# CABRINI RESEARCH GOVERNANCE HANDBOOK

**Last updated – 4 November 2024**

This document is subject to amendment as required by the
Cabrini Research Governance Committee.
Copies of the most recent version of the document are available:
Online: www.cabrini.com.au

# Contents

# 1. CABRINI RESEARCH GOVERNANCE

The Cabrini Research Governance Office (CRGO) is located at the Patricia Peck Education and Research Precinct:

154 Wattletree Road
Malvern VIC 3144
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Email: researchgovernance@cabrini.com.au

The Cabrini Research Governance Committee (CRGC) comprises an extensive, multidisciplinary membership including representatives from the research executive, research operations, medical administration, legal counsel, oncology trials, pharmacy, quality systems, the CRGO and consumers. The CRGC Terms of Reference are available on Prompt. CRGO, reporting to the CRGC, reviews and approves research projects that involve human participants to be conducted at Cabrini, to ensure:

- the research affirms Cabrini's mission and values and the teachings of the Catholic Church;
- ethical standards are maintained to protect the interests of the research participants, the investigators and the institution; and
- compliance with institutional governance requirements to mitigate legal, financial and reputational risk.

Additionally, any activity that involves sending Cabrini patient data to other institutions in the name of research must be reviewed by the CRGO or Cabrini's Data Governance Committee if unrelated to research.

CRGO primarily conducts its business in accordance with:

- the National Statement on Ethical Conduct in Human Research 2023 (National Statement), issued by the National Health and Medical Research Council (NHMRC) and associated guidelines;
- NHRMC's Ethical Considerations in Quality Assurance and Evaluation Activities
- The Australian Code for the Responsible Conduct of Research – Cabrini's Research Quality Manager, Research Governance Manager and Research Governance Officers are the nominated Research Integrity Advisors, responsible for promoting and upholding the principles of the Code;
- the Cabrini Research Governance Framework (located on Prompt);
- *Chapter 6: Research*, Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001);
- the Privacy Act 1988 (Commonwealth);
- the Health Records Act 2001 (Victorian);
- The National Clinical Trials Governance Framework
- https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdfIntegrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)
- Cabrini Research policies and procedures including Research Integrity and Misconduct Policy, Monitoring of Research Policy, Safety Monitoring and Reporting in Research, Authorship and Publication in Research, Research Participants Complaints and Compliments, Data Management, Sharing and Access Policy – available on Prompt and Cabrini's website. More policies and guides are currently being developed, including an Informed Consent in Research Guide. Contact researchgovernance@cabrini.com.au should you wish have queries about the draft guidance for informed consent or email-datagovernance@cabrini.com.au for data management.
- other relevant federal and state legislative and regulatory guidance.

# 2. APPLICANTS

## 2.1 BEFORE YOU GET STARTED

Researchers should familiarise themselves with Cabrini's mission statement, Cabrini's research strategy and the relevant legislation and guidelines listed in section 1.

### 2.2 RESEARCHER TRAINING

All Cabrini researchers must provide evidence of current Good Clinical Practice (GCP) training that meets the minimum criteria set out by TransCelerate Biopharma Inc. A free course 'Good Clinical Practice (GCP) = Good Research Practice' is delivered by the Australian Clinical Trials Education Centre.

Principal Investigators (PIs) must also provide evidence of Research Integrity training, renewable every 3 years. Cabrini recommends 'Research Integrity and the Code' delivered by Australian Clinical Trials Education Centre which is free and takes approximately 30 minutes to complete.

### 2.3 TYPES OF REVIEW

All projects must receive appropriate ethical and governance approval prior to commencement. ***CRGO is unable to review projects retrospectively.***

#### 2.3.1 Higher Risk and Multicentre Studies – Ethical Review

Projects deemed higher risk, as defined in Chapter 2.1 of the National Statement, must be approved by an NHMRC-certified Human Research Ethics Committee (HREC) that is part of the National Mutual Acceptance (NMA) Scheme. Cabrini is a member of Monash Partners and recommends using Monash Health or Alfred Health to obtain HREC approval. Cabrini will accept the HREC approval of other NHMRC-certified NMA HRECs.

#### 2.3.2 Lower Risk Studies – Ethical Review

Expedited ethical review and approval processes via a non-HREC pathway apply to quality assurance (QA) and lower risk projects. Final assessment of risks (see Chapter 2.1 of the National Statement) is the domain of the CRGO (not the researcher).

Please read Cabrini's privacy statement for clear guidance about how patient information may be used and NHRMC's Ethical Considerations in Quality Assurance and Evaluation Activities regarding the parameters for QA versus projects that trigger ethical review. Any QA projects (e.g. audits, staff surveys, access to medical records by someone involved in the patient's care) that are developed with the intention of publishing or promoting outcomes externally will be reviewed under the lens of lower risk research.

To determine if your project is QA or lower risk, complete a Level of Risk Checklist. If QA or lower risk review is indicated, send this completed checklist, a project protocol and any project tools and patient information to the CRGO for review.

CRGO cannot provide ethical review of QA work that has already occurred. Should an opportunity arise for originally internal QA projects to be promoted externally, CRGO may consider providing an authority to publish depending on the nature of the work and the type of data involved, however this will not constitute ethical review and approval.

CRGO cannot provide ethical review of multicentre lower risk research. Applicants must seek ethical review via the NMA Scheme, before obtaining governance approval via CRGO.

#### 2.3.3 Governance

Cabrini will accept the HREC approval of NHMRC-certified NMA HRECs. This does not mean all HREC-approved studies will be deemed suitable for Cabrini. All studies undertaken at Cabrini need to undergo a governance review to ensure they align with Cabrini's research agenda, the Catholic Health Australia Code of Ethical Standards and all Victorian government requirements.

Although ***literature*** and ***systematic reviews*** do not require ethics or governance approval, it is important to inform CRGO of your intention to conduct such reviews to ensure:

- Cabrini is aware of ALL research being conducted by its representatives, regardless of risk level, and can acknowledge the work;
- There is no duplication of research;
- The reviews contribute to your department's research productivity tally; and
- The reviews are acknowledged in Cabrini Research's annual report of research activity.

