



Cancer Institute NSW
Clinical Research Ethics Committee

***Standard Operating Procedures for
Researchers***

Research Ethics in Australia

The term “research ethics”, as used in this Manual, refers specifically to those issues covered by the provisions of the National Statement and Cancer Institute NSW policy. Section 1 of the National Statement describes the principles of research ethics as being:

Integrity – a genuine search for knowledge, adherence to recognised principles of research conduct, honest conduct, and the dissemination and communication of results;

Respect for persons – a regard for the welfare, rights, perceptions, customs and cultural heritage of participants (both individuals and collectives);

Beneficence – the responsibility of the researcher to minimise risks or discomfort to participants (the Cancer Institute NSW absolutely endorses the principle that respect for the dignity and well-being of participants must take precedence over the expected benefits to knowledge);

Justice – there must be a fair distribution of the benefits and burdens associated with participation in the research, and any inclusion / exclusion of subjects on the basis of gender, race, age, etc is essential to the purposes of the research;

Consent – with only the strictest exceptions, the informed and voluntary consent of potential participants must be obtained before they are included in research; and

Research merit and safety – research must be justifiable on the basis of its potential contribution to knowledge.

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 001
Title:	Applying for Ethical Review
Function:	To describe the process of applying for ethical review by the Cancer Institute NSW Clinical Research Ethics Committee

Introduction

The Cancer Institute NSW Clinical Research Ethics Committee will only review research involving the participation of humans. This involvement of humans in research extends beyond traditional concepts of participants, and also includes research which impacts upon humans. Consequently, the scope of research involving humans is extremely broad and includes everything from a telephone survey to a clinical drug trial, from focus group work to the use of an innovative therapeutic procedure. Therefore, ethical principles should appropriately be considered when proposing research involving humans.

The National Statement defines research that involves human participation as, *“the use and/or collection of personal, collective or cultural data from participants or from their records, which may include their oral testimony or observed cultural activities, the testing of responses to conditions devised by researchers or invasive testing of new therapies.”*¹

It goes on to state that,

*“some research, particularly outside the health and medical fields, is not performed directly on human subjects but rather involves their informed cooperation in the researcher’s investigation of some human behaviour or some local knowledge base in, for example, the social, cultural, biological or physical environment. This kind of research involves the exchange of knowledge between the researcher and those with whom he or she interacts.”*²

Obtaining appropriate ethical clearance from the Cancer Institute NSW Clinical Research Ethics Committee ensures that researchers:

- Receive assistance/advice from the Committee to ensure they conduct their research in accordance with the relevant regulations / legislation;
- Potentially improve the research design by ensuring that ethical considerations are an integral component of the project; and
- Have their research protocol indemnified by the Treasury Managed Funds, or relevant body.

¹ National Health and Medical Research Council *“National Statement on Conduct in Research Involving Humans”* (1999) page 6

² Ibid, page 7

Procedures

1. Research protocols submitted to the Ethics Committee will be review in accordance with the National Statement.
2. Applications must be received by the relevant closing date to be included on the agenda for the next Ethics Committee meeting.
3. In order to submit an application for ethical review, researchers are required to complete the NHMRC's National Ethics Application Form (NEAF) available at www.neaf.gov.au
4. The following documentation must also be submitted to the Ethics Committee secretariat as per the above procedures;
 - 4.1. Completed application form
 - 4.2. A separate research protocol / project plan
 - 4.3. Any documentation that will be given to research participants
 - 4.4. An Investigation Brochure
5. All documentation is to be completed as follows:
 - 5.1. Text to be no less than 11 point, and in ARIAL font
 - 5.2. Text must be written in a language that can be read, and understood, by a person with an educational level of a fourteen year old child.
6. All documentation received by the Ethics Committee will remain confidential, and be kept in accordance with the Committee's Standard Operating Procedures, the National Statement, and the Cancer Institute NSW Document Retention Policy.
7. Researchers are to follow the procedure listed below when submitting an application:
 - 7.1. Electronically submit one (1) copy of the application via email to ethics@cancerinstitute.org.au quoting 'Clinical Research Ethics Committee' in the title;
 - 7.2. Send, via Australia Post, fifteen (15) copies - (1) application with original signatures plus 14 copies, to:

The Secretariat
Clinical Research Ethics Committee
Cancer Institute NSW
Level 1, Biomedical Building
Australian Technology Park
Eveleigh, NSW 2015
8. Following successful submission of an application, the Ethics Committee Secretariat will email a 'Confirmation of Submission' notice to the relevant contact. This will provide researchers with:
 - 8.1. A unique project number for the application;
 - 8.2. The date of the Ethics Committee meeting their application will be considered; and
 - 8.3. Any other information deemed necessary.
9. Submitted applications reviewed by the Ethics Committee in accordance with its Terms of Reference and Standard Operating Procedures.

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 002
Title:	Outcomes of Ethical Review
Function:	To describe the outcomes of an ethical review by the Cancer Institute NSW Clinical Research Ethics Committee

1. Following review of an application, the Ethics Committee will make one of the following decisions:
 - 1.1. **Approval** - Confirmation that the project has been granted ethical clearance, and notification that the project can be commenced;
 - 1.2. **Approval Pending Clarification / Correction** - Confirmation that the project has been granted conditional ethical clearance, but further information must be submitted about the project (which may include minor modifications to the project);
 - 1.3. **Request further information** – Further information / correction / clarification is required by researchers. The application will be reviewed again following these actions; or
 - 1.4. **Withhold approval** - The project has not been granted ethical clearance (although the researcher may be invited to resubmit once the application / project has been revised.)
2. Researchers will be notified of the outcome of their submission within ten (10) working days of the Ethics Committee meeting at which their application was reviewed.

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 003
Title:	Site Specific Assessments
Function:	To describe the process of obtaining scientific review prior to review by the Ethics Committee

Introduction

As part of the Cancer Institute NSW's move toward single ethical review, a separation of governance issues relating to institutional specific issues is to occur. It is aimed that this separation will result in the Ethics Committee considering issues relating more specifically to research ethics – refer to Section 1 of the National Statement – and governance issues such as contracts, liability, and site suitability will be assessment by each institution wishing to conduct research.

To support this separation, the Cancer Institute NSW is supporting the implementation of Clinical Cancer Research Support Program. A facet of this program is the introduction of Clinical Regulatory Affairs Officers (CRAO) who will be located within Area Health Services throughout NSW. It is the role of these officers to provide researchers with assistance in designing and submitting their research protocols, but also to undertake the assessment of an institutions capability to undertaken research from a governance perspective.

Procedures

1. Researchers are required to make contact with the appropriate CRAO to begin the research governance process. The procedures for doing this may different between Area Health Services, therefore researchers are to refer to the specific institution for further details on this.
2. Researchers must provide the Ethics Committee with confirmation from the appropriate CRAO that the process of research governance assessment has been commenced. This must occur with the initial application submission.
3. The process of research governance assessment will occur in parallel to Ethics Committee review. However, research cannot commence until both the Ethical and Research Governance approval has been granted.
4. Once the research governance assessment has been completed, an approval letter, signed by the Chief Executive Officer of the Area Health Service conducting the researcher, in order to formally approve the research protocol.
5. This copy of this letter will be sent to the Ethics Committee secretariat, and the Chief Investigator. On receipt of this letter, and approval from the Ethics Committee, researchers may commence their study.
6. Researchers are therefore, not required to submit an application for ethical approval to a local HREC if they have submitted an application to a lead human research ethics committee. The decision of the lead HREC will be accepted by local HRECs within NSW Health

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 00
Title:	Multi-Centre Clinical Trials
Function:	To describe the process of obtaining ethical approval for multi-centred clinical trials in NSW

Introduction

Ethical issues relating to, and the clearance arrangements for, multi-institution research can be quite different from those which apply to other projects. Multi-institution research is defined by the [National Statement](#) as including:

- “A research project conducted at more than one institution or organisation either by the same or different researchers, eg a clinical drug trial;
- A research project conducted jointly by researchers affiliated with different institutions or organisations; and
- A research project being conducted by a researcher who changes affiliation from one institution or organisation to another.”³

Under the [Cancer Institute Act 2003 \(NSW\)](#), a requirement to provide a system that facilitates expeditious ethical approval for multi-centre clinical trials and other cancer related research was established by the Cancer Institute NSW.

In association with NSW Health, the Cancer Institute NSW has developed a process of streamlined ethical review for multi-institution research. For the most part, such multi-centre research occurs within the NSW public health system, therefore the following section relates to interactions between the Cancer Institute NSW and NSW Health.

