NSW SUPPLEMENT: A USER GUIDE

To be inserted immediately after page 2 of the National Statement. The balance of pages to be inserted as per their page numbers.

Background

Researchers conducting research in the NSW public health system, in addition to complying with the NHMRC and AVCC, *National Statement of Ethical Conduct in Human Research* (March 2007) (**National Statement**), must comply with NSW laws and requirements of NSW Health. Others who have an interest in the lawful and ethical conduct of research in the NSW public health system include Human Research Ethics Committees (**HRECS**), (potential) participants in research, administrators and members of the community.

To assist all those concerned with the lawful and ethical conduct of research in the NSW public health system, NSW Health has developed the *NSW Supplement to the National Statement of Ethical Conduct in Human Research* (**NSW Supplement**).

The Research and Ethics Branch of the NSW Department of Health commissioned Geoffrey Bloom & Associates to prepare the first edition of the *NSW Supplement*.

Scope

The NSW Supplement supplements the National Statement for the use of the National Statement within the NSW public health system.

The NSW Supplement summarises relevant New South Wales law and policy. The NSW Supplement often omits relevant New South Wales law and policy where that law or policy adds nothing to the requirements already set out in the National Statement.

For example, the National Statement contains a requirement that no pressure may be used on a subject to obtain consent at paragraph 2.2.9. This same requirement is mirrored in a section of the NSW Health Policy Directive, PD2005_406, Consent to Medical Treatment – Patient Information at section 5. The NSW Supplement makes no mention of the relevant section of the NSW Health Policy Directive.

Use

Researchers, HRECs, administrators and others involved in human research in the NSW public health system should consult the NSW Supplement alongside the National Statement when considering matters dealt with in the National Statement.

To help identify the NSW Supplement within the National Statement, it is preferable for it to be printed on coloured paper, with sections relevant to issues in the National Statement inserted on the page immediately following the relevant page in the National Statement.

For example, a comment about NSW law and policy relating to page 53 of the National Statement will be on a page numbered 53A (or 53B, and so on), to be inserted immediately after page 53.

Updated version of the NSW Supplement

The NSW Supplement in its most updated version is available from NSW Health's website at: **http://www.health.nsw.gov.au/pubs/index.html**

Inserting updates to the NSW Supplement

NSW Health may release updates to the NSW Supplement from time-to-time, to cover changes in NSW law and policy.

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WHEN IS ETHICAL REVIEW NEEDED?

Site specific assessment

NSW Health's PD2007_043, Authorisation of proposals to conduct research on humans within the NSW Public Health System is concerned with the fact that, in addition to any ethical and scientific reviews required for research to be conducted at a NSW public health organisation, the public health organisation must also ensure that the research project meets its research governance requirements. A public health organisation is defined as an area health service, statutory health corporation or affiliated health organisation in respect of its recognised establishments and recognised services. These research governance requirements might include:

- whether the use of its resources (such as facilities, staff and equipment) are appropriate;
- whether the project adheres to its site-specific policies (such as sign-offs from appropriate Heads of Department);
- whether the researchers involved in the project have the relevant training, expertise and experience; and
- whether the project adheres to any other administrative requirements (such as evidence of adequate insurance and indemnity, clinical trial agreement).

These research governance matters are generally site-specific and must therefore be considered for each research project and for each site at which the project is to be conducted. This review or 'site-specific assessment' must be undertaken before the project can be granted authorisation to commence at a site. This is the responsibility of the public health organisation, not its HREC, as the site-specific assessment has a different purpose to, and is separate from, the review undertaken by an HREC.

> *See page 87A of the NSW Supplement for comments about site specific assessment for multi-centre research.*

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RESEARCH MERIT AND INTEGRITY

NSW Health Policy Directive PD2007_035, Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials, covers the issue of research merit and integrity as regards clinical trials. In summary, it provides that:

- All clinical trials (both single-centre and multi-centre) must be scientifically reviewed in accordance with minimum standards before being approved by a NSW Health HREC.
- The conduct of this review is to be evidenced by the completion of an Assessment Checklist and Certification of Scientific Review.
- HRECs should, where possible, rely on their own local arrangements (that is, their own scientific review, review by a clinical trials committee, local expertise, etc) to undertake the scientific review and complete the Assessment Checklist and Certification of Scientific Review.
- Where the HREC cannot rely on its own local arrangements, it must either refer the trial to the Shared Scientific Assessment Scheme (but only if it is a clinical drug trial) or refer the trial to the Therapeutic Goods Administration (TGA) Clinical Trial Exemption (CTX) Scheme and use the documentation approved by the TGA together with the scientific expertise available to the HREC to complete the requisite sections of the Assessment Checklist and Certification of Scientific Review.

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INTRODUCTION: NSW CONSENT POLICY

On the subject of consent to medical treatment within NSW Health generally, see NSW Health Policy Directive, PD2005_406, Consent to Medical Treatment – Patient Information.

2.2.5 Consent to be in writing

Although the general law of consent allows valid consent to be given orally or in some form other than in writing, NSW Health Policy Directive, PD2005_406, Consent to Medical Treatment – Patient Information requires that written consent be obtained for major procedures, using the model consent form that is an attachment to PD2005_406. Major procedures include:

- all operations or procedures requiring general, spinal, or regional anaesthesia or intravenous sedation;
- any invasive procedure or treatment where there are known significant risks or complications;
- blood transfusions or the administration of blood products; and
- experimental treatment for which the approval of an ethics committee is required (unless there are sound reasons for doing otherwise).

The last point is of particular relevance. If a procedure is part of experimental treatment for which the approval of an ethics committee is required, then written consent must be obtained unless there are sound reasons for doing otherwise.