For literature and systematic reviews, email researchgovernance@cabrini.com.au advising:

- Type of review
- Research question / study title
- List of investigators
- Brief summary of research method
- Intentions for publication

Where researchers simply wish for Cabrini to be a referral site and for posters or promotional material to be displayed to aid recruitment, CRGO must be contacted for advice and approval. Although governance review is not required, approval to promote the study will be required by the academic head of department and clinical craft group lead. While clinicians can hand out or display flyers or pamphlets in their rooms, they are not permitted to review Cabrini medical records for potential participant information or provide names and contact details to the study team to aid recruitment.

All research advertising on noticeboards within the hospital environment and the media requires the approval of the CRGO. The advertisement should include a statement about the ethical review it has undergone and that the study complies with the NHMRC's National Statement on Ethical Conduct in Human Research.

### 2.4 APPLYING

Submit a completed Low Risk & Governance Application Form. CRGO also accepts the Human Research Ethics Application (HREA) or approved equivalent. If submitting a HREA, you must still complete a Low Risk & Governance Application Form but may refer to the relevant section from the previously completed HREA to minimise duplication.

As Victorian and Commonwealth Government requirements vary, if you use the HREA, you must ensure you consider Victorian-specific issues of the Health Records Act, Ionising Radiation and Guardianship. The Victorian Specific Module (VSM) is designed to address these issues and supplement the HREA in Victoria. VSM Section 1 – 3 addresses decision making capacity, legal obligations regarding the collection/use/disclosure of data, and use of human biospecimens. VSM Section 4 must be completed for any research involving ionising radiation. The Victorian government prescribes radiation risk statement wording that must be incorporated into Cabrini participant information and consent forms.

#### 2.4.1 Lower risk single site review

Submit the Low Risk & Governance Application Form, signed by all investigators, and relevant attachments via email to researchgovernance@cabrini.com.au.

#### 2.4.2 Governance review of higher risk and multicentre research

Submit the Low Risk & Governance Application Form, signed by all investigators, including the HREC approval, all listed approved documents and site specific documents to researchgovernance@cabrini.com.au.

#### 2.4.3 Low Risk & Governance Application Form

The Low Risk & Governance Application Form is available from the Cabrini website. The application is divided into eight sections.

Section 1: Administrative information

**PI Eligibility:** Eligibility to be a PI requires the applicant to be a Cabrini employee or Visiting Medical Officer (VMO). Trainee doctors can serve as co-PIs alongside their Cabrini supervisor if they have valid Cabrini accreditation and current GCP.

The contact details for PIs, Associate Investigators (AIs) and other research staff must be representative of professional or academic affiliations. Personal emails (gmail, hotmail, ymail etc) are often not accepted in HREC submissions.

PhD students can function as an AI only and must identify if their role in the study contributes towards their PhD, with their Cabrini supervisor listed as PI. A coordinating PI cannot serve as a site PI if they do not have immediate site responsibilities for Cabrini's involvement in the study.

If you are a student, or the project forms part of your tertiary study, you must ask your university supervisor and the head of the relevant Cabrini Department to write a letter of endorsement to accompany the application stating that they have reviewed the scientific methodology of the study and the methodology is appropriate.

In determining PI and AI eligibility, consult Cabrini's Authorship and Publications for Research Policy to ensure appropriate research roles have been assigned. PI and all AIs who are listed on a project that is conducted in full or in part at Cabrini, must include Cabrini in their listed author affiliations for all publications, presentations and media coverage resulting from any research conducted at Cabrini, requiring Cabrini resources or funded by Cabrini.

**Honorary Appointments:** Where one or more researchers are not connected with Cabrini and/or the research is being carried out in conjunction with agencies outside of Cabrini, the connection to Cabrini for all researchers and the names of all agencies participating in the project must be listed. External researchers wishing to access **identifiable** Cabrini data must apply for an honorary appointment. External researchers with honorary appointments who are accessing identifiable data can only do so under the supervision of their Cabrini clinical supervisor or Cabrini PI.

A standard honorary appointment will permit the researcher regular site access to Cabrini clinical and corporate campuses for the duration of the project. The application process requires the review and acknowledgement of Cabrini's research and privacy policies, evidence of mandatory vaccinations, and completion of mandatory training modules. If a researcher is involved in multiple projects, only 1 honorary appointment is required. A pre-existing appointment can be extended to accommodate the expected completion date of the latest project. Honorary appointments have a 2 year duration and require renewal if an extension is needed. Contact honoraryappointment@cabrini.com.au for more information.

Certain types of mandatory training will be waived for any researcher who will not visit any Cabrini campus (clinical or corporate) for the project. Their appointments will stipulate that site access is prohibited. If this situation changes, the researcher is obliged to inform the CRGO so training can be undertaken and the honorary appointment status updated.

**Payment Details / Submission Fees:** CRGO fees are available via the Cabrini website. If the project is billable, an invoice for submission fees will be sent during the review process. If a purchase order is necessitated by your institution for payment to be processed, please obtain and submit this with your application.

Section 2: Resource summary

This section outlines the resources necessary and available to carry out the project to completion. The Project Resourcing and Costing Template must be completed if Cabrini departments are required to

support the project. Budgets must include all anticipated expenses and project income, and detail any internal or external funding supporting the project.

Grant offer letters or funding agreements must be supplied and the assigned Cabrini Finance Reference Code stated. Ensure any variations in research project titles are aligned or appropriately communicated and justified with CRGO to minimise confusion i.e. the wording of project titles can vary between a grant application, protocol and ethics application.

Section 3: Project summary

The project summary (or plain language statement) should be written in simple language suitable for lay people, aimed at the reading comprehension of a 14-year-old. It should include background from literature, rationale for the project, aims, methodology and method of analysis. It should include any disease or PBS implications that would be outside the understanding of lay person. It should be no longer than one A4 page. The project summary should always be supplemented by a separate study protocol which formally documents all aspects of project design.

Section 4: Project details

Ensure any attachments provided to support the response have an appropriate footer, including the name of the document, version number, date and page number / total pages.

Within the patient's explanatory / information statement (PIS) or participant information consent form (PICF), you must outline the potential risks arising from the project (Section 2.1 of the National Statement apply), the potential consequences of those risks and the measures to be taken to deal with those consequences. Explain the monitoring, reporting and other procedures to be put in place to manage serious adverse and other unforeseen events. This includes adverse events of a physical or emotional nature, as well as adverse events relating to project information, such as de-identified information becoming identified. Refer to Cabrini's Site Specific PICF Checklist to assist in creation of a compliant Cabrini PICF.

