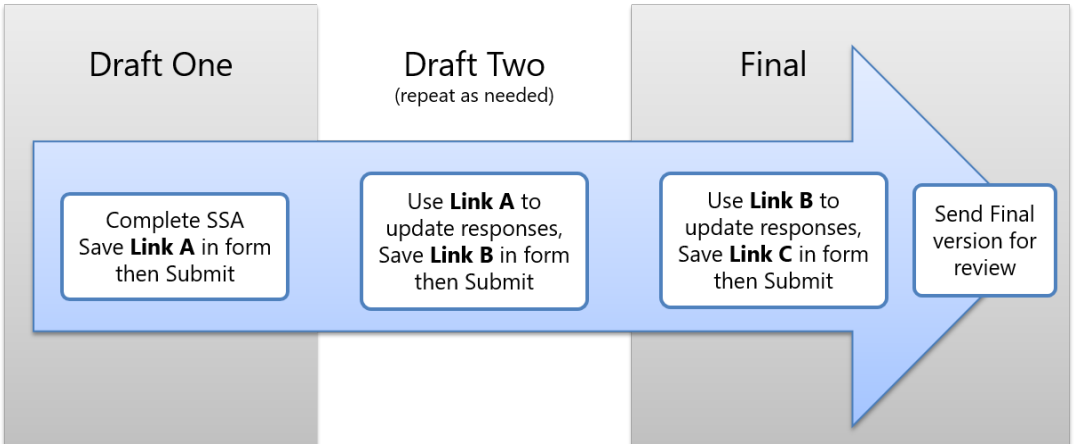
You must paste this link into the box below on the last page of the form before submitting.



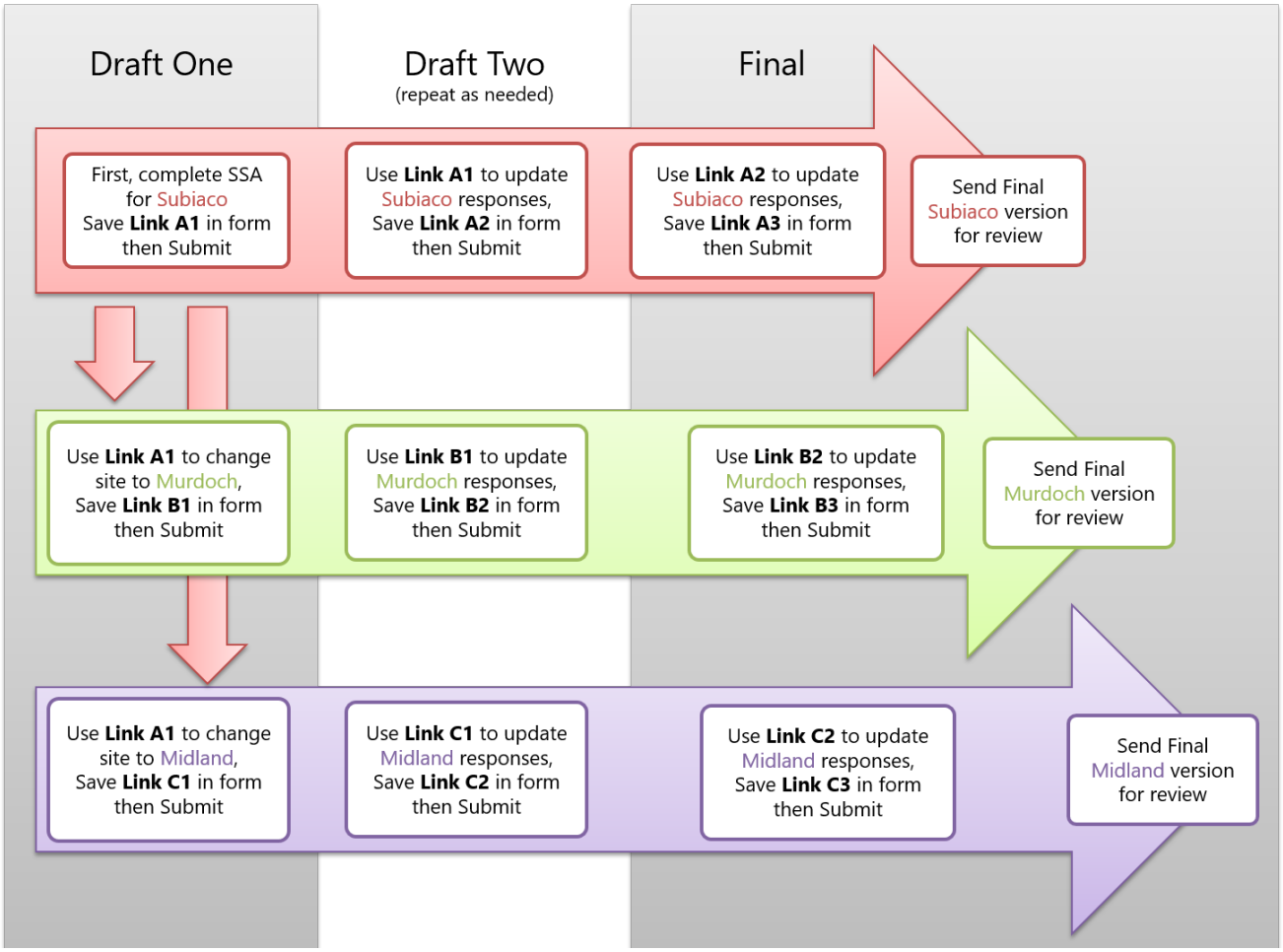
4. When you click the Submit button, you can no longer edit the responses on the form and will be automatically emailed a PDF copy of the completed form. The Version number (e.g. Draft Version 1) will be in the header each page.
5. Send this URL or Draft PDF form to key stakeholders of relevant departments to review responses
6. If stakeholders have queries, amend responses as necessary. (Ensure that you update the Version number on the first page of the online form when you update your responses.)

7. When no further amendments are necessary, ensure the most recent "Save and Complete Later" URL is pasted in the form, sign the PI/CPI Responsibilities section of the form and then Submit
8. A PDF copy of the Final version of the completed form will be automatically emailed to you. Please send this to the appropriate contact at the participating site, including the email addresses of any stakeholders who will electronically sign the form.

Please refer to the graphic below which explains the "Save and Complete Later" process for research to be conducted at one participating site:



Please refer to the graphic below which explains the "Save and Complete Later" process for research to be conducted at more than one participating site:



For research to be conducted at a SJG site AND in private consulting rooms/Visting Medical Officer (VMO) rooms based at these hospitals, please submit the completed SSA form to the relevant SJG governance site.

CONDITIONS OF APPROVAL

All research (other than case studies) requires prior SJGHC HREC approval before commencement. SJGHC HREC will not grant retrospective ethics approval for a research proposal (including QI project/audit) that has already commenced/been completed.

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 the ethics approval letter.

Failure of researchers to comply with any of the conditions of approval may result in suspension or withdrawal of ethics approval of the study. 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 institutional approval (SIA) be rescinded, or otherwise suspended until such a time as specific conditions are met. SJGHC can also decide to suspend or withdraw institutional approval for a study at any of its participating sites, for any broader governance reason(s) – in which case SJGHC will advise the researcher and the SJGHC HREC accordingly.

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 end of the study timeframe /approval 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. updates to 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.

PLEASE NOTE: Before making an ethics submission to the SJGHC HREC for changes to existing approved research, researchers should first seek SJG participating site governance approval (by contacting the relevant SJG site ROM) for the following types of study changes: Protocol Amendments, Investigator (PI and co-investigator) changes, and extension requests. The SJG site(s) may require corresponding updates to the SSA Form and/or legal agreement before endorsing these changes from a site governance perspective.

3. **Adverse Events, Unforeseen Events, suspected Serious Breaches, Withholding/Withdrawal of Approval, Allegations/Suspicion of Breaches of the Code/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. This includes anything that is likely to affect to a significant degree the safety or rights of a study participant, or the reliability and robustness of the data generated in the study:

a. serious and suspected unexpected serious adverse events on participants, a significant safety issue (SSI), unforeseen events (e.g. new information about the experimental drug, new potential conflict of interest) and any suspected significant protocol deviations i.e. serious breaches,
b. any withholding or withdrawal of study approval by another HREC or institution,
c. any allegation or suspicion of research misconduct.
PLEASE NOTE: Please refer to the following sections in the Handbook for further details: Adverse Event Process and Serious Breaches

4. **Reporting on Study Progress:** SJGHC through its research governance framework requires that researchers complete regular study progress reports (annually at a minimum, and six-monthly for Phase 1 studies) and a final study report at the conclusion of a research project and forward this to the SJGHC HREC as well as all SJG Participating Site(s). Annual Reports are due on the anniversary of when SJGHC Institutional approval was granted. As part of the final study report, researchers are requested to also provide copies of any publications/ presentations of research findings where applicable (although these may only be available after completion of the final study report).

   In the particular case of notification of study closure i.e. where a decision is made by the researcher to cease a research project before the expected completion date, the SJGHC HREC along with the relevant SJG participating site(s) must be advised immediately, with an explanation of the reason(s).

   These reporting requirements 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 result in a lapse of approval of the study and a new application will need to be submitted to reinstate ethics approval.

SJGHC DEFINITION OF RESEARCH STUDY CLOSURE

At SJGHC, research studies are required to be closed as soon as all direct research activities have been completed, including submission of amendments, protocol violation or serious breach reports, safety reports, and any other correspondence. In the context of an externally sponsored clinical trial, this corresponds to the 'close-out' visit. At this time of study closure, a final report (either for the entire study or site-specific only) is due and must be submitted to the SJGHC Participating Site(s) and the SJGHC HREC.

It is noted that research activities such as analysis and reporting of already collected data can continue after study closure, subject to these activities being in compliance with the most recent ethics approval of the study. Outputs that arise from a research study (e.g. Clinical Study Report (CSR), publications, presentations) should continue to be submitted to the SJGHC Participating Site(s) and the SJGHC HREC, even after study closure has been acknowledged.

PATHWAYS FOR CLOSURE OF A RESEARCH PROJECT

Closure of a project can be requested by the principal investigator (or delegate) of a project. Closure in the context of failure to commence or complete a project should be distinguished from closure following completion of all direct research activities, as outlined in the study protocol.

A project may also be closed at the direction of SJGHC. Such closure can be directed to occur at all or some participating SJGHC hospitals and services. If ethical approval is withdrawn by the responsible ethical review body, SJGHC is responsible for directing the closure (or suspension) of the project.

SUSPENSION OF A RESEARCH PROJECT

Either the principal investigator (or delegate) or SJGHC can suspend some or all of the components of the direct research activities. Suspension will occur when intention is for the project to recommence the direct research activities that have been suspended.

Information and Advice for Researchers Making New Submissions

ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

All research specifically involving Aboriginal and Torres Strait Islander People submitted to the SJGHC HREC, also requires prior approval by the Western Australian Aboriginal Health Ethics Committee (WAAHEC) or by one of the other two Aboriginal specific HRECs in Australia (where conducted outside of WA and as appropriate to the requirements of that HREC).

Approval from the WAAHEC is required when research projects involve research in, or in relation to, Western Australia, and the following applies:

- ✓ The research is related to health and wellbeing; and
- ✓ the experience of Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
- ✓ data collection is explicitly directed at Aboriginal people; or
- ✓ research outcomes explicitly related to Aboriginal people; or
- ✓ it is proposed to conduct sub-group analyses and separately analyse Aboriginal people in the results; or
- ✓ the information, potential over-representation in the dataset, or geographic location has an impact on one or more Aboriginal communities; or
- ✓ Government Aboriginal health funds are a source of funding.

If the research meets any of the above criteria then the researcher should demonstrate that they have addressed in their research proposal the *NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2023) [the latest edition]* and include a copy of the WAAHEC or other Aboriginal specific HREC (as appropriate) in their ethics submission to the SJGHC HREC.

In keeping with the above requirements, the Human Research Ethics Application Form (HREA) section 2 states “The research will involve the following participants” and lists the tickbox options as:

- ✓ Women who are pregnant and the human fetus,
- ✓ Children and Young People,
- ✓ People highly dependent on medical care who may be unable to give consent,
- ✓ People with a cognitive impairment, intellectual disability or mental illness,
- ✓ People in dependent or unequal relationships,
- ✓ People who may be involved in illegal activities,
- ✓ People in other Countries,
- ✓ Aboriginal and Torres Strait Islander Peoples.

Researchers should only tick as participants those for which the research is ***explicitly directed at or analysing their data***, or for which the research will be impactful or if government funding has been specifically sourced.

Please do not tick any of the above listed participants if the research design specifically excludes a group/s of participants or for which there is likely to only be probably coincidental recruitment and for which the research will not likely specifically impact on the group or for which government funding has not been specifically sourced for the conduct of the research.

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 the 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 the HREA which is available online: https://hrea.gov.au/

CLINICAL QUALITY REGISTRIES

Clinical Quality Registries (CQRs) should be registered with the Australian Registry of Clinical Registries operated by the Australian Commission on Safety and Quality in Health Care ("the Commission").

The Commission has developed the Australian Register of Clinical Registries to facilitate collaboration and awareness of registry activity among key stakeholders. Once a clinical registry is registered via the online form, Commission staff will contact the registrant to confirm the information provided. A brief summary of the registry, web link and registry contact details will be published on the Commission's website.

Visit the Australian Register of Clinical Registries to either register and provide details on your clinical registry, or to update previously provided information.

CLINICAL RESEARCH RECORD FORM

When a participant is enrolled in a clinical trial, a Clinical Research Record Form acts as a "safety alert" to advise medical staff of the patient's participation in a clinical trial and what research intervention they are receiving or have received. This form should be completed by research staff and inserted into the patient's hospital medical record upon their enrolment into a clinical trial. Please direct all enquiries regarding this form to the Participating Site.

CLINICAL TRIAL

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

Clinical trials include but are not limited to:

- Surgical and medical treatments and procedures
- Experimental drugs and diagnostics
- Biological products

- Medical devices
- Health-related service changes
- Health-related preventative strategies
- Health-related educational interventions.

From a regulatory perspective, clinical trials can be categorised in to regulated or non-regulated trials.

1. A ***regulated trial*** corresponds to trials that must have submitted an application to the Therapeutic Goods Administration (TGA) under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes. All trials of medicines, devices, and biological treatments that are not licensed (i.e., not entered into the Australian Register of Therapeutic Goods (ARTG) are classified as regulated. All trials in which the intervention is a licensed therapeutic product (i.e., entered on the ARTG) but the therapeutic product is being applied to a different indication (off-label) or utilise the product with a substantially modified dose or route of administration are also classified as regulated.