2.2.6 Information to be provided to participants

Paragraph 2.2.6 of the National Statement has an extensive list of information to be provided to potential participants in research.

NSW Health's Guideline, GL2007_035, Human Research Ethics Committees – Standardised Patient Information Sheets (PIS) contains three standardized patient information sheets, containing standardized information, with room for customization, to be provided to potential participants in research. They aim to be in clear, non-technical language in a 'question and answer' format to aid understanding by potential participants. Use of the forms is recommended but optional. The PISs do not replace the need for consent forms, but they do assist a potential participant in deciding whether to consent. The three PISs cover, respectively:

- clinical trials (excluding genetic testing and collection/storage of human tissue),
- trials involving genetic testing and collection of human tissue, and
- tissue 'banking' or storage of tissue samples.

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2.2.14-18 Consent to future use of data and tissue in research

> *See page 19A of the NSW Supplement for information about Standardised Patient Information Sheets (PISs) developed by NSW Health, to be provided to potential participants in research. There are specific PISs covering trials involving genetic testing and collection of human tissue, and tissue 'banking' or storage of tissue samples.*

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2.3.6 Waiver and privacy

Paragraph 2.3.6 of the National Statement states that before deciding to waive the requirement for consent for research using person information in medical research, or personal health information, an HREC or other review body must be satisfied that, among other things:

…

(e) there is sufficient protection of their privacy;

…

(i) the waiver is not prohibited by State, federal, or international law.

Both considerations raise the issue of regulation of privacy in the area of research in New South Wales.

> *See page 29A of the NSW Supplement for a general discussion of NSW privacy law and policy in research.*

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INTRODUCTION: PRIVACY

Privacy generally in NSW Health

NSW Health's PD2005_593, Privacy Manual, Version 2 provides a guide to the legislative obligations imposed on the health system by the *Health Records and Information Privacy Act 2002 (NSW)* ***(NSW Health Privacy Act)*** and outlines procedures to support compliance with the Act in any activity that involves personal health information.

Privacy in research in NSW

This area is primarily covered by the *NSW Health Privacy Act* and the legally binding *Statutory Guidelines on Research* (**Statutory Guidelines**) issued by the NSW Privacy Commissioner under the NSW Health Privacy Act. The Act and the Statutory Guidelines determine the circumstances in which, and the procedures by which, it is permissible to collect, use and disclose health information for the purposes of research in New South Wales.

Nothing in New South Wales law on privacy and research should be inconsistent with the National Statement but New South Wales law does impose some additional requirements and procedures. The Statutory Guidelines restate the requirements in the NSW Health Privacy Act, so that compliance with the Statutory Guidelines will generally ensure compliance with the NSW Health Privacy Act. They also give guidance on how to comply with that Act, and impose additional procedures and requirements. For research that raises the issue of privacy, it will be necessary to review the Statutory Guidelines.

The Statutory Guidelines are on the website of Privacy NSW.

To assist with identifying the applicability of the Statutory Guidelines, the following is an overview of their contents:

- checklist stating when it is permitted to use and disclose health information for research or statistics, and whether it is necessary to comply with the specific requirements of the Statutory Guidelines
- discussion of important considerations for determining whether it is necessary for a specific research proposal to comply with the Statutory Guidelines
- application of the Statutory Guidelines
- procedures to be followed in the use or disclosure of health information pursuant to Health Privacy Principles 10(1)(f)(iii) and 11(1)(f)(iii),including guidance for preparing a proposal to an HREC
- procedures to be followed in the collection of health information consideration by an HREC.

Under the Statutory Guidelines, each year each HREC in New South Wales is required to send the NSW Privacy Commissioner a report on its activities in the previous year, on a form that appears as Appendix C to the Statutory Guidelines.

Similarly, under the Statutory Guidelines, each year each organisation with responsibility for a HREC in New South Wales is required to send the NSW Privacy Commissioner a declaration that its HREC

has complied with the Statutory Guidelines in the previous year, on a form that appears as Appendix D to the Statutory Guidelines.

NEAF

The National Ethics Application Form (***NEAF***) is a project co-sponsored by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice Chancellors' Committee.

NEAF is a web-based tool that has been developed to assist researchers of all disciplines to complete research ethics proposals for submission to HRECs, and to assist HRECs to consistently and efficiently assess these proposals. It has been designed to meet the requirements of relevant national policies with the aim of increasing the efficiency and quality of the ethical review process for all parties involved.

NSW Health has developed a version of NEAF customised to the requirements of research within the NSW public health system. Policy Directive PD2007_026, Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health contains the form, and some comments about the form's specific use within NSW Health. NSW Health's NEAF contains separate questions to help NSW Health HREC's complete their report to the Privacy NSW each year.

Researchers not submitting proposals on NEAF are required to complete the additional NSW Health privacy questions outlined in the "Privacy Addition to HREC Application Form" that is an attachment to Policy Directive PD2007_026, Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health.

Tissue and data

> *See page 19A of the NSW Supplement for information about Standardised Patient Information Sheets (PISs) developed by NSW Health, to be provided to potential participants in research, including a PIS specifically dealing with trials involving genetic testing and collection of human tissue.*

Banking

> See page 19A of the NSW Supplement for information about Standardised Patient Information Sheets (PISs) developed by NSW Health, to be provided to potential participants in research, including a PIS specifically dealing with tissue 'banking' or storage of tissue samples.