Section 5: Ethical issues

Ensure your responses reference the Cabrini-specific storage and data protection requirements, including local servers, desktop computers, offices etc. Contact email-datagovernance@cabrini.com.au for further information.

Section 6: Drugs and therapeutic devices

Respond or follow the form instructions if this section is not applicable.

Section 7: Human Biospecimens

Read chapter 3.2 of the National Statement. Respond or follow the form instructions if this section is not applicable.

Section 8: Declaration

It is the PI's responsibility to ensure the research is conducted in accordance with the guiding principles, regulatory requirements and legislation referenced in Section 1 of this document. It is their responsibility to ensure any AI and other staff they may engage to conduct research activities are familiar with these requirements and abide by them.

In their absence, PIs may delegate responsibility to an appropriate AI. Clinical trials will use a delegation log while non-trial research will include a clear statement of investigator roles and responsibilities in the study protocol. PIs must notify the CRGO immediately of any intended changes to the protocol, PIS/PICF or project personnel after the project has been approved.

All signature fields must be completed, including academic head and clinical craft lead approvers. Contact researchgovernance@cabini.com.au if uncertain about who holds these positions for your area of research.

### 2.5 SUBMISSION

Only electronic copies of research documents are required and can be emailed to researchgovernance@cabrini.com.au

If research agreements and indemnities are required, electronically executed contracts with approved e-signature software (e.g. Docusign, Adobe Sign) will be accepted. Refer to Cabrini's Research Agreements Guide for instructions and templates.

| **DOCUMENT TYPE** | Lower Risk Single Site **(non-HREC review)** | Higher Risk / Multicentre **(governance review)** |
|---|---|---|
| Level of Risk Checklist | √ | |
| Low Risk & Governance Application Form | √ | √ |
| Cabrini Project Resource and Costing Form | √ | √ |
| Academic Head / Clinical Craft Group Lead Letter of Support (or signed Application Form) | √ | √ |
| List of Surgeons recruiting / participating and evidence of their support | | √ For surgical interventions |
| Evidence of Anaesthetics Head of Department Approval | | √ For surgical interventions |
| Theatre Approval | | √ For surgical interventions |
| Evidence of Peer Review (where applicable) | √ | √ |
| Evidence of Consumer Review (where applicable) | √ | √ |
| Data Governance Audit Tool (for database and registry projects) | | √ |
| Protocol / Protocol Summary | √ | √ |
| Budget | √ | √ |
| Grant offer letter or funding agreement | √ | √ |
| Methodology Flow Chart (if available) | √ | √ |
| Participant Information Sheet (PIS) | √ | √ |
| Participant Information Consent Form (PICF) | | √ |
| Advertisements / recruitment material | √ | √ |
| Research Tools questionnaires, surveys, data collection form, patient diaries | √ | √ |
| HREA or equivalent | | √ |
| HREC initial approval letter | | √ |
| HREC amendment approval letters | | √ |
| VSM Sections 1-3 | | √ |
| VSM Section 4 (Ionising Radiation) | | √ |
| Independent Medical Physicist Risk Assessment | | √ |
| Clinical Trial Notifications (CTN) | | √ |
| Investigator Drug / Device Brochures | | √ |
| Data Management Plan | √ | √ |
| Data Dictionary | | √ |
| Draft Research Collaboration Agreement or Clinical Trials Research Agreement | | √ |
| Draft Standard Indemnity Agreement | | √ |
| CV (all investigators) | √ | √ |

| | | |
|---|---|---|
| GCP training certificate (all investigators) | √ | √ |
| Research Integrity training certificate (PI) | √ | √ |
| Honorary Appointment Evidence | | √ |

# 3. GENERAL INFORMATION

## 3.1 WRITING A RESEARCH PROTOCOL

A research protocol provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed. Plenty of sample templates are available online. The depth of information provided will correlate with the level of risk and complexity of the study. A simple lower risk research project may only require a shorter protocol whereas a complex interventional drug trial may warrant a protocol in excess of 150 pages. As a rule, an investigator-initiated clinical trial or clinical research protocol must always address:

- **Background and literature review** - What is already known about the research topic in relation to the wider community and the specific site(s) to be studied?
- **Rationale** - How might new information from the study inform / improve future practice?
- **Aims and research questions** - What gaps in knowledge do you hope to fill?
- **Consumer Consultation** – has a research consumer reviewed your research proposal or contributed to its design? Do they believe in the value of the research and that any potential burden on a participant outweighs the risk? Do they feel the information presented to a participant is clearly articulated and easily understood? Do they believe the methodology optimises recruitment? Higher risk or multicentre research with HREC-approval, and projects that have been awarded federal grant funding (e.g. NHMRC, MRFF etc) will generally have existing evidence of consumer consultation, which Cabrini will acknowledge. Investigator-initiated studies, Cabrini-led and Cabrini-funded studies must provide evidence of meaningful consumer consultation. Cabrini Research can facilitate access to research consumers via its Consumer and Community Involvement Committee. Contact researchgovernance@cabrini.com.au for more information.
- **Timeline** - how long will each stage of the project take i.e. ethics, governance, recruitment, delivery of intervention, data collection, follow-up, data analysis, write up, journal submission
- **Methods** - How will the research be conducted? It may be beneficial to include a flowchart.
- **Recruitment - inclusion / exclusion criteria** - What are the parameters for participant selection? How many are targeted for recruitment? Does the methodology allow for recruitment of culturally and linguistically diverse (CALD) populations? Do the costs for interpreter/translators or document translation need to be incorporated into study budgets? Is asking for Aboriginal and Torres Strait Islander Identity part of the recruitment onboarding process? Refer to Cabrini's *Aboriginal and Torres Strait Islander Health - asking for Aboriginal and Torres Strait Islander identity procedur*e (located on Prompt) for further information.
- **Consenting procedures** – Will data be collected prospectively? How will participants be consented to use their data for research? What consent tools will be used? Even where a retrospective review of records is proposed, patients are still considered research participants and these questions must be addressed, unless a waiver of consent can be justified – refer to National Statement 2.3.10. Only a HREC can approve a waiver of the requirement for consent or an opt-out approach. The PI must also familiarise themselves with National Statement 3.1.17 in relation to recruitment of participants such as patients or employees, with particular consideration to addressing a potential power imbalance and avoiding coercion.
- **Risks and benefits** – Review Chapter 2 Section 2.1 of the National Statement and consider the possible impact, outcomes and repercussions for participants and the wider community by conducting this research.
- **Randomisation procedures**
  If comparing one intervention to another or to a placebo or no intervention, how will participants be allocated to different groups?