   It is noted that a trial in which the protocol specifies that any aspect of trial conduct, not just the intervention, that utilises an unlicensed therapeutic product is a regulated trial. For example, a trial for which the intervention is not a therapeutic product but utilises an unlicensed diagnostic test as part of assessment of eligibility or measurement of outcome would still be classified as a regulated trial.

   Any trial in which the intervention is used off-label is always classified as a regulated trial, even if the therapeutic product is widely used in clinical practice for that indication.

   Further, there are no placebo products listed on the ARTG and, as such, all trials that utilise a placebo are regulated, even if the active intervention is licensed and being used within its license.

2. A trial is ***non-regulated*** if the trial intervention or any other aspect of the trial protocol utilises a therapeutic good, within its license. For example, a clinical trial that compares the comparative effectiveness of two licensed medicines and the inclusion / exclusion criteria of the trial define a population that corresponds to lie within the licensed indication is not a regulated trial. Similarly, a trial of a physiotherapy intervention will typically be non-regulated.

All clinical trials conducted in Australia must have a trial sponsor that is an Australian entity. The trial sponsor is responsible for the overall conduct of the trial, including (but not limited to) initiation, management and financing of the trial and carries the medico-legal responsibility associated with its conduct.

A Certificate of Insurance is essential to ensure adequate compensation/ indemnity provisions for trial related injury/misadventure and to protect both study participants and researchers.

A Clinical Trial Research Agreement (CTRA) or other appropriate legal agreement is also required to outline the respective responsibilities of, and financial arrangements between the parties involved in the trial or provision of clinical trial services

SJGHC recommends that caregivers or VMOs interested in conducting a clinical trial ensure that they discuss the proposed trial activity with the SJG participating site(s) for guidance on sponsor

requirements. At the current time SJGHC is not in a position to act as the sponsor of regulated clinical trials.

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. Lastly, as per the National Statement on Ethical Conduct in Human Research (NHMRC, 2025) [latest edition], section 3.1.7, sponsors/researchers must prospectively register their clinical trial on a public registry such as the WHO ICTRP (http://www.who.int/ictrp/en/), clinicaltrials.gov, ANZCTR (www.anzctr.org.au) or other equivalent public registry. NOTE: The SJGHC HREC also strongly encourages sponsors/researchers to register observational research on a public registry.

CONSUMER AND COMMUNITY INVOLVEMENT (CCI)

Researchers are encouraged from the onset to seek consumer and community involvement (i.e. lived experience) in research and to include consumer and community co-design and partnership approaches over the study life-span. Consumer & Community involvement (CCI) is a **core requirement** under the National Clinical Trial Governance Framework (NCTGF) and User Guide (ACSQHC, Feb 2022) linked to the National Safety and Quality Health Service (NSQHS) Standard 2: Partnering with Consumers. Useful resources for how to engage consumers and community include the NHMRC Toolkit for Consumer and Community Involvement in Health and Medical Research (2020): Consumer and community engagement | NHMRC and the ACTA CT:IQ Consumer Involvement & Engagement Toolkit: Consumer involvement and engagement toolkit (clinicaltrialsalliance.org.au)

Consumer and community input should influence decisions about what to research, the particular research design, the conduct of the study, how to disseminate and translate study results and how to assess research impact. Where consumer and community representatives have been involved in this process, please advise the names, and what the interests are, of these representatives.

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. Public websites which detail final study results are also an efficient way of dissemination of research findings to the community.

* 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.

CULTURALLY AND LINGUISTICALLY DIVERSE (CALD) POPULATIONS

With Australia being described as a CALD population (i.e. one in every four Australians were born overseas), it is important that CALD persons are included in the consumer and community engagement in research.

As per section 5.3.6 of the National Statement, researchers should present information about the research to participants in ways that help them make informed choices about their participation and to this end, researchers should include accurate and reliable translation (written and/or oral) of the information into a participants first language/dialect.

Thus, where study documentation is available in other language(s), please include a translation certificate confirming that the translation is true and accurate. Alternatively, where the services of an accredited interpreter are used, please ensure that they also sign any PICF as an impartial witness, confirming that they have witnessed the participant signing the consent form. The use of interpreter services should also be appropriately documented in the local study records.

DATA MANAGEMENT PLAN (DMP)

As per section 3.1.44 of the National Statement on Ethical Conduct in Human Research (NHMRC, 2025) [latest edition], researchers should develop a DMP that addresses their intentions related to custodianship, generation, collection, access, use, analysis, disclosure, storage, retention, disposal, data sharing and re-use of data, identifying what the risks of these activities are and how these risks will be managed.

The DMP should include as a minimum the following details:

a) physical, network, system security and any other technological security measures
b) policies and procedures
c) contractual and licensing arrangements and confidentiality agreements
d) training for project team members and others (as appropriate)
e) form in which data will be stored
f) purposes for which data will be used and/or disclosed
g) conditions for access to the data by others
h) what details about DMP need to be communicated to study participants
i) if data will be collected using extended or unspecified consent for future research
j) if a waiver of consent will be requested from the review body or HREC.

It is important that a DMP is developed early on in the research process to ensure ethical, effective and efficient data management that supports high quality data and researcher integrity as per the FAIR Data Principles (findability, accessibility, interoperability and reusability) and CARE indigenous data principles (collective benefits, authority to control, responsibility and ethics) and which minimises such risks as loss of data and privacy breaches.

Many Australian universities have DMP policies, tools and templates available free to use by researchers e.g. Health Sciences example DMP from Curtin University.

For further information on DMPs, refer: Data Management Plans | Australian Research Data Commons | ARDC

DETERMINING YOUR RESEARCH DESIGN

Please use this form to determine the best type of study design according to the research question(s) your study will answer. This document is based on the Research Design Algorithm that was developed by the American Dietetic Association in 2010.

ETHICS REVIEW FOR EXTERNAL SITES

The SJGHC HREC is an NHMRC-Certified HREC, and therefore has a national research ethics role as a "reviewing HREC" committed to facilitate the efficient and effective ethics 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 ethics review of research for other Australian institutions/external sites.

For submissions to be conducted at external sites within Australia, the process of ethics review is as described in SJGHC Approval Process for Research & Pathways of Review and administrative fees will be charged where applicable as per the Administrative Fee Schedule. The SSA will automatically exclude questions specific to SJGHC research governance, and should be signed by the relevant Director/CEO from the external institution.

The SJGHC HREC will take this signed SSA to be evidence of governance approval from the external site. Should the study be approved, the SJGHC HREC will send a letter confirming ethics approval only. It is the responsibility of the external site for other research governance processes e.g. legal review or issuing institutional approval. SJGHC will not issue an institutional approval letter in this case, as the external site falls outside of the jurisdiction of SJGHC.

MULTICENTRE RESEARCH

NHMRC defines "multicentre research" as research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations of a single institution (such as more than one SJGHC hospital or service).

"SJGHC collaborative research" refers to research that is conducted at more than one SJGHC hospital or service.

NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK - SHORT NOTICE ASSESSMENT

Any research project that meets the definition of a clinical trial and is being conducted at a SJG participating site will be in-scope for assessment under the National Clinical Trials Governance Framework, as part of the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme. The Principal Investigator and Trial Sponsor must comply with all reasonable requests from the SJG participating site to provide information and attend interview as requested by assessors regarding the trial, which may include but is not limited to:

- Study overview (Study objective, intervention, recruitment)
- Trial conduct
- Safety of trial participants
- Reporting
- Clinical leadership

Where the involvement of the SJG participating site is restricted to provision of standard of care (SOC) services or a specific aspect of the clinical trial, only the aspect of clinical trial service provision that is outlined in the service level agreement is considered in-scope for assessment under the Framework.

Please note that SJG participating sites are provided with 24 hours' notice of assessment and SJGHC respectfully requests that both Trial Sponsor and PI give urgent attention to site requests for study information and availability for interview.

NO OR LIMITED INVOLVEMENT FROM SJGHC (ADVERTISTING STUDY ONLY, ETC.)

If you are proposing a study that already has ethics approval from another HREC which has no or limited SJGHC involvement (e.g. advertising study only on a SJGHC site, standard of care (SOC)

treatment only at a SJG Participating Site as part of a clinical trial), the following are the steps to gain approval at SJGHC:

1. Submit a project synopsis along with any DMP (if applicable) to the SJG Participating Site(s) for site governance review. The SJG site may require the researcher to complete an Attestation document to confirm that there is indeed no or limited SJG involvement in the study.
2. Complete the Ethics Submission Form attaching the Attestation document, latest approved Protocol, advertising flyer, and copy of the other HREC ethics approval letter for the study.
3. As the study already has HREC approval, it will be reviewed by the SJGHC HREC Chair OOS and an ethics letter will be issued in acknowledgement. Where there is no SJG involvement in the study, this ethics approval will be a "HREC review only" letter acknowledging that the approval will be the institutional responsibility of the non-SJGHC party as the legal entity.
4. Depending on the risk level of the study, the study may also require the Sponsor to indemnify the SJG Participating Site (e.g. a higher risk clinical trial with SOC treatment only at a SJG Participating Site).
5. A letter of Institutional approval (SIA) from SJGHC will only be issued in those cases where applicable.

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 ethics 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) 6116 0542) on a confidential basis. Your concerns will be drawn to the attention of the Committee that is monitoring the study."*

PARTICIPANT INFORMATION SHEET AND CONSENT FORMS (PICFS)

PICFs need to be in plain language, avoiding jargon, ambiguities and misleading statements and should be kept 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 CT:IQ (Clinical Trials: Impact & Quality) simplified, participant-centric PICF template has been designed as part of the InFORMed Project with input from over 700 survey respondents, including consumers, researchers, contract research organisations and human research ethics committees. Researchers can freely access this PICF Template and accompanying User-Guide to help potential participants make better-informed decisions about research participation and future sharing of their research data: https://www.informedpicf.com.au/

PHASE 1 CLINICAL TRIALS

Phase 1 clinical trials undergo the Higher Risk pathway, with the following additions:

a) The Principal Investigator must provide a current resume and evidence of current GCP certification for all research personnel involved with the study at the site;

b) The Principal Investigator (or delegate) must be available to attend the meeting where the study will be reviewed by the SRC and/or HREC. Any other research personnel involved with the study are also welcome to attend;
c) Six-monthly progress reports will be required as a condition of ethics approval.

PREGNANCY WORDING IN PICFS

There should be no reference made to "artificial contraception" or "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]."*

PRIVACY DECLARATION

All external researchers (i.e. excluding SJGHC caregivers and accredited practitioners) conducting research at a SJGHC site where they will be accessing identifiable SJGHC health records, are required to sign a separate Privacy Declaration Form as part of their study submission to the SJGHC HREC.

PRIVACY PRINCIPLES, WAIVERS OF CONSENT & OPT-OUT APPROACH TO CONSENT

The Australian Privacy Principles (or APPs) are the cornerstone of the privacy protection framework in the *Privacy Act 1988*. There are 13 APPs that govern the standards, rights and obligations around the collection, use and disclosure of personal information. Researchers who are seeking to undertake a study which will involve the collection, use and/or disclosure of identifiable data without prior patient consent are required to provide a justification under Section 95 or Section 95A of the Privacy Act for a waiver of consent, and identify the APP/s which are relevant to the submission. Please refer to this quick reference for more information.

PLEASE NOTE: in regards to APP6, the definition of "use of personal information" according to Section 95A of the Privacy Act includes the **accessing and reading of identifiable personal information**, such as from medical records. Even in the case where a researcher is collecting de-identified data, if the researcher has directly sourced this from identifiable records, then a waiver of consent must be sought. A waiver of consent for clinical data is required, as research is not necessarily a legitimate secondary use directly related to the primary purpose for which clinical data was originally collected i.e. for use in clinical treatment.

Thus, where a researcher in the conduct of a study will be directly accessing identifiable medical records without prior patient consent, they will need to justify a waiver of consent under both Section 95 (if public records) or 95A (if private institution records) as well as meet all the requirements for a waiver of consent as outlined in section 2.3.10 of the National Statement on Ethical Conduct in Human Research (NHMRC, 2025) ("latest edition").

An opt out approach refers to a research recruitment method where study information is provided to potential participants and their participation is presumed unless they take action to decline to participate e.g. participant is required to contact researcher within 2 weeks to "opt-out" of the study,

otherwise they will be part of the study. An opt-out approach is often used in Registries where the project is of such scale (large sample number) and significance (public benefits) that using explicit consent is neither practical or feasible.

PLEASE NOTE: Opt-out approach is unlikely to constitute "consent" when applying Commonwealth Privacy Legislation (i.e. Privacy Act 1988) for the handling of identifiable health information. Thus, researchers applying to use an opt-out approach in cases where identifiable health information will be used/collected also need to provide justification for a Waiver of Consent under S95/S95A Privacy Act 1988.

As per NS2.3.12, given the importance of maintaining public confidence in the research process, SJGHC will make publicly accessible (e.g. via Annual Reports) *summary descriptions* of all its research projects approved with a waiver of consent – but will otherwise not make details of these research projects publicly accessible until the research has been completed.

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, instructions 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.

QUALITY IMPROVEMENT (QI) PROJECTS

Quality improvement (QI) projects in health services are about evaluation of clinical practice with the intention of improving immediate 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: "higher risk" or "lower 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 requirements for formal submission to the SJGHC HREC of certain QI projects only for prior ethics approval.

RESEARCHER CONCERNS ABOUT THE ETHICS 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 ethics 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 of the 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 SJGHC Ethics Team 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. Researchers conducting Phase 1 studies will be expected to attend the SRC and/or SJGHC HREC meeting when the initial submission is considered.

RESEARCH INVOLVING ADULTS WITH IMPAIRED CAPACITY IN WA

The WA Department of Health has supporting documents for Guardianship and Administration Act (GAA) Medical Research requirements available on the WA Research Governance Service website.

The documents include:

1. GAA Medical Research Guidance Document. Note in particular 6.3 Flowchart on page 9 of this document.
2. GAA Medical Research Decision Form. This form to be part of the study records, must be used by the researcher to document the decision when enrolling an incapable person in health and medical research, with the consent of a research decision-maker.
3. GAA Medical Research Decision Form – Urgent Treatment. This form to be part of the study records, must be used to document the decision when enrolling an incapable person in health and medical research with the consent of a research decision-maker; OR without consent if approved by a HREC (e.g. in an emergency medicine setting.)
4. GAA Medical Research Decision Report. Under the Act, it is a requirement that the researcher complete the report for each adult with impaired capacity who is recruited into a study where a research decision has been made on their behalf. The report must be provided to the WA Department of Health within 15 calendar days of patient recruitment.