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3.2.1 Planning a databank

Paragraph 3.2.1 requires researchers who are planning a databank to describe clearly how their research data will be collected, stored, used and disclosed. Researchers and other institutions who intend to use or disclose individually identifiable data collected for a primary purpose other than use in research should familiarise themselves with the applicable considerations and requirements in the legally binding *Statutory Guidelines on Research* (**Statutory Guidelines**) issued by the NSW Privacy Commissioner under the *Health Records and Information Privacy Act 2002 (NSW)* on 1 September 2004. Among other things, the Statutory Guidelines:

- have a checklist to help determine when it is permitted to use and disclose health information for research or statistics, and whether it is necessary to comply with the specific requirements of the Statutory Guidelines (Part 1, section 1.1)
- list the information to be included in an application for HREC approval (Part 2, section 2.9)
- state the requirements for an HREC considering an application (Part 2, section 4)

3.2.3–7 Data usage

These paragraphs of the National Statement should be read together with the Statutory Guidelines on Research (**Statutory Guidelines**) issued by the *NSW Privacy Commissioner under the Health Records and Information Privacy Act 2002 (NSW)*, which regulate the use or disclosure of individually identifiable data collected for a primary purpose other than use in research. The Statutory Guidelines elaborate on, and impose duties additional to, the National Statement.

> *See page 29A of the NSW Supplement for further information about the Statutory Guidelines.*

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3.3.11 Records

Record keeping for NSW Health is regulated by the State Records Authority of NSW, *General Retention and Disposal Authority 17: Public Health Services: Patient/Client Records* (GDA17). Part 1.4, Retention periods and disposal actions, section 8.0.0 deals with research management.

Records relating to clinical research

Paragraph 8.1.1 states that "Records relating to the conduct of clinical research [including] records or documentation relating to the recruitment and consent of research participants, the collection and analysis of data, preliminary findings, surveys and results [should be retained for] a minimum of 15 years after the date of publication or termination of the study, then destroy[ed]."

This position is mirrored in NSW Health Policy Directive PD2007_038, Clinical Research: Standard Clinical Trial Research Agreement for NSW Public Health Organisations which adopts the standard form Medicines Australia Clinical Trials Agreement, see especially clause 4(9). The agreement must be used for clinical trials that are sponsored by pharmaceutical companies and conducted in NSW public health organisations.

Under paragraph 8.1.3, "Records of requests to access records for approved clinical research purposes where the research proceeds" must also be kept for 15 years after research publication or termination and then destroyed.

Records relating to non clinical research or research not involving humans

Under paragraph 8.1.2, "Records relating to the conduct of non clinical research or research not involving humans [including] records or documentation relating to the recruitment and consent of research participants, the collection and analysis of data, preliminary findings, surveys and results [must be retained for a] minimum of 5 years after date of publication or completion of the research or termination of the study, then destroy[ed]."

Under paragraph 8.1.4, "Records of requests to access records for approved non clinical research purposes where the research proceeds" must also be kept for 5 years after the expected research completion date or date of termination of the study, and then destroyed.

Finally, under paragraph 8.1.5, "Records of requests relating to projects where the research does not proceed [should be retained for a] minimum of 3 years after last action, then destroy[ed]."

3.3.13–18 Respect

A proper consent process is a major component of respect to participants.

On the subject of consent to medical treatment within NSW Health generally, see NSW Health Policy Directive, PD2005_406, Consent to Medical Treatment – Patient Information which provides useful detailed guidance on the topic of consent.

3.3.20 Monitoring of approved clinical research

NSW Health's PD2006_030, Incident Management Policy is NSW Health's policy covering reporting, managing and reviewing serious adverse events, serious adverse drug reactions (ADRs), serious unexpected suspected adverse reactions (SUSARs) and serious adverse device events. This includes such events that occur in the course of human research.

In addition, NSW Health's Guideline GL2005_059, Human Research Ethics Committees (HRECs) – Operations Manual for NSW Health, Standard Operating Procedure 015 contains requirements for researchers with HREC approval to notify the approving HREC about anything that might warrant review of the ethical approval of the project, including serious or unexpected adverse events. The Guideline has a notification form at Attachment F.

For multi-centre research that has received single scientific and ethical review, see NSW Health Policy Directive PD 2007_072, Model for Single Ethical & Scientific Review of Multi-Centre Research. Within the Policy Directive, Standard Operating Procedure 023 relates to reporting to, and review by, the lead HREC of serious and unexpected adverse events.

Standard Operating Procedure 024 relates to monitoring of ethically approved research projects. Among other things, it states that the frequency and type of monitoring shall reflect the degree of risk to research participants. It also requires co-ordinating investigators, for each site at which the research is being undertaken, to provide reports to the approving lead HREC.

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INTRODUCTION: ADDITIONAL CONSENT REQUIREMENTS UNDER NSW LAW

Anatomical examination of a deceased body

Anatomical examination will often be a necessary precursor to the removal of human tissue for research purposes. The *Anatomy Act 1977 (NSW)* imposes a consent and authorisation regime for the anatomical examination of the body of a deceased person.

Under Policy Directive PD2005_341, Use and retention of human tissues including organ donation, post-mortem examination and coronial matters, Section 2, all hospitals or forensic institutes where there are facilities for post-mortem examinations are required to assign at least one Post-mortem Coordinator. The Post-mortem Coordinator is required to provide information, support and assistance to the senior available next-of-kin and relatives when consent for a post-mortem examination is being sought or when a death is being reported to the Coroner.

Researchers must comply with this legislative and policy regime in addition to any requirements in the National Statement.

Consent for use of human tissue

The *Human Tissue Act 1983 (NSW)* overrides, or otherwise affects, the operation of the National Statement in the area of consent for the use of human tissue in research. Sometimes the Act prohibits, or imposes additional conditions on, things that are permitted under the National Statement. Since research involving human tissue in NSW must comply with both the Act and the National Statement, it is important to know about both.