- **Data Management - collection, use, storage and disposal of data (including samples)**
  What is the data source? Who will collect the data? How long will data be stored? Where will it be stored? Who will have access? How will it be disposed of or archived? Contact email-datagovernance@cabrini.com.au for further information.
- **Privacy / Confidentiality**
  Use the following accepted terms to describe how data / samples will be labelled at each stage of the research
  - Identifiable e.g. name, UR and date of birth
  - Re-identifiable e.g. using a unique study identification code which only specified study personnel can link back to the participant – specify how the 're-identification key' will be stored and who will have access
  - Non-identifiable / de-identified – no possible way of linking back to the participant
- **Statistical analysis** - How will the data be analysed to answer the research questions? CRGO strongly encourages researchers to consult a biostatistician ***during*** protocol development to ensure the data will answer the research question. This process will also assist with securing an estimated cost for statistical analysis for inclusion in project budgets and grant submissions. Cabrini employs a biostatistician, Associate Professor Mohammad Asghari-Jafarabadi. Statistical support is available to Cabrini researchers at a rate of $100 per hour. Associate Professor Asghari-Jafarabadi can be contacted via biostats@cabrini.com.au
- **Dissemination of Results / Research Output**
  How do you plan to report, present or publish results?

### 3.2 PEER REVIEW

All research applications, apart from audits of retrospectively collected data, should demonstrate that independent peer review of the study has been sought. Higher risk or multicentre research with HREC-approval, and projects that have been awarded federal grant funding (e.g. NHMRC, MRFF etc) will generally have existing peer review, which Cabrini will acknowledge. Investigator-initiated studies, Cabrini-led and Cabrini-funded studies must provide evidence of peer review. Cabrini Research can facilitate a peer review service for researchers without access to independent expertise. An independent reviewer can be sourced for you, or alternately, a panel consisting of a Cabrini biostatistician, senior researcher and research executives can be convened (subject to availability) to provide peer review. Contact researchgovernance@cabrini.com.au for more information.

### 3.3 CLINICAL TRIALS

#### 3.3.1 National Clinical Trials Governance Framework

Cabrini Research's clinical trials program complies with the National Clinical Trials Governance Framework (NCTGF). The NCTGF was developed by the Australian Commission on Safety and Quality in Health Care (the Commission) and is an extension of Standards S1 (Clinical Governance) and S2 (Partnering with Consumers) to include the conduct and accreditation of clinical trials in hospitals. The intention is to embed clinical trials into routine health service provision and strengthen governance arrangements. It incorporates 27 actions under S1 and S2.

As Cabrini is now subject to short notice (SNAP) assessments for accreditation under the NCTGF, it is Cabrini's expectation as part of study approval that PIs make every effort to be available for interview with assessors from the Commission. Assessors will provide 24-48 hours to schedule meetings with investigators, study coordinators, trial participants where applicable, and Cabrini Executive.

Cabrini's Research Agreements Guide contains a new NCTGF clause which must be added in Schedule 7 of Medicines Australia CTRA / MTAA CIRA (Schedule 4 for CRG studies) which imposes obligations on the sponsor and the institution to meet the requirements of the NCTGF. For the Medicines Australia CTRA (CRO acting as Local Sponsor), the new clause number would be 5.11. The new clause number would be 5.10 for CRG studies using the Medicines Australia CTRA template.

### 3.3.2 Clinical Trial Business Hub

Cabrini offers a fee for service clinical trials service including study coordination, study coordinator staffing, patient trial procedure management, ethics and CRGO submissions management, and budget and contract evaluation and approval. Contact clinicaltrials@cabrini.com.au about using this service. The clinical trials service will assess the appropriateness of the patient population and Cabrini's clinical expertise to support the trial. Cabrini runs a number of First Time in Patient (FTIP) Phase 1A trials.

### 3.3.3 Trial Registration

All drug, device and technology (AI) clinical trials must be registered with the Therapeutic Goods Administration. Clinical trials must also be registered on a publicly accessible register complying with international standards e.g. International Clinical Trials Registry Platform (ICTRP) trialsearch.who.int, ClinicalTrials.gov or ANZCTR.org.au. Attach evidence of registration notifications to your application, even if provisional or draft, and provide a copy of the trial acknowledgement once issued. The sponsor must provide evidence the trial is publicly registered on a primary registry prior to enrolment of the first patient.

### 3.3.4 Informed Consent in Clinical Trials

Refer to Cabrini's Site Specific PICF Checklist to ensure your clinical trial PICF complies with Cabrini's governance requirements. These governance requirements address alternatives to wording that is in contravention of Catholic Health ethics, privacy, data transfer, ionising radiation effective dosage, private health out of pocket expenses, local complaint contact details and QR codes for Open Disclosure and the Australian Charter of Healthcare Rights.

### 3.3.5 Clinical Trial Sponsor

All clinical trials conducted in Australia must have a trial sponsor that is an Australian entity. The trial sponsor is responsible for the initiation, management and financing (or arranging the financing) of the trial and carries the medico-legal responsibility associated with its conduct. The Australian trial sponsor is also the entity that is responsible for submitting a CTN or CTA. A comprehensive list of sponsor responsibilities are outlined in:

- The Australian Clinical Trial Handbook (pages 23-26)
- Integrated Addendum to ICH: E6 (R1): Guideline for Good Clinical Practice ICH E6(R2) – Chapter 5

The National Statement Chapter 5.4 advised that *sponsors of clinical trial research also have significant monitoring and reporting responsibilities and allocation of monitoring responsibilities amongst sponsors, institutions, review bodies and researchers should be clear to all of these for each research project.*

Cabrini Research does not currently have the infrastructure to assume the role of study sponsor in clinical trials as it cannot meet the obligations prescribed by the TGA and ICH GCP.

## 3.4 RESEARCH AGREEMENTS

Research agreements are required where there is more than one organisation involved in the research. Refer to Cabrini's Research Agreements Guide for information regarding pre-approved templates, advice on which agreements to use for different types of research, Cabrini's legal entity information, mandatory research clauses and conditions, and other useful contract information. Cabrini encourages the use of pre-approved templates (Medicines Australia / Medical Technology Association of Australia for clinical trials) and the Monash Partners Research Collaboration Agreement for non-trial research to minimise or expedite legal review. Commercially-sponsored studies require that Cabrini is indemnified by the sponsor.