RESEARCH PROTOCOL/PROJECT DESCRIPTION

The protocol provides a justification of the study i.e. background/literature review including references to 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 size 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 SPIRIT 2025 Statement (Standard Protocol Items: Recommendations for Interventional Trials) – refer https://www.consort-spirit.org/ is an evidence-based guideline which recommends *the minimum items* required to be addressed in a protocol (specifically a RCT with a two-group parallel design). However, SPIRIT 2025 can also be applied to other types of trials and indeed has some wider relevance to other research more broadly.

SPIRIT emphasises the importance of the protocol as the "source of truth" which serves as the formal record of planned research methods and conduct, providing sufficient detail that it can be reviewed from a scientific, ethical, safety and governance perspective, followed by trial/research support staff, and can be used after research completion to understand and interpret study results.

All protocols should have a tracking system (version x dated x) to ensure that amendments made during the research can be clearly documented with an audit trail. Researchers and others are encouraged to refer to SPIRIT in the planning stages of a trial to ensure a complete, clear, and open and transparent protocol.

https://www.consort-spirit.org/ includes protocol writing tools and training materials for researchers, research trainees, peer reviewers, journal editors, and patients and the wider public.

RESUMES/CVS

Researchers should include an abbreviated, current resume (and publication list)/CV which outlines their academic qualifications, registration (where applicable), experience and skills to carry out research. For all clinical trials investigators must maintain currency and provide evidence of GCP certification throughout the duration of their involvement in the trial. For higher risk clinical trials including Phase 1 trials, investigators are also required to provide evidence of current GCP certification for all research personnel involved with the trial at the participating site.

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 the key budget details of interest to study participants i.e. sources of research funding (and any perceived conflicts of interest), direct payments/reimbursements to study participants of study related expenses, and any out of pocket expenses that study participants may be faced with while participating in the study.

Also, as per National Statement section 3.1.9, researchers should confirm in their ethics submission that there is a plan in place to ensure that resources are sufficient to conduct and complete the research as designed.

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 clearly and easily tracked and the latest version quickly identified. In particular, the Protocol is the "source of truth" and serves as the formal record of planned research methods and conduct, and thus must provide sufficient detail that it can be reviewed from a scientific, ethical, safety and

governance perspective, followed by trial/research support staff, and used after research completion to understand and interpret study results. The Protocol should have a tracking system (version number and date) to ensure that amendments made during the conduct of the research can be clearly and easily traced with an audit trail.

TRANSLATION OF RESEARCH – USE OF REPORTING GUIDELINES & REGISTRATION OF RESEARCH

The EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network is an international initiative that seeks to improve the reliability and value of published health research literature (i.e. ensure the reproducibility and reliability of health research) by promoting transparent and accurate reporting and wider use of robust reporting guidelines. The EQUATOR website www.equator-network.org has a one-stop library that provides an up-to-date collection of reporting guidelines/standards for all types of health research design. Whilst the target audience is journal editors and peer reviewers, the resources on this website are also helpful for researchers in their protocol/project description and conduct.

Researchers are strongly encouraged to use reporting guidelines to assist in the development of their study protocol, to guide the conduct of their study, and to ensure quality reporting of study results.

Sponsors/Researchers are also strongly encouraged to prospectively register their clinical trial and other research including observational research (where possible) on a public registry such as the WHO ICTRP (http://www.who.int/ictrp/en/), clinicaltrials.gov, ANZCTR (www.anzctr.org.au) or other equivalent public registry. Indeed, for clinical trials, public registration is a mandatory requirement under the National Statement on Ethical Conduct in Human Research (NHMRC, latest edition), section 3.1.7:

For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.

Registration should occur ***at the same time (or before)*** an ethics submission with the details of the registration to be provided to the SJGHC HREC as part of the ethics submission for proposed new clinical trials. Prospective registration of research in a public registry promotes research transparency and ensures that 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 research, 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.

Thus, the use of reporting guidelines together with the prospective registration of a study facilitates research translation, i.e. a study is more likely to be recognised as well designed and reported, with findings that provide evidence and have the potential for implementation in practice or can be a solid foundation for subsequent follow-up research.

Some of the more common guides for different types of studies include:

Systematic Reviews:

1. PRISMA 2009 Checklist & Flowchart: The 27 checklist items pertain to the content of a systematic review and meta-analysis, which include the title, abstract, methods, results, discussion and funding. The flow diagram depicts the flow of information through the different phases of a systematic review. It maps out the number of records identified, included and excluded, and the reasons for exclusions.

2. PRISMA-P Checklist 2015: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.

3. PROSPERO – an international prospective register for systematic reviews in health and social care.

Clinical Trials:

1. CONSORT 2025 Statement (CONsolidated Standards of Reporting Trials) and Extensions of the CONSORT Statement (for different trials/methodologies):

2. SPIRIT 2025 Statement (Standard Protocol Items: Recommendations for Interventional Trials) and Extensions of the SPIRIT Statement (for different trials/methodologies):

Both SPIRIT and CONSORT are evidence-based guidelines and "living documents" which have recently been updated in unison (version 2025) to ensure alignment and consistency between the statements. Both include fillable Checklists, diagrams and explanation documents which recommend *the minimum items* required to be addressed in a protocol, and in a report of a RCT (specifically a RCT with a two-group parallel design), respectively. All these documents are available on a new joint website: https://www.consort-spirit.org/ This website also includes protocol writing tools and training materials for researchers, research trainees, peer reviewers, journal editors, and patients and wider public.

Researchers and others are encouraged to refer to the Statements in the planning stages of a trial to ensure complete, clear, and open and transparent Protocols and reporting of RCTs to support:

a) critical appraisal by peer reviewers, funders, HRECs and journals,
b) accessibility,
c) reproducibility of results
d) translation of research for ultimate implementation of evidence-based healthcare.

The Statements can also be applied to other types of trials and indeed have some wider relevance to other research more broadly.

However, existing extensions to SPIRIT and CONSORT for different types of trials/methodologies (e.g. adaptive trials, cluster trials, etc.) can still be used in the interim. It is planned that these extensions will undergo a future process of alignment with the main SPIRIT and CONSORT 2025 statements.

3. ANZCTR (Australian New Zealand Clinical Trials Registry): ANZCTR is one of many online public registries for clinical trials. ANZCTR is specifically a register of clinical trials being conducted in Australian and New Zealand. The ANZCTR is recognised by the World Health Organization (WHO) as a Primary Registry in the WHO Registry Network. ANZCTR is also a registry recognised by the International Committee of Medical Journal Editors (ICMJE). ANZCTR includes trials from the full

spectrum of therapeutic areas of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies.

Cluster Randomised Trials (CRTs):

1. The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials (2012) is a consensus statement which provides guidance on the ethical design and conduct of CRTs in health research, primarily for researchers and research ethics committees. It builds upon—but does not replace—national and international ethics guidelines for randomized controlled trials and other human research. The consensus statement should be interpreted in light of the laws and regulations of the host country or countries, as well as other applicable international standards.

2. Consort 2010 Statement: extension to cluster randomised trials include a checklist for the reporting of CRTs.

Pragmatic Clinical Trials (PCTs):

1. CONSORT Statement Extension for Pragmatic Trials (2008): A pragmatic trial (a term first used in 1967 by Schwartz and Lellouch) can be broadly defined as a randomised controlled trial whose purpose is to inform decisions about practice. This extension of the CONSORT statement is intended to improve the reporting of such trials and focuses on applicability.

2. The PRagmatic Explanatory Continuum Indicator Summary-2 (PRECIS-2) is a validated tool that helps researchers make decisions about the elements of the trial to match the overall purpose and intent of the trial along the explanatory/pragmatic continuum. The tool can help guide researchers in the design of more or less explanatory (testing interventions under ideal conditions) trials versus pragmatic trials (which test interventions in real-world conditions).

Observational Studies:

1. STROBE Statement (STrengthening the Reporting of OBservational studies in Epidemiology): various checklists of items that should be included in reports of different types of observational studies e.g. cohort studies, case-control studies, cross-sectional studies, conference abstracts.

2. ANZCTR: is one public registry that does accept both interventional and observational studies for registration. For observational studies, “observational” must be selected for the “study type” field.

Qualitative Studies:

1. Standards for Reporting Qualitative Research: A Synthesis of Recommendations by Bridget C. O’Brien et al, 2014, Academic Medicine 89(9): 1245-1251

Diagnostic/Prognostic **Studies:**

1. STARD 2015 (Standards for Reporting of Diagnostic Accuracy Studies): checklist of essential items for reporting diagnostic accuracy studies.

Quality Improvement (QI) Studies:

1. SQUIRE 2015 Guidelines (Standards for Quality Improvement Reporting Excellence): provides a framework for reporting of QI studies that describe system level work to improve the quality, safety and value of healthcare, and uses methods to establish that observed outcomes were due to the intervention(s).

Case Studies:

1. CARE 2013 Toolkit: consists of a checklist, writing template, timeline examples, that aim to improve the completeness, transparency and usefulness of case reports for clinicians, researchers, educators and patients. Case reports have historically been important in (a) recognising new or rare diseases, (b) evaluating the therapeutic effects, adverse events, and costs of interventions; and (c) improving problem-based medical education. They provide evidence for effectiveness in a real-world setting.

Case Series (in surgery):

1. PROCESS 2017 Guidelines (Preferred Reporting of Case Series in Surgery): consists of an eight item checklist that aims to improve the reporting quality of surgical case series.

Economic Evaluations:

1. CHEERS 2013 Statement (Consolidated Health Economic Evaluation Reporting Standards): The 24 item Checklist lists what to report in economic evaluations of health interventions.

Pre-clinical Animal Studies:

1. ARRIVE Guidelines (Animal Research: Reporting of In Vivo Experiments): a checklist to improve the design, analysis and reporting of research using animals.

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.

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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 ethics 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 prior ethics review by the SJGHC Human Research 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 ethics 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 before project commencement. Also, if there is an intention or possibility that the findings of the Human QI may be published or presented externally (e.g. at a conference), it is important that the project can demonstrate scientific merit and validity. To facilitate the translation of results, the SJGHC HREC strongly encourages researchers to use the SQUIRE 2015 Guidelines (Standards for Quality Improvement Reporting Excellence) to assist in the Human QI project design, to guide the conduct of the project and to ensure a high standard in the reporting of findings.

PLEASE NOTE:

If you choose not to seek prospective ethics approval from the SJGHC HREC for your Human QI project, you are likely to lose the possibility of publishing your results in the future. **The SJGHC HREC will not provide retrospective ethics approval for a Human QI project (or indeed any research) that has already commenced or being completed.**

Those proposing to undertake Human QI projects should thus refer to the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014) and overleaf the *Checklist for Essential Criteria for Human QI Projects* and *Checklist for Assessing the Level of Risk of Human QI Projects* to discern whether there is a need for prior review by the SJGHC HREC. The SJGHC Ethics Team can also be contacted for further advice. Often Human QI projects will either be "lower risk" or "minimal risk" and will thus undergo expedited review rather than a full review process by the SJGHC HREC.

CHECKLIST FOR ESSENTIAL CRITERIA FOR HUMAN QI PROJECTS

All Human QI projects should 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

CHECKLIST FOR 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* (2025) [latest version] ("the National Statement") provides a basis for ethics review of Human QI, which is often classified as "lower risk" or "minimal risk." Both lower risk and minimal risk research undergoes an expedited review process by the SJGHC HREC. 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 Human QI project and summarised as follows:

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)

- ✓ Researcher is not affiliated with any of the external organisations involved in the QI
- ✓ Researcher does not receive financial or other benefits 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

RECAP

Irrespective of whether a project is research or quality improvement (QI) (otherwise referred to as QA/audit/evaluation), the same ethical principles apply. The researcher must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy. Thus, whilst being mainly "low or minimal risk", some level of ethical consideration and oversight is necessary for "Human QI" projects, and many will require ethics review by a HREC.

At SJGHC, Human QI where there is an intention to publish results should be reviewed by the SJGHC HREC. This will undergo expedited review rather than a formal, full review process.

"Pure QI" that looks solely at processes/systems/programs and does not use data about or samples taken from people, **does not require prior ethics review by the SJGHC**. These projects should be registered with the Quality and Risk Department of the relevant SJG Division/Hospital.

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

Guidelines on how to become an authorised prescriber* (AP) of an unapproved product for multiple patients i.e. for a class of patients with the same condition (under Section 19(5) or Section 41HC of the Therapeutic Goods Act 1989), can be found on the Therapeutic Goods Administration (TGA) website. Applications are made either via the "established history of use pathway" or the "standard pathway." The latter pathway requires the prior endorsement of a Human Research Ethics Committee (HREC) or a specialist college.

It is the responsibility of the applicant to complete the application to become an authorised prescriber of an unapproved product (i.e. a pharmaceutical, device or biological**), as outlined in these TGA guidelines and provide justification for the proposed duration of authorisation (which can vary depending on the product and historical use of the product, from 1 to 5 years).

Please note that these TGA guidelines also outline what evidence applicants should provide to the HREC to justify use of the unapproved product, and what should be included in the plain language written Patient Informed Consent Form Template that must accompany the submission to the HREC.

If approved, the HREC will issue a written endorsement letter, and the applicant can then complete their AP application to the TGA. This endorsement letter includes a section titled "Conditions imposed by the HREC." At SJGHC, these conditions are:

1. Written 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) or Unanticipated Serious Adverse Device Effects (USADEs) from the use of the unapproved product. Any such adverse event must be reported to the site Director of Medical Services (DMS) and entered into RiskMan.
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/USADEs and demonstrating compliance with the conditions imposed by the TGA on the Authorisation.

There is a 3 step process to obtain SJGHC endorsement of Authorised Prescriber status:

1. Firstly, written endorsement of ***each*** local (SJGHC) site Scope of Practice (SOP) Committee is required i.e. ***each*** site where the clinician intends to use the unapproved product. This is to confirm that the clinician ***can prescribe the unapproved product within their scope of practice.*** The SOP Committee will also decide if any supervision and/or audit reports may be required as part of the scope of practice process. NOTE: A copy of the required documents listed on the Authorised Prescriber Form should also be forwarded to the SOP Committee.