Factors that affect the requirements for consent include whether the tissue:

- was removed before or after 1 November 2003 (the date on which the relevant provisions of the Act came into force),
- was removed from a living person or deceased body,
- was removed from a person alive at the time of the proposed research or since deceased;
- was removed from a child or young person or other person not competent to consent on their own behalf; and
- is in the form of a tissue block or slide.

The Act may require consent not just from the person, or someone permitted to consent on their behalf. It may also require authorisation from the designated officer for the relevant hospital.

NSW Health's main guidance specifically on use of human tissue in research is Guideline GL2006_021, Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research & use of tissue. It is a complicating factor that the Guideline refers to the previous edition of the National Statement however the Guideline is still an excellent guide to the applicable detailed provisions of the Act.

The Guideline:

- *the Act*: outlines the relevant provisions of the Act;

- *HREC responsibilities:* suggests how an HREC should deal with differences between the Act and the National Statement; and
- *conditions on approvals:* suggests wording for conditions on HREC approvals depending on factors that affect the requirements for consent.

Although GL2006_021 is the NSW Health document most likely to be relevant for issues covered in the National Statement, it is worth being aware of NSW Health's policy on human tissue generally: Policy Directive PD2005_341, Use and retention of human tissues including organ donation, post-mortem examination and coronial matters.

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3.4.5 Information and consent

> *See page 19A of the NSW Supplement for information about Standardised Patient Information Sheets (PISs) developed by NSW Health, to be provided to potential participants in research. There are specific PISs covering trials involving clinical trials, genetic testing and collection of human tissue, and tissue 'banking' or storage of tissue samples.*

3.4.7 Additional requirements for written consent

The *Human Tissue Act 1983 (NSW)* imposes requirements for written consent in relation to the use of human tissue in research, over and above the requirements in the National Statement, depending on several factors.

NSW Health's main guidance specifically on use of human tissue in research is Guideline GL2006_021, Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research & use of tissue.

> *See page 39A of the NSW Supplement for more information about the Act and the Guideline.*

3.4.8–9 Cadaveric tissue

The *Human Tissue Act 1983 (NSW)* imposes requirements for written consent in relation to the use of cadaveric human tissue in research, over and above the requirements in the National Statement, depending on several factors.

NSW Health's main guidance specifically on use of human tissue in research is Guideline GL2006_021, Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research & use of tissue.

> *See page 39A of the NSW Supplement for more information about the Act and the Guideline.*

3.4.10 Commercialisation

The *Human Tissue Act 1983 (NSW)* contains its own prohibition on trade in human tissue, independent of the prohibition in the National Statement.

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3.5.7 Transfer of genetic material

Paragraph 3.5.7 imposes conditions on which genetic material may be transferred. Where the genetic material is in the form of human tissue, then the *Human Tissue Act 1983 (NSW)* will apply, possibly imposing additional conditions.

> *See comments on page 39A of the NSW Supplement about the application of the Human Tissue Act 1983 (NSW) to the National Statement.*

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3.5.8 Disclosure of genetic information to family members

The National Statement states that, where people are asked to consent to the collection of their genetic material or information for research, they should be advised of certain information, including under clause (g) of paragraph 3.5.8 that, if the research discloses that a family member may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the approval of an HREC, be offered by a clinician to the family member, even if the research participant does not consent to this.

It is possible that disclosure in the above circumstances may breach the *Health Records and Information Privacy Act 2002 (NSW)*. While disclosure may sometimes be permitted under HPP 11 (1)(c)(i) of that Act, that would only be in the case of a serious and imminent threat to the life, health or safety of the individual or another person. It is recommended to obtain legal advice before disclosing in these circumstances.

3.5.12 Other information to be given

> *See page 19A of the NSW Supplement for information about Standardised Patient Information Sheets (PISs) developed by NSW Health, to be provided to potential participants in research. There are specific PISs covering trials involving clinical trials, genetic testing and collection of human tissue, and tissue 'banking' or storage of tissue samples.*

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3.5.12 Indefinite storage of genetic information

Under clause (d) of paragraph 3.5.12, those whose consent is being sought, for collection of identified or potentially identifiable genetic material or potentially identifiable genetic material or related information, should also be informed that if such consent is not given, the genetic material and data will be disposed of at the end of research, once the sample storage and record-keeping requirements of good research practice have been met.

In the NSW public health system, such records should not be disposed of at the end of research but instead should be kept indefinitely.

Record keeping for NSW Health is regulated by the State Records Authority of NSW, *General Retention and Disposal Authority 17: Public Health Services: Patient/Client Records (GDA17)*. Information relating to genetic reports and records should be retained indefinitely by the organisation responsible for their management under clause 4.2.5 of GDA17. Likewise, records documenting the diagnosis of genetic or inherited disorders should be retained indefinitely by the organisation responsible for their management under clause 1.6.0 of GDA17.

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Legislation: Changes to legislation on stem cells

Since the release of the National Statement, there have been amendments to the Commonwealth legislation that creates the regulatory regime for research on human embryos in Australia, namely, the *Research Involving Human Embryos Act 2006 (Cth)* and the *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*.

Amendments achieving the same effect have been enacted in New South Wales' mirror legislation to confirm that the amended Commonwealth regulatory regime applies in New South Wales. The New South Wales mirror legislation is *Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (NSW)* and the *Research Involving Human Embryos Act 2003 (NSW)*.

The National Statement refers to Ethical guidelines on the *use of assisted reproductive technology in clinical practice and research* (NHMRC, 2004). These guidelines are to be replaced to reflect the legislative amendments referred to above.

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4.1.11–23 The human foetus, or foetal tissue, after separation

Under the *Human Tissue Act 1983 (NSW)*, foetal issue is included in the definition of human tissue, except where the context or subject matter otherwise suggests or requires. That means that the requirements imposed by the Act, that are additional to those in the National Statement, may also apply to a foetus or foetal tissue.