### 3.5 INSURANCE AND INDEMNITY

Where Cabrini research projects fall within *standard of care (SOC),* they will be covered by the hospital's insurance policy.

Any treatment by professionals (doctors or therapists) which exposes them to litigation will not be covered by the hospital's insurance and is the responsibility of the professional involved. All professionals involved in treating patients should provide details of their professional indemnity cover and a record kept of this information. This is a requirement for all accredited VMOs at Cabrini. Accredited VMOs undertaking clinical trials must advise their professional indemnity provider and supply correspondence within their application confirming insurance cover for their research activity.

Any queries regarding indemnification of the medical professionals involved should be addressed to the practitioner's medical defence/insurance organisation.

Any clinical trial involving a new device, medication, biological agent or technology (such as AI) must be fully indemnified by the sponsor and evidence of that indemnification will be kept on file. This indemnification needs to cover all aspects of the treatment and any potential future complications. Such cover must include the hospital and all trial personnel. Cabrini cannot allow any trials not fully indemnified to proceed.

Where the placebo arm of a controlled trial involves an invasive procedure that is not part of *standard of care*, a separate insurance policy would need to be in place to cover potential litigation. The 'up front excess' requirements of hospital policies in Australia would mean it would not be financially viable to carry out such trials at Cabrini. Placebo arms are not permitted in Phase 1 trials.

Cabrini employed researchers should first discuss with CRGO if their research will be covered by Cabrini's insurance policy. Research areas prohibited by Cabrini's insurance policy include pregnant women and mesh implants. Cabrini's insurer must first be consulted if a researcher wishes to engage in gene therapy research or research involving children under the age of 5.

### 3.6 DATABASES / REGISTRIES

All new database and registry applications require ethical review by an NHMRC-certified NMA HREC. A governance submission must be presented to the Data Governance Committee to ensure that its function adds value to Cabrini, the database does not duplicate data already being collected and that the effort required to collect the data is minimised. We recommend researchers seek Data Governance Committee advice on new proposals ***prior*** to HREC submission. The Cabrini Research Data Governance Audit Tool must be completed and included with a new application submission.

### 3.7 OBSERVERS

Observation of a standard of care (SOC) procedure associated with a research project by a non-member of the research team for the purposes of education is permitted without the need to notify an HREC. The PI must, however, seek approval from the relevant department head and ascertain the requirements of that department to permit the presence of an observer. For example, to observe an SOC procedure in theatre, the Nurse Director Perioperative Services must authorise the presence of the observer and will advise specific training, certification and administrative requirements (if any).

Observation of and participation in a research procedure requires HREC approval.

## 4. INFORMING RESEARCH PARTICIPANTS

Cabrini's *Informed Consent in Research Policy* will soon be available to support Cabrini Researchers to understand Cabrini's expectations regarding achieving fully informed consent. Templates for participant information and consent forms (PICF) are available from the Victorian Government's Clinical Trials and Research website. Cabrini encourages succinct, simplified participant information consent forms that enable participants to make an informed decision about whether to participate. Cabrini is supportive of study sponsors adopting CT:IQ's InFORMed project template.

Refer to Cabrini's Site Specific Checklist for all Cabrini approved wording addressing Catholic health ethics, private health expenses, privacy obligations, overseas data transfer, compensation resulting from injury related to the study, and NCTGF requirements.

### 4.1 TRIAL LANGUAGE

The PICF may refer to the investigational product as 'agent', 'drug' or 'medication' as long as it is prefaced by 'trial' or 'study' so patients do not assume therapeutic benefit. If the word 'treatment' must be used in reference to administration of a trial agent, it should be prefaced by the word 'trial' or 'study'.

### 4.2 RISKS

The risk of side effects from an investigational product should be stated in order of seriousness and probability. Risks of therapeutics approved for the study indication should *not* be included.

Consideration should also be given to potential risks inherent with sharing information. Cabrini's Site Specific Checklist prescribes particular wording regarding distribution of patient data and the obligations of the sponsor in the handling of this data.

PICFs must include the wording prescribed by the APRANSA guide, the Victorian Government's Standard Radiation Risk Statement and that of the independent medical physicist report. Effective dose limits for ionising radiation involved in the clinical research that is above standard of care must be disclosed to the participant in the PICF. Refer to Cabrini's Site Specific Checklist for the prescribed risk wording.

### 4.3 REQUIREMENTS FOR RESEARCH IN HUMANS OF REPRODUCTIVE AGE

CRGO has concerns about any research study involving drugs with potential side effects on the unborn child. All women participating in studies involving drugs with an unknown effect on the unborn child are required to have a pregnancy test prior to entering the study and to be informed they could potentially be excluded from the study.

As a Catholic healthcare service, Cabrini is committed to reflecting the Church's teachings regarding respect for the personal dignity of human life in all stages. It is imperative there is certainty of causing no harm to the life or integrity of a human embryo or foetus. As such, CRGO requires the **unedited** approved Catholic Health Australia statement (refer to Cabrini's Site Specific Checklist) regarding pregnancy avoidance to be included in the information provided to participants in medical research.

A disclaimer statement is provided in the Cabrini's Site Specific Checklist where wording that is in contravention of Catholic Health ethics is legally required. A recommended statement regarding concerns about the impact on fertility is also supplied.

Cabrini's Research Agreements Guide provides a clause that must be included in Schedule 3 Special Conditions of a research collaboration agreement regarding prohibiting the use of gifted reproductive biospecimens for research related to in vitro fertilisation (IVF), intra-cytoplasmic sperm injection (ICSI) or artificial insemination by donor (AID).

### 4.4 PARTICIPANTS – CHILDREN AND YOUNG PEOPLE

Chapter 4.2 of the National Statement must be adhered to if you are recruiting participants under the age of 18. Ensure an explanation is included in 4.2.4 of the Low Risk & Governance Application Form addressing how children and young people will be appropriately consented.