The current program of single ethical review for multi-centre cancer research is working towards fulfilling this statutory requirement. For further information about this process, please refer to the following documents:

- NSW Health Issues Paper, [‘Streamlining the Ethical Review of Multi-Centre Research for NSW Health’](#) (July 2005)
- Cancer Institute NSW Consultation Report: Program 27.1 NSW Cancer Plan [“Streamlining human research ethics review of cancer research in NSW”](#) (November 2005)

NSW Health has accredited the Cancer Institute NSW as a ‘Lead Human Research Ethics Committee’ under their program of single ethical review of multi-centre clinical trial research, primarily in the area of cancer research. Under this system of single ethical review, a research protocol involving multi-centre clinical trials, submitted to a lead human research ethics committee, does not require review by local HREC.

³ National Health and Medical Research Council, *“National Statement on Conduct of Research in Humans”* (1999), Section 3, pp 23 - 24

Procedure

1. Research protocols are to be submitted to the Ethics as per Standard Operating Procedure # 1.
2. If a research protocol has been previously been reviewed by a Lead Human Research Ethics Committee, under the NSW Health model of Single Ethical Review, researchers are not required to submit a new application to the Cancer Institute NSW Clinical Research Ethics Committee.
3. Submitted applications reviewed by the Ethics Committee in accordance with its Terms of Reference and Standard Operating Procedures.

**Cancer Institute NSW Clinical Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 00
Title:	Expedited Review of Research Protocols
Function:	To describe the process of ethical review through an Executive Sub-Committee of the Cancer Institute NSW Clinical Research Ethics Committee

1. Some research protocols put forward for ethical review by the Cancer Institute NSW Ethics Committees, may qualify for expedited ethical review. Protocols which involve clinical drug trials, any invasive physical procedures, or research involving sensitive personal or cultural issues do not qualify for expedited ethical review.
2. The following types of research may qualify for this level of review:
 - 2.1. Research involving a standard or previously approved data instrument;
 - 2.2. Research where the risks associated with the study can be easily minimised, or if they do manifest, easily managed; or
 - 2.3. Research which can be characterised as evaluative or quality improvement activity.
3. If a researcher believes their project qualifies for an expedited ethical review, they should:
 - 3.1. Complete an Expedited Review form available on the Cancer Institute NSW website which will electronically be sent to the Secretariat of the Committee.
4. An Executive Sub-Committee of the Cancer Institute NSW Clinical Research Ethics Committee, who will determine whether or not the project qualifies for expedited ethical review.
5. Possible outcomes following expedited review include:
 - 5.1. Confirmation that the project has been granted ethical clearance by expedited ethical review, and notification that the project can be commenced;
 - 5.2. Confirmation that the project has been granted conditional ethical clearance by expedited ethical review, but further information must be submitted about the project (which may include minor modifications to the project);
 - 5.3. Advice that the project has been referred to the next meeting of the Ethics Committee for consideration; or
 - 5.4. Advice that a full application must be submitted for consideration at the next meeting of the Ethics Committee.
6. All decisions of the panel are subject to ratification at the next meeting of the Cancer Institute NSW Ethics Committee. However, in most cases the researcher will be authorised to commence their project on the basis of the panel's decision.

**Cancer Institute NSW Clinical Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 00
Title:	Scientific Review
Function:	To describe the process of ethical review through an Executive Sub-Committee of the Cancer Institute NSW Clinical Research Ethics Committee

Introduction

The question of whether the assessment of scientific merit should be part of the ethical review process is often a source of considerable disagreement, even within ethics committees. The National Statement discusses the importance of having a system of peer review to ensure that research protocols have scientific merit in their design and objectives specifying that:

- “Every research proposal must demonstrate that the research is justifiable in terms of its potential contribution to knowledge and is based on a thorough study of current literature as well as prior observation, approved previous studies, and where relevant, laboratory and animal studies”.⁴
- All research proposals must be so designed as to ensure that any risks of discomfort or harm to participants are balanced by the likely benefit to be gained.⁵

Research must be conducted or supervised only by persons or teams with experience, qualifications and competence appropriate to the research. Research must only be conducted using facilities appropriate for the research and where there are appropriate skills and resources for dealing with any contingencies that may affect participants.⁶

One of the issues considered during the scientific merit review of a project is the degree to which the stated objectives / expected benefits will be achieved. Where a project is deemed unlikely to achieve its stated objectives / expected benefits this may reopen the question of whether or not the risks associated with the project have been appropriately balanced.

⁴ National Health and Medical Research Council, “*National Statement on Ethical Conduct in Research Involving Humans*”, (1999) Section 1.13

⁵ Ibid, Section 1.14

⁶ Ibid, Section 1.15

Procedures

1. All projects put forward to the Ethics Committee, will be referred to a member(s) the Cancer Institute NSW Scientific Review panel for scientific review.
2. On receipt of an ethical review application, the Ethics Committee secretariat will refer research protocols for scientific research. Reviews will be undertaken by a panel of international and national experts who will be appointed according to the Cancer Institute NSW policy.
3. Scientific reviewers will be required to complete a standard review form via the IT platform which is to be submitted to the scientific review panel for final consultation prior to being released to the Ethics Committee. For a full explanation of the scientific review process, please refer to the Standard Operating Procedure – Scientific Review.

1. Insurance and Indemnity

Researchers and human research ethics committees working within the NSW Public Health Sector are indemnified in respect to “lawful and proper actions” relating to research approved and / or authorised by NSW Health and its authorised bodies, including the Cancer Institute NSW. In practice this means researchers conducting research within NSW, who have obtained appropriate ethical clearance for their work, and who comply with the provisions of the NSW Health research ethics arrangements, the [National Statement](#), and any relevant legislation / regulations will be indemnified by the Treasury Managed Fund for that activity.

If a researcher fails to seek appropriate ethical approval, NSW Health may hold that the researcher has not “diligently and conscientiously endeavoured to carry out his or her duties.” NSW Health, and the Cancer Institute NSW, may also conclude that the activity (eg the conduct of their research project) is neither approved nor authorised. As a consequence such a researcher may not be indemnified by the NSW Treasury Managed Funds for matters relating to their project.

1.1. Legal action relating to a research project

If any member of the research team becomes aware that there may be the potential for legal action to arise from the conduct of their research project, they should not only notify the relevant officer at their institution conducting the research, but also the Cancer Institute NSW Ethics Manager immediately. Such legal action may include a person wishing to seek compensation for alleged damages suffered as a result of the project. The Ethics Manager will initiate contact between the Area Health Service Executive, the NSW Health Legal Branch, the Research Institution, and the research team to investigate the potential action.

Researchers must take every precaution to avoid situations which may result in a research subject taking action against them or the NSW Department of Health, and its authorised bodies. The NSW Department of Health takes this responsibility extremely seriously and expects all researchers will observe their duty of care in regards to research participants and other stakeholders.

1.2. Clinical Trial Notification (CTN) Scheme

The Cancer Institute NSW Ethics Committee is responsible for ensuring that an assessment of the scientific validity of clinical trial design and the safety and efficacy of the medicine or device as well as the ethical acceptability of the trial process occurs prior to granting approval for a clinical trial to commence. All material relevant to a proposed trial should be submitted to the Cancer Institute NSW Ethics Committee by the researcher at the request of the sponsor. The [TGA](#) does not review any data relating to such a trial.

The principal investigator (PI) is required to submit a CTN form to the Cancer Institute NSW Ethics Committee and to the Approving Authority (AA) (where the trial is to be conducted). Once the form is signed by the PI, Chair of the Ethics Committee and the responsible officer of the AA, it is submitted by the sponsor of the trial to the TGA (along with the appropriate notification fee).

1.3. Clinical Trial Exemption (CTX) Scheme

The CTX Scheme is intended to assist HRECs when information about a drug or device is limited, or further advice is required for some other reason. The CTX Scheme involves a sponsor submitting data to the [TGA](#) for evaluation and comment. If no objection is raised, the researcher submits the data to the Cancer Institute NSW Ethics Committee. The Ethics Committee would consider the data, along with comments from the [TGA](#), and assume responsibility for the assessment and where appropriate, approval of the proposal.

The Ethics Committee would normally decide whether a proposed clinical trial should proceed by the CTN or CTX route. To do this effectively, adequate documentation of the process would be required for investigators and the Ethics Committee members.