It is necessary to obtain the consent of a pregnant woman for the use of a foetus or foetal tissue, after separation, for research. The Act regulates this situation and must be considered together with the National Statement.

> *See page 39A of the NSW Supplement for more information on the relationship between the Act and the National Statement.*

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INTRODUCTION: NSW POLICY ON CONSENT BY CHILDREN AND YOUNG PEOPLE

The National Statement in the Introduction describes a regime for involvement in decision making for children and young people who may take part in human research. This regime is consistent with NSW law and policy, although NSW Health policy adds some extra considerations.

In is NSW Health policy in PD2005_406, Consent to Medical Treatment – Patient Information that:

- *Under 14 years old:* for research participants under the age of 14 years, the consent of the parent or guardian is necessary;
- *14 or 15 years old:* for research participants who are 14 or 15 years old, it is necessary to make a judgment about the consent to be obtained, whether the participant's consent is sufficient, or whether it should be supplemented by the consent of the parent or guardian; and
- *16 years old and over:* for research participants 16 years old and over, their own consent is sufficient.

Consult PD2005_406, especially sections 25–27, for further elaboration of the basic positions summarised above.

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4.2.7 Respect: Involvement of parents or guardians

> *See comments on page 55A of the NSW Supplement about the necessary level of involvement of parents or guardians in decision making about the participation of a child or young person in human research.*

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4.4.6 Respect: Emergency treatment of children and young people

Under section 174 of the *Children and Young Persons (Care and Protection) Act 1998 (NSW)*, a medical practitioner may carry out medical treatment on a person under 18 years old without the consent of the child or young person or a parent, if the medical practitioner is of the opinion that it is necessary, as a matter of urgency, to carry out the treatment on the child or young person in order to save their life or to prevent serious damage to their health.

This is relevant to research into emergency treatment of children and young people.

4.4.9–13 Process to be followed: People highly dependent on medical care

The National Statement provides at paragraph 4.4.10 that, "Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making a decision, consent should be sought from the participant's guardian, or person or organisation authorised by law..."

Where a person is under 16 years old and cannot consent to their own participation in health research, their parent or guardian has the power to give consent to their participation in human research on their behalf.

> *See page 55A of the NSW Supplement for more information.*

For people 16 years old and over who cannot consent to their own participation in clinical trials, the *Guardianship Act 1987 (NSW)* provides a mechanism for substitute decision making.

This mechanism overrides the statement in paragraph 4.4.13 of the National Statement that "When neither the potential participant nor another on his or her behalf can consider the proposal and give consent, an HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent" subject to stated conditions. In New South Wales, for a person over 16 years old who cannot consent for themselves to be a participant in human research requiring consent, it will never be the HREC that provides the substitute consent and it will always be a person acting pursuant to the *Guardianship Act*.

NSW Health Policy Directive, PD2005_406, Consent to Medical Treatment – Patient Information at Attachment A outlines how the *Guardianship Act* applies to, among other things, clinical trials. This Policy Directive should be consulted for guidance in this area.

The *Guardianship Ac*t has special provisions relating to clinical trials. These are outlined in two documents from the Guardianship Tribunal and available on its website:

- *Access to new treatments through clinical trials; and*
- *Application for approval of a clinical trial.*

An application must be made to the Guardianship Tribunal when a treatment – usually a new treatment – is only available in New South Wales if the recipients take part in a clinical trial and at least one of the likely participants is a person who cannot give valid consent to their own treatment.

The Guardianship Tribunal may not give approval to people unable to provide their own valid consent taking part in a particular clinical trial, unless the following criteria are satisfied:

- only people who have the condition to be treated may be included in the clinical trial;
- there are no substantial risks to the patient, or no greater risks than those posed by existing treatments;
- the development of the treatment has reached a stage at which safety and ethical considerations make it appropriate for the treatment to be available to people who cannot consent to their own treatment;
- the trial has been approved by the relevant ethics committee;
- any relevant National Health and Medical Research Council guidelines have been complied with; and
- when the potential benefits are balanced against potential risks, it is clear that it is in the best interests of people who have the condition to take part in the trial.

These safeguards mean that, for people without capacity to consent, only a people who have suffered a stroke can be enrolled in a trial of medication that, for example, seeks to reduce the level of disability resulting from a stroke. Similarly, for people without capacity to consent, only people who have dementia can be enrolled in a trial that seeks to test medication designed to delay the progress of memory loss resulting from dementia.

These safeguards allow a person without capacity to consent to participate in a clinical trial that either will have therapeutic benefit for that person and/or will be in the best interests of people generally with that condition, subject to compliance with the other safeguarding criteria mentioned above.

It should be noted that in some clinical trials some of the participants will be given a placebo and not the treatment itself.

The 'person responsible' will fit into at least one of the categories listed in the definition under the *Guardianship Act* of 'person responsible', such as guardian, spouse or close personal friend or relative.

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4.5.5–4.5.9 Respect: Consent

> *See notes on page 62A of the NSW Supplement for more information on the process to be followed to obtain valid consent for people with a cognitive impairment, an intellectual disability, or a mental illness.*

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INTRODUCTION

Another document relevant to conduct of research into Aboriginal health is NSW Health's, *NSW Aboriginal Health – Information Guidelines*, which aims to ensure consistency and good practice in the management of health and health-related information about Aboriginal peoples in NSW. This extends to issues surrounding the collection, ownership, storage, security, access, release, usage, reporting and interpretation of information, as well as issues of confidentiality and privacy.

Note the strong recommendation in paragraph 6.4 of the *Guidelines*, where the proposed research has a substantial Aboriginal component, to submit a research proposal to the NSW Aboriginal Health & Medical Research Council's Human Research Ethics Committee, in addition to consideration by a NSW Health HREC.