### 4.5 GUIDELINES FOR INFORMING PARTICIPANTS ABOUT THE OUTCOME OF RESEARCH

CRGO notes that:

- the results of a study may not be available for many years and their relevance to participants may become remote;
- the results may not be in the public domain, that is, they may remain the property of the sponsoring agency;
- it may be that the release of results is not in the best interests of participants;
- confidentiality could be seen to be questionable if participants are contacted after studies are completed;
- researchers seldom have editorial control of publications; and
- the ability to deliver results in a secure and confidential manner is dependent on many factors, including the ability of a researcher to maintain an accurate participant database.

Notwithstanding the above and in line with paragraphs 1.3 (d) and 1.5 of the National Statement, CRGO believes that participants should have the opportunity, where possible and appropriate, to hear the outcome of a study they have participated in and encourages researchers to consider this in their study design.

### 4.6 WAIVER OF CONSENT

Obtaining consent is always preferable when recruiting participants to research. However, instances may arise where seeking explicit consent is neither practical nor feasible. Only an HREC may grant a waiver of the requirement for consent for research using personal information in medical research, or personal health information - National Statement Chapter 2.3.9. The researcher must justify the waiver request to the HREC - refer National Statement Chapter 2.3.10.

### 4.7 OPT-OUT APPROACH

An opt-out approach to participant recruitment may be approved by a HREC when a project is of such scale and significance that using explicit consent is neither practical nor feasible.

The Opt-Out approach is not considered informed consent as there is no guarantee the participant has read the information which has prompted them with the choice to decline participation. The researcher must justify their opt-out approach request by adequately addressing National Statement Chapter 2.3.5.

### 4.8 PRIVACY AND CONFIDENTIALITY

All PICFs must contain a concise paragraph on how the research will comply with the *Health Records Act 2001 (Vic)*, the *Privacy Act 1988*, NHMRC Guidelines under Section 95 of the *Privacy Act 1988* and all other NHMRC privacy guidelines and regulations. This wording is addressed in Cabrini's Site Specific PICF Checklist.

### 4.9 DATA PROTECTION

Where possible, data should be collected without identifiers. Any research data collected should adhere to the following:

- Hard copy data should be stored onsite (closest to the area of collection) in a locked office in a locked cabinet (or fridge for tissue samples).
- Electronic data should be stored in an encrypted file on a password protected non-portable computer, only accessible by an approved site PI or AI.
- All data should be stripped of its identifiers and assigned a unique code that prohibits re-identification of the source data other than by the approved PI or AI.
- The key-coded file that can match re-identifiable data with its original owners must also be encrypted and stored separately to the location of the source data, accessible only by an approved site PI or AI.
- All data must be stored on Australian servers that adhere to Australian privacy laws.

- Data sent off-site must be in a de-identified state (re-identifiable by the local PI only) and used for HREC approved purposes only.
- Data Transfer Agreements or Research Collaboration Agreements are required for any data sharing arrangement and must outline the parameters of data use and commit the parties to lawful, HREC-approved treatment of the data. Refer to Cabrini's Research Agreements Guide.

Review Cabrini's Data Classification and Labelling Standard Policy for more information regarding data protection, and contact email-datagovernance@cabrini.com.au with further queries.

### 4.10 OVERSEAS DATA / SAMPLES TRANSFER

If identifiable or re-identifiable data, including biological samples, are being transferred outside of Australia, participants must be informed that privacy laws outside of Australia may be less stringent. Cabrini's Site Specific PICF Checklist prescribes particular wording regarding distribution of patient data and the obligations of the sponsor in the handling of this data.

Clinical Trial Research Agreements must impose privacy obligations on the Sponsor. If the Sponsor is an Australian company, they will be captured by Australian privacy laws. However, if the Sponsor is transferring data overseas, including to an international related body, affiliate or third party, the agreement must include a new Clause 10.3 (detailed in Cabrini's Research Agreements Guide) in the Schedule 7 Special Conditions to ensure the Sponsor and their representatives understand their data protection obligations to Australian privacy law and the consequences of a breach.

If the sponsor is an international entity, legal advice should be sought on the nature of the Agreement to ensure appropriate privacy protections are in place.

### 4.11 DATA STORAGE FOR CABRINI RESEARCHERS

Cabrini researchers (employees and affiliates) should utilise the shared drives specific to their department to store their research data as these drives are secure and regularly backed up. Locked folders can be created within these drives and assigned specific, unlimited membership access to enable collaboration and sharing by members of the research team. These folders should be encrypted if they contain sensitive, identifiable data – Windows encryption is preferred. ***Under no circumstances can the H:drive (personal drive) be used to store Cabrini research data.*** Submit your request to researchgovernance@cabrini.com.au for creation of a locked folder, specifying the Cabrini project title and number, membership access list and whether encryption is required.

Researchers who wish to avoid data unwittingly being sent overseas, and unknown privacy implications due to privacy laws of other countries differing from Australia, need to ensure that an Australian server is enlisted for electronic data storage.

The NHMRC's Australian Code for the Responsible Conduct of Research 2018 recommends the minimum period for retention of research data is 5 years from the date of publication. Most clinical trials will retain research data for 15 years or more if necessary. State and Federal legislation may vary on this position. Researchers must ensure they have adequate storage arrangements in place and have factored any storage fees into their research budgets. Review Cabrini's Data Classification and Labelling Standard Policy for more information regarding data protection, and contact email-datagovernance@cabrini.com.au for Cabrini's complete data retention guidelines.

### 4.12 PAYMENT OF PARTICIPANTS IN RESEARCH PROJECTS

CRGO considers it appropriate to offer participants reimbursement for 'direct out of pocket' expenses (such as travel expenses). CRGO encourages researchers to consider such reimbursement when planning clinical studies, though reimbursement should be structured so as not to be considered an inducement to participants. It is also important that lack of reimbursement does not exclude patients from participation in a research study.

If payments are intended, researchers should provide CRGO with:

- A rationale for proposed payments
- The method and timing of disbursements
- Information on how prospective participants will be advised of the provision of payments

CRGO will assess whether the payments are adequate and proportionate, and will ensure the potential for undue influence is minimised.

Review NHMRC's 2019 publication 'Payment of participants in research: information for researchers, HRECS and other ethics review bodies' for further guidance.

### 4.13 COMPENSATION FOR INJURY ATTRIBUTABLE TO THE STUDY

Cabrini's Site Specific PICF Checklist prescribes compensation wording for commercially-sponsored studies in the event of study-related injury. If your study is not sponsored, please substitute an appropriate paragraph. Participants who suffer any injury as a result of participation in research conducted at Cabrini are expected to have access to treatment for that injury at Cabrini, at no cost to them. Researchers will need to clearly articulate in the protocol and PICF how these expenses will be covered. Alternately, Cabrini's Site Specific PICF Checklist provides an alternate statement that can be used for non-sponsored studies.