2. Secondly, the SOP Committee endorsement letter should be copied to the local (SJGHC) site DMS and the SJGHC Chief Medical Officer (CMO). Both the site DMS and SJGHC CMO must be formally advised of the SOP Committee endorsement.
3. Once steps one and two are complete, please complete your Authorised Prescriber submission to the SJGHC HREC. Written endorsement from the SJGHC HREC is required before applying to the TGA.

* NOTE: The Authorised Prescriber scheme for unapproved products is available to *medical practitioners only.* Nursing Practitioners, for instance can only administer an unapproved product via the Special Access Scheme.

** NOTE: The Authorised Prescriber scheme applies to Therapeutic Goods regulated in Australia by the Therapeutic Goods Administration (TGA). Therapeutic goods include medicines, medical devices and biologicals. A *therapy* that is not considered a "therapeutic good" falls outside all TGA approval and registration processes including the Authorised Prescriber scheme and CTN/CTA processes.

Meeting and Submission Dates

HIGHER RISK STUDIES REQUIRING FULL REVIEW

Submission Dates	SRC Meeting Dates	HREC Meeting Dates
7 July 2025	18 July 2025	13 August 2025
8 September 2025	19 September 2025	8 October 2025
10 November 2025	21 November 2025	10 December 2025
12 January 2026	23 January 2026	11 February 2026
9 March 2026	20 March 2026	8 April 2026
11 May 2026	22 May 2026	10 June 2026
13 July 2026	24 July 2026	12 August 2026
7 September 2026	18 September 2026	7 October 2026
9 November 2026	20 November 2026	9 December 2026

STUDIES FOR EXPEDITED REVIEW AND LOW RISK STUDIES*

Submission Dates	HREC Meeting Dates
30 June 2025	9 July 2025
4 August 2025	13 August 2025
1 September 2025	10 September 2025
30 September 2025	8 October 2025
3 November 2025	12 November 2025
1 December 2025	10 December 2025
2 February 2026	11 February 2026
3 March 2026	11 March 2026
30 March 2026	8 April 2026
4 May 2026	13 May 2026
2 June 2026	10 June 2026
29 June 2026	8 July 2026
3 August 2026	12 August 2026
31 August 2026	9 September 2026
29 September 2026	7 October 2026
2 November 2026	11 November 2026
30 November 2026	9 December 2026

* Please note that studies for expedited review and low risk studies will be usually added to the agenda for the upcoming HREC or SRC meeting. In special circumstances to be discussed prior with the SJGHC Ethics Team, these studies can be circulated for review OOS with approval usually granted within a week of submission.

PICF updates due to safety concerns, safety reports, local SAEs/SUSARs/USADEs 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.

For administrative purposes, the SJGHC Ethics Team prefers to receive one submission per study per meeting. If you are expecting to submit more than one item per study per meeting (e.g. an updated IB and a resulting PICF amendment), please submit these items at the same time.

Submission Contacts

The SJGHC Research Submission process is paperless, and thus all study submissions should be submitted electronically.

SJGHC GROUP RESEARCH OFFICE (GRO) CONTACT DETAILS

Group Directors of Research:

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Prof Eli Gabbay
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Group Manager Research Office:

Taryn Quartermaine
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For all new research enquiries involving one or more SJG Participating Sites or the wider SJGHC Group, please contact the SJGHC Research Office at Research.Governance@sjog.org.au.

SJGHC HREC POSTAL ADDRESS

St John of God Health Care HREC
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PERTH WA 6831

SJGHC ETHICS TEAM CONTACT DETAILS

Telephone: (08) 6116 0542

Email: ethics@sjog.org.au

Executive Officer to Committee:

Ms Gorette De Jesus
Email: gorette.de.jesus@sjog.org.au

Research Ethics Officers:

Ms Karen Roberts (0.5FTE)
Email: karen.roberts@sjog.org.au

Ms Martha Henneberry (0.5 FTE)
Email: martha.henneberry@sjog.org.au

SITE RESEARCH GOVERNANCE CONTACT DETAILS

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SJG Ballarat	Sangeeta Rathi, Research Lead	Ballarat.Research.Governance@sjog.org.au
SJG Bendigo	Sangeeta Rathi, Research Lead	Bendigo.Research.Governance@sjog.org.au

SJG Site	Contact	Email Address
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SJG Burwood & SJG Richmond	Sangeeta Rathi, Research Lead	NSWMH.Research.Governance@sjog.org.au
SJG Geelong	Sangeeta Rathi, Research Lead	Geelong.Research.Governance@sjog.org.au
SJG Geraldton	Sangeeta Rathi, Research Lead	Geraldton.Research.Governance@sjog.org.au
SJG Healthcare at Home	Sangeeta Rathi, Research Lead	HAH.Research.Governance@sjog.org.au
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SJG South East Melbourne (Berwick, Frankston, Langmore)	Sangeeta Rathi, Research Lead	SEM.Research.Governance@sjog.org.au
SJG Subiaco	Natalya Beer, Manager Clinical Trials	Research.network@sjog.org.au
SJG Warrnambool	Sangeeta Rathi, Research Lead	Warrnambool.Research.Governance@sjog.org.au
SJGHC Group Research Office (Multi-site enquiries)	GRO Governance Team	Research.Governance@sjog.org.au

Administrative Fee Schedule

Significant SJGHC funding is required to support formal ethics 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 except for Phase 1 trials/First In Human studies	$6,000 + GST
Phase 1 trials/First In Human studies	$7,000 + GST
Addition of New Site for Commercially Sponsored Studies	$500 + GST
Commercially Sponsored External Studies where SJGHC will contribute patients to recruitment but will not be formally named as a primary clinical trial site	$2,500 + 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 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.) at the discretion of the SJGHC HREC.

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 *which are not commercially sponsored external 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 SJGHC Ethics Team:

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.

Useful References

Researchers may find these references helpful in conducting research:

1. *National Statement on Ethical Conduct in Human Research* (NHMRC, 2025) [latest edition] ("the National Statement") provides guidelines to researchers making submissions to Ethics Committees throughout Australia.
   https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2025

2. *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* (CHA, 2001) [latest edition]
   https://www.cha.org.au/wp-content/uploads/2021/06/Code-of-ethicsfullcopy.pdf

3. *Guidelines approved under Section 95A of the Privacy Act 1988* (NHMRC, 2024) [latest edition] provides a framework to ensure privacy protection of (identifiable) health information (considered "sensitive 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. Where there is no prior explicit consent obtained from patients for the collection, use or disclosure of their health information for research purposes, the researcher must request prior approval from a HREC. The researcher needs to demonstrate that it is impracticable to obtain an individual's explicit consent to the use of their information, that the purpose of the research cannot be served by using non-identifiable information, and that they comply with the Guidelines under Section 95 of the Privacy Act 1988 (S95 guidelines) or the Guidelines approved under Section 95A of the Privacy Act 1988 (S95A guidelines) (as applicable) to ensure that their handling of personal information does not breach the Privacy Act 1988.

   NOTE: an opt-out approach (i.e. a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement, and where their participation is presumed unless they take action to decline to participate) is unlikely to constitute consent under the Privacy Act 1988. **Thus, when pursuing either a "waiver of consent" or an "opt-out approach" for the collection, use or disclosure of identifiable health information in research, a researcher is also required to meet the privacy guidelines i.e. S95/S95A of the Privacy Act 1988.**
   https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988

4. *Australian Code for the Responsible Conduct of Research* (NHMRC, 2018) [and related guidelines] and the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* (NHMRC, 2018) ("the Guide"). The Code sets out broad principles and responsibilities that both researchers and institutions are expected to follow when conducting research. It applies to all research across all disciplines. Compliance with the Code is a mandatory requirement for the receipt of funding by NHMRC and ARC. The Guide sets out a model for managing and investigating potential breaches of the Code some of which may be designated as "research misconduct."
   https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-

research-2018
https://www.nhmrc.gov.au/sites/default/files/documents/reports/guide-managing-investigating-potential-breaches.pdf

5. *World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects* (WMA, 2024)
https://www.wma.net/policies-post/wma-declaration-of-helsinki/

6. Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (2016) written in collaboration with the World Health Organisation (WHO) are an international set of guidelines which focus primarily on the rules an principles to protect and safeguard the rights and welfare of humans in health-related research
https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

7. *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice E6(R3) adopted 06 January 2025* Good Clinical Practice (GCP) is an international, ethical, scientific and quality standard for the conduct of trials that involve human participants. Clinical trials conducted in accordance with this standard will help to assure that the rights, safety and well-being of trial participants are protected; that the conduct is consistent with the principles that have their origin in the Declaration of Helsinki; and that the clinical trial results are reliable.
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

8. *Note for Guidance on Good Clinical Practice* (TGA, 2016). 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 NS requirements exceed those of ICH-GCP.
https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

9. *The Australian Clinical Trial Handbook: Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods* (TGA, 2018)
https://www.tga.gov.au/publication/australian-clinical-trial-handbook

10. *Authorised Prescriber Scheme*. 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/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-multiple-patients-authorised-prescriber

11. *Ethical Considerations in Quality Assurance and Evaluation Activities (NHMRC, 2014)*. Irrespective of whether a project is research or quality assurance (QA/QI/audit/evaluation), the same ethical principles apply: the researcher must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy. Thus, whilst being mainly "lower or minimal risk", some level of ethical oversight is necessary for QI activity, and some should trigger ethical review by a HREC (e.g. At SJGHC, "human QI" with an intention to publish results should be reviewed by the SJGHC HREC).

https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities

12. *CT:IQ (Clinical Trials: Impact & Quality) simplified, participant-centric PICF template* has been designed as part of the InFORMed Project with input from over 700 survey respondents, including consumers, researchers, contract research organisations and human research ethics committees. Researchers can freely access this PICF Template and accompanying User-Guide to help potential participants make better-informed decisions about research participation and future sharing of their research data.
https://www.informedpicf.com.au/

13. *NHMRC National Certification Scheme: Institutions with certified ethical review processes* For a current list of all NHMRC-Certified HRECs, please consult the following document.
https://www.nhmrc.gov.au/sites/default/files/documents/attachments/List-of-certified-institutions-9-Jan-2025.pdf

14. *Safety monitoring and reporting in clinical trials involving therapeutic goods* (NHMRC November 2016)
https://www.nhmrc.gov.au/guidelines-publications/eh59

15. *Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods* (NHMRC, 2018) is available for download at the bottom of the following page:
https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

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

17. *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

18. *EQUATOR Network*. This is an international initiative that seeks to promote the writing and publishing of high-impact health research. The website has a searchable library to freely access up-to-date reporting guidelines/checklists for different types of studies that can assist with protocol design, guide study conduct and ensure quality reporting of study findings.
www.equator-network.org/

19. *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

20. *NHMRC Policy on Complaints*
https://www.nhmrc.gov.au/about-us/resources/nhmrc-complaints-policy

21. *Statement on Consumer and Community Involvement in Health and Medical Research* (NHMRC, September 2016)
https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research

22. *Keeping research on track II* (NHMRC, 2018) and *Ethical Conduct in Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (NHMRC, 2018).

These documents guide ethical health research on Aboriginal and Torres Strait Islander (A&TSI) peoples, written with a framework of A&TSI values and principles.
https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples

23. *Challenging Ethical Issues in Contemporary Research on Human Beings* (NHMRC, 2009) illustrates challenging issues that arise in considering human research proposals.
https://www.nhmrc.gov.au/about-us/publications/challenging-ethical-issues-contemporary-research

24. *Western Australian Health Translation Network (WAHTN)* is a National Health and Medical Research Council (NHMRC) recognised Advanced Health Research and Translation Centre (AHRTC). It is a collaboration of contributing member partners consisting of WA's universities, medical research institutes, public and private hospitals, PathWest, the WA Department of Health, and associate partners working together to broadcast and transfer the knowledge from health and medical translation into the community and health care system. SJGHC is a founding partner of WAHTN. The WAHTN Research Education and Training Program (RETProgram) provides online research education for researchers to upskill and maintain current research standards/practices. Access to online education modules is complementary for users based at WAHTN partner organisations. External users and university students pay a nominal charge to access RETP.
https://wahtn.org/
https://www.retprogram.org/

25. *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

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

27. *The Medical Technology Association of Australia (MTAA)* has a dedicated Clinical Investigation Research Agreement (CIRA) template, indemnity forms and compensation guidelines for commercially sponsored studies of medical technology/devices. These are based on those developed by Medicines Australia (for drug studies).
https://www.mtaa.org.au/

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

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

30. The *Australian Privacy Principles* are the cornerstone of the privacy protection framework in the *Privacy Act 1988*. They govern the standards, rights and obligations around the collection, use and disclosure of personal information.
https://www.oaic.gov.au/privacy/australian-privacy-principles/

31. *The NHMRC Toolkit for Consumer & Community Involvement in Health and Medical Research 2020* provides detailed information and tools on five individual areas of interest:
    a. Expectations and Value – Framework for Effective Consumer and Community Engagement in Researcher
    b. Measuring Alignment with Consumer and Community Expectations in Research
    c. Measuring Effectiveness of Consumer and Community Involvement in Research
    d. Considering Impact of Research from a Consumer and Community Perspective
    e. Self-assessment of Consumer and Community Involvement in Research

    https://www.nhmrc.gov.au/about-us/consumer-and-community-engagement
32. *Guardianship and Administration Amendment (Medical Research) 2020 Supporting Documents* for research involving adults with impaired capacity in Western Australia
    https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx
33. *The Australian Centre for Value-Based Health Care* acknowledges the World Economic Forum definition of value: The health outcomes that matter to patients relative to the resources or costs required. Established by the Australian Healthcare and Hospitals Association (AHHA), it aims to support the creation of a healthcare system where health care is funded and delivered with a prime focus on outcomes achieved at an affordable cost for patients and distributed equitably throughout the community.
    https://valuebasedcareaustralia.com.au/resources/
34. *Western Australian Translation and Collaboration in Health Economics (WATCHE)* supports capacity building in health economics through research, teaching and knowledge transfer. Health Economics has become an increasingly important factor to be incorporated into research so as to facilitate translation into practice and contribute to value-based healthcare.
    https://wahtn.org/activities/statewide-projects/health-economics/
35. *Australian Atlas of Healthcare Variation Series* by the Australian Commission on Safety and Quality in Health Care (ACSQHC) investigates variation in health care according to geography, possible underlying reasons, and suggests specific achievable actions to reduce unwarranted variation. The aim is to promote safe care, optimal patient outcomes, and health equity. Researchers can use the Atlas series to inform and guide their research into gaps in existing healthcare in Australia. Refer also to the User Guide for the Review of Clinical Variation in Health Care.
    https://www.safetyandquality.gov.au/publications-and-resources/australian-atlas-healthcare-variation-series
    https://www.safetyandquality.gov.au/sites/default/files/2021-05/nsqhss_user_guide_for_the_review_of_clinical_variation_in_health_care.pdf
36. *The Australian Living Evidence Consortium* recognises that research provides the evidence base to update clinical guidelines. It aims to accelerate knowledge translation from research to point-of-care via continuous evidence surveillance and rapid response pathways that incorporate new relevant evidence from systematic reviews and other evidence synthesis activities (e.g. Registries, audits), into clinical practice guideline recommendations as soon as it becomes available.
    https://livingevidence.org.au/
37. *The National Clinical Trial Governance Framework (NCTGF) and User Guide* (ACSQHC, February 2022) Clinical Trials is a core, routine function of Health Service Organisations. The Framework embeds clinical trial services into the existing clinical and corporate governance systems of Health

Service Organisations to ensure that clinical trials are undertaken in the most efficient and effective way possible. Meeting the Framework requirements which are tied closely to National Safety and Quality Health Service (NSQHS) Standard 1: Clinical Governance and Standard 2: Partnering with Consumers, is mandatory under the ACSQHC Hospital accreditation scheme for those public and private Health Service Organisations/Hospitals that provide clinical trial services.

https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide

Useful Forms

Submissions to the SJGHC HREC are now to be completed via the Ethics Submission Form. Questions and fields are generated depending on the answers provided. There is also the option for users to save, review and complete the form later. To do this, click on the "Save and Complete Later" link at the bottom of the page. A popup will then appear with a unique URL link to the form, and the option to enter an email address to have this link sent to you.

