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**Revision History**

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### Introduction

* The formally establishes procedure for the Tasmanian publicly funded health system to approve non-HREC levels of ethical and governance reviews for health and medical research projects, in accordance with the *Research Governance Policy Framework* (RGPF) and *National Statement*, unless otherwise stipulated in the Exemption Category (refer Section: [Exemptions from Ethical Review](#_Exemptions_from_Ethical)).
* “Institutions are responsible for establishing procedures for the ethical review of human research” and can “establish levels of ethical review according to the degree of risk involved in the research” and research that carries only low risk “institutions may choose to establish other levels of ethical review and establish a non-HREC level of ethical review” in accordance with the [*Research Governance Policy Framework*](https://www.health.tas.gov.au/about/research/research-governance#research-governance-policy-framework) (RGPF), underpinned by the [National Health and Medical Research Council (NHMRC), *National Statement on Ethical Conduct in Human Research*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1593) *(*2007, updated 2018*)* (the “National Statement”)

### Mandatory Requirements

* The *LRR Procedure* relates to the ethical and scientific review of a health and medical research project only. It remains an institutional decision, following the review of the site-specific assessment (SSA), whether the research project should be conducted at the site.
* The *LRR Procedure* applies to all Tasmanian publicly funded health system health services, inclusive of the Tasmanian Department of Health (DoH) and all the associated service delivery areas, including Communities, Mental Health and Wellbeing.
* The *LRR Procedure* applies to all staff, officers, volunteers, contractors; external individuals, organisations, entities, bodies or institutions (e.g. commercial, non-commercial sponsors and tertiary institutes) that propose to conduct, manage, review and govern low risk research that requires the use of Tasmanian public health system facilities, access to participants (patient and/or public health service employees) and/or their data (medical and personnel records of information) and/or tissue collections held within the authority of the Tasmanian publicly funded health system.
* A health and medical research project regardless of the “risk level” must not commence within the Tasmanian publicly funded health system nor access data without both an ethics approval and institutional approval from the Chief Executive (or equivalent Delegated Authority).
* The *LRR Procedure* is a mandatory statewide procedure to establish a minimum standard and promote a consist approach for non-HREC levels of review in accordance with the *National Statement*, *RGPF* and the *National Mutual Acceptance, Low and Negligible Risk Standard Operating Procedures*.

### Procedure

#### Determination of Risk and Level of Review

* Tasmanian publicly funded health service will use the New South Wales Office of Health and Medical Research Guidelines to determine risk and level of review (Appendix 1).

#### Low Risk Research Non-HREC Reviews

* In accordance with the *LRR Procedure*, the Tasmanian publicly funded health system will conduct non-HREC level of reviews and grant ethical approval for low-risk health and medical research projects conducted within its sites.
* Projects meeting the criteria for low-risk according to the *National Statement and the LRR Procedure* must be submitted on a *Human Research Ethics Application* (HREA). Applicants must also submit a Protocol and all Supporting Documents. Refer *Protocol and Supporting Documents Procedure*.
* In accordance with the National Mutual Acceptance (NMA) Scheme a research project should only undergo one single ethical review. Therefore, only one HREA is required for each research project as it will cover all Tasmanian publicly funded health service sites.
* The committee conducting the non-HREC level of review and granting ethical approval must be independent e.g., the Head of Department (HoD) who is responsible for approving the Financial Analysis as part of the site-specific assessment cannot not also be the authority to give ethical approval.
* The committee conducting the non-HREC review and granting approval must undertake ethical training and have a delegated authority to grant a health and medical research ethics approval within the Tasmanian publicly funded health service.
* The committee must have a committee charter, guiding principles and processes in which to review, approve (and monitor) LRR projects, including authority to refer the project to the Quality Improvement pathway or refer to a full HREC review.
* The committee must document decisions, maintain records and communicate decisions to the applicant via an approval letter.
* Approval letters should clearly:
* List all sites that are approved that are approved from the ethical review.
* State the ethical approval date and the duration of ethical approval.
* Specify the date on which the annual site progress report is due (Refer Monitoring).
* List documents, with version identification and date, associated with the research project that was reviewed and approved.
* Indicate that the research cannot commence at a listed site until site authorisation has been endorsed by the participating site.
* Specify the conditions of the ethics approval and any further specific approval requirements.