1.4. Reporting of Serious Adverse Events

**Cancer Institute NSW Clinical Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref: SOP 00

Title: Responsibility of Researchers

Function: To describe the responsibilities of researchers granted ethical approval by the Cancer Institute NSW Clinical Research Ethics Committee

Introduction

The principal responsibility for the ethical conduct of research lies with the researchers themselves. While the Cancer Institute NSW has established policy positions on a range of research issues and research ethics arrangements relating to the clearance, conduct and reporting of research projects, it is the responsibility of individual researchers to ensure their research is conducted in an ethical, legal and appropriate manner.

The Ethics Committee has formulated these standard operating procedures to assist researchers in meeting their responsibilities/obligations. However, the assistance of these resources does not negate the necessity that researchers themselves are aware of the principles which guide ethical research.

Having obtained ethical approval for their research, a researcher must conduct their project in accordance with:

- Their submission to the Cancer Institute NSW Ethics Committee;
- The conditions of approval; or
- Obtain approval for a modification to their project.

The project must at all times be conducted in accordance with the core principles of ethical conduct in research (eg justice, beneficence, and respect for persons). The research team must also continue to conduct their research in accordance with the Cancer Institute NSW ethical review process and the relevant external requirements. If any unexpected ethical issues arise, the research team must bring these to the attention of the Ethics Committee immediately and seek guidance.

Procedures

1. During the conduct of a project, a researcher must immediately report anything which might warrant review of the ethical clearance granted to the project. Under the National Statement such events may involve:
 - 1.1. Serious or unexpected adverse effects on participants;
 - 1.2. Proposed changes in the protocol; and
 - 1.3. Unforeseen events that might affect continued ethical acceptability of the project.⁷
2. The researcher must also:
 - 2.1. Advise the Cancer Institute NSW Ethics Manager immediately if any complaints are made, or expressions of concern are raised, in relation to the project;
 - 2.2. Suspend or modify the project if the risks to participants are found to be disproportionate to the benefits, and immediately advise the Research Ethics Officer of this action;
 - 2.3. Stop any involvement of any participant if continuation of the research may be harmful to that person, and immediately advise the Research Ethics Officer of this action; and
 - 2.4. Provide reports on the progress of the project (including at the completion of data collection / experimentation), as requested by the Committee (see above).
3. Researchers who are unclear of their responsibilities in relation to the ethical conduct of their research and reporting to the Cancer Institute NSW should consult with members of the Cancer Institute NSW Ethics Division.

⁷ National Health and Medical Research Council, '[National Statement on Ethical Conduct in Research Involving Humans](#)' (1999), page 20

**Cancer Institute NSW Clinical Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 001
Title:	Reporting Requirements
Function:	To describe the requirements of researchers granted ethical approval by the Cancer Institute NSW Clinical Research Ethics Committee in reporting to the Ethics Committee

Introduction

Under the National Statement, a HREC must ensure that regular monitoring of ethical compliance occurs for all research protocols granted ethical approval. To do this, the Cancer Institute NSW Clinical Research Ethics Committee requires that researchers submit an annual progress report to the Ethics Committee for review, and determination of ongoing ethical approval.

Procedures

1. The research team must provide the Ethics Committee with reports as outlined in the Cancer Institute NSW Ethics Committee Standard Operating Procedures.
2. Researchers will be required at least annually and/or on the completion of the project, whichever is sooner to submit a progress report to the Ethics Committee for assessing of ongoing ethical approval.
3. The research team must also immediately report to the Committee on any adverse events, complaints or unanticipated ethical issues.
4. The Cancer Institute NSW Ethics Committee has produced a progress report form, which covers such matters as:
 - 4.1. The status of the project;
 - 4.2. Changes to a project / ethical clearance;
 - 4.3. Reporting on the consent obtained for the project;
 - 4.4. Reporting on the effectiveness of risk minimisation / management strategies;
 - 4.5. Whether the identified benefits have / will be achieved; and
 - 4.6. Whether new ethical issues have come to light since the research began.
5. A progress report must be submitted for continued ethical approval at least once every twelve months. When granting a project ethical clearance, the Ethics Committee may decide to request more frequent progress reports.

6. A progress report must also be submitted when the project has been completed.
7. The Cancer Institute NSW Ethics Committee secretariat will issue a reminder letter to the Chief Investigator when a progress report is due.
8. Progress report forms can be accessed at the Cancer Institute NSW website, and a copy with an original signature of the Chief Investigator must be sent to:

The Secretariat
Clinical Research Ethics Committee
Cancer Institute NSW
PO Box 41
Alexandria, NSW 1435

Or email to ethics@cancerinstitute.org.au

9. Progress reports are placed upon the file for the ethical clearance, and maintained in accordance with the Cancer Institute NSW's Document Retention Policy.
10. Researchers who fail to submit an appropriate progress report when asked to do so may have their ethical clearance revoked and/or the ethical clearance of other projects suspended.

**Cancer Institute NSW Clinical Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 001
Title:	Making Changes to a Research Protocol
Function:	To describe the process of making amendments to a research protocols previously given ethical approval by the Cancer Institute NSW Clinical Research Ethics Committee

Introduction

It is not uncommon for research protocols to need some form of changes after it has been submitted for ethical clearance. While it may not be necessary to resubmit the project for full ethical review again, the Cancer Institute NSW has established a formal process for seeking and making such changes.

Research protocols that are altered without observing these arrangements may no longer covered by an ethical clearance. Such a situation may represent a breach of Cancer Institute NSW policy and the [National Statement on Ethical Conduct in Research Involving Humans](#), and could result in serious action being taken against the research team.

Except in the most extenuating and urgent of circumstances approval, the Cancer Institute NSW holds the position that researchers must always be obtained approval from the Cancer Institute NSW Clinical Research Ethics Committee prior to making any modification, minor or major, to a protocol which has been previously submitted for ethical review.

Minor changes to projects include, but are not limited to, such things as:

- Modifications to the research team;
- The inclusion of additional testing / experimentation / data collection (which is consistent with the procedures previously approved by Cancer Institute NSW Ethics Committee); and
- Minor modifications to the participant pool, including the inclusion of new groups (as long as this does not significantly alter the ethical considerations previously reviewed by Cancer Institute NSW Ethics Committee).

Major changes to projects are any changes which cannot be characterised as minor changes. They include, but are not limited to, such things as:

- Significant modifications to the objectives of a project;
- Changes to data collection procedures;
- Additions / changes to research 'sites'; and
- Changes which introduce significant new ethical issues and / or risks.

Procedures

1. Applications for minor changes should be the Chief Investigator, but can be requested by another named member of the research team.
2. Requests should be made in writing, and include:
 - 2.1. The project title,
 - 2.2. The reference number for the ethical clearance granted for the project, and
 - 2.3. The details of the proposed change.
3. Following the receipt of a request, the Ethics Committee secretariat forwards applications for minor changes to the Chair of ethics committee. The Chair is authorised to consider and approve requests for minor changes, in consultation with the Executive Officer of the ethics committee.
4. Upon receiving notification of the Chair's decision, the ethics committee secretariat will write to the Chief Investigator (or nominated contact person) to advise him / her whether or not the request has been approved.
5. The Chair's approval of any minor change is subject to ratification at the next meeting of Cancer Institute NSW Ethics Committee. However, researchers are generally authorised to commence their revised project, on the basis of the Chair's decision, prior to the Committee's ratification.
6. The Ethics Committee secretariat will only write to the Chief Investigator again in relation to this matter if the Committee has any concerns / comments in relation to the minor change.

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 007
Title:	Complaints against Researchers
Function:	To describe the process of handling complaints about researchers and/or research protocols.

Introduction

The [National Statement](#) requires Human Research Ethics Committees (HREC) to monitor the conduct of approved research. The minimum monitoring is annual reporting. The National Statement also requires HRECs to have mechanisms to receive complaints and review decisions. The Cancer Institute NSW supports and complies with the monitoring and investigation requirements of the National Statement.

In monitoring the conduct of research, the Cancer Institute NSW attempts to ensure research is conducted in a manner which complies with highest ethical standards while not being overly intrusive in the efforts of researchers. However, researchers have specific responsibilities in relation to the conduct of research and reporting to the Ethics Committee.

Procedures

1. The National Statement requires institutions to establish mechanisms to receive and investigate complaints or concerns about the conduct of research. This includes:
 - 1.1. Complaints / concerns from participants in research (or contacted potential participants); and/or
 - 1.2. Other appropriate persons (e.g. the parent / guardian of participants, persons excluded from the participant pool, interested third parties).
2. When receiving a complaint from someone other than a participant in the research, the Executive Officer of the Ethics Committee, in conjunction with the Chairperson of the Committee, will determine whether or not the complaint should be accepted / investigated.
3. In accordance with the provisions of the [National Statement](#) informed consent material distributed to potential participants in research must indicate that they can contact the human ethics committee that reviewed the project to raise any complaints or concerns about the ethical conduct of the project.