### 4.14 OUT OF POCKET COSTS

Cabrini's Site Specific PICF Checklist provides 2 options (commercially sponsored and non-commercial / non-sponsored studies) for informing a participant about their potential to incur out of pocket expenses as a result of participating in research at a private health institution.

### 4.15 DISCLOSURE REGARDING POTENTIAL REWARDS FOR RESEARCHERS

Researchers are asked to describe the arrangements, costs and potential rewards and benefits of the study within the PICF or PIS. This includes, but is not limited to:

- study budget, grants, sources of funding and additional study costs and payments incurred by investigators;
- organisational structure of the study, any beneficial interests, duality and/or conflict of interest for the investigators; and
- intellectual property ownership, impact on career and reputation, requirements for course work or higher education, travel grants and publications.

The PICF should include a statement advising who is paying for the study, who benefits from the outcomes, and what are the financial and organisational arrangements underpinning the study.

### 4.16 COMPLAINTS

Chapter 5.7 of the National Statement discusses handling complaints. All PICFs must direct participants needing to lodge a complaint about the conduct of a research project to Cabrini's Customer Relations team so that it can be logged in Riskman's feedback module. Check Cabrini's Site Specific PICF Checklist for complaints contact details.

### 4.17 GENETICS AND PHARMACOGENETIC STUDIES

#### 4.17.1 Impact of genetic research

Useful references about the impact of genetic research, particularly regarding the insurance, employment and other implications for participants, include:

- Chapter 3.3: Genomic Research from the National Statement
- Life insurance products and genetic testing in Australia

### 4.17.2 Ethically Defensible Plan

Where use of human biospecimens in laboratory-based research (National Statement Chapter 3.2) and Genomic Research (National Statement Chapter 3.3) have the potential to reveal information that could be of significance to the health of participants, relatives or other family members, researchers should prepare and follow an ethically defensible plan to disclose or withhold findings or results of research. The structure of an ethically defensible plan is outlined in National Statement Chapter 3.1.64. CRGO can provide researchers with sample templates to support development of an ethically defensible plan.

### 4.17.3 Genetic research involving human embryos

As outlined in Chapter 6 of Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, any genetic research that involves techniques that are contrary to respect for human life or human dignity are prohibited. Chapter 6.18 states *'Genetic research must not involve any techniques that may lead to the asexual creation or reproduction of human embryos or other eventualities that are contrary to respect for human life or human dignity. These techniques currently include: producing, damaging or dismembering a human embryo to remove stem cells or to ensure its truncated development; producing totipotent cells which (without the addition of other genetic material) may be capable of human embryogenesis; introducing the whole or parts of the human genome into animal gametes; forming a chimera with or to create a human embryo; and animal gestation of human embryos.'*

CRGO may request a signed statement from the PI affirming an understanding of Cabrini's ethical position on the treatment of human tissue in research and compliance with the treatment of human tissue only as outlined in the HREC-approved study protocol. CRGO can provide a sample template if required.

### 4.18 WITNESSES

Cabrini does not require witnesses to be included in the consent process as this cannot be audited, however Cabrini will permit interpreters serving as impartial witnesses.

## 5. POST-APPROVAL

Report notable events and submit revised documents for review via email to researchgovernance@cabrini.com.au.

- PI must authorise events or documents being presented either via email or signed CRGO submission form.
- CRGO will acknowledge, via return email, once documents have been reviewed and noted.

### 5.1 POST-APPROVAL DOCUMENTS REQUIRING REVIEW

Researchers should immediately report anything which might warrant ethical review, that might impact participant safety, the ongoing conduct of the study, or data integrity, including:

- Proposed changes in the protocol and participant consent (e.g. revised protocols, investigator brochures, PICFs / PISs, dear investigator letters and memos, surveys or questionnaires, audio/video tools, recruitment material such as advertisements and letters of invitation etc) – use Documents to be Presented (Amendment) form
- Administrative amendment – removal and addition of new research team members – use Administrative Changes form
- Reportable safety events – refer to Cabrini's Safety Monitoring and Reporting in Research Policy for further information. Use Sponsor SAE or CIOMS form, Victorian Government Safety Report Form or Cabrini Safety Reporting Form. Only 1 form is needed – Cabrini will accept the form preferred by the study sponsor.
- Breaches of conditions or unforeseen events that might affect the ethical acceptability or governance approval of the study – use the Events to be Noted form

- Protocol deviations that have the potential to result in harm of the participant or impact the scientific value of the research – use the Events to be Noted form
- Serious breaches of GCP– use the Events to be Noted form
- Privacy and/or Data breach – use the Events to be Noted form
- Research complaints – use the Events to be Noted form
- Progress Reports - use the Progress Report Template

All post approval documents should first be submitted to the reviewing HREC (where applicable) for approval, then sent to the CRGO for site-specific review and noting. CRGO does not require submission of extra documents with no ethical content, such as patient diaries and patient cards.

To facilitate review, all changes to previously submitted documents must be shown using '***tracked changes***' i.e. underlining for additions and ~~strikethrough~~ for deletions. Revised documents must include an updated version number and date (preferably in the footer). Both 'tracked' and 'clean' copies must be submitted for review.

CRGO does not support the ***unnecessary re-consenting*** of participants, particularly if they have completed treatment and are only in survival follow-up. Re-consenting can be a stressful and even traumatising experience for vulnerable, unwell participants, particularly given the large volume of information that can be delivered through a PICF. Re-consenting will only be considered in the event there is a ***significant practice change*** for a participant on active treatment, or a ***new or increased risk*** has been identified, resulting in a protocol amendment. Administrative changes or minor practice changes that do not have the potential to negatively or adversely affect a participant may be noted in a PICF update, however re-consenting must be deferred until a future amendment warrants re-consenting as per CRGO guidelines. Ethics submission specialists are advised to first check with the PI if they support re-consenting of proposed changes prior to CRGO submission.

For any Events to be Noted, an explanation of the event and some comment as to what action has been taken to avoid a repeat occurrence needs to be provided. Comment on any impact on participant safety, ongoing conduct of the study or data integrity must also be included. A root cause analysis and correct action and prevention plan (CAPA) may be required. CRGO can provide a CAPA sample template.