#### Monitoring Approved Low Risk Research Projects

* The reviewing committee is also responsible for monitoring the approved project in the same manner as a human research project approved by a full HREC in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007). Refer: *Safety and Monitoring Procedure*.
* Annual or more frequent progress reports to the reviewing committee should be provided by the Coordinating Principal Investigator (CP)I to maintain the approval for the designated period. Continuing approval will be contingent upon receipt of an annual (or more frequent) report. An annual progress report will be due on the **anniversary date of HREC approval** (not on the anniversary date of site authorisation or project commencement).
* Changes required to an approved human research project must be submitted to the committee as an Amendment. This may include, but is not limited to, a change to the protocol or an approved document or addition of a new site.
* Safety events, particularly breaches should be reported on the Safety Reporting Learning System by the responsible investigator as soon as possible. The committee must then be fully informed, and an ethical decision made to allow the research to continue, before a formal amendment process occurs.
* Extension of the ethical approval period may be requested to the reviewing committee prior to expiry of the approval period.

#### Quality Assurance (QA) /Quality Improvement (QI), Audit and Evaluation Activities

* In accordance with the *National Health and Medical Research Council (NHMRC),* [*Ethical Considerations in Quality Assurance and Evaluation Activities*](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities) guideline, the primary purpose of a quality assurance or quality improvement (QA/QI) activity is “to monitor or improve the quality of service delivered by an individual or an organisation” and “terms such as ‘peer review’, ‘quality assurance’, ‘quality improvement’, ‘quality activities’, ‘quality studies’ and ‘audit’ are often used interchangeably”.
* The guideline defines ‘evaluation’ as a “term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives”.
* Regardless of if a proposed project is ‘low risk, QA/QI, audit or evaluation’ all proposed projects should have a level of “ethical consideration or ethical oversight”, but do not systematically require ethical approval from a HREC. Refer to the *Healthcare Quality Improvement Partnership,* [*Guide to managing ethical issues in quality improvement or clinical audit projects*](https://www.hqip.org.uk/wp-content/uploads/2021/01/Final-2021-Guide-to-managing-ethical-issues-in-QI-and-CA-projects.pdf).
* Data collection and analysis for QA/Q activities should be collected and analysed:
  + in accordance with standard operating procedures and clinical practice protocols based on evidence-based practice and benchmarking with state, national and international standards; and
  + expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained.
* Clinical audits are part of continuous QI/QA processes and focus on specific clinical practices and patients’ clinical outcomes (e.g., rates and types of complications following a surgical procedure) and analysis is usually just presentation of simple descriptive measures (averages, proportions etc) or basic measure of difference between groups (e.g., t-tests).
* QA/QI, clinical audits and evaluation activities should be conducted at a departmental level and should be directed/managed by the appropriate department head and/or nursing/allied health lead for internal departmental purposes.
* In accordance with the Department of Health (DoH) *Undertaking Quality Improvement Protocol* (in draft), employees must register their QA/QI activity on the Safety Learning and Reporting System (SRLS).
* Where a staff member has lodged a QA/QI, clinical audit and evaluation activity on the SRLS and the department head and/or nursing/allied health lead determines the proposed activity meets the criteria for non-HREC level, the department head and/or nursing/allied health lead should direct staff to the research pathway (Refer Appendix 1, Figure 1).

#### Publications, Presentations and Journal Requests

* It is not a requirement of the Tasmanian publicly funded health service for a research project or a project meeting the “QA/QI or evaluation” criteria to receive ethics approval for the purposes of publications or presentations of research project outcomes.
* It is the responsibility of the applicant prior to the commencement of any QI/QA or research project to develop a communication output plan and investigate/identify prospective journals and their requirements.
* All persons within the Tasmanian publicly funded health service employed under the *State Service Act* must follow the *DoH Communication Polices* and the accompanying procedures if wanting to publish or present outcomes of a research project or QA/QI, clinical audit or evaluation project.
* An ethics approval from a HREC / non-HREC level of review is not an automatic entitlement to publish or present a research project outcomes and staff must submit a draft of their proposed publication or presentation to the HoD (or the Delegated Authority) as per the DoH [*Delegation Schedule*](https://www.health.tas.gov.au/intranet/ots/ots/corporate_planning_and_risk/dhhs_delegations_and_administrative_authorities) for approval.
* If ethical approval is required by a journal as a condition of publication, a HREC, other ethics review body or non-HREC committee can review a research project and grant ethical approval. However, Editors of most journals will usually accept a letter from the institution confirming that an appropriate ethical review process was used or that ethical review was not required.
* External persons cannot undertake QA/QI, clinical audit or evaluation activities as they are not employed under the *State Service Act*. To be participate or undertake what would be deemed QA/QI, clinical audit or evaluation activities, applicants must follow the RGPF.

