ST ANDREW'S HOSPITAL
MEDICAL & SURGICAL EXCELLENCE

St Andrew's Hospital
Research & Ethics Committee

PROCEDURES AND DOCUMENTATION GUIDELINES FOR RESEARCHERS

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1. CHECK LIST

This checklist is intended as a guide to the submission of proposals to the St Andrew's Hospital Ethics Committee. Not all points will be relevant eg in qualitative research. Where a proposal is being or has been submitted to another Ethics Committee, that submission is suitable providing all the points below are covered. A charge of $3,000 (inc. GST) for projects that are for an outside investigator should be paid with the project submission.

The Committee is willing to accept an independent single assessment from a recognised, approved Health Research Ethics Committee (HREC) of the scientific/technical aspects of a multicentre study, which could be used for all HREC applications relating to that proposal.

1.	**Project Title:**	
2.	**Investigators Details:**	Qualifications and contact details
3.	**List of places where research is being undertaken:**	
4.	**Project background, rationale and objectives:**	
5.	**Proposed Methods:**	Design of study (control group should receive the best treatment currently available) Duration of the study Selection of patients Exclusion and withdrawal criteria Statistical analysis, including justification of sample size, if relevant Outcomes (How will the outcomes of the study be evaluated? Can the aims be realised?)
6.	**Drug Profile:**	Check lists A and B where appropriate
7.	**Procedures including drug treatment involving the subject:**	Dosage and mode of administration of drugs including those associated with procedures such as bronchoscopies, endoscopies etc Concurrent treatment Measures to be taken on withdrawal of the study drug either because the study has ceased, or because an extension study has not been given ethical approval Details of invasive procedures. Facilities for dealing with contingencies
8.	**Specific Safety Considerations**	If radiation exposure is an aspect of the research plan, the following should be detailed: Why are subjects exposed to ionising radiation? The number of subjects to be exposed. Precautions to be taken to keep exposure to a minimum Exposure dose report from Radiation Safety Officer
9.	**Assessment of patients:**	Clinical Laboratory Questionnaire/s (please provide a copy) Other (eg. radiological) Monitoring adverse (eg. drug) effects

Note: All serious adverse events should be reported to the Ethics Committee at the **same** time as they are reported to sponsoring organisations. Other adverse events should be described in the Annual Report to the Committee.

10. Administrative aspects:

Source of drug supply
Formulation of placebo
Special facilities (approval required of Director of Service involved)
Notification of other Divisions that may be involved
Use of hospital facilities
Name of pathology facilities to be used, accreditation status and whether results will be available in a timely fashion
Medical records required

11. Financial Statement

Submissions for commercially sponsored trials of drugs or devices must be accompanied by a copy of the financial agreement between investigator and sponsor.
There must be a declaration of any financial interest which the researcher may have in the outcome of the research project-this applies regardless of whether or not investigational drugs or devices are involved.

12. Consent Form:

Who will obtain consent?

Note: Whenever a subject is in a dependent relationship to an investigator, it is recommended that the written consent be obtained by a third party.

Prepare the consent form as it will be administered, using a copy of the **relevant** form on page 12 of these guidelines.

13. Information Sheet:
(for more detail see page 7)

Purpose of study/benefits for subjects or otherwise
Account of procedure to be performed including:
Explanation that placebo is to be administered (if relevant)
Risks, adverse effects (nature and probability)
Comparison with other drugs and procedures for same purposes
Discomfort/inconveniences, restrictions, immediate and late
Availability of drug/treatment at the conclusion of the study
Statement of freedom to withdraw from the study without prejudice
Assurance of confidentiality
Name and telephone number of at least one member of research group
Name and telephone number of Executive Secretary of the Ethics Committee (or alternative committee contact person)

Prepare the information sheet as it will be provided to the subjects of research for submission to the Committee