4. The Contact Information for the Ethics Committee is:

Mr. Rodney Ecclestone
Ethics Manager
Cancer Institute NSW
PO Box 41
Alexandria, NSW 1435
Rodney.ecclestone@cancerinstitute.org.au

5. Upon receiving a formal complaint the contact person will forward any such complaints / concerns to the CCO for investigation and resolution in accordance with the Ethics Committee's Standard Operating Procedures.
6. Complaints and/or concerns will be investigated in a manner determined by the CCO. This may be either a less formal meeting or a formal investigation by the CCO.
7. The Ethics Committee secretariat will confirm receipt of the complaint / concern and indicate to the complainant the investigation process which will be followed and the anticipated timeframe for the investigation;
8. For matters that may be dealt with in a less formal manner, the Chairperson and the Ethics Manager will liaise with the complainant and the Chief Investigator in an attempt to resolve the matter to the satisfaction of all parties. In the event no such resolution can be reached, the matter will be treated as a formal complaint.
9. During the course of the investigation, the project's ethical clearance will be suspended, and no further recruitment or data collection will be undertaken until the outcome is known;
10. However, the CCO or his delegate may decide not to suspend the ethical clearance during the investigation. Researchers wishing to continue data collection must seek, in writing, permission from the CCO.
11. The CCO, or his delegate, may access the documents relating to the project, such as the committee records (eg the original ethics application, progress reports received), and the project records (completed consent forms);
12. It may also be necessary for the CCO, or his delegate, to interview other parties in relation to the project. Depending upon the nature of the complaint, the CCO, or his delegate may also seek internal and external expert advice;
13. The complainant, the researcher(s) and the Ethics Committee should be notified by the CCO, or his delegate of the outcome of the investigation;
14. The CCO, or his delegate should provide the researcher(s) with the details of the complaint, but not the identity of the complainant, or any information which might otherwise identify the complainant, unless it is necessary to do so (in which case the consent of the complainant must be obtained);
15. The researcher(s) will be given have the opportunity to respond to the complaint / concerns;

16. Following an investigation into the alleged complaint, the outcomes may include:
 - 16.1. No action required, beyond noting the complaint and providing a formal response to the complainant;
 - 16.2. The Cancer Institute NSW Ethics Committee reviewing the project's ethical clearance, and recommending revisions to the protocol;
 - 16.3. The project's ethical clearance being withdrawn;
 - 16.4. The matter being considered further under the relevant institutional misconduct / grievance procedures.
17. The Cancer Institute NSW should be notified of the outcome of this process so that it can consider whether its responsibilities under the National Statement have been discharged.
18. The [National Statement](#) requires institutions to establish mechanisms to receive and investigate allegations of breaches of the National Statement. Such complaints could be made by any person, regardless of whether or not they are directly or indirectly involved in the research.
19. Upon receiving a formal complaint, and compiling the relevant documentation, the Ethics Manager forwards any such complaints / concerns to the Chief Cancer Officer/Chief Executive Officer for investigation and resolution in accordance with the procedures outlined in the Cancer Institute NSW Standard Operating Procedures.

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 006
Title:	Appealing a Decision
Function:	To describe the process of appealing a decision of the NSW Population & Health Services Research Ethics Committee

Introduction

Under the National Statement, the Cancer Institute NSW is required to establish mechanisms to receive and investigate appeals against decisions of the Ethics Committee. Such requests could be made by a researcher or member of the Committee. In accordance with these provisions, such requests for appeal are considered by the Chief Cancer Officer/Chief Executive Officer of the Cancer Institute NSW in accordance with the procedures outlined here.

Procedures

1. An investigator may lodge an appeal against a decision of the Ethics Committee to the Chief Cancer Officer or the Chairperson of the Committee.
2. On receipt of an appeal, the CCO or Chairperson will determine whether there is a prima facie case to be considered:
 - 2.1. Whether the Cancer Institute NSW Ethics Committee decision-making process was in accordance with Institutional policy and the National Statement; or
 - 2.2. Whether the substance of the decision is in accordance with the spirit of Institutional policy and the National Statement.
3. If the CCO considers that there is indeed a need for an investigation they must establish a panel to consider the complaint / request for review.
4. The panel should include the following members:
 - 4.1. Chief Cancer Officer/Chief Executive Officer or nominee as the panel's Convenor;
 - 4.2. Two nominees of the Chief Cancer Officer / Chief Executive Officer who would not normally be drawn from the membership of the Cancer Institute NSW Ethics Committee; and
 - 4.3. The Ethics Manager.
5. The panel should afford the Cancer Institute NSW Ethics Committee the opportunity of clarifying its reasons for the decision in dispute.
6. The panel should afford the complainant the opportunity to view and respond to, the clarification provided by the committee.
7. The panel may access the documents relating to the project, such as the committee records (eg the original ethics application, progress reports received). It may also be necessary for the panel to interview other parties in relation to the project (eg representatives of the institution conducting the research).

8. Depending upon the nature of the complaint, the panel may also seek internal and external expert advice.
9. The complainant, the researcher(s) and the Cancer Institute NSW Ethics Committee should be notified by CCO of the outcome of the investigation.
10. Outcomes of an appeal of a decision of the Ethics Committee may be one of the following:
 - 10.1. The appeal is dismissed without investigation;
 - 10.2. The original decision should be upheld;
 - 10.3. The original decision should be set aside and the Committee are asked to reconsider the decision.
11. The decision of the panel cannot discard the original decision of the ethics committee, hence it cannot grant ethical approval for a project.

**NSW Population & Health Service Research Ethics Committee
Standard Operating Procedures – Researchers**

Ref:	SOP 006
Title:	Appealing a Decision
Function:	To describe the process of appealing a decision of the NSW Population & Health Services Research Ethics Committee

Introduction

The risks associated with a research project can be one of the most contentious ethical issues raised by a research protocol. The Cancer Institute NSW Ethics Committee considers the issue of risk in research extremely seriously, and researchers are expected to meet the highest standards in their approach to this important issue

The [National Statement](#) specifically states that, “research proposals must be designed as to ensure that any risks of discomfort or harm to participants are balanced by the likely benefits to be gained”.⁸

Nevertheless, a substantial public benefit cannot be used to justify a substantial detriment to a minority or an individual, unless the subjects have given their voluntary, competent and informed consent to participate in such a study. Even where such consent is obtained, researchers must be confident that their protocol meets the basic ethical principles of research - respect for persons, justice and beneficence. The research team must also be confident that the benefits, in the first instances to the participants, but also to the wider community, justify the risk.

Procedures

1. In developing research protocols, researchers should ensure they consider the risk their proposed research may have on participants. A risk factor must be identified when they are considered to be greater than those experienced in ordinary day-to-day life, and they can be characterised as significant either in terms of likelihood of occurrence and / or seriousness of occurrence.

2. Risks may include:
 - 2.1. Physical pain or discomfort;
 - 2.2. Injury or illness;
 - 2.3. Infection; or
 - 2.4. Psychological distress.
 - 2.5. Loss of professional standing or employability;
 - 2.6. Damage to personal or professional relationships;
 - 2.7. Loss of entitlements or benefits; and
 - 2.8. Exposure to civil, criminal or other liability / proceedings.