It is mandatory that the email address of the Principal Investigator (PI) is entered on every form submission. Once the form is submitted, a PDF copy of the completed form will be sent to the SJGHC Ethics Team. The SJGHC Ethics Team will forward this to the person who submitted the form, the PI and any other persons who the submitter has requested to be included on the electronic receipt of the submission. (This process replaces the previous policy "Electronic Signatures for Submissions to SJGHC HREC".) This acknowledgement email will also include the date of the meeting where the submission will be reviewed.

ETHICS SUBMISSION FORM

The Ethics Submission Form is a dynamic online document which is to be utilised for ALL study submissions to be reviewed by the SJGHC HREC: new study submissions, amendments, extensions, annual and final reports, other study updates and notifications including study closures.

SITE SPECIFIC ASSESSMENT FORM

The Site Specific Assessment Form documents site governance approval from all departments at a participating site that will be impacted by the proposed research. It is a dynamic online form (superseding the previous dynamic PDF version), and progress can be saved and returned to at any time by clicking on the "Save and Complete Later" link. Please refer to Submission Process – Steps to Approval for information about how to complete this form.

OTHER FORMS FOR NEW RESEARCH SUBMISSIONS

Please refer to the online form Determining Your Research Design for guidance on the design of your study. The following documents are static PDF forms for new research submissions to be completed in Adobe Reader:

- Privacy Declaration for External Researchers
- Declaration of Interest

The following checklists are now incorporated into the Ethics Submission Form, but have been reproduced here for reference.

CHECKLIST FOR NEW SUBMISSIONS – LOWER RISK

- ✓ Complete Final Version (fully signed or unsigned) Site Specific Assessment Form (SSA)
- ✓ Human Research Ethics Application Form (HREA) or other Ethics Application Form. Complete online and download pdf version to your computer to include as attachment in Ethics Submission Form

- ✓ Research Protocol/Project Description
- ✓ Participant Information and Consent Form(s) (PICF) unless a waiver of consent is sought
- ✓ Data collection tool(s) e.g. data fields form, questionnaires, interview questions, survey tool
- ✓ Data Management Plan (DMP)
- ✓ Study advertisements and other material used to recruit potential study participants e.g. fliers
- ✓ All other participant/patient-facing documents e.g. Verbal Script/Phone Script/eScript explaining study and seeking consent, Introductory letter or email templates to participants
- ✓ Privacy Declaration Form (external researchers only)
- ✓ Declaration of Interest Form (for all Site Investigators)
- ✓ Abbreviated, current resume and publication list of researcher(s)
- ✓ Documentation of other HREC decisions (i.e. final/conditional/withheld/revoked approvals)
- ✓ Legal Agreement/Contract (where applicable) (if not complete and fully executed at time of ethics submission, please forward copy to Ethics Team in due course)

CHECKLIST FOR NEW SUBMISSIONS – HIGHER RISK

- ✓ Complete Final Version (fully signed or unsigned) Site Specific Assessment Form (SSA)
- ✓ Human Research Ethics Application Form (HREA) or other Ethics Application Form. Complete online and download pdf version to your computer to include as attachment in Ethics Submission Form.
- ✓ Research Protocol/Project Description
- ✓ Data Management Plan (DMP) (this may be incorporated already in the Research Protocol/Project Description)
- ✓ Participant Information and Consent Form(s) (PICF)
- ✓ Questionnaires, surveys, psychological scales or inventories, interview questions to be covered in the study
- ✓ Participant documentation e.g. patient diary, treatment log
- ✓ Study advertisements and other material used to recruit potential study participants e.g. fliers
- ✓ All other participant/patient-facing documents e.g. Verbal Script/Phone Script/eScript explaining study and seeking consent, Introductory letter or email templates to participants
- ✓ Investigator Brochure (IB) or Product/Procedure Information (available on TGA website with ARTG information)
- ✓ Copy of descriptor for system for tracking participants (implantable device trials only)
- ✓ Constitution (name/s, role/s and affiliation/s) of Independent Data Safety Monitoring Committee and/or Independent Medical Monitor (clinical trials only – please note these roles cannot be filled by a study co-investigator)
- ✓ Constitution (name/s, role/s and affiliation/s) of Data Safety Monitoring Board or Data Safety Officer Biostatistician
- ✓ Imaging Frequency Declaration Form
- ✓ Independent Radiation Dosimetry Assessment Report (studies involving additional tests, therapy or novel radiology/nuclear medicine only)
- ✓ Infection Control Protocol (e.g. Biohazards management for studies which involve live viruses etc.)
- ✓ License for Genetically Modified Products (for clinical trials involving genetically modified viruses etc.)
- ✓ Study Budget (if not complete at time of ethics submission, please forward finalised budget to Ethics Team in due course).
- ✓ Administrative Fee made out to "St John of God Health Care"
- ✓ Privacy Declaration Form (external researchers only)
- ✓ Declaration of Interest Form (for all Site Investigators)

- ✓ Abbreviated current resume and publication list of researcher(s) (for Phase 1 studies, a current resume and evidence of current GCP certification is required for all research personnel involved with the study at the participating site)
- ✓ Indemnity Form(s) or Letter from Insurer stating researcher is covered for the study (if not complete and fully executed at time of ethics submission, please forward copy to Ethics Team in due course)
- ✓ Certificate of Currency of Insurance
- ✓ Clinical Trial Research Agreement (CTRA)/Contract/Legal Agreement (if not complete and fully executed at time of ethics submission, please forward copy to Ethics Team in due course)
- ✓ Australian Register of Therapeutic Goods (ARTG) Certificate for all study drugs/devices (available on TGA website)
- ✓ Clinical Trial Notification (CTN) Form (please include the completed online form with your submission)
- ✓ Documentation of other HREC decisions (i.e. final/conditional/withheld/revoked approvals)

CHECKLIST FOR NEW SUBMISSIONS – EXPEDITED REVIEW

In addition to the documents listed above in the Checklist for New Submissions – Higher Risk:

- ✓ Research is not investigator-initiated research
- ✓ Research does not specifically involve pregnant women, children or device implants
- ✓ Research is not a Phase I/II pharmaceutical clinical trial
- ✓ Evidence of Peer/Scientific Review Process and Support for the research* (e.g. NHMRC grant sponsored research, investigational product licence, etc.)
- ✓ Documentation of at least one other NHMRC-Certified hospital-based HREC (please refer to list available here) or by the DOHWA HREC (in the case of WA Data Linkage Branch studies only)

* Peer/Scientific Review of research is defined as "independent", "expert" and "formal" review of the study that occurs prior to HREC submission, as per question 1.9.1.1 and 1.9.1.2 of the HREA. For commercially sponsored research, peer review should be external (i.e. conducted outside of the Sponsor and their partners in research.) Please note that this does not include review and approval by another HREC.

CHECKLIST FOR WAIVER OF CONSENT

What patient-identifiable information will be **accessed** under the waiver of consent?

- Data
- Biospecimens
- Data and Biospecimens

Before deciding to waiver the requirement for consent for research, a HREC must be satisfied that ALL of the following requirements are met to justify a waiver of consent:

- ✓ Study is "lower risk" i.e. the only foreseeable risk is one of discomfort
- ✓ Benefits of study justify any risks of harm associated with not seeking consent
- ✓ Impracticable to obtain consent (e.g. due to the quantity, age or accessibility of records)
- ✓ No known or likely reasons for thinking that participant would not have consented if they had been asked
- ✓ Sufficient protection of their privacy
- ✓ Adequate plan to protect the confidentiality of data
- ✓ Plan to feedback study results to participants (where of significance to their welfare) e.g. website, news media

- ✓ Possibility of commercial exploitation of derivatives of data/tissue will not deprive participants of any financial benefits to which they would be entitled
- ✓ Waiver is not prohibited by State, federal or international law e.g. Privacy legislation, various legislation relating to participants with impaired capacity to provide informed consent for *research* where they receive *treatment*

If the study involves access to patient identifiable data, the following questions also apply. Please note that Section 95A of the Privacy Act will apply if the research involves researcher **ACCESS** to patient identifiable data (even if identifiable data is not collected and/or included for study purposes).

What Australian Privacy Principles are relevant to your submission?

- APP3: Collection of solicited personal information e.g. researcher to prospectively solicit and collect "additional" personal information for inclusion in a record/publication
- APP6: Use or disclosure of personal information e.g. researcher to access personal information that is already collected in personal/medical records
- Other APP/s

What is the purpose of your research? (As per D.2, Section 95A of Privacy Act) Please choose ONE of the following three options which most applies to your study.

- Research is relevant to public health or safety
- The compilation of analysis or statistics relevant to public health or safety
- The management, funding or monitoring of a health service

What considerations are involved in weighing the public interest in the proposed project against the public interest in the protection of privacy? (As per D.5, Section 95A of Privacy Act) Please choose only those options which most apply to your study.

a) The proposed collection, use or disclosure of health information is necessary to the functions or activities of the organisation
b) The research is relevant to public health or public safety
c) The research is likely to contribute to:
    i. The identification, prevention or treatment of illness, injury or disease; or
    ii. Scientific understanding relating to public health or safety; or
    iii. The protection of the health of individuals and/or communities; or
    iv. The improved delivery of health services; or
    v. Enhanced scientific understanding or knowledge; or
    vi. Enhanced knowledge of issues within the fields of social science and the humanities relating to public health or safety
d) The research will lead to benefits to individuals, to the category of persons to which they belong, or the wider community
e) In particular, the research will lead to benefits for:
    i. Children and young people; or
    ii. Persons with intellectual or psychiatric disability; or
    iii. Persons highly dependent on medical care; or
    iv. Persons in dependent or unequal relationships; or
    v. Persons who are members of collectivities; or
    vi. Aboriginal or Torres Strait Islander peoples; or
    vii. Persons whose information relates to their mental or sexual health

f) The research design can be satisfied without needing to apply S16B(2) and/or S16B(3), and scientific defects might arise if the research was designed differently
g) There would be a cost if the research was not done (to government, the public, the health care system etc.)
h) The research is important to the public
i) The data being sought are usually available to the public from the organisation that holds the data
    i. The way the research uses the data is consistent with the purpose for which the data was made public
    ii. The research doesn't require alteration of the format of the data that would constitute a breach of APPs
j) There is minimal risk of harm to an individual whose health information is to be collected, used or disclosed in the research, based on the information provided in proposals submitted under paragraphs A.2.6; or A.3.6; or B.2.6; or B.3.6; or C.2.6 of these guidelines
k) The standards of conduct that are to be observed in the research, including:
    i. The study design and the scientific credentials of those involved in conducting the study are appropriate
    ii. If the study involves contact with participants, they will be treated with integrity and sensitivity and no intrusive questions will be asked
    iii. Access to health information will be adequately restricted to appropriate research personnel involved in conducting the research
    iv. The procedures that are to be followed will ensure that the health information is permanently de-identified before the publication of results
    v. At the completion of the research, all data-containing health information will be at least as secure as they were in the sources from which the data was obtained, including the date when the data will be destroyed or returned, in accordance with APP 11

CHECKLIST FOR OPT-OUT APPROACH TO CONSENT

When it is feasible to contact some or all participants, but where the research is of such scale and significance that using explicit consent is neither practical nor feasible, an Opt-Out approach to participant recruitment may be appropriate. The HREC must be satisfied that the following requirements are met to justify an opt-out approach:

- ✓ Study is "lower risk" i.e. the only foreseeable risk is one of discomfort
- ✓ Public interest in the research outweighs the public interest in the protection of privacy
- ✓ Research is likely to be compromised if participation rate is not near 100% (and requirement for explicit consent would compromise recruitment rate)
- ✓ Reasonable attempts are made to provide all prospective participants with appropriate plain language information explaining nature of the information to be collected, purpose of collecting it, and the procedure to decline/opt-out of participation or withdraw from research
- ✓ Reasonable time period is allowed between the provision of information to prospective participants and the use of their data so that an opportunity for them to decline to participate/opt-out is provided before the research begins
- ✓ A mechanism is provided for prospective participants to obtain further information and decline to participate/opt-out

- ✓ Data collected will be managed and maintained in accordance with relevant security standards
- ✓ Governance process in place that delineates specific responsibility for the project and for the appropriate management of the data
- ✓ Opt-out approach is not prohibited by State, federal or international law e.g. participants with impaired capacity to provide informed consent for *research* where they receive *treatment* *

* There are different models of consent permitted by law and the requirements within each jurisdiction (State/Territory) differ according to the type of *research*: clinical trial, experimental health care, comparative research. *Treatment* is also defined differently within the various jurisdictions.