14. Ethical Considerations:

Benefit anticipated from the study
Risks including risk of causing physical disturbance, discomfort, anxiety or pain, rather than just risk of serious harm. For guidance, the primary ethical principle is respect for the subjects
Research on people in dependent relationships eg the mentally ill, intellectually impaired, or minors
Separation of research and clinical responsibilities
Regular volunteers (source, honoraria)
Method and nature of advertising (enclose advertisement and state placement)
Protection of privacy and preservation of confidentiality
Restriction of use of data
Any other particular ethical consideration

15. Privacy considerations:

Statement on the specific uses to which the personal information acquired or developed during the study will be put

The estimated time of retention of the personal information
Security procedures to be applied to the personal information
A statement that the data will be retained in accordance with good scientific practice and in a form that is at least as secure as it was in the sources from which the data was obtained
The safeguards that will be applied to protect personal information that will be made available to other researchers or third parties
A list of personnel with access to the personal information
The proposed methods of disposal of the personal information having regard to the State and Commonwealth records and any relevant legislative requirements
Whether, and in what form, the final results will be published or made available to other researchers
What will be done with personal information on completion of the study.
Compliance with the Guidelines under section 95A of the Privacy Act

Sign the form "Privacy Statement" (page 11) and provide the details required concerning privacy issues as detailed therein.

16. Other Ethics Committees to which the protocol has been submitted

17. Date of proposed commencement

18. Indemnity: Provide a signed indemnity statement where there is an external sponsor for the study.
Please provide approval/evidence from your Medical Defence Organisation/University/Employer that you have obtained satisfactory insurance coverage for this project.
Please confirm that this insurance cover will be maintained during the course of the project and for appropriate run-off cover at the completion of the project.

19. References: Suitable references should be cited.

20. Monitoring: The researcher should provide the Committee with suggestions as to the way in which the study can be best monitored by the Committee to ensure that the rights and interests of the subjects are maintained, the researchers are conducting ethical research, and the institution's reputation is maintained

☐ 12 copies of all documentation, except the Investigator's Brochure, must be submitted to the Executive Secretary of the Ethics Committee, St Andrew's Hospital, 350 South Terrace, Adelaide. Only two copies of the Investigator's Brochure are required.

☐ Please be advised that the Principal Investigator/Representative will be required to present their submission in person at a Meeting of the Ethics Committee. Please contact the Executive Secretary of the Ethics Committee to schedule this presentation.

1.1 CHECK LIST A:

Information required about investigational drugs, i.e. drugs which do not have current marketing approval for use in Australia.

Note: The Department of Health requires that research sponsors provide Health Research Ethics Committees with specific information regarding investigational drugs if the application is submitted under the Clinical Trial Exemption (CTX) Scheme. Researchers should ensure this information is available to the Committee. However the Regulatory Authorities have not issued guidelines on the type of information to be submitted to Health Research Ethics Committees under the Clinical Trial Notification (CTN) Scheme. For suggested guidelines for CTN applications, refer to Check List B.

1. Name of drug

2. Manufacturer: Source

3. Pharmacological properties

4. Indications

5. Usual dosage, range and route of administration

6. Proposed dosage form, strength and dosage range to be used in investigation

7. Toxicology Data:

Summary of positive findings in:

1. animal studies
2. human studies

8. Teratology Data:

Summary of positive findings in:

1. animal studies
2. human studies

9. Carcinogenicity Data:

Summary of positive findings in:

1. animal studies
2. human studies

10. Side effects reported with therapeutic doses in clinical studies

11. Treatment of overdose (if any specific measures)

12. Appropriate references pertaining to information provided.

1.2 CHECK LIST B:

Minimum data to be provided by the investigator to support an application under the CTN scheme.