⁸ National Health and Medical Research Council, ‘[National Statement on Ethical Conduct in Research Involving Humans](#),’ (1999), section 1.14

3. The identification of risks in research is considered a key planning issue which researchers should address when formulating their research. Failure to consider risks as a research design issue can lead a researcher to make easily avoidable mistakes and result in the delays in obtaining ethical clearance for their work.
4. The research team must disclose in their research ethics submission any and all risk factors.
5. Researchers who fail to appropriately identify and weigh the risks of their study may find that the Ethics Committee reaches the conclusion that they have not considered these risks or sufficiently acknowledged their responsibilities, consequently, deciding against granting ethical approval.
6. The research team must formulate appropriate risk negation / minimisation and management strategies; and
7. The research team must disclose to potential research participants the risk factors, and the risk negation / minimisation and management strategies.
8. In the event of unforeseen adverse events occurring (including a higher than expected incidents of risk factors, or more serious than expected reactions), the research team must suspend their research and immediately report this event to the Ethics Committee.
9. In the case of some risk factors, for example psychological distress or physical harm, the research team should consider the provision of support / treatment services as an appropriate risk management strategy. Such a provision might be made for during or after the research.
10. Services should be made available to research participants free of charge to them (which may require some negotiation with the provider).
11. The research team should consider and discuss issues such as the appropriateness of the service, the ease of access to the service, and the limitations on access to the service. The provision of such services is considered an appropriate risk management strategy.
12. Researchers have a legal duty to take reasonable care in providing other information to participants so they can make an informed choice about whether to take part. This includes information about potential risks and side effects. A person who is not given sufficient information of this type and agrees to a procedure to which he or she would not have agreed if adequately informed, may be able to sue in negligence if he or she suffers injury or loss as a result of the procedure, even if there is no negligence in its actual performance.
13. When providing information to potential participants, researchers must:
 - 13.1. Identify and weigh the risks involved in participation in the project;
 - 13.2. Outline the strategies to negate / minimise the risk; and
 - 13.3. Explain what will be done to manage the risk factors if they occur.
14. Failure to adequately advise potential participants of the risks associated with the study undermines their ability to give their informed consent to participate.

1. Introduction

Recruitment is the phase of a project which involves the participants in the research being identified, approached, screened, and prepared for consent. The recruitment mechanisms used by researchers can raise some serious ethical issues, which, if not handled properly, can:

- Result in the project failing to adhere to the principles which underpin the ethical and appropriate conduct of research;
- Undermine the rights of participants;
- Result in a low participation rate; and
- Lead to official complaints being made about the project/research team to the Cancer Institute NSW.

Unnecessary delays in the commencement of a project often occur when the research team has failed to adequately plan for the ethical issues relating to the recruitment phase of their project, or when their application for ethical clearance fails to provide a complete description of this process.

2. Planning for recruitment

When planning for the recruitment phase of a project, researcher should consider a number of ethical issues when designing their protocol. If such consideration is given during the design phase of the research protocol, the likelihood of ethical issues being raised by the Cancer Institute NSW Ethics Committee is minimised. In relation to the potential pool of participants, research should consider the following ethical issues:

- The details of the project's potential participant pool
 - Will participants be limited to a particular demographic;
 - Why was the participant pool selected;
 - Whether there any special ethical issues relating to the participant pool and their recruitment;
 - Are the potential participants in a dependent relationship with the research team or sponsoring agency;
 - Are the potential participants minors;
 - Do the potential participants have a mental or intellectual impairment?
- Identification of the potential participants
 - Are they already known to the research team,
 - Are they the users of a particular service, or
 - Do they appear on a database of some kind?
- First contact with the potential subjects
 - Will a letter of introduction provided to the potential subjects by another party,
 - Will participants be sought by advertisement, or
 - Will the first contact be via face-to-face contact or direct mail

- Whether the subject pool will be screened
 - There should be consideration of justice issues relating to the project and the involvement of the proposed participants;
 - Are there any issues in relation to the equitable distribution of burdens and benefits;
 - Whether or not the potential participants could feel under any pressure to participate, and if so, how this will be managed;
 - Does the research team need to be able to identify respondents from the data collect
 - Why, and does this raise any special ethical issues.
 - Will third parties be able to identify respondents from the data collected or published results?
 - Why and how will this be addressed?
 - Whether the research will involve any physical contact with a person, however slight and the issues regarding the concept of battery;
 - Whether the research will be conducted with participants external to Australia and does this participation raise issues regarding potentially exploitative research relationships with third world populations. This must be considered carefully in relation to research involving financial aid or other benefit to people who are extremely disadvantaged and thus may feel unduly pressured to participate.

There is not a single right or preferred recruitment mechanism. Different types of recruitment are appropriate for different kinds of research methodology and research issues. However, when applying for ethical clearance the research team must demonstrate that they have considered, responded to, and addressed the ethical issues relating to the recruitment of participants. Failure to do so may result in delays in the project being awarded final ethical clearance.

3. Recruiting through Cancer Registries

The Cancer Institute NSW has implemented policy surrounding the recruitment of participants for research protocols through cancer registries managed by the Institute. In particular, the Central Cancer Registry and Pap Test Register have identified processes that researchers must adhere if they wish to recruit participants via these data sets.

4. Access to mailing lists or other information about potential participants

A project can often involve recruiting participants who appear in another organisation's mailing, client or employee list (e.g. patients with a particular condition who are clients of a local clinic, employees of a business, or parents of students with behavioural problems). This is an acceptable starting point for a recruitment mechanism and may be a highly appropriate to some studies. However, such an approach can cause significant concern amongst potential participants and raise several ethical issues which must be addressed.

The organisation which possesses the information must approve the use of this information for the purposes of the research project. As a general principle, researchers should not access personal information held by another agency / organisation, unless this access has been approved by the participants. Access and use of personal information is within the scope of relevant privacy legislations that exist at both a State and Federal level.

Potential subjects should preferably be contacted by the organisation which possesses the information, or the initial contact from the researcher should be distributed by the organisation. Any correspondence with potential participants should carefully explain what information about them has already been supplied to the research team.

If the researcher is also an officer / member of the organisation which possesses the information, there needs to be a clear process to ensure there is no conflict of interest, they have approval to access and use the data for research purposes, and the informed consent materials supplied to potential participants clearly explains the role of the researcher (eg are they collecting data only for the purposes of the project, or will it also serve some purpose for the organisation).

5. First Contact

During recent years, the initial contact between the research team and the participants has proven a common source of research subject anxiety and concern. Some research projects involve issues or data which might be considered highly sensitive or personal nature (eg relating to medical conditions, illegal conduct or sexual behaviour).

The risk that a potential participant will react negatively to a researcher's initial contact is much higher for research of this kind. They are also likely to be considerably more sensitive to the issue of how their personal information became known to the researchers (see above) and how their confidentiality will be protected.

The Cancer Institute NSW Ethics Committee strongly recommends that where possible, and almost without exception for highly sensitive or personal research, the initial contact be made by a third party who is known to the potential subjects (treating medical practitioner, support group, etc). The potential participants can then decide whether or not they are interested in participating and can then initiate contact with the research team. It is also recommended that the researchers not know the identities of the potential participants until they contact the research team. Obviously there are other forms of mechanisms which allow for the same kind of "one step removed" recruitment (eg advertisements).

The materials / information provided to potential participants must provide a brief explanation of the project, and invite them to contact the research team for further information. Potential participants should also be informed of whether or not the research team has been provided any identifying and personal information about them (such as their address), so that they can indicate whether they wish this information to be destroyed.

6. Reimbursing participants

The decision to reimburse participants generally indicates that the researchers are concerned that they will not recruit a sufficient participant pool unless they reimburse the subjects for their expenses and time. However, the need to "reward" participants for their decision to participate in a study raises questions as to the degree to which their decision is voluntary and informed (especially if the level of the "reimbursement" could be seen as highly attractive to the potential participant pool).

Some reimbursements, such as those to directly cover transportation to the research site, are relatively straightforward and appropriate. Anything which simply involves

reimbursing the participants for their out of pocket expenses, incurred as a result of their participation in the project, is likely to be considered acceptable.

However, if reimbursement is offered to participants for out of pocket expenses, the research team must ensure that the participants are aware of the maximum dollar value of the reimbursement, the amount of proof / documentation which must be provided, and how long it will take for the reimbursement to be paid. Furthermore, even if a participant withdraws partway through your study, they must still be reimbursed for the costs they have incurred.

7. Screening

The principal reasons for incorporating a screening mechanism into a project's recruitment process are either to:

- Identify potential participants who, for whatever reason, do not match the profile of persons sought for the participant pool; or
- Exclude those persons who are considered to have a higher than acceptable chance of suffering from the identified risks for the project, or if the risk factors occur they may suffer a greater than acceptable outcome.

There are several issues which should be considered by researchers in relation to screening and their project's recruitment process.

8. Risk factors

Researchers should carefully consider whether their potential participant pool may include persons who are particularly susceptible to the identified risk factors, or who will suffer greater consequences if the risk factors occur (eg when conducting research involving endurance testing, the research team may need to screen persons with certain medical conditions). If a researcher believes their potential participant pool may include such persons they should include in their recruitment process a mechanism to identify these persons and exclude them from the study.

Potential participants should be advised of the details and purpose of any screening mechanism so they are aware of:

- Why, despite their interest in participating in the project, they might be excluded;
- The existence of greater risks for some persons, and;
- So potential participants can self identify if they are aware they belong to a group who should be excluded from the project.