PLEASE NOTE: Opt-out approach is unlikely to constitute "consent" when applying Commonwealth Privacy Legislation (i.e. Privacy Act 1988) for the handling of identifiable health information. Thus, researchers applying to use an opt-out approach **in cases where identifiable health information will be used/collected** also need to provide justification for a Waiver of Consent under S95/S95A of the Privacy Act 1988.

CHECKLIST FOR CONSENT OF PEOPLE WITH COGNITIVE IMPAIRMENT

People with a cognitive impairment include those with an intellectual disability or mental illness. The capacity of these people to consent to research and ability to participate will vary, so research should take into account the often "more-than-usual" vulnerability of these people and minimise potential forms of discomfort and stress. In approving the process of consent to research, the HREC should consider:

- ✓ The study takes into account the specific nature of the impaired capacity i.e. the person's condition, their medication or treatment, the complexity of the research and fluctuations in the condition (i.e. impaired capacity is transient)
- ✓ Bearing in mind the participant's distinctive vulnerability, the risks of the research are justified by the potential benefits of the research
- ✓ Study has a detailed process of how it is proposed to determine the capacity of a person with a cognitive impairment, an intellectual disability or a mental illness to consent to the research
- ✓ In seeking consent, include discussion of any possibility that his/her capacity to consent or to participant in the research may vary or be lost altogether, and what he/she would wish to happen in such circumstances
- ✓ The impaired capacity is transient AND it is practicable to seek consent when the person is capable of consenting
- ✓ Consent should be *witnessed* by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research, knows the participant and is familiar with his/her condition
- ✓ When the impaired capacity is NOT transient OR it is NOT practicable to seek consent, then consent should be sought from the participant's guardian or person or organisation authorised by law
- ✓ Where consent has been given by a person authorised by law, the researchers should nevertheless explain to the participant, as far as possible, what the research is about and what participation involves
- ✓ Should the participant at any time recover the capacity to consent, the researcher should offer him/her the opportunity to continue participation or to withdraw

- ✓ For a HREC to grant approval without prior consent, the research does NOT constitute a *clinical trial* (in NSW, there is no legislative basis for delayed consent or waiver of consent for *clinical trials* on patients incapable of consenting)
- ✓ If the research is interventional, for a HREC to grant approval without prior consent, inclusion in the research is not contrary to the interests of the participant

CHECKLIST FOR CONSENT OF PEOPLE HIGHLY DEPENDENT ON CARE

People highly dependent on care may include those who are in intensive care (ICU), neonatal ICU, emergency, palliative care, or are unconscious. Consent should be sought from people highly dependent on care wherever they are capable of giving consent and it is practicable to approach them. When the impaired capacity is NOT transient OR it is NOT practicable to seek delayed consent, then consent should be sought from the participant's guardian or person or organisation authorised by law.

When neither the potential participant nor another on his/her behalf can consider the proposal and give consent, a HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent if the following conditions are met:

- ✓ Research does not constitute a *clinical trial* (in NSW, there is no legislative basis for delayed consent or waiver of consent for *clinical trial* on patients incapable of consenting)
- ✓ There is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent
- ✓ The risks of harm are minimised
- ✓ The research is not controversial
- ✓ If the research is interventional, the research supports a reasonable possibility of benefit over SOC
- ✓ If the research is interventional, any risk of the intervention to the participant is justified by its potential benefits to the participants
- ✓ If the research is interventional, inclusion in the research is not contrary to the interests of the participant
- ✓ As soon as reasonably possible, the participant and/or the participant's relatives and authorised representative should be informed of the participant's inclusion in the research and of the option to withdraw from it without any reduction in quality of care

APPLICATIONS TO BECOME AN AUTHORISED PRESCRIBER

The Authorised Prescriber Form is to be completed for new applications and renewal applications for HREC Endorsement to become an Authorised Prescriber of an Unapproved Product, and the submission of other documentation or usage reports. The Checklist for Submissions to become an Authorised Prescriber has been integrated into this form, but has been reproduced here for reference:

- ✓ Indications for use of the Unapproved Product: the site(s) (i.e. hospital, private rooms) to be covered by the endorsement, the indications for use of unapproved product including with which patients and exceptions the product will not be used
- ✓ Product Information Brochure (should be most current brochure detailing Unapproved Product name, model and supplier, with product specifications relating to safety and any associated serious adverse events/complications)

- ✓ Evidence-Based Literature and/or Peer Review that supports the use of the Unapproved Product for the proposed indication for use
- ✓ Details of any Alternative/Substitute products and rationale for why the Unapproved Product is being pursued instead of these alternatives
- ✓ Synopsis of the Current Status of Unapproved Product in Australia: why the product does not yet have TGA approval, and current stage of TGA approval of the Unapproved Product
- ✓ Details of existing overseas approval of the same product (e.g. FDA approval)
- ✓ Written endorsement from the site(s) confirming clinician's credentialing to prescribe the unapproved product for requested time period. This should also include written endorsement from the SJGHC Chief Medical Officer (CMO).
- ✓ Relevant Speciality College letter of support to become an Authorised Prescriber
- ✓ Patient Information and Consent Form (PICF) (please include a Patient Information Sheet providing details of the Unapproved Product including its benefits as well as any associated risks/adverse events, and attach with the TGA Patient Consent Proforma)
- ✓ Mechanism for recording of utilisation of an Unapproved Product and for tracking of any adverse events

NOTE: For requests for renewal of Authorised Prescriber Status of an Unapproved Product, please include the above information – in particular, noting any differences to the original submission made to the SJGHC HREC and providing the latest update information (e.g. most current Product Information Brochure).

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
- Addition of a new SJG participating site (Researchers should submit a fully completed and signed SSA for the new site should be included, CV of site investigator (where applicable), site investigator Declaration of Interest Form and Privacy Declaration Form (where applicable) and any site specific study documents e.g. PICF)

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 Ethics Submission Form. All requests for research amendments and study extensions will be placed on the next SJGHC Human Research Ethics Committee (HREC) meeting agenda unless the amendment is due to safety concerns, in which case it will be placed on the next Scientific Review Sub-committee meeting agenda.

For administrative purposes, the SJGHC Ethics Team prefer to receive one submission per study per meeting. If you are expecting to submit more than one item per study per meeting (e.g. an updated IB and a resulting PICF amendment), please submit these items at the same time.

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.

All amendment submissions are to be sent to the SJGHC Ethics Team via the Ethics Submission Form with all attachments in PDF format. a clean copy of any amended document(s), amended document(s) with tracked changes, and a summary of changes.

NOTE: For amendments with resource/implementation implications for SJGHC, an amended Site Specific Assessment Form (SSA) must also be completed by the relevant department(s) who will be affected by the proposed change. It is not necessarily required for the CEO/Executive of the participating site to sign off on the amended SSA, but it should be acknowledged by the appropriate participating site Research Operations Manager. If the change in resource implications is not an ethical issue, the amended SSA does not need to be reviewed by the SJGHC HREC but a copy of the amended SSA should be sent to the SJGHC Ethics Team for our records.

Adverse Event Process

This Protocol is a SJGHC requirement for continued ethics approval of clinical trials. It is based on the NHMRC *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (November 2016) which outlines the respective safety monitoring and reporting responsibilities of the trial Sponsor, Principal Investigator (PI), the Human Research Ethics Committee (HREC) and the institution. Where the institution (e.g. SJGHC) is also named as the Sponsor, the institution also assumes the Sponsor responsibilities. PIs who do not meet the following requirements may have the SJGHC HREC approval withdrawn.

Please note, these NHMRC 2016 safety monitoring and reporting 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 by the Sponsor directly to the SJGHC Site PI within the stipulated timeframes (i.e. Development Safety Update Report (DSUR) annually, Significant Safety Issue (SSI) and any temporary halt or termination of a trial for safety reasons within 15 days, and Urgent Safety Measure (USM) within 3 days). The SJGHC Site PI will then refer these to the SJGHC HREC using the Ethics Submission Form.

Related* Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), Unanticipated Serious Adverse Device Effects (USADEs), annual trial safety updates and other related safety information are reviewed by the Scientific Review Sub-committee (SRC) and then tabled at meetings of the SJGHC HREC. SSIs, USMs and any temporary halt or termination of a trial for safety reasons will be notified to and acknowledged by the SJGHC HREC Chair out of session (OOS) and subsequently tabled at a meeting of the SJGHC HREC or SRC whichever is scheduled to meet first, in order to allow for expeditious review.

* Related Serious Adverse Events (SAEs) refer to events the SJGHC Site PI has determined are either related, possibly related or probably related to the study intervention.

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

1. The SJGHC HREC only require related local SJGHC site SAEs to be submitted for review, unless otherwise considered significant to the study or if specifically requested by the sponsor to be submitted. Unrelated local SAEs are not required to be submitted for SJGHC HREC review. All local site SAEs related to the study intervention should be reported to the SJGHC HREC using the designated SJGHC SAE/SUSAR/USADE section of the Ethics Submission Form. Related local site SAEs should be reported promptly as and when the event has resolved.
2. The Site PI is required to report local site SUSARs or USADEs to the SJGHC HREC within 3 days of becoming aware of the event using the designated SJGHC SAE/SUSAR/USADE section of the Ethics Submission Form.
3. To allow the SJGHC HREC to monitor both local and other site SAEs/SUSARs/USADEs considered related to study intervention with perspective and ensure that any changes in the benefit/risk balance of a clinical trial are compatible with continued ethics approval, the researcher is also required to provide the following:

a. Their own opinion in regard to potential impact of related SAEs/SUSARs/USADEs on need for action and continued ethical acceptability of a clinical trial. There are specific questions on the Ethics Submission Form 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, SUSARS AND USADES OCCURRING AT OTHER AUSTRALIAN AND INTERNATIONAL SITES

1. Site PIs are NOT required to complete the Ethics Submission Form for individual SAEs, SUSARs and USADEs from all other Australian and international sites.
2. Site PIs 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, SUSARs and USADEs from all other Australian and international sites.

SIX MONTHLY LINE LISTINGS/SUSARS

1. Site PIs are NOT required to provide to the SJGHC HREC a six monthly listing of all SUSARs.

ANNUAL TRIAL SAFETY UPDATES

1. Site PIs are required at least annually and until the local end of the trial (i.e. last patient last visit in Australia), 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. European Union Annual Safety Report (ASR);
    d. other trial update reports e.g. DSUR consistent with section 5.4.3 of the National Statement and consistent with Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA).

SIGNIFICANT SAFETY ISSUES (SSI)

1. A SSI and a USM (as one type of SSI where sponsors or site investigators act immediately to protect participants from immediate hazards), can adversely affect the health and safety of participants or materially impact the continued ethical acceptability of a trial. Often, SSIs and USMs do not fall within the definition of a SUSAR or USADE. They are not reported as SUSARs or USADEs, but require other action such as eliminating the immediate hazard to participant safety, or an amendment, temporary halt or early termination of a trial. SSIs should be submitted to the SJGHC HREC on the Ethics Submission Form as a Safety Update.

Serious Breaches

PREAMBLE

One of the conditions for ethics and site-specific approval is the reporting of serious breaches to SJGHC and the SJGHC HREC. Sponsors and researchers should be aware of and comply with the reporting framework for protocol deviations and serious breaches as described in:

1. *Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018).*

The purpose of this framework is to enable the escalation of issues concerning both participant safety and welfare and trial integrity in clinical trials involving therapeutic goods.

Although the NHMRC Serious Breach policy applies to trials involving therapeutic goods, the Serious Breach policy at SJGHC applies to **all** research (irrespective of level of risk) approved to be conducted at SJGHC. If the approved project does not have a Sponsor, the identified Principal Investigator (PI) is required to undertake the role of Sponsor in relation to the SJGHC Serious Breach policy.

PROTOCOL DEVIATIONS & SERIOUS BREACHES

A **deviation** is any breach, divergence or departure from the requirements of Good Clinical Practice (GCP) or the clinical trial protocol. A **serious breach** describes a small sub-set of deviations in which there is a breach of Good Clinical Practice (or the principles of Good Clinical Practice applied to trials that are not evaluating an investigational product) or the protocol that is likely to affect to a significant degree:

a) the safety or rights of a trial study participant, or

b) the reliability and robustness of the data generated in the clinical trial.

For further detail and examples of what constitutes a serious breach, please refer to the above NHMRC reference available online at the NHMRC website. The Group Directors of Research (GDR) can also provide advice as to whether an occurrence meets the definition of a Serious Breach. Ultimately, responsibility as to whether a deviation is a Serious Breach lies with the Sponsor. However, SJGHC reserves the right to manage a deviation as though it were a Serious Breach, even if the Sponsor does not identify the incident as a Serious Breach.

The NHMRC policy requires the Sponsor of a trial involving therapeutic goods to conduct a root cause analysis (RCA). In association with or separate to a Sponsor conducted RCA, SJGHC will conduct an RCA or other investigative methodology approved by the GDRs or Chief Medical Officer (CMO).

REPORTING OF SERIOUS BREACHES TO SJGHC

The Site PI is responsible for reporting the Serious Breach to SJGHC. All Serious Breaches must be reported by the Site PI to:

- GDRs and CMO;

- SJGHC site management i.e. Research Operations Manager (ROM) and hospital Chief Executive Officer (CEO)/Director of Medical Services (DMS). At sites with a ROM, the ROM can be responsible for onward reporting to hospital CEO, DMS, GDR and CMO;
- Reported in RiskMan.

Reporting to SJGHC is necessary as serious breaches may impact on patient and participant safety, medico-legal risk, the responsible conduct of research (refer to SJGHC Research Conduct and Protocol to Address Complaints about Research Conduct in this *Research Handbook*), or adherence to contractual obligations.

Serious Breaches may be identified by the Sponsor either through their routine monitoring of clinical trials or through direct reporting of protocol deviations from trial sites/PIs. At SJGHC, primary responsibility for identification and reporting of serious breaches lies with the site PI as well as delegated investigators and research caregivers. However, third parties (i.e. an entity other than the Sponsor or site investigators/staff) may also report suspected breaches which are yet to be formally confirmed as a serious breach by the Sponsor.

Whilst GCP requires that all protocol deviations be reported to the trial Sponsor, only serious breaches are required to be reported to SJGHC and the SJGHC HREC as soon as they are identified. Minor protocol deviations are still required to be reported to the SJGHC HREC in the SJGHC Annual/Interim Report, as numerous or persistent minor deviations in aggregate may constitute a serious breach if they impact on the safety/rights of participants or the reliability/robustness of data (see Appendix III of the above NHMRC Serious Breach policy).