#### Submitting a Request for Exemption from Ethical Review

* To request a QI/QA or evaluation activity where there is intent to publish the activity and request an exemption from ethical review:

1. Submit a cover letter addressed to the non-HREC person(s) or committee containing the following:
   1. Statement of what is being requested, e.g. "I am writing to seek an exemption from Human Research Ethics Committee review for the following Quality Assurance activity with intent to publish the findings”
   2. Descriptive title of the activity.
   3. Brief summary of the activity with justification of why this is a Quality Assurance / Audit activity rather than a research study and the ethical issues identified (refer to the *National Statement on Ethical Conduct in Human Research* (p6-7); and *Ethical Considerations in Quality Assurance and Evaluation Activities* (2014);
   4. Contact details (postal address, telephone number and e-mail address) of the applicant.
2. A separate *Proposal Document* containing the following:
   1. Descriptive title of the activity.
   2. Investigators involved (e.g., to the level of potential authorship on any resultant publication);
   3. Literature review including standards of care and relevant indicators.
   4. Aim and Background: Why is this activity being undertaken? What are the standards of care that apply in this case? If standards are not known, what is to be determined? How will the results be used?
   5. Method: Details on participants, or data, to be included (inclusion / exclusion criteria, numbers involved, relevant time periods); what, if anything, participants will be asked to do; variables to be reported on, including outcomes of interest; method of data collection (e.g. chart review); methods used to maintain confidentiality / anonymity; the form the results will take (e.g. descriptive statistics); study timelines; how the exercise might be fed back into an audit or service improvement cycle; where the results are anticipated to be presented external to the institution; references (where relevant).
   6. The *Proposal Document* may be brief but should provide sufficient detail (e.g., 2 - 3 pages). A research protocol template can be used and modified as appropriate (e.g., sample size calculations may not be relevant).
3. Any associated study materials (e.g., data collection tools, patient satisfaction questionnaires).

### Research Governance Review

* The institution providing the non-HREC level of review must ensure that a process of research governance review/institutional authorisation/site specific assessment (referred to collectively as SSA) is undertaken by each participating sites within the Tasmanian publicly funded health organisation.
* **A health and medical research project must not commence at a site until the research project has received site authorisation from the CE (or equivalent Delegated Authority) at the site where the proposed research project is to be conducted regardless of the level of risk to the participant.**

### Roles and Responsibilities/Delegations

#### Chief Executive (CE)/Chief Executive Officer (CEO) (or equivalent) – is responsible for:

* Ensuring adequate resources and structures are in place for effective research governance to meet the requirements of this policy directive and national safety standards; and promote and support a culture of safety and high-quality for research activities.

#### Executive Director/Director (or equivalent) – is responsible for:

* Ensuring compliance with this guideline and promote and support a culture of safety and high-quality in the conduct of research activities conducted at their public health service site.

#### Heads of Department/Division/Supporting Departments – are responsible for:

* Ensuring alignment of the research project to institutional and/or departmental strategic plans and priorities, and the institution has the appropriate facilities and infrastructure to conduct the research.

#### Non-HREC Committee - is responsible for:

* Reviewing the proposed human research project to form a view on its ethical and scientific acceptability (in accordance with the National Statement and this Guideline) and providing the CPI with the outcome of the ethical review. The non-HREC committee decision may include referring the project to the full HREC.
* Monitoring the conduct of the research project including annual progress and/or final reports, safety events particularly misconduct of researchers.
* Ensure the Terms of Reference (ToR) should include membership and meeting dates and reporting arrangements if the non-HREC person(s) or committee is affiliated with a Registered HREC. The non-HREC c person(s) or committee will also need to respond to requests for information from the Registered HREC.

#### Ethics Officer (EEO) - is responsible for:

* Providing expert advice to investigators seeking to undertake research in accordance with relevant national standards, guidelines and institutional policies.
* Providing consultative advice on the LRR / non-HREC process for the ethical review of research projects, including consultative advice to refer staff to QA/QI, evaluation and audit pathways.
* Providing high level secretariat support to the person(s) / LRR committee including documenting decisions and maintain a current record on research activities and communicating review outcomes.
* Providing ongoing monitoring of research activities, including managing amendments, adverse events, annual progress and final reports, managing appeals and notification of complaints, misconduct and conflicts of interest.
* Preparing the annual reporting of LRR activity to the affiliated HREC, NHMRC and DoH.