9. Negative consequences of inclusion or exclusion

Persons who are included or excluded from a project may suffer negative consequences (eg young women participating in research where they are excluded because of a risk of pregnancy may suffer negative consequences because of the right or wrong assumption by others that they are in fact pregnant).

The research team must carefully plan to minimise this secondary risk associated with the project. This may require a modification to the recruitment mechanism to protect the confidentiality / anonymity of potential participants.

10. Consent for screening

In many cases it may be necessary or desirable to screen potential participants prior to their giving informed consent for their participation in the project. Where there are any risks associated with the screening (including the kind of negative consequences described above) written informed consent should preferably be obtained prior to the conduct of the screening process. However, where this is not possible, the research team should carefully describe the procedure, the risks, the minimisation and management of these risks, and the purposes of the screening, before obtaining verbal consent (which should be recorded, dated and countersigned by the researcher) for the procedure.

11. Information to be provided to potential participants

Potential participants should be provided, in lay terms, a description of:

- How they were identified;
- What information the research team has access to about them;
- Whether there will be any screening of potential participants (see above); and
- Whether potential participants are being asked to self identify (eg if they have particular medical conditions).

Some of this information might be most appropriately provided at the point of first contact (eg initial approach letter, or advertisement) and / or with further information provided in the informed consent package provided to those potential participants who appear to be interested in participating and have not been excluded by the screening process.

12. Information to be provided to Cancer Institute NSW Ethics Committee

Researchers should ensure that, in addition to providing the Ethics Committee with a complete description of their recruitment process, screening mechanism and response to the ethical issues arising from them, they also provide the Ethics Committee with:

- Copies of any agency approvals for access to information relating to potential participants, or to distribute information to potential participants; and
- Copies of any material to be used to recruit participants (eg initial approach letter, material to be supplied to third parties who may approach potential participants or advertisements).

Where this documentation is not yet available, the research team should indicate whether it is in the process of being sought.

1. Introduction

Obtaining consent from participants in research is one of the most important elements of the ethical conduct of a project. Researchers can obtain consent from participants of research, however, to be considered ethically acceptable this consent must be:

- Voluntary;
- Competent;
- Informed; and
- Understood.

With the release of the National Statement, the Australian research community has clearly established that all research involving the participation of humans (not just medical research) must be conducted in an ethical fashion and consent should be obtained from participants before any project can be conducted. The [National Statement](#) states, “the ethical and legal requirements of consent have two aspects: the provision of information and the capacity to make a voluntary choice.”

In relation to the provision of information, the Cancer Institute NSW Ethics Committee requires that in obtaining consent, researchers should:

- Provide participants with information, at their level of comprehension, about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research (including the likelihood and form of publication of research results); and
- The exercise of a voluntary choice to participate.

Secondly, the principal of the National Statement that a person may refuse to participate in a research project and need give no reasons, or justification for that choice is also upheld by the Cancer Institute NSW Ethics Committee. Where consent to participate is required, research must be so designed that each participant's consent is clearly established, whether by a signed form, return of a survey, recorded agreement for interview, or other sufficient means. The consent of a person to

participate in research must not be subject to any coercion, or to any inducement or influence which could impair its voluntary character.

A participant must be free at any time to withdraw consent to further involvement in the research. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained.⁹

1. Do I need to obtain consent?

The Cancer Institute NSW expects that consent will be obtained from potential participants prior to their involvement in a research project. However, some exceptions to this do apply. This Section outlines some of the established exceptions from these requirements.

When a researcher has sought, and obtained, approval from officers/agencies with responsibility over an area/population to be involved in the research, this does not negate the need to obtain consent from the individual participants. This is a fundamental principle of ethical conduct in research.

2. Consent mechanisms

As noted previously, informed consent involves the exercise of a voluntary choice to participate in a project. There is no one right mechanism to obtain this consent (or put another way, no one right way to obtain the indication from each potential participant of their voluntary choice to participate). Possible mechanisms for obtaining consent include:

- Completion of questionnaire;
- A return of a completed questionnaire indicates consent;
- Verbal consent;
- Researchers make file notes in relation to an individual's decision to participate in the research;
- Written consent;
- A returned signed consent form; or
- Other.

Researchers should determine which consent mechanism is most appropriate for their particular project. The Cancer Institute NSW Ethics Committee will make a case by case judgment as to whether the proposed mechanism is appropriate for the specific project. As well as being an important ethical principle, obtaining and keeping a record of participant consent is an important protection medium for the researchers, not least because it serves as a record of the informed and voluntary nature of the individual participant's decision to participate in the project.

2.1. Completion of a questionnaire

Many projects involve the use of a questionnaire or some form of survey. Where there are no special ethical considerations which apply to the project, the return of a completed questionnaire can be accepted as an indication of the respondent's consent to participate in the project. The researcher's record of consent is a copy of the information provided to potential participants (eg the coversheet used for the questionnaire) and the returned questionnaires.

⁹ National Health and Medical Research Council, 'National Statement on Ethical Conduct in Research Involving Humans' (1999), Pages 12-13

2.2. Verbal consent

While not the most preferred mechanism for obtaining consent, there are situations where verbal consent is considered appropriate, or even desirable. Research in some contexts (e.g. prisons, households experiencing domestic violence) may be such that distributing, collecting and returning written informed consent packages may be inappropriate. In fact, thoughtless action in some cases may place participants at greater risk.

As well as a face-to-face indication of consent, verbal consent mechanisms can include consent which is recorded on audio-video format. Any record of verbal consent must identify the participant (for later reference, if required), and will need to be retained or transcribed. To protect the anonymity / confidentiality of participants, the record of consent should be separated from the collected data and stored in a secure location where access can be controlled.

To be considered acceptable by the Cancer Institute NSW Ethics Committee, there must be compelling reasons for obtaining verbal, rather than written consent. The Cancer Institute NSW Ethics Committee does not regard as persuasive the argument that potential participants will not be prepared to complete a consent form, as this raises questions in relation to the voluntary and informed nature of the consent being sought.

However, persuasive arguments might include;

- The written language competence of the potential participants;
- Justifiable reluctance on the part of participants to sign a consent form (eg if they are undercover law enforcement officers); or
- The actual data collection method (eg telephone interview) makes the signing of a consent form impracticable).

The researcher's record of consent is a copy of the information provided to potential participants (eg the consent script used) and their file note as to the indications of consent received from participants.

2.3. Written consent

Written consent is the most common consent mechanism. However, the term 'written consent' actually covers a range of approaches. A consent form must be written in language which is appropriate for the participant pool. This may mean that the researchers may have to produce separate consent forms for the various cohorts of participants. The researcher's record of consent is a copy of the information provided to potential participants (eg the information package) and the returned and signed consent forms.

2.4. Other consent

The researcher may decide that another consent mechanism may be more appropriate for their project. The Cancer Institute NSW Ethics Committee will only approve the use of another consent mechanism if its use (rather than the more standard mechanisms described in this section) has been justified and any ethical issues arising from the mechanism have been appropriately addressed.

3. Who should consent?

The [National Statement](#) and Cancer Institute NSW policy intentionally employs the broad term participant (as opposed to subject) because it is possible for a person to participate in a project, without being the subject of research.

Consent must be obtained from every participant in the research. This means that the researcher should have a record to confirm that information was provided to each participant and that they subsequently consented to participate in the research (see the previous section of this booklet for more in relation to the mechanisms for providing information to potential participants, obtaining and recording consent).

3.1. Obtaining informed consent

Potential participants in a project will normally be invited to consent after the point of initial contact. This may mean that the potential participants probably already knew something about the project, its purpose and what their involvement may entail. They may also have already indicated some interest in receiving more information in relation to the project.

However, this will vary depending on the type of research being undertaken. For example, some epidemiological research requires the release of personal information without individual consent in order to get details to allow researchers to actually contact potential participants.

4. Duty of care and consent

Researchers have a duty of care to ensure that, prior to obtaining consent from a potential participant, they are satisfied that the person is:

- Capable of giving informed consent; and
- That they have obtained appropriate consent from any person with legal responsibility/guardianship for the potential participant in cases of most minors and/or young people.

Researchers are urged to err on the side of caution. The consent of potential participants should not be accepted unless the researcher is satisfied that they are capable of giving informed consent (unless, as well as the potential participant agreeing, the person with legal responsibility / guardianship for them also gives their consent). If during the conduct of a project it becomes apparent that one of the participants is no longer (or indeed never was) capable of making an informed decision in relation to their participation in the project, the researcher should normally terminate their involvement. Failure to act carefully and appropriately in this regard could have serious consequences.