REPORTING SERIOUS BREACHES TO THE SJGHC HREC

Sponsors should submit the serious breach to the SJGHC HREC via the Ethics Submission Form within seven (7) calendar days of confirming a serious breach has occurred (and provide follow-up reports when required). The Sponsor should also notify the site PI of serious breach within seven (7) calendar days of confirming a serious beach has occurred. ***The Sponsor also has obligations to notify the TGA and the SJGHC HREC if the serious breach leads to the closure of the site/study.***

As an exception, third parties (e.g. site PI) in liaison with their institution may also report a suspected breach directly to the SJGHC HREC (rather than the Sponsor within 72 hours of becoming aware of the suspected breach) via the Ethics Submission Form.

The role of the SJGHC HREC in reviewing a serious breach is to evaluate the impact of the serious breach on the continued ethical acceptability of the study and to satisfy itself that the serious breach is managed appropriately. Where a third party has notified the SJGHC HREC of a suspected breach, the SJGHC HREC will inform the Sponsor of this and ask for written confirmation as to whether they consider it a serious breach, requesting an explanation/justification of the Sponsor's position.

The participating institution (e.g. SJGHC site where the trial is being conducted) is obliged to inform the SJGHC HREC if a serious breach leads to withdrawal of participating site approval for the study.

All Serious Breaches and Suspected Breaches with details of corrective and preventive actions (CAPAs) should be submitted to the HREC via the Ethics Submission Form. The SJGHC HREC will address the acknowledgement letter to the party that submitted the deviation or serious breach (i.e. sponsor or PI), copying in any other relevant parties unless requested not to do so.

SERIOUS BREACH NOT TO BE CONFUSED WITH "BREACH OF THE CODE"

Note: Some protocol deviations/serious breaches (particularly repeated or persistent breaches of GCP or the protocol) may be considered as a "breach of the Code" (*The Australian Code for the Responsible Conduct of Research,* NHMRC 2018) 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*.

PRIVACY AND DATA BREACHES AT SJGHC

If the Serious Breach constitutes a data breach at a SJGHC participating site, there are other governance processes that must be followed in line with SJGHC policies in addition to reporting to SJGHC (as outlined above) and the SJGHC HREC. Please consult the Quality and Risk Manager at the SJGHC participating site for more information regarding this.

Time Limits on Research

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 specified 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 Ethics Submission Form.

Research Data Management and Retention

PREAMBLE

The *Australian Code for the Responsible Conduct of Research* (2018) ("the Code") describes a framework for responsible research conduct: 8 high-level principles and 29 responsibilities that apply to both researchers and institutions to ensure high-quality research, credibility and community trust in research. The Code is supported by supplementary guidance on specific topics.

This current SJGHC Research Data Management and Retention protocol is based on the Code's supplementary guideline: "Management of Data and Information in Research (2019)" which sets out 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, 2023) [latest edition], Chapter 3.1: The elements of research, Element 4: Collection, Use and Management of Data and information.

Researchers conducting research involving SJGHC, their research units/SJGHC Division(s) involved in the research and the SJGHC Ethics Team (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 ethics review processes maintained by the SJGHC Ethics Team.

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/Coded 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 i.e. 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

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.
2. Research data should be recorded in:
    - 2.1 a durable form (preferably electronic with a backup system),
    - 2.2 a secure form to ensure confidentiality and privacy of identifiable, sensitive data,

2.3 an appropriately referenced and retrievable/accessible form.

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.

4. The minimum period of research data retention is determined by the specific type of research. As per section 2.1.1 of the Code, 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:

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

   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.

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

   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.

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

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.

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.

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

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

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

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.

9. Researchers cannot access identifiable data in a databank without prior ethics review.

10. For databanks, participant consent should specify:

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

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

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

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

12. Whenever research using re-identifiable data reveals information that bears on the wellbeing of participants, researchers 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.

13. Separate to Registers maintained by the research unit/SJGHC Division, the SJGHC GRO 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. ethics, legal, operational, final approval) and study progress i.e. from submission, to final destruction (OR permanent archive) of the research record.

14. 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/coded form that allows reference by third parties without breaching confidentiality and privacy.

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

16. 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.

17. 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.

18. 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.

19. 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:

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

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

Researcher Guide to De-identification of Data

PREAMBLE

This guide is for researchers accessing, collecting and/or sharing personal data as part of their research, which may or may not include data analytics[1]. Personal data, under the *Privacy Act 1988* (s6(1)) is defined as "information or an opinion about an identified individual, or an individual who is reasonably identifiable, whether the information or opinion is true or not, and whether it is recorded in a material form or not." A subset of personal data is ***sensitive data*** which is afforded an even higher level of privacy protection under the *Privacy Act 1988*. Health information is considered sensitive information.

This guide is based on *OAIC, March 2018 "De-identification and the Privacy Act"*: https://www.oaic.gov.au/privacy/guidance-and-advice/de-identification-and-the-privacy-act/ and *OAIC, March 2018 "Guide to Data Analytics and the Australian Privacy Principles"*: https://www.oaic.gov.au/privacy/guidance-and-advice/guide-to-data-analytics-and-the-australian-privacy-principles/

CONSIDERATIONS FOR DE-IDENTIFICATION

De-identification is a process for privacy enhancement and risk mitigation to prevent data breaches that disclose personal or confidential information. This process also ensures compliance with Australian Privacy Principles (APPs) in the *Privacy Act 1988*, particularly the collection of solicited personal information (APP3) and the use or disclosure of personal information (APP6).

The *Privacy Act 1988* encourages researchers to use de-identified data where possible. Personal information is de-identified where there is no reasonable likelihood of re-identification of an individual. The objective with de-identification is not to eliminate the risk of re-identification altogether, but rather to ensure the risk of re-identification is low. It is important that the access/collection/sharing of personal data in the research project is limited to what is reasonably necessary to pursue the research objectives, and that once the de-identification process is complete, it is reasonably unlikely that re-identification will occur.

De-identification is broader than just anonymisation and confidentialisation. With de-identification, there is no one size fits all. Researchers should consider what is most appropriate for each individual study, in the ***context*** of that study, whilst ensuring the data remains useful for its intended research purpose.

As well as using this guide, researchers may also develop a Data Management Plan for their research study, undertake Penetration Testing, complete a Data Analytical Risk Assessment and/or complete a Privacy Impact Assessment[2].

Researchers should follow a 2-step process for de-identification:

STEP 1: Consider the context for the individual study

- ✓ What is the nature and volume of the data itself?
  Does the study involve rich/detailed data? Sensitive data?
- ✓ Who, what, where and how will the data be accessed, stored and used? This may involve the sharing or release of data outside organisational boundaries:
  - Open Access (making data freely and publicly available) e.g. web page
  - Delivered Access (requested data is delivered to approved users under specified conditions) e.g. State Government Data Linkage Branches provide data to a researcher
  - On-site Safe Settings (on approval, data is accessed in a secure, controlled location) e.g. researcher reviews medical records within the hospital
  - Secure Virtual Access (an approval, data is accessed via a secure link) e.g. RedCAP database
- ✓ What is the environment where the data will be released – is it mediated, or open access?
  NOTE: Open/public data environments may necessitate significant de-identification and are generally inappropriate for data derived from personal and sensitive information, due to a higher risk of de-identification.

STEP 2: Consider the de-identification process and risk of re-identification

- When is it most appropriate for the data to be de-identified?
  - At what stage in the research project is the personal data no longer needed?
    E.g. After the data is collected, prior to analysis, prior to sharing or releasing data externally to a third party, prior to publication?
  - Will access be given to the entire data record, or a large proportion of it?
  - Is the personal data sensitive and/or confidential?
    If yes, this data may actually need to be destroyed (not just de-identified) once its research purpose has been achieved. If not, the researcher may retain a separate copy of the original dataset/code list to enable the re-identification of data subjects.
  - It is important to promote consumer and community trust and manage expectations about the research and researchers, e.g. public concerns about social or ethical harm, discrimination, profiling, denial of benefit/service.
- Choose an appropriate de-identification technique(s) – for more information refer next page, section titled “De-identification Techniques.”
  NOTE: This may require technical expert advice.
- Assess the imminent and ***future*** risk of re-identification from both legitimate and unauthorised access to data
  NOTE: Be wary of ongoing technological advancements with the ability to re-identify data, e.g. data analytics/algorithms, use of Artificial Intelligence/machine learning, the internet of things
  - What other information is available to those who will have access to the data that could be matched up or used to re-identify the data? What is the risk of attribute disclosure or spontaneous recognition?
  - How practicable (difficult, costly) will it be to use the data to re-identify a person?
  - What motives may there be to attempt re-identification? Consider who and what the data relates to.
  - What is the gravity of harm that could arise from re-identification?

DE-IDENTIFICATION TECHNIQUES

Direct identifiers such as name, address, date of birth and UMRN should be removed from the dataset. Quasi-identifiers (other information that could potentially be used to re-identify an individual, such as unique or uncommon characteristics) should also be de-identified.

The following table describes de-identification techniques that may be used:

Remove/reduce/alter/obscure/aggregate/protect data
• Sampling (providing access to only a fraction of the data) • Choice of variables (removing quasi-identifiers) • Rounding (combining information, e.g. age may be combined and expressed in ranges) • Perturbation (altering information in a small way without significantly affecting aggregate data) • Swapping information that is likely to enable identification of a person for another person • Manufacturing Synthetic Data • Coding/Encryption (e.g. Data Linkage Branches obscure the original identifier(s) by translating into another form/code, rather than removing the identifier(s) altogether)
Use controls and safeguards in data access environment (who, what, where and how)
✓ Restricted/tiered access to the data with authorisation protocols ✓ Physical and IT measures for the security and durability of data storage, data access, data transfer and data linkage to guard against misuse, interference, loss, unauthorised access and unauthorised modification of data (e.g. data lab, password protection, locked office, storage on a server with regular backup or if on web with anti-virus/anti-malware, network security measures, audit trails etc.) ✓ Enabling data analysis and providing results instead of raw data ✓ Privacy Declaration (for external, non-SJGHC researchers) ✓ Legal contract with binding obligations for access, use and distribution of the data between the various parties (e.g. Registry Agreement) ✓ Other governance measures (e.g. Data Management Plan that includes response to data breaches and details for data retention and destruction, Penetration Testing, Data Analytical Risk Assessment and/or Privacy Impact Assessment[2].)

[1]Data analytics describes activities designed to obtain and evaluate data to extract useful information and includes 'big data', 'data integration', 'data mining' and 'data matching.' Data analytics can lead to the creation of personal information e.g. this can occur when analysing a larger variety of non-identifying information and in the process of analysing the information it becomes identified or reasonably identifiable. This generation of new personal information through 'collection via creation' can come from: a) observed data recorded automatically e.g. online cookies, b) derived data generated from an original dataset using calculations/algorithms, c) inferred data produced by using more complex analytics to find correlations between datasets and using this to categorise or profile people and predict their outcomes. As well as 'collection via creation', data analytics also tends to have privacy implications in that: a) it collates data from a wide variety of different sources including from third parties, b) uses data insights for a range of different purposes including new purposes that may have not been anticipated, c) retains data for longer than usual as it may be useful in the future for unspecified purposes.

[2]Privacy Impact Assessments (PIAs) are undertaken by APP entities for 'projects' to assess the risk of non-compliance with privacy and make recommendations for managing, minimising or eliminating privacy impact. PIAs are an iterative process which continues to develop throughout the lifecycle of a project. 'Projects' is used loosely to refer to a wide range of activities including databases and data analytics projects as well as policy proposals, new or amended legislation, new or amended programs, activities, systems, new methods or procedures for service delivery or information handling, and changes to how personal information is stored.

Radiological Imaging Frequency in Clinical Trials

PREAMBLE

Clinical trials in oncology often involve the use of frequent radiological scans to measure and quantify the effect of study treatment. There is an absence of evidence to guide the optimal frequency of follow-up scans in most tumour types. Both the pros and cons of doing scans more or less frequently need to be weighed up.

Whilst frequent scanning can increase health risks to patients with the substantial radiation exposure and the associated burden of meeting the cost of these scans, it can also guide faster discontinuation of ineffective therapy and provide patients with the option of changing to a potentially better alternative. Ultimately the aim should be to consider patient characteristics and outcomes that might eventually permit rational personalisation of scan frequency. However, in trials the typical frequency of follow-up scans is every 6-8 weeks or every two cycles of therapy, although this varies with tumour and treatment type.

JUSTIFICATION FOR FREQUENCY OF RADIOLOGICAL IMAGING

When a Higher Risk study involves exposing participants to ***any ionising radiation*** through radiological imaging (e.g. nuclear medicine scans, PET scans, CT scans, X-rays), even if the frequency of imaging and total effective dose is considered "standard of care" (SOC), the type and frequency of imaging is required to be justified to the SJGHC HREC according to these criteria:

1) Clinical need/valid clinical reason(s) for the imaging

2) Optimal scan frequency based on a number of factors and measures

3) Potential benefits of the imaging significantly outweigh the risks involved

This is to be documented on the Frequency of Radiological Imaging Form which should be completed and signed by a representative for the Sponsor. (The Committee notes that the *Australian Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (RPS 8)* places the responsibility for minimising the level of radiation exposure on study participants with the researcher/PI, however in clinical trials it is the Sponsor that determines the frequency of radiological imaging).

The completed form is to be provided to the participating site at the time of site selection and included with the initial submission of the study for scientific and ethics review by the SJGHC HREC. Also, the participating site and Sponsor/CRO should ensure that the cost for **ALL** radiological imaging used in the study is negotiated at the time of site selection, and that this is documented in the Radiology section of the Site Specific Assessment Form.

Where the frequency of radiological imaging is deemed to be greater than SOC, the PI should organise for a review and report from an Independent Medical Physicist to include in the submission to the SJGHC HREC and to inform the wording in the PICF. The fee for the Independent Medical Physicist report when radiation exposure is deemed above SOC should be covered by the Sponsor.

As of May 2021, the Radiation Council of WA raised the threshold for those studies requiring prior approval by the Council, so that prior approval is only required for those studies where the effective dose is 20mSv above that which patients would receive if they chose SOC.

References: Vach W et al, "How to study optimal timing of PET/CT for monitoring of cancer treatment", Am J Nucl Med Mol Imaging 2011; 1(1)54-62; Stewart DJ et al, "Optimal frequency of scans for patients on cancer therapies: A population kinetics assessment", DOI 10.1002/cam4.2571

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* (2023) [latest edition] ("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* (2018) and subsequent guides ("the Code") and the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (NHMRC, 2018)* ("the Guide").