Coordinating Principal Investigator (CPI) / Principal Investigator (PI) - is responsible for:

* The overall conduct, management and reporting of the project at a public health service site. For single-centre project the CPI/PI roles are generally synonymous.
* Communicating and reporting to the LRR Committee with respect to all information related to the research throughout the life of the research project.
* Taking on the responsibilities as the PI at their own site (as outlined below) if the LRR project is single centre.
* Submitting the research governance forms and supporting documents for site authorisation and liaising with the site Research Governance Officer (RGO) throughout the life of the research project.

Sponsor - is responsible for:

* The initiation, management and financing (or arranging for financing) of the trial and carries the medico-legal responsibility associated with the conduct of the research.
* Where the public health service is the trial Sponsor (e.g. investigator-initiated/collaborative group) the institutions governing body is the Sponsor and ensures that its overarching governance and quality management systems delineate its responsibilities as a trial sponsor from its responsibilities as a trial site and ensures that the requirements of Sponsorship can be met.

**Research Governance Officer (RGO) (or equivalent) -** is responsible for:

* Establishing effective and efficient processing of the governance review processes within the public health service in accordance with relevant guidelines, regulations, and legislation.

### Key Definitions

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| Certified HREC | A Human Research Ethics Committee (HREC) that is certified under the National Certification Scheme may also be referred to as a Lead HREC. |
| Ethical review | The consideration of research by a HREC or other body. |
| Ethical approval | A determination by an ethical review body that a research project satisfies ethical standards and requirements, of the NHMRC, National Statement on Ethical Conduct in Human Research 2007 (National Statement). |
| Evaluation | The systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goal or objective. |
| Human Research Ethics Application Form (HREA) | The HREA is a national, web-based application form for investigators of all disciplines to complete research ethics proposals for submission to HRECs. |
| Human Research Ethics Committee (HREC) | An institution that has established an ethical review body in accordance with NHMRC, National Statement on Ethical Conduct in Human Research 2007 (National Statement) to conduct the scientific and ethical review of research. Internationally, HRECs may be referred to as an Institutional Review Board (IRB) and Institutional Ethics Committee (IEC). |
| Low risk research | Where the only foreseeable risk to the participant is one of discomfort. Discomforts may include things like minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. |
| National Certification Scheme | The certification of HRECs pertains to the certification of their sponsoring institution. To be identified as a ‘Certified Institution’, the institution’s ethical review process has undergone an independent assessment conducted by the NHMRC. Certification is dependent upon a satisfactory demonstration of institutional conformance with specified criteria which, in part, are based on the National Statement - including that the HREC is appropriately constituted, and that its institution’s policies, processes and procedures meet an agreed national set of criteria. A *List of institutions with certified ethics review processes* is available from the NHMRC. |
| National Mutual Acceptance (NMA) | The system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions (public health organisations only) whereby one certified HREC provides the ethical review for a research proposal that is accepted by the other institutions participating in the multi-centre research. |
| Negligible risk research | No foreseeable risk of harm or discomfort and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. |
| Non-HREC level alternative | A person or body (e.g. subcommittee or delegate) that conducts an ethical review of a research project which is an alternative to that of a full HREC. |
| Multi-Centre Research | Research that is conducted at more than one site within the Australian public health system. |
| Participant Information and Consent Form (PICF) | The form providing the reason the participant is being invited to take part in the research project. It uses plain language to explain to potential participants in writing a description of the research and includes a Consent Form to sign. |
| Quality Improvement (QI)/ Quality Assurance (QA) | An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as ‘peer review’, ‘quality assurance’, ‘quality improvement’, ‘quality activities’, ‘quality studies’ and ‘audit’ are often used interchangeably. |
| Research | “Original investigation undertaken to gain knowledge, understanding and insight” (*Australian Code for the Responsible Conduct for Research, 2007*). |
| Single-Centre Trial | Research that is conducted at one site only within the public health system (i.e. single-site research). |
| Single Ethical Review | A process whereby one certified HREC provides the ethical review for a research proposal that is accepted by the other institutions participating in the multi-centre research. See also NMA. |
| Site (institution) | Any public or private entity or medical facility where research is conducted. |
| Site-Specific Assessment (SSA) | A mechanism used by the health service to ensure that the proposed research project complies with governance requirements, and to consider whether the research should be conducted and supported at the proposed site. |
| Site Assessment | A process that assesses research against institutional requirements and strategies and any applicable jurisdictional requirements (including legal obligations). The outcome of a site-specific assessment is site authorisation: a determination by an organisation that a research project to be conducted at one or more of its sites or under its auspices satisfies organisational requirements and may commence at the site/s over which it exercises its authority. |
| Site Authorisation | A determination by an organisation that a research project to be conducted at one or more of its sites or site/s under its auspices satisfies organisational requirements and may commence at the site/s over which it exercises its authority. Site authorisation is the outcome of the site-specific assessment process. |