- ☐ The research protocol according to the guidelines already outlined in main checklist
- ☐ The investigator's drug brochure (for non-marketed drugs). **Two copies only are needed**
- ☐ Indication of any approval for marketing and/or clinical trial by approved regulatory authorities
- ☐ The summary data package submitted to regulatory authorities to support marketing or clinical trial applications
- ☐ An indication of refusal or questioning of the drug, together with appropriate details, in relation to a marketing or clinical trial application either to an acceptable regulatory authority or to a Health Research Ethics Committee
- ☐ Available evaluation reports from any accepted regulatory agency prepared in relation to a submission for marketing or clinical trial application of the drug
- ☐ For drugs already marketed and for which there is a proposal for a new use, dose, duration, route, formulation or patient group, none or not all of the foregoing information may be available. In such a case, the investigator should provide the product information which demonstrates the marketing status of the drug, and any other information which appropriately supports the case

2. Information Sheet Guidelines

The St Andrew's Hospital Ethics Committee requires an Information Sheet to be given to potential research subjects to assist them in their decision about involvement.

An information sheet must accompany every consent form. It must be written in simple language and must not contain technical terms or jargon. It must describe the research study clearly and directly enough to be understood by a wide range of people.

Use short, simple sentences and short words of few syllables. If you must use a technical term, explain it in lay language when you first use it. If you wish to use an acronym or abbreviation, write it in full with the acronym or abbreviation following it in brackets when it first appears. Consideration should be given to the design and layout of the document, including the font size and lettering chosen, as this will affect your ability to produce clear, unambiguous material that people will be able to understand.

The following general guidelines apply:

- The Information Sheet is one aspect of providing information so that people may come to informed decisions about their involvement in research. It must not replace personal communication between the investigator and the potential subject.
- The investigator should ensure that the potential subject has the mental capacity and English comprehension necessary and is given sufficient time to consider the verbal and written information provided, and to discuss it with other people, before being asked to give consent to involvement.
- The Information Sheet is to remain the property of the subject and a copy of the signed Consent Form should also be provided on request.

The following information is considered necessary, if relevant, for the provision of informed consent:

- the purpose of the study
- the fact that the study is a research procedure
- the duration of the study
- the expected benefits from the study, either for the subject or community, including a statement indicating that these benefits are no means assured.
- an account of all procedures to be performed, including the use of drugs or radioisotopes
- alternative procedures or treatments for patients, if they elect not to enter the study
- the risks and adverse effects, if known, that are reasonably likely to be experienced by the subject
- a comparison of the nature and probability of adverse effects from the drug or procedure proposed by the researcher with those from other drugs or procedures used for the same purpose
- an explanation that a placebo is involved and what this means
- the discomforts, inconveniences and restrictions, both immediate and late (especially after leaving hospital) that will be involved. This includes absence from work and travel
- that the subjects should advise the investigator of any other studies in which they are participating
- that the subjects be advised that should they require elective or emergency surgery or other medical care
- they should inform the doctors looking after them about the study in which they are participating
- a statement that the subject may withdraw from the study at any time without prejudice to their ongoing care and treatment
- the measures that will be taken in the event of therapeutic failure or an adverse event
- the insurances and other procedures for compensation in case of injury due to the study
- a statement regarding availability of drug/treatment at the conclusion of the study
- that the subject's study records may be viewed for the purposes of source data audit by authorised persons within (e.g. research committee) or outside (e.g. sponsors or regulatory bodies) the hospital
- assurances of confidentiality
- the name and telephone number of at least one member of the research group who can be contacted by the subject if any problems arise and also of the nominated member of the Ethics Committee to provide access to an independent opinion.

The following information expands on that specified above

- **Include the title of the study. The title must match exactly the title on the consent form.** If the title is complex, a simplified title should also be used, and both titles should appear as a heading, with the complex title in brackets**.**

- **Invite the person to take part in the study** eg '*You are invited to take part...*', '*We are inviting people, such as yourself, with condition X ....'*. Be careful with your pronouns. Use the second person (you) pronoun throughout the entire information sheet and the first person (I) in the consent form.

- **State the purpose and length of the study**
  --Explain *all* the purposes of the study.

  --Make it clear that the study involves research and/or the use of an experimental drug or method of treatment.

  --State how long the participant will be involved in the study.

- **Describe the procedures to be performed, including drugs to be administered**
  --State the approximate number of subjects to be involved in the study.

  --Name all procedures, processes, tests, questionnaires that will involve the subject.