The Code and Guide jointly issued by National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) and Universities Australia, describes the principles of responsible/good clinical practice (GCP), and identifies the respective responsibilities of institutions and researchers in research data management, conflict of interest, researcher training/mentoring, publication and authorship, and handling of breaches of the Code and research misconduct, etc. The Guide sets out a model for managing and investigating potential breaches of the Code, of which some serious breaches may be designated as "research misconduct." The aim of the Guide is to ensure that institutions adopt processes for managing and investigating potential breaches of the Code which are both procedurally fair and do not hinder the timely implementation of all corrective actions.

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 across all disciplines 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. This protocol is based on the Code – being a prerequisite for receipt of NHMRC and ARC funding – and should be read in conjunction with the Code. As per the

Code, the following 8 principles of responsible research conduct should underpin all research conducted under the auspices of SJGHC: ***honesty, rigour, transparency, fairness, respect, recognition, accountability and promotion/fostering of a responsible research culture.***

Institutions have foremost a responsibility to foster a research culture that encourages and supports responsible research conduct. Institutions are also responsible for establishing and maintaining good governance and management practices (i.e. have SOPs (standard operating procedures) for research, make available appropriate research training and education, ensuring supervision of research trainees, providing the infrastructure and processes for effective research data management and encouraging and facilitating the responsible dissemination of research findings) so as to sustain responsible research conduct.

KEY RESPONSIBILITIES OF RESEARCHERS

Researchers also have responsibilities to uphold the principles of responsible research conduct in all aspects of their research.

1. Honesty/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. Rigour

Rigour is about researchers adopting methodology that is appropriate to the aims of the research so as to ensure study conclusions are justified by the results. It is also about retaining clear, accurate, secure and complete records of all research including research data and primary materials – such that would allow someone else to replicate the research results following the same methodology. Where possible and appropriate, researchers should allow access to these by interested parties.

3. Transparency e.g. Management of Conflicts of Interest, Publication and Authorship,

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 conflicts 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.

Anyone listed as an author on a publication should accept responsibility for ensuring content familiarity and can identify their contribution to it. All others who have contributed to the research must be acknowledged. Other relevant work must be cited and acknowledged appropriately and accurately.

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 integrated in the Ethics Submission Form.

4. Fairness e.g. in collaborative research and peer review

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.

In terms of peer review, researchers should participate in a way which is fair, rigorous and timely and maintains the confidentiality of the content.

5. Respect (and Recognition) for Research Participants, the wider community, animals and environment

Researchers have a responsibility to respect research participants, taking particular care to the needs of minority groups and vulnerable people and engaging research participants throughout the lifecycle of the research. Demonstrating respect can involve, for example where possible and appropriate, researchers providing study participants the opportunity to receive their individual results/feedback about the outcome of the study in which they have participated. Likewise, researchers are encouraged to publish all research findings (whether these are positive or negative) 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. The research findings should be disseminated responsibly, accurately and broadly to the wider community, and where the record needs to be corrected, researchers should take this action in a timely manner.

The concept of respect extends to the recognition of the right of Aboriginal and Torres Strait Islander (A&TSI) peoples to be engaged in research that affects or is of particular significance to them. Researchers should refer to the *Keeping research on track II* (NHMRC, 2018) and *Ethical Conduct in Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (NHMRC, 2018). These documents guide ethical health research on A&TSI peoples, which respects their legal rights and local laws, customs and protocols.

In terms of research involving animals, researchers should be mindful of the 3Rs (replacement, reduction and refinement) so as to minimise the impact on animals used in research and support animal welfare.

All effort should be made by researchers to minimise the adverse effects of the research on the environment.

6. Accountability

Accountability for the development, undertaking and reporting of research requires that researchers comply with relevant legislation, policies and guidelines relating to research and research ethics, ensure good stewardship of public resources used to conduct research, and consider the consequences and outcomes of research prior to its communication/dissemination of results.

7. Promotion of Responsible Research Practices: 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.

8. Promotion of Responsible Research Practices: Training and Mentoring

All researchers should have the skill and expertise to undertake a particular research project appropriately or otherwise undertake prerequisite training before engaging in the research. In support of this, SJGHC provides the opportunity for internal researchers (from the least to the most experienced) to access relevant induction and continuing education/training courses in research such as ICH GCP at no or minimal cost for e.g. through the Western Australian Research Translation Network Research and Ethics Training Program (WAHTN RETP) and to seek guidance from professional bodies in developing their research expertise. Access to educational resources in research ethics is also available to internal and external researchers through the SJGHC Ethics Team and Catholic Bioethics Perth (Mt Hawthorn, Western Australia).

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.

9. Promotion of Responsible Research Practices: Reporting Breaches of the Code and Research Misconduct

All researchers (including SJGHC caregivers and accredited practitioners) are obliged to report suspected or actual research misconduct in a timely manner. Throughout SJGHC's investigation or management of a complaint, the welfare of the complainant and respondent will be a key concern and support for both parties will be offered where available. "Breaches of the Code" occur on a spectrum from minor (less serious) – this may include honest errors in design or execution of research or interpretation of results, and may occur through research inexperience - to major (more serious) breaches.

BREACH OF THE CODE

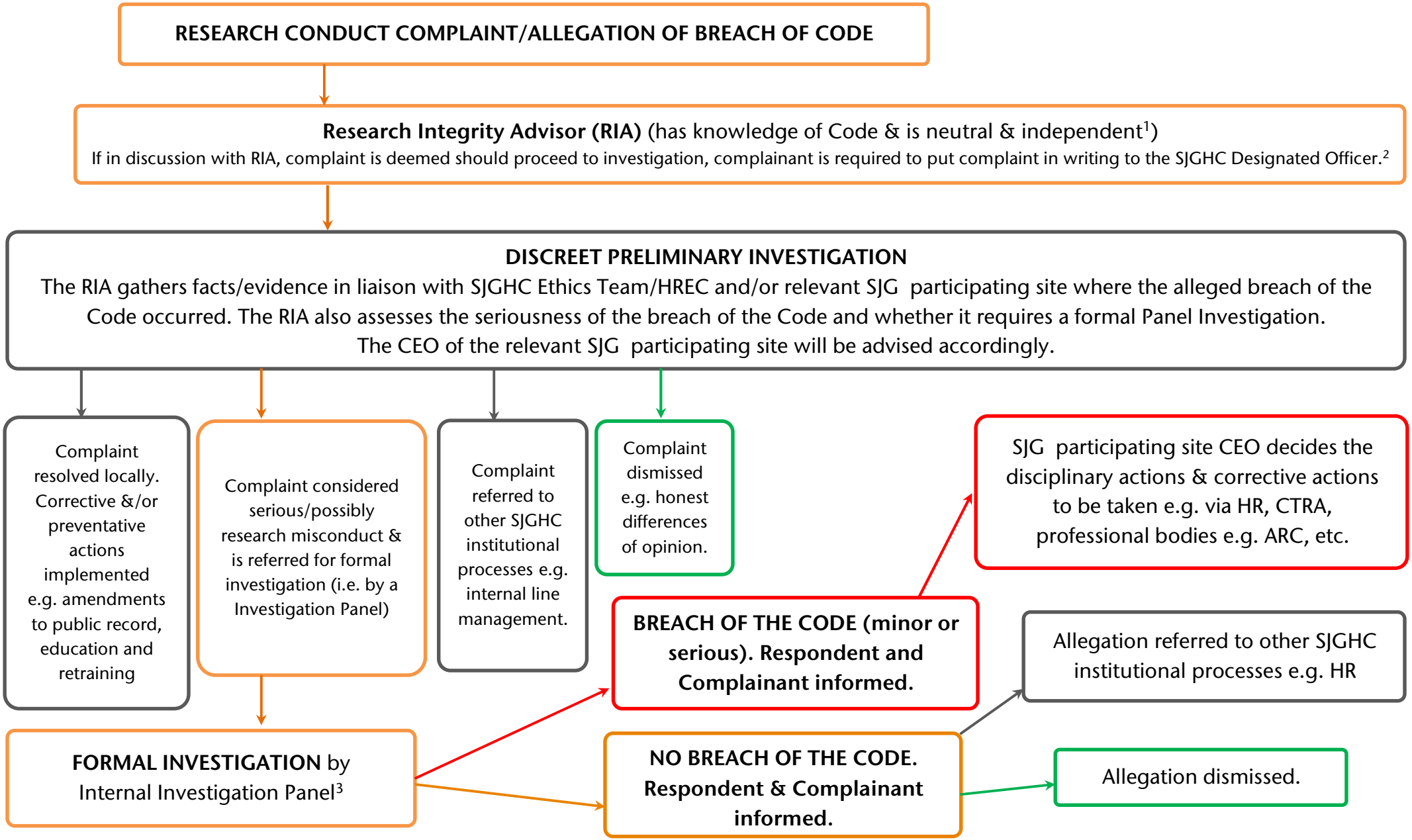
A ***breach of the code*** is defined as a failure to meet the principles and responsibilities of the Code, and may refer to a single breach or multiple breaches. They occur on a spectrum from minor (less serious) to major (more serious). Research misconduct is a subset of major/serious breaches. ***Research misconduct*** is a serious breach of the Code that is also ***deliberate/intentional, reckless or negligent*** and is likely to be ***repeated*** or ***persistent***.

Some examples of a breach of the Code include:

1. Not meeting required research standards and/or failure to observe the National Statement, the Code or SJGHC SOPs as per this *SJGHC Research Handbook* especially where there is unreasonable risk or harm to research subjects (e.g. conducting research without the requisite approvals, failure to conduct research as approved by a HREC, misuse of research funds)
2. Fabrication, falsification, plagiarism, deception in proposing, carrying out or reporting research results, misrepresentation (of research data or source material), fabrication to obtain research funding
3. Inappropriate research data management (refer to: Research Data Management and Retention)
4. Inadequate supervision
5. Misleading ascription to Authorship
6. Failure to disclose and/or manage Conflicts of Interest
7. Failure to conduct peer review responsibly
8. Facilitation of research misconduct

All official complaints of research misconduct will be investigated and acted upon as per the principles of procedural fairness outlined in the Guide: ***proportional, fair, impartial, timely, transparent and confidential.*** Every effort will be made to act proportionate to the seriousness of the complaint, to treat parties fairly, to conduct investigations without bias, and with transparency and confidentiality and in a prompt manner so as to remedy the situation and to maintain public confidence in research.

SJGHC PROTOCOL TO ADDRESS RESEARCH CONDUCT COMPLAINT/ALLEGATION OF BREACH OF CODE



NOTES ON SJGHC PROTOCOL TO ADDRESS RESEARCH CONDUCT COMPLAINT/ALLEGATION

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.

   If a complaint/allegation of breach of code cannot be resolved to everyone's satisfaction at the departmental level, then it should be referred to the Research Integrity Advisor (RIA). Ideally, an internal (or external) auditor of research (who has knowledge of the Code & is neutral & independent) can fulfil both of the roles:

   RIA – nominated to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of the Code.
   Assessment Officer (AO) – nominated to conduct the Preliminary assessment of a complaint about research.

   However, in the absence of an auditor to act as the RIA/AO, depending on the nature of the complaint, who the complainant is and who is potentially implicated, and with consideration of potential conflicts of interest, the complaint should in the first instance be referred to the SJGHC Ethics Team. The SJGHC Ethics Team will be able to advise (in liaison with the SJGHC HREC and SJGHC Hospital Executive) the most appropriate pathway for progressing the complaint if deemed it should proceed to investigation. For example, it may be that the respondent is an external researcher in which case the institution in which the respondent belongs/is employed should be the one to progress with the investigation.

2. If it is deemed a complaint should proceed to investigation, then the complainant is required to put the complaint officially in writing to the SJGHC Designated Officer (DO). The DO at SJGHC is the Chief Medical Officer (CMO) or delegate. The DO will commence the process of a formal internal investigation by an internal Investigation Panel ("Panel") i.e. prepare a statement of allegation(s), terms of reference for the investigation, nominate the Panel and Panel Chair (when the Panel is more than one person), and seek legal advice on matters of process where appropriate.

3. An internal Investigational Panel ("Panel") will be formed on a case-by-case basis, composed of one or more persons (internal and/or external) with the appropriate skills and expertise and who are deemed to be free from conflicts of interest/bias, so as to conduct a fair and robust review that will maintain public confidence in research. The respondent will be advised of the composition of the Panel with the opportunity to raise any concerns. The Panel will conduct the review as per the Guide and prepare a written report detailing the facts and any recommendations based on a determination of whether having regard to the evidence and on the balance of probabilities the respondent has breached the Code.

   The Panel report will be provided to the CMO, the SJGHC HREC and SJGHC Executive e.g. the relevant SJG participating site CEO(s) and the findings communicated to both complainant and respondent, as well as any other relevant bodies (e.g. funding bodies, publishers) with consideration made as to whether a public statement should also be released, if appropriate.

4. If there is a breach, the relevant SJG participating site CEO(s) will decide the disciplinary actions and corrective actions to be taken depending on the severity of the breach and whether it is considered research misconduct, via e.g. Human Resources (HR), CTRA arrangements, professional bodies e.g. Australian Research Council (ARC), etc.
5. 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. Required action is likely to include correcting the public record of the research.
6. Where systemic issues are identified as a contributing factor, these will be addressed by relevant departments at SJGHC to prevent similar breaches of the code occurring in the future.
7. Where the finding is that there is no breach of the Code, efforts will be made to restore the reputations of the alleged person engaged in improper conduct. Likewise if the allegation is found to have been frivolous or vexatious, action will be taken to address this with the complainant. Thus, the allegation whilst found not to be a breach of the Code may nonetheless be referred to other SJGHC institutional processes e.g. HR for further action if deemed to be required.
8. Both parties (i.e. respondent and complainant) will be advised of their right to contest findings and to request an external review of SJGHC's Code investigation by the Australian Research Integrity Committee (ARIC).

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 "lower 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 Approval (CTA) schemes).

3. CLINICAL TRIAL RESEARCH AGREEMENTS

3.1 Is a CTRA Required?

Unless SJGHC determines that a clinical trial is "lower 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 lower 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) i.e. 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, Accredited Doctor
- SJGHC CTRA Template – Registry, Contracted Doctor
- SJGHC Material Transfer Agreement Template