### Related Documents/Legislation

The following documents provide the guidelines and framework for national approach to single for ethical and scientific review for multi-centre human research project.

* [National Health and Medical Research Council (NHMRC), National Statement on Ethical Conduct in Human Research](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1593)
* [NHMRC, Framework for Monitoring: Guidance for the National Approach to Single Ethical Review of Multi-centre Research](https://www.nhmrc.gov.au/sites/default/files/documents/reports/framework-monitoring.pdf)
* [NHMRC, Research Governance Handbook: Guidance for the National Approach to Single Ethical Review](https://www.nhmrc.gov.au/sites/default/files/documents/reports/research-governance-handbook.pdf)
* [National Mutual Acceptance, Single Ethical Review of Multi-centre Research Projects: HRECS, RGOS AND ORGANISATIONS](https://www.health.tas.gov.au/research/national_mutual_acceptance)
* [National Mutual Acceptance of scientific and ethical review for multi-centre human research projects conducted in public health organisations: Brochure](https://www.health.tas.gov.au/research/national_mutual_acceptance)
* [National Mutual Acceptance of ethical and scientific review for multi-centre human research projects conducted in public health organisations: FACT SHEET](https://www.health.tas.gov.au/research/national_mutual_acceptance)
* [National Mutual Acceptance, Single Ethical Review of Multi-centre Human Research Projects: STANDARD PRINCIPLES FOR OPERATION](https://www.health.tas.gov.au/research/national_mutual_acceptance)
* [Department of Health, Research Governance Policy Framework](https://www.health.tas.gov.au/research/research_governance)
* [Department of Health, Research Governance Procedures](https://www.health.tas.gov.au/research/research_governance)
* [Department of Health, Research Governance Fees Policy](https://www.health.tas.gov.au/research/research_governance)
* [Department of Health, Patient Information and Consent Form Guidelines](https://www.health.tas.gov.au/research/research_governance)
* Department of Health, Quality Improvement Framework
* [Healthcare Quality Improvement Partnership, Guide to managing ethical issues in quality improvement or clinical audit projects](https://www.hqip.org.uk/resource/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects/)