5. Special Circumstances

5.1. *Consent and the concept of battery (physical contact)*

Under the law of battery, sometimes called trespass, any physical contact with a person, however slight, without his or her consent, or other lawful justification, may give rise to a legal claim for compensation. Researchers are reminded that initiating, directing or engaging in research that involves touching a person is responsible, under the law of battery, for ascertaining that the person has consented to the procedure.

A person's consent is legally effective if that person is informed in broad terms of the nature of the intended procedure and then gives consent. The procedure is then not a battery even if the person does not fully understand what is involved unless there has been misrepresentation or fraud, which may impair the quality of the consent.

5.2. *Consent and minors*

The participation of minors in research raises specific issues relating to consent. However, the following are the general principles which apply to the question of obtaining consent for the participation of minors and/or young people in research:

- The decision of the individual minor/young person themselves must be respected;
- Consent from the individual minor/young person's parent or legal guardian should ordinarily be sought;
- When the researcher is satisfied that the minor / young person is capable of giving their informed consent (i.e. they understand the purpose, nature and risks of the project, and are able to exercise a voluntary and informed decision), their consent must be sought*1; and
- The approval of any agency will legal responsibility for the minor / young persons must be sought.

5.3. *Obtaining consent from persons who are unfamiliar with the language being used*

Some research projects involve the participation of persons who will be unfamiliar with the language being used for the project (eg research conducted within Australia in English, which involves the participation of some subjects of Non-English speaking background, or research conducted overseas in a country with distinct cultural and language groups). The Cancer Institute NSW has established some policy positions on research involving persons unfamiliar with the language being used for the project.

In summary, the Cancer Institute NSW requires special accommodation be made for any such projects (eg consent materials to be produced in the relevant language and/or the availability of an independent person who can translate the materials and assist in seeking additional information about the project).

5.4. *Consent issues and participants who are highly dependent on medical care*

The Cancer Institute NSW recognises the special ethical issues which arise from research involving persons who are highly dependent on medical care, and requires researchers to comply with the relevant provisions of the [National Statement](#). Therefore, the Cancer Institute NSW Ethics Committee requires that the standard requirements in relation to consent be met, but recognises that there may be situations where special arrangements are necessary (eg research where the participants are

unconscious or otherwise unable to communicate, and no special advance health corrective exists).

6. Research involving human tissue

Some research projects will involve the use of cadaveric tissues or other human materials. These tissues / materials may have been extracted / donated specifically for the purposes of a particular research project, for research in general, or extracted as part of a medical procedure. In New South Wales, the use of such tissues / materials is subject to the provisions of the [Human Tissue Act \(NSW\)](#).

These arrangements apply to situations where the tissues/materials to be used in a project were originally extracted / harvested for medical purposes, for example a diagnostic or therapeutic procedure, rather than being extracted / harvested specifically for a particular research project. In summary, the following special consent arrangements apply to such research:

- Where practicable and possible, consent should be obtained from the “donors” or their next of kin for their extracted tissue to be used for research purposes. Such consent should be in accordance with existing legislative provisions;
- Where specific consent is not possible, researchers should obtain from the supplying agency confirmation that:
 - At the time of extraction of the tissues, general consent was obtained from the “donors” or next of kin for them to be used for research, teaching or other scientific purposes; and
 - The supply of these tissues to the research team, for the purposes of the particular research project, is in accordance with the Act.

6.1. Retesting of Human Tissue

In some instances, human tissues and other body materials collected or obtained for a specific project will be banked after the completion of the project. The Cancer Institute NSW Ethics Committee recognises that the retesting of these samples can yield extremely useful information, such as an evaluation of testing procedures, and can limit the burdens placed upon the community through the reuse of samples, therefore reducing the number of samples needed.

However, such retesting raises questions in relation to the consent from “donors” for their samples to be reused. Consequently the Cancer Institute NSW Ethics Committee has established special arrangements for the retesting of human tissues and other body materials.

In summary, researchers planning projects involving human tissues or other body materials collected directly from “donors” are encouraged to include in the informed consent materials a section where the “donors” can indicate their consent for retesting. In all cases, the research team, or persons responsible for maintaining the “bank” of materials, should keep a record of the type of consent obtained from the “donor” for the use of their sample.

For example, a record may indicate that general consent for research was gained when the sample was removed for medical purposes, or specific consent, and consent for retesting, was obtained as part of their participation in a particular project. Researchers proposing the retesting of human tissues or other body materials will need

to obtain ethical clearance for the project. On a case by case basis the Cancer Institute NSW Ethics Committee will decide whether it is appropriate to waive the requirement to obtain specific informed consent from the original “donors”.

7. Information for participants

As noted previously, informed consent also involves the provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research project. The researcher must also have a record to confirm that sufficient information was provided to potential participants so as to enable them to make an informed decision as to whether or not to participate.

Just as there are different consent mechanisms, the Cancer Institute NSW Ethics Committee accepts that potential participants can be provided information in different ways. Some approaches used to deliver information to potential participants works best with a particular consent mechanism. Possible approaches include:

- Questionnaire coversheet;
- An information sheet is attached to the front of the questionnaire/survey;
- Informed consent script;
- The researcher reads a consent script to the potential participant and makes a file note to record that this has occurred;
- An information package;
- This is provided to potential participants with the consent form; or
- Other

1. Children

The Cancer Institute NSW acknowledges it is essential for research to be conducted which has the potential to advance knowledge about, and potentially improve the health and well-being of children and / or young persons suffering or at risk of cancer. However, the conduct of such research raises extra ethical issues which must be considered and addressed. This Section provides an overview of these issues, as well as offering hints and tips to researchers who are planning research involving the participation of children and/or young persons.

Research is essential to advance knowledge about the treatment and prevention of cancer in children and young people, but research involving children and young people should only be conducted where:

- The research question posed is important to the health and well-being of children or young people;
- The participation of children or young people is indispensable because information available from research on other individuals cannot answer the question posed in relation to children or young people;
- The study method is appropriate for children or young people; and
- The circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person.

A HREC must not approve, and consent cannot be given for, research which is contrary to the child's or young person's best interest. A child's or young person's refusal to participate in research must always be respected. The [National Statement](#) includes a specific section (s4) on research involving children and young people. The Cancer Institute NSW Ethics Committee endorses this section and requires its researchers to comply with its provisions.

1.1. *Appropriateness of research involving children*

When conducting research involving the participation of humans, researchers are required to weigh the risks and benefits of the proposed project. Research is generally only considered permissible where the risks to the individual are outweighed by the benefits to the individual, or where the risks to the individual are relatively minor.

The risks for research involving children and / or young people must be negligible or completely outweighed by benefits to the participants (rather than just to the body of knowledge). A project involving children and / or young people cannot be conducted if the research is contrary to the child / young person's best interests.

The [National Statement](#) indicates that research involving children and/or young people should only be conducted where:

- The research question posed is important to the health and well-being of children or young people;
- The participation of children or young people is indispensable because information available from research on other individuals cannot answer the question posed in relation to children or young people;
- The study method is appropriate for children or young people; and

- The circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person.¹⁰

1.2. *Clinical trials involving children*

Historically, data related to children have often been omitted in applications to register new drugs. This has significantly disadvantaged children because it has led to non-availability of paediatric formulations of drugs, as well as a lack of information on which paediatric dosages could be based. Therefore it is important that clinical trials are conducted involving children, although participation by children in clinical trials should only be approved where it is indispensable because information available from research on other individuals cannot answer the question posed in relation to children'.¹¹

1.3. *Consent to children participating in research*

In most cases the consent of the parent / guardian would be necessary before a child / young person could participate in a research project. In a legal sense, it would usually be the parent / guardian who provide consent on behalf of their child.

However, in practice, researchers are encouraged to adopt the following principles:

- When the child / young person is considered able to make a voluntary and informed decision, they should be regarded as the person who will be asked to provide primary consent (i.e. the informed consent materials should be addressed to them), and the parent / guardian should be asked to countersign their son / daughter's consent;
- When the child / young person is considered unable to make a voluntary and informed decision, primary consent should be obtained from the parent / guardian, and consent should normally be obtained from the child / young person through the use of a separate appropriately worded informed consent package; and
- An "invitation to participate"* should be used where it is not considered appropriate to provide the child / young person with a separate appropriately worded informed consent package (eg where the child is very young).