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5.1.1 Research governance

NSW Health research governance

NSW Health has developed an extensive array of policies and guidelines to direct and support its HRECs. The most significant of these include:

1. Human Research Ethics Committees: Operations Manual for NSW Health HRECs, GL2005_059
2. Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW, GL2007_020
3. Human Research Ethics Committees – Standardised Patient Information Sheets (PIS), GL2007_035
4. Human Research Ethics Committees: Ethical Review for External Entities, PD2007_039
5. Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials, PD2007_035
6. Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health, PD2007_026
7. HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research, PD2007_046
8. Model for Single Ethical & Scientific Review of Multi-Centre Research, PD 2007_072
9. Research – Authorisation of proposals to conduct research on humans [Includes the Site Specific Assessment (SSA) Form & Guidance document for completing the SSA Form], PD2007_043
10. Clinical Research: Standard Clinical Trial Research Agreement for NSW Public Health Organisations – NSW Department of Health, PD2007_038

These NSW Health publications were prepared with reference to the National Statement, or its predecessor, and assist NSW Health in satisfying its obligation under paragraph 5.1.1(b) to ensure that human research conducted within public health organisations is ethically reviewed and monitored in accordance with the National Statement. The NSW Supplement refers to relevant parts of these NSW Health publications.

5.1.3 Ethical review of research proposed by entities external to NSW Health

Paragraph 5.1.3 of the National Statement recognises that institutions may use the processes for ethical review of research established by another organisation. NSW Health permits the use of its HRECs by entities external to NSW Health, under certain terms and conditions set out in Policy Directive, PD2007_039, Human Research Ethics Committees: Ethical Review for External Entities.

The Policy Directive sets out the requirements that must be met for a NSW Health HREC to undertake ethical review of research proposals for individuals or organisations external to the public health system. It also contains a standard agreement between a public health organisation and an external entity, setting out the terms and conditions upon which such ethical review may be conducted. A public health organisation is defined as an area health service, statutory health corporation or affiliated health organisation in respect of its recognised establishments and recognised services.

See NSW Health Policy Directive PD2007_046, Human Research Ethics Committees: Fee Policy for Review of Commercially Sponsored Research, for fees to be charged by public health organisations for:

- carrying out a research governance review of commercially sponsored research (site specific assessments)
- review of commercially sponsored research by their Human Research Ethics Committees (HRECs)
- application fees for the use of the Research Ethics Database (AU RED) which is an electronic application tracking and management system to be used to underpin the operation of the NSW Health system of single ethical and scientific review of multi-centre research.

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5.1.6 Processes for ethical review

The National Statement identifies different types of research according to different levels of risk: negligible, low, or more than low. It may not be necessary to obtain HREC approval for low or negligible risk research.

NSW Health's Guideline, GL2007_020, Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practical Guide for NSW, provides guidance on whether a quality improvement exercise raises ethical risks to participants requiring review by a HREC.

Features of a quality improvement exercise that may require ethical review include whether the exercise involves:

- direct contact with patients, consumers or the public
- risks or burdens beyond routine care, or is otherwise not directly related to routine care, or requires collection of data that is not normally collected in routine care
- collecting data that is sensitive in nature or application
- handling or disclosing identifiable patient data
- data about rare conditions, a small community, Aboriginal or Torres Strait Islander status, or ethnic, religious or minority status
- 'new' interventions, protocols or equipment
- allocation of patients to groups to enable comparisons
- genetic tests/testing
- potentially infringing the rights, privacy or professional reputation of carers, health professionals or institutions
- use of a placebo
- generation of data that may lead to publication.

There is a checklist at Appendix A of the Guideline to help identify features of quality improvement exercises that may require HREC review.

5.1.8 Research involving no more than low risk

Privacy issues may be relevant to the decision on whether research involves no more than low risk.

> *See page 29A of the NSW Supplement for a discussion of issues of privacy and research.*

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5.1.22 Research that can be exempted from review

Privacy issues may be relevant to the decision on whether research can be exempted from review.

> *See page 29A of the NSW Supplement for a discussion of issues of privacy and research.*

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5.1.27 HREC terms of reference

NSW Health's, GL2005_059, Human Research Ethics Committees: Operations Manual for NSW Health HRECs contains extensive sample terms of reference and standard operating procedures, to be customised and adopted by each NSW Health HREC. Topics covered include:

- objectives
- functions
- scope of responsibility
- status of the HREC within the Health Service
- accountability of the HREC
- membership
- conduct
- post approval responsibilities and activities
- complaints and review

5.1.28 Institutional responsibilities for good operation of HRECs

NSW Health's Guideline, GL2005_059, Human Research Ethics Committees: Operations Manual for NSW Health HRECs covers most of the elements identified in the National Statement, paragraph 5.1.28, as institutional responsibilities for the good operation of HRECs.

The table below cross references the elements in the National Statement with the relevant reference in the Guideline, in the terms of reference (**TOR**) section or standard operating procedures (**SOP**) section. Whereas the elements in the National Statement are a simple list, the Guideline generally contains substantial detail, elaborating on the elements.