  --Explain the nature of each procedure in lay terms. It may be helpful to think of the procedures in the following terms:
    i) clinically indicated procedure performed with routine amount/frequency
    ii) clinically indicated procedure performed with greater than routine amount/frequency
    iii) experimental procedure

  For a procedure of the first type it may be satisfactory to include a brief description in the information sheet and to provide separately the standard information which would normally be provided to a patient undergoing this procedure as part of their routine clinical care. (A copy of any additional documentation to be provided to subjects should be submitted to the Committee). For the second type of procedure you should discuss the risks associated with having the procedure in more than the usual amount/frequency. For an experimental procedure you must give a comprehensive description.

  If you take **blood samples** you must disclose how much blood you will be taking and how often. The amount of blood should be described both in mls and more commonly understood amounts, such as teaspoonsful. The risk associated with the procedure should also be disclosed.

  For example,
  "You will be asked to allow a 10 ml (about two teaspoonsful) sample of blood to be collected. The blood sample will be collected from a vein in your arm with a needle (venepuncture). Whenever a blood sample is taken, there is a very small risk of local irritation and pain, bruising, infection or feeling faint."

  Sometimes arterial blood gas samples are required in research studies and the following wording is recommended.
  "Arterial blood gas analysis means taking a 2ml (less than half a teaspoonful) sample of arterial blood with a small needle from an artery in your forearm to measure the levels of oxygen and carbon dioxide in your blood. There is a mild to moderate amount of pain associated with this and there can be swelling and bruising after the needle is withdrawn. You will be asked to put pressure on your wrist over the spot where the blood was withdrawn for 5 to 10 minutes to reduce the chance of swelling or bruising."

  If you need to perform any procedure that exposes the subject to **radiation**, state the total exposure during the study by relating it to a common procedure that the subject is likely to be familiar with, for example, a chest X-ray. However, if the radiation is to be taken internally then equating it with an external source, such as a chest X-ray, may be inappropriate. Advice should be sought from the South Australian Health Commission Radiation Protection Branch.

  If a **drug** is to be administered then you need to specify the name of the drug, the route of administration, the dose to be given, describe any reasonable foreseeable risks and adverse effects. In some circumstances it may be appropriate to state that the treatment may involve risks that are currently unforeseeable.

  For example, "*Since X is an experimental drug not all the side effects are known at this time."*
  It may be also appropriate to tell the subject that they will be advised of any significant new findings which develop during the course of the research which may affect their willingness to continue. For example, *"Any new findings which might cause you to change your mind about participating in this study will be reported to you immediately".*

You should state that there is no guarantee that continued treatment with the study drug will continue at the conclusion of the study.

In the case of **investigational drugs** it is necessary to disclose to whom the study records will be made available.

For example*, "You should be aware that the results from this study may be processed by computer, but your name will not be used in the data entered on the computer. Representatives from the Ethics Committee, the sponsoring company for this study and Government Regulatory Authorities may need to access your medical record for information related to the study. You are asked to consent to this access should it be required. All data collected during the study will be regarded as confidential".*

Members of the Committee may need to access study records for the purposes of monitoring, and the following statement can be used: *"As part of its responsibilities members of the Ethics Committee may need to access study and medical records from time to time. This will be done in a way that respects and protects your privacy."*

If a **placebo** is to be used then this should be disclosed.

For example, *"During the study you may receive a capsule/tablet/injection that contains no active ingredient (placebo) yet appears identical to the active treatment. Neither you nor your doctor will know until the study is complete whether you received active treatment or the inactive (placebo) treatment. The reason for using placebo capsules is to reduce the chance of any bias occurring in the results of the study. If in an emergency your doctor needs to know which treatment you have received then the code can be broken."*

Trying to communicate difficult concepts such as clinical uncertainty and **randomisation** to patients is not easy. The following wording is recommended: *"You will be allocated to one of the treatment groups by a process called randomisation which will ensure that there is an equal chance of you being allocated to either (any one) treatment group."*

The name of the sponsoring company should be omitted. It should be referred to as 'the sponsor'.