### 5.2 POST APPROVAL MONITORING – INTERNAL

Under Chapter 5.5. of the National Statement, CRGO is responsible for ensuring that all approved research is monitored, and the PI is responsible for notifying the reviewing HREC that appropriate monitoring mechanisms are in place. Such monitoring includes:

- Audits/site visits/interviews to ensure compliance with conditions of approval;
- Review of completed annual progress reports, final reports and publications which can be emailed to researchgovernance@cabrini.com.au. For a single site (Cabrini-specific) study, the reviewing HREC progress and final report templates will be accepted. For multisite studies, either the reviewing HREC or government progress / final report templates will be accepted as long as Cabrini-specific data is highlighted against the aggregated data, otherwise Cabrini's Progress Report Template is required.
- Review of safety event reporting.

#### 5.2.1 INTERNAL AUDIT

Monitoring of research projects is an important aspect of the work of the CRGO and a requirement of the National Statement as outlined in Chapter 5.4.

CRGO selects a handful of Cabrini projects to audit each month. An audit questionnaire is provided to the PI and approximately 2 weeks allocated for completion. CRGO will review all study documents and meet with research team members if required to ensure a sound understanding of the contemporary status of the project in relation to Cabrini. The audit is also an opportunity for researchers to raise any

issues of concern regarding the project or to suggest ways the CRGO might be able to provide a better service. The outcomes of the project audits are presented to the CRGC each month.

### 5.2.2 PROGRESS REPORTS

Annual progress reports and resulting research output (publications, presentations and reports) are presented to the CRGC each month. CRGO will assess whether recruitment targets are being met, whether activity has stalled, challenges faced, where study changes have occurred, reasons for participant withdrawal and gauge whether the study remains viable. PIs are provided with approximately 1 months' notice to provide their annual progress report. CRGO will consider an extension if a valid reason is justified. However, a study will be suspended at Cabrini and the reviewing HREC notified if a report is not provided by the third (and final) reminder.

Approval granted by the CRGO is ongoing for the life of the project, subject to satisfactory compliance and reporting. Progress reports and their respective acknowledgments can be shared with relevant parties if evidence of active approval and monitoring is required, however updated approval letters will not be issued.

### 5.2.3 SITE CLOSURE / FINAL REPORT

A study at Cabrini is considered active until a site closure/final report is received. A final report is due on completion of the study, or if the research is discontinued prematurely. As per Cabrini's Monitoring of Approved Research Policy the trigger for submission of site closure/final report to CRGO are as follows:

- For commercially sponsored clinical trials, the study is considered complete once the site closeout visit has concluded
- For Investigator Initiated clinical trials, the study is considered complete once the last patient has completed follow up and the data has been analysed
- For other research projects, the study is considered complete once data analysis is complete and there is no further contact with patients or access to medical records or other sources of personal or health information.

The Site Closure/ Final Report will be reviewed and acknowledged by CRGO.

### 5.2.4 SAFETY MONITORING AND REPORTING

Review Cabrini's Safety Monitoring and Reporting Policy which is available via Prompt and Cabrini's website. Use Sponsor SAE or CIOMS form, Victorian Government Safety Report Form or Cabrini Safety Reporting Form. Only 1 form is needed – Cabrini will accept the form preferred by the study sponsor if it adequately addresses all the information required for appropriate monitoring and safety assessment.

### 5.2.5 RISK REGISTER

Cabrini CRGO maintains a Risk Register with monthly reporting to CRGC and quarterly aggregate reports to the Cabrini Research Committee. The following risks are reportable to CRGO and recorded in the register:

- Reportable safety events
- Breaches of conditions or unforeseen events that might affect the ethical acceptability or governance approval of the study
- Protocol deviations that have the potential to result in harm of the participant or impact the scientific value of the research
- Serious breaches of GCP
- Privacy and/or Data breaches
- Research complaints
- Progress report deficiencies
- Mandatory training deficiencies
- Contractual/resourcing and financial risks
- Policy non-compliance

- Matters of research integrity
- Deficiencies identified by CRGO monitoring audit

### 5.3 POST-APPROVAL MONITORING – EXTERNAL

Commercially-sponsored clinical trial monitoring involves stringent, regulated processes largely dictated by the trial sponsor. However, monitors are required to adhere to specific local site requirements including presentation of vaccination evidence and mandatory mask requirements as well as use of mutually approved data sharing platforms. Sponsored trials are still subject to internal monitoring.

For collaborative research group studies and trials, the monitoring protocol, processes and data sharing platforms proposed by the coordinating site must receive HREC and site governance approval.

Refer to the Monitoring of Approved Research Policy for further information.

### 5.4 CABRINI ACKNOWLEDGEMENT IN RESEARCH OUTPUT

Cabrini must be acknowledged in all publications, presentations and media coverage resulting from any research conducted at Cabrini, requiring Cabrini resources or funded by Cabrini. CRGO will review a project's research output to ensure Cabrini's involvement is appropriately referenced. Failure to do so may have implications on a project's approval status, funding, and future research applications.

## 6. OTHER RESOURCES AND REFERENCES

Alfred Health HREC
Australian Clinical Trials Education Centre
Australian Code for the Responsible Conduct of Research (2018)
Australian National Data Service guide
Australia New Zealand Clinical Trials Registry
Australian Privacy Principles (Office of the Australian Information Commissioner)
Cabrini Privacy Policy (located on Prompt)
Cabrini Research Data Governance Audit Tool
Cabrini Research Governance Framework (located on Prompt)
Catholic Health Australia - Code of Ethical Standards
Catholic Health Australia - PICF statement where pregnancy must be avoided
ClinicalTrials.gov
Health Records Act 2001
How to make an HREC application
International Clinical Trials Registry Platform
Medicines Australia Clinical Trials Research Agreement
Medicines Australia Standard Indemnity Agreement
Medical Technology Association of Australia Research Agreements
Monash Health HREC
Monash Partners
National Clinical Trials Governance Framework
National Clinical Trials Governance Framework Fact Sheets
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research 2023
Victorian Specific Module
Therapeutic Goods Administration
Therapeutic Goods Administration Guidance on clinical safety data management: definitions and standards for expedited reporting
Victorian State Government Standard Radiation Risk Statements
World Health Organisation's Recommended Format For a Research Protocol