National Statement	**Guideline**
Member expertise and experience	TOR 12 (HREC Composition), TOR 16 (Education for HREC members), SOP 2 (Membership composition)
Member induction and continuing education	TOR 16 (Education for HREC members), SOP 3.11 (Attending education and training), SOP 4 (Orientation of new HREC members)
Thorough review of research proposals	TOR 20 (Submissions, notifications and approvals), SOP 9 (Consideration of applications)
Expeditious processes	TOR 21 (Expedited review), SOP 11 (Expedited review)
Transparent, consistent and promptly communicated decisions	TOR 7-11 (Accountability), TOR 23 (Advocates and interpreters), TOR 26 (Records), SOP 10 (Minutes), SOP 12 (Notification of decisions), SOP 20 (Record keeping), SOP 24 (Reporting requirements)
Identification and management of conflicts of interest	TOR 15.3 (Declarations of conflicts of interest), SOP 23 (Conflicts of interest)
Publicised HREC membership	No NSW Health policy equivalent
Good communication between the institution, the HREC and researchers	TOR 7–11 (Accountability of HREC), TOR 27(HREC monitoring, researcher reporting of adverse events), TOR 30-32 (Complaints and review), SOP 5 (Submission procedure for new applications), SOP 12 (Notification of HREC decisions), SOP 13 (Amendments and extensions to approved projects), SOP 14 (Handling of adverse events), SOP 15 (Monitoring of approved research), SOP 16 and 17 (Complaints), SOP 24 (HREC reporting requirements)
HREC workload	No NSW Health policy equivalent
Compliance with the National Statement	TOR 1.4 (Compliance with National Statement), SOP 1 (Function of HREC), SOP 9 (Consideration of applications)

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5.1.34-36 Appointment of HREC members

NSW Health's Guidelines, GL2005_059, Human Research Ethics Committees: Operations Manual for NSW Health HRECs covers appointment procedures in detail, including:

- appointment procedures within the area health service
- period of appointment
- signing of undertaking to maintain confidentiality, declare possible conflicts of interest and consent to review of criminal or disciplinary action records
- requirement to attend education and training sessions
- lapse of membership due to lack of attendance.

5.1.37 HREC Procedures

Under the legally binding *Statutory Guidelines on Research* (**Statutory Guidelines**) issued by the NSW Privacy Commissioner under the NSW Health Privacy Act, each year each HREC in New South Wales is required to send the NSW Privacy Commissioner a report on its activities in the previous year, on a form that appears as Appendix C to the Statutory Guidelines.

> *See notes on page 80A, section 5.1.27 of the NSW Supplement for an outline of NSW Health policy on HREC terms of reference and standard operating procedures generally.*

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5.2.2 Review body member responsibilities

In addition to the responsibility to ensure that proposals meet the standards of the National Statement, members of NSW Health HRECs should ensure that proposals comply with NSW laws and NSW Health policy. This NSW Supplement is designed to assist with that responsibility.

> *See notes on page 77A, section 5.1.1 of the NSW Supplement for a list of NSW Health policies dealing specifically with the operation of HRECs.*

5.2.5–12 Researcher responsibilities

> *See notes on page 87A of the NSW Supplement for information about the form that must be completed to seek ethics review.*

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5.2.21-22 Making and communicating decisions

NSW Health's Guidelines, GL2005_059, Human Research Ethics Committees: Operations Manual for NSW Health HRECs, standard operating procedure 9 covers this topic in detail, including that:

- absent HREC members can provide written comments as part of the application consideration process
- the applicant and/or an advocate for any participant or group of participants may be invited to a HREC meeting to aid consideration of an application
- translated participant information sheets and an interpreter should be provided for targeted recruitment of people unfamiliar with English
- decisions on applications should preferably be unanimous, but will be considered carried by a two-thirds majority, as long as that includes at least one lay person; minority views held by two or more members should be noted in the minutes
- where a HREC has asked an applicant for clarification, the provision of further information, or modification of a project, the HREC may delegate authority to review the subsequent submission, and approve the project between meetings, to one of:
  - chairperson alone, or
  - chairperson, in consultation with one or more named members who were present at the meeting or who submitted written comments on the application, or
  - a sub-committee of the HREC.
- a HREC may conduct expedited review of projects in accordance with standard operating procedure 011.

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5.2.23–27 Documents and records

> *See page 36A of the NSW Supplement, section 3.3.11, for information about NSW Health's requirements for keeping and disposing of records relating to research.*

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5.2.31 Degree of agreement needed for HREC decisions

NSW Health's Guidelines, GL2005_059, Human Research Ethics Committees: Operations Manual for NSW Health HRECs, term of reference 24.4 and standard operating procedure 009, paragraph 8 state that while a unanimous decision is preferable a two thirds majority is sufficient for a valid HREC decision, as long as one lay member is included in the majority. Minority views of two or more members should be noted in the minutes.

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INTRODUCTION: SINGLE ETHICAL AND SCIENTIFIC REVIEW OF MULTI-CENTRE RESEARCH

System of single review

NSW Health Policy Directive PD 2007_072, Model for Single Ethical & Scientific Review of Multi-Centre Research establishes a policy under which all human research conducted at multiple sites within the NSW Health will be ethically and scientifically reviewed once only (single review). This means that human research projects that are to be conducted at more than one site and within the jurisdiction of more than one NSW Health HREC (multi-centre research), must be submitted to an accredited lead HREC for single review. This eliminates the need for each local HREC, that is the HREC for each site, to conduct its own review.

Lead HRECs

A lead HREC is one that has been accredited by the NSW Department of Health to conduct the single ethical and scientific review of multi-centre research projects within the NSW public health system. A lead HREC will be accredited in one or more of the following categories of research:

- First Time in Humans (FTIH) and First Time in Patient (FTIP) clinical trials;
- clinical trials other than FTIH or FTIP;
- epidemiological research;
- public health research; and
- health services research.

A list of lead HRECs with their relevant accreditation is available on the NSW Health website at www.health.nsw.gov.au/healthethics.

The applicant may choose to which lead HREC they submit an application for a multi-centre trial, as long as the lead HREC is accredited in the relevant category of research.