If a **questionnaire** is to be administered you need to state the time required to complete it and include a brief outline of the nature of the questions involved. If possible the questionnaire itself should be provided for the Committee's consideration. In particular, disclose if some questions are of a sensitive nature and whether subjects are allowed to skip questions which they find intrusive or unable to answer.

The subject should be informed of the **length of time** of each visit needed for the study.

- **A statement that the subject may withdraw from the study at any time without prejudice to their ongoing care and treatment should be included**
  For example, *"Your participation in the study is entirely voluntary and you have the right to withdraw from the study at any time. If you decide not to participate in this study or if you withdraw from the study, you may do this freely without prejudice to any future treatment St Andrew's Hospital. If you have a concession or veteran entitlement, this will not be affected by your participation in or withdrawal from this study."*

- **An assurance of confidentiality should be given**
  For example, *"All records containing personal information will remain confidential and no information which could lead to identification of any individual will be released."*

- **The name and telephone number of at least one member of the research group who can be contacted by the subject if any problems arise and also of the Executive Officer of the Research and Ethics Committee to provide access to an independent opinion**
  For example*, "Should you require further details about the study, either before, during or after the study, you may contact.....Tel....."*
  "This study has been approved by the Ethics Committee at St Andrew's Hospital, Adelaide. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study, or your rights as a participant, you may contact
  ……..
  of the Ethics Committee at St Andrew's Hospital, Adelaide telephone 8408 2111."

St Andrew's Hospital

PRIVACY STATEMENT for RESEARCH PROTOCOLS

Name of Principal Investigator	
Name of study	
To what uses will the personal information acquired or developed during the study be put?	
What security procedures will be applied to personal information?	
Explain how the data will be retained in accordance with good scientific practice and in a form that is at least as secure as it was in the sources from which the data was obtained	
What safeguards will be applied to protect personal information that will be made available to other researchers or third parties eg sponsors, auditors?	
Who has access to the personal information?	
How long will the personal information be kept?	
Will the final results will be published or made available to other researchers?	
How will this be done?	
What will be done with personal information on completion of the study?	
Will you be using a data base?	
Is the data base de-identified?	

Researchers must identify which Information Privacy Principles (IPPs) might be breached. Copies of the IPPs are available from the Executive Secretary of the Committee.

As the Principal Investigator I hereby certify that I am familiar with the current NHMRC Privacy Guidelines and Guideline under section 95A of the Privacy Act and will comply with these Guidelines and instructions. I will assure that all personnel working on this project are aware of the policies and procedures required to safeguard the personal information acquired or developed during the study.

_____ _____

Signature of Principal Investigator: **Date:**

ST ANDREW'S HOSPITAL *SAMPLE* CONSENT FORM FOR RESEARCH PARTICIPANTS

PROTOCOL TITLE

INVESTIGATOR/S:

I, (name of participant) …….
declare that,

- I freely agree to participate in this research project according to the conditions in the Participant Information Sheet which I confirm has been provided to me.
- I understand, and am satisfied with the explanations that I have been given about the procedures and risks of this research project
- I understand that the procedure/s of this research project may not be of any direct benefit to me
- I declare that I am 18 years of age or over.
- I understand that the results of these studies may be published, but my identity will be kept confidential.
- I have had the opportunity to discuss taking part in this study with a family member or friend.
- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.
- I understand that I am free to withdraw from the study at any stage without prejudice to medical care, both now and in the future. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I understand that representatives from the Hospital Ethics Committee, sponsoring company or Government Regulatory Authorities may need to access my medical record for information related to the study for the purpose of audit. I authorise access to my medical record for this purpose.
- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I understand that I will be given a signed and dated copy of this document to keep.

Signature of Study Participant _____ Date: _____

Declaration by Principal Investigator (PI) or Co-Investigator (CI

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

Signature of PI or CI _____ Date: _____

Witness Declaration (if applicable) –

I declare that I have been present when the research was explained to the above-named participant and to the best of my observation and belief was understood and the consent freely given.

Full Name: _____