There are instances where it would be appropriate not to provide the child / young person with any materials, and instead rely solely on the parent / guardian for consent (eg where the child is an infant or considered unlikely to understand the kind of "invitation to participate" described above).

However, in the submission to the Cancer Institute NSW Ethics Committee, the research team must demonstrate that they have considered the issues in relation to the participation of minors in research and provide a justification of their decision in relation to the consent / decision of the minors.

1.4. *Research without parent / guardian consent*

There will be situations where it is neither practical nor appropriate to obtain the consent of the parent / guardian (eg research involving "runaway" children where there is some possibility of abuse within the home). The recruitment of children / young persons without parental consent is only considered to be permissible when the

¹⁰ National Health and Medical Research Council, '[National Statement on Ethical Conduct in Research Involving Humans](#)' (1999) page 25

¹¹ Ibid, Section 4.1(b)

research involves no appreciable risk and where the potential participants are of a sufficient age / competence to provide their consent.

In these cases the Cancer Institute NSW accepts that consent can be obtained only from the child / young person themselves. However, it is the researcher's responsibility to determine whether potential participants are capable of providing informed and voluntary consent.

The researcher may elect to consult with an adult who provides care or support to the child / young person (eg a social worker) to confirm whether that person believes the potential participant is capable of providing informed consent for the project. Respecting the decision of the children and / or young people

The [National Statement](#) specifies that, "a child's or young person's refusal to participate in a research project must be respected."¹² In practice this means that regardless of whether or not primary consent (or indeed any consent) is being obtained from the child / young person, their decision as to whether or not to participate in a research project (or to withdraw at a later stage) must be respected.

When the researcher is not dealing directly with the child / young person during the recruitment phase of their project they must take steps to ensure that the child / young person is able to indicate their views on their participation prior to, and during, the project. This can be especially critical when the recruitment or obtaining of consent is being conducted by an authority figure in the child / young person's life (eg parent or teacher).

1.5. Approval by other agencies

The researcher may need to obtain approval from other agencies (eg Department of Child Services) if the research will be conducted on that agency's premises or during a period of time when the potential participants are in the agency's care. Furthermore, prior approval from that agency may be required if the potential participants are to be approached / recruited on the agency's premises or during a period of time when the potential participants are in the agency's care.

Researchers should attach a copy of this approval to their research ethics documentation. Where this approval is pending, an indication of this, and the expected notification date, should be attached to the research ethics documentation.

¹² National Health and Medical Research Council, '[National Statement on Ethical Conduct in Research Involving Humans](#)' (1999), section 4.4

2. Research involving Indigenous Populations

The [National Statement](#) is the authoritative statement on research involving humans. However, the Australian Government has added further information for researchers wishing to conduct research involving indigenous populations. The NHMRC's publication, '[Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research](#)' is, in addition to the National Statement, the authoritative statement on health research involving Aboriginal and Torres Strait Islander Peoples.

This statement has the same status and authority as the National Statement. This means that for health research involving Aboriginal and Torres Strait Islander Peoples both the National Statement and these guidelines apply.

The [National Statement](#) sets out basic principles and guidance specific to types of participants and types of research. To help identify the connection between the National Statement and these Aboriginal and Torres Strait Islander guidelines, the National Statement basic principles are listed under the heading for each of the values identified in the Guidelines.

Research involving human participation is subject to a variety of legal regulation at federal, state and territory levels. Researchers need to conform to relevant legal requirements, and HRECs need to be satisfied that the conduct of research that they approve is lawful. In the event that both the legal requirement and an ethical guideline apply, the legal requirement will prevail, although they will normally be consistent. Where the guidelines prescribe a standard that exceeds that required by law, researchers should apply this higher standard.

2.1. Values & Ethics in Aboriginal and Torres Strait Islander health research

Reciprocity - A mutual obligation exists among members of Aboriginal and Torres Strait Islander families and communities to achieve an equitable distribution of resources, responsibility and capacity and to achieve cohesion and survival of the social order. This mutual obligation extends to the land, animals and other natural elements and features. In contemporary settings the value of reciprocity continues in various forms, and may vary between locations. Examples include the redistribution of income, benefits from the air, land and sea, and the sharing of other resources such as housing.

Respect - Respect for human dignity and worth as a characteristic of relationships between people, and in the way individuals behave, is fundamental to a functioning and moral society. Within Aboriginal and Torres Strait Islander cultures respect is reinforced by and in turn strengthens dignity. A respectful relationship induces trust and cooperation. Strong culture is a personal and collective framework built on respect and trust that promotes dignity and recognition.

Equality - One of the values expressed by Aboriginal and Torres Strait Islander Peoples and cultures is the equal value of people. One of the ways this is reflected is a commitment to distributive fairness and justice. Equality affirms Aboriginal and Torres Strait Islander Peoples right to be different.

Responsibility - Central to Aboriginal and Torres Strait Islander societies and cultures is the recognition of core responsibilities. These responsibilities include those to country, kinship bonds, caring for others and the maintenance of harmony and balance

within and between the physical and spiritual realms. A key responsibility within this framework is to do no harm, including avoiding having an adverse impact on others' abilities to comply with their responsibilities. As well, one person's responsibilities may be shared with others so that they will also be held accountable.

Survival and protection - Aboriginal and Torres Strait Islander Peoples continue to act to protect their cultures and identity from erosion by colonisation and marginalisation. A particular feature of Aboriginal and Torres Strait Islander cultures and these efforts has been the importance of a collective Identity. This collective bond reflects and draws strength from the values base of Aboriginal and Torres Strait Islander Peoples and cultures.

Spirit and integrity - This is an overarching value that binds all others into a coherent whole. It has two components. The first is about the continuity between past, current and future generations. The second is about behaviour, which maintains the coherence of Aboriginal and Torres Strait Islander values and cultures. Any behaviour that diminishes any of the previous five values could not be described as having integrity.

2.2. Researchers Responsibilities

Researchers need to put forward proposals in which each of the following phases of the research process, where relevant, is ethically defensible on the grounds of each of the values of these guidelines:

- Conceptualisation
- Development and approval
- Data collection and management
- Analysis
- Report writing
- Dissemination

Consultation and other strategies that facilitate Aboriginal participation are critical in all phases of this research process.

Although the NHMRC Guidelines are written specifically for health research, the areas relating to ethical relationships in Section 1.3.1 (page 2) and integrating written guidelines with the development of ethical relationships in Section 1.3.2 (page 4) would apply to all research involving Aboriginal and Torres Strait Islander Peoples.

3. Language Difficulties

Either by design, or coincidentally, a research project can involve the participation of persons who are not familiar with the language in which the research is to be conducted. Such research can raise special ethical considerations which must be identified and addressed before such a project can be conducted. This section provides some guidance for researchers in relation to the conduct of such research.

When planning a research project, researchers must consider whether the nature of their participant pool is likely to include persons who will not be familiar with the language in which the research is to be conducted. Furthermore, researchers must ensure that when recruiting participants (especially when recruitment is to be conducted by a third party or at a distance) they are familiar with the language being used.

In itself, the fact that a project involves a person not familiar with the language in which the research is being conducted does not mean that it will require some level of ethical review. As is the case with other projects, the topic, participant pool, risks and other ethical issues associated with the research will must be submitted for some level of ethical review.

The conduct of such research may raise additional ethical issues, which requires the project to be subject to a different level of ethical review than it would be otherwise (e.g. as this may expose the participants to some potential less of employability).

3.1. Recruitment

The recruitment mechanism for a project will need to include special provisions if it is to involve persons who are not familiar with the language in which the research is being conducted. Appropriate modifications include the production of initial contact materials in the relevant language(s) and the use of an interpreter.

A researcher should take similar steps if they only become aware during recruitment that a potential participant is not familiar with the language being used. However, the researcher must be confident that the consent they obtain from such a participant is truly voluntary and informed. Any modification to the recruitment mechanism should be reported to the Cancer Institute NSW Ethics Committee as soon as is practicable.

3.2. Informed consent

If a significant number of potential participants are not familiar with the language in which the research is to be conducted it may be appropriate to draft the informed consent materials in a more appropriate language. Alternatively, the researcher might arrange for an interpreter to assist potential participants to read and understand the informed consent package.

When seeking ethical clearance, the research team should provide a copy of the consent form in the language(s) to be used, an English-language translation, and an assurance that the consent of both packages is the same. If an interpreter is to be used (e.g. to translate the consent form, answer questions from potential participants, or if verbal consent is to be obtained), the details of this person and something indicating their willingness to undertake this role should be provided with any ethics documentation submitted for the project.