Special review requirements exist for some types of research. See NSW Health Policy Directive PD 2007_072, Model for Single Ethical & Scientific Review of Multi-Centre Research at paragraphs 2.5 and 2.6 for research relating to:

- prisoners
- Aborigines or Torres Strait Islanders
- access to statewide data collections managed by NSW Health or the Cancer Institute NSW.

Choosing the right ethics application form

The National Ethics Application Form (**NEAF**) is a project co-sponsored by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice Chancellors' Committee.

NEAF is a web-based tool that has been developed to assist researchers of all disciplines to complete research ethics applications for submission to HRECs, and to assist HRECs to consistently and efficiently assess these applications. It has been designed to meet the requirements of relevant national policies

with the aim of increasing the efficiency and quality of the ethical review process for all parties involved.

NSW Health has developed a version of NEAF customised to the requirements of research within the NSW public health system. The form, and information about the form, are in Policy Directive PD2007_026, Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health. Applications using NEAF are prepared electronically on this version of the form, available at **http://www.ethicsform.org/au** but are then submitted to the relevant HREC in hard copy.

For single site research, local HRECs may continue to accept research applications submitted using the HREC's own application form, though they may also choose to make use of NEAF mandatory. For multi-site research, ethics applications must be submitted on NEAF. The electronic version of NEAF interfaces with the Research Ethics Database (AU RED) which is a web-based research tracking and management mechanism that underpins the multi-site review system.

The use of NEAF will enable NSW Health HRECs to:

- determine whether a research project complies with the *Health Records and Information Privacy Act 2002 (NSW)*, and
- complete the annual report required by Privacy NSW.

Researchers conducting single site research who do not submit applications on NEAF are required to complete the additional NSW Health privacy questions outlined in the "Privacy Addition to HREC Application Form" that is an attachment to Policy Directive PD2007_026, Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health.

Site-specific assessments

Public health organisations (**PHO**s, that is, area health services, statutory health corporations and affiliated health organisations in respect of their recognised establishments and recognised services) retain responsibility for authorising the commencement of research to be undertaken within their institutions. PHOs are required to undertake a site-specific assessment (**SSA**) of each research project, to allow the PHO to consider whether it has the capacity to conduct the research at that site. The SSA will involve consideration of such matters as resources, staff, and patient availability but does not constitute another ethics review.

It is necessary for the researcher to complete a separate SSA Form in addition to the application submitted to the HREC, as only the PHO has responsibility for considering matters of research governance (not the HREC). For multi-centre research, the SSA Form should be completed by the principal investigator at each site, using the online version of the form at **http://www.ethicsform.org/au**.
The online version of the form interfaces with the Research Ethics Database (AU RED) which is a web-based research tracking and management mechanism that will underpin the new system. For single site research, the SSA Form can only be completed online if the NEAF is being used for the ethics application and both forms are being completed at **http://www.ethicsform.org/au**. Otherwise the form may be obtained from the area health service's research ethics and governance unit.

The SSA and lead HREC ethical review may occur in parallel. However the decision to authorise or not authorise the commencement of a research project will only be made by the Chief Executive (or delegate) of the PHO, once the lead HREC has granted approval and the SSA has been satisfactorily completed.

For more information about SSAs, see NSW Health's PD2007_043, Authorisation of proposals to conduct research on humans within the NSW Public Health System, which includes a hard copy of the SSA form and a guidance document for completing the form.

Post authorisation issues

There are a number of issues that may arise once authorisation has been received for research at a specific site, including:

- amendments to an authorised research project
- notification and review of serious and unexpected adverse events
- monitoring of ethically approved projects
- suspension or withdrawal of ethical approval, or authorisation, for a research project
- extension of a multi-centre research project to additional sites.

These issues are covered in NSW Health Policy Directive PD 2007_072, Model for Single Ethical & Scientific Review of Multi-Centre Research.

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NSW Health has an extensive policy dealing with conflicts of interest in Policy Directive PD2005_469, Conflicts of Interest in the Public Health System. The Policy Directive may be helpful in considering any conflict of interest issues that arise in the context of research.

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> *See notes on page 36A, section 3.3.20 of the NSW Supplement, for a discussion of NSW Health policies dealing specifically with monitoring approved research.*

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Handling complaints

NSW Health's Guidelines, GL2005_059, Human Research Ethics Committees: Operations Manual for NSW Health HRECs address procedures in NSW Health for dealing with complaints about the conduct of:

- researchers or research: term of reference 30.1, (Complaints concerning the conduct of a project) and standard operating procedure 16 (Complaints about the conduct of a project), and
- HRECs: term of reference 31.1 (HREC review processes), term of reference 32 (HREC rejection of an application), and standard operating procedure 17 (Complaints regarding the HREC's review processes).

The provisions establish procedures involving the Chief Executive of the area health service housing the HREC. The intent is to involve a party from the area health service that is separate from the HREC, especially for complaints in which the conduct of the HREC is at issue.

Managing records relating to complaints

Record keeping for NSW Health is regulated by the State Records Authority of NSW, *General Retention and Disposal Authority 17: Public Health Services: Patient/Client Records* (GDA17). Part 1.4, Retention periods and disposal actions, section 1.14.0 deals with legal matters and incident management.

Under paragraph 1.14.1, records relating to issues, claims or case matters of major public interest or controversy, or which are precedent setting in nature, or which result in significant changes to the service's or facility's policy or procedures must be kept as State archives.

Under paragraph 1.14.2, records relating to other issues, claims or case matters involving legal action should be kept for a minimum of 15 years after completion or resolution of legal action, or last known contact, and then destroyed.

Under paragraph 1.14.3, records relating to complaints and incidents not involving legal action should be retained for a minimum of 7 years after the last action and then destroyed.

> *See page 36A of the NSW Supplement, paragraph 3.3.11, for managing records relating to research generally.*