# Appendix 1

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| **NSW OHMR Guidelines for Low and Negligible Risk (LNR) Research Review Processes or Exemption from Ethics Review**  This Guideline represents NSW Health’s Office for Health and Medical Research’s (OHMR’s) interpretation of the *National Statement on Ethical Conduct in Human Research* (the “National Statement”) as it applies to low and negligible risk research. It is intended to provide greater consistency amongst HRECs and others in interpreting and clarifying some of the concepts contained in the National Statement. It should not be used as a substitute for reading and applying those concepts as directly expressed in the National Statement and other related documents.   1. **Determination of level of risk and appropriate level of review per the National Statement**   The National Statement defines risk as *“the function of the magnitude of a harm and the probability that it will occur”.* The types of harm that may be encountered when research is conducted are described below.   |  |  | | --- | --- | | **Types of harm** | **Possible examples** | | Physical harm | Including injury, illness, pain | | Psychological harm | Including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease | | Devaluation of personal worth | Including being humiliated, manipulated or in other ways treated disrespectfully or unjustly | | Social harms | Including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation, findings of previously unknown paternity status, reputational harm to a participant, researcher, institution or community | | Economic harms | Including the imposition of direct or indirect costs on participants | | Legal harms | Including discovery and prosecution of criminal conduct |   Adapted from National Statement, 2007 (updated 2018)  The National Statement permits institutions to establish levels of ethics review that are proportionate to the degree of risk involved, and provides the following definitions:   * **Negligible risk research:** Where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than an inconvenience to participants. Examples of inconvenience in human research may include filling in a form, participating in a de-identified survey or giving up time to participate in a research activity. * **Low risk research:** Where the only foreseeable risk is one of discomfort. Discomforts include, for example, minor side-effects of medication, discomforts related to measuring blood pressure and anxiety induced by an interview. * **More than low risk research:** Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.   Researchers, Human Research Ethics Committees (HRECs) and other ethics review bodies are required to determine the existence, likelihood and severity of risk based on a number of factors including the study’s methodology and design, participant characteristics and the research activity. In some cases, the requirement for full HREC review may be mandated by Australian law (e.g., Commonwealth or state privacy legislation, the Therapeutic Goods Regulations 1990 and the Research Involving Human Embryos Act 2002). Where no such mandate exists, determination of the appropriate review pathway is influenced not only by the risk to participants, but also by a range of other contextual considerations:   * **The level of complexity of the research**: For certain types of research such as complex qualitative research or clinical trials, the HREC may wish undertake/confirm that a rigorous assessment of the methods used to avoid or reduce bias has taken place, as poorly designed research poses risks to data validity and credibility. * **Whether a research activity raises associated ethical issues:** For example:   + The handling of findings that may have health implications for the participant and/or their family   + For research involving the analysis of bio-specimens, the context in which the bio-specimens were acquired or any known limitations the donor(s) placed on their use during the consent process. * **Participant characteristics:** The National Statement outlines ethical considerations specific to participants in Section 4, which may influence the level of ethics review required. For example**:**   + Cultural or religious considerations or the possibility that a dependent relationship may compromise the voluntary character of the participant’s decisions   + Whether participants have the capacity to give their informed consent * **The intent of the research:** For example,   + Whether the research aims to expose illegal activity or involve active deception or planned concealment * **The risks to researchers or staff:** For example,   + Research assessing emergency services or research requiring home visits * **The nature and context of the test/procedure/measure**: For example,   + The frequency of its use   + The degree of its invasiveness   + The skill and experience of the person performing it   + Whether there is adequate supervision of the activity   + Whether the measure is already part of the **standard of care** is also relevant to the determination of whether a research project is suitable for review under low or negligible risk processes. Section 3.1.6 of the National Statement should be considered:   *In health research involving an intervention, the risks of an intervention should be evaluated by researchers and reviewers in the context of the risks of the health condition and the treatment or treatment options that would otherwise be provided as part of usual care.*   1. **Projects that must be reviewed by an HREC**   According to the National Statement, if the project includes any of the following types of research and/or participants and/or approaches to consent, it will require HREC review[[1]](#footnote-1) regardless of the level of risk:   * Waiver of consent (2.3.9 – 2.3.10) for research using personal information in medical research, or personal health information, including: * Use of human biospecimens obtained without specific consent for their use in research, or where the proposed research is not consistent with the scope of the original consent (3.2.14) * Genomic research (3.3.14) * The sharing of genomic data or information (3.3.24b) * Emergency care research (4.4.6) * Research involving the derivation of embryonic stem cell lines or other products from a human embryo (3.2) * Research involving ***prospective collection*** of human biospecimens including establishment of a biobank (3.2.1) * Exportation of bio-specimens for research in accordance with institutional policy (3.2.9 b) * Research involving the ***use*** of human bio-specimens that may give rise to information that may be important for the health of the donors, their relatives or their community (3.2.15) * Research including genomics (3.3) † * Animal-to-human xenotransplantation (3.4) ‡ * Research on women who are pregnant, research on the human foetus in utero, and research on the separated human foetus or on foetal tissue (4.1)\* * Research involving people highly dependent on medical care who may be unable to give consent (4.4)\* * Research involving people with a cognitive impairment, an intellectual disability or a mental illness (4.5)\* * Research that is intended to study or expose, or is likely to discover, illegal activity (4.6)\* * Research with Aboriginal and Torres Strait Islander Peoples (4.7)   *† As* a general principle, research including genomics will require review by an HREC; however, if no information that can identify an individual is used and no linkage of data is planned, the research may be determined to carry low risk (3.3).  ‡ *Xenotransplantation research must also be ethically reviewed and approved by an institutional animal ethics committee.*  **\*** *Except where that research uses existing collections of data or records that contain only non-identifiable data about human beings and involves negligible risk and which, therefore, may be exempted from ethics review.*   1. **Projects that may2 be suitable for review by ‘other ethics review bodies’/non-HREC levels of ethics review dependent on the context of the research**   These examples were generated in consultation with NSW public health organisations.  ***a) Examples of projects involving the collection, storage and disclosure of data***   * Surveys or questionnaires where the data are not identifiable or potentially identifiable to the researcher (e.g. returned anonymously) where the questions are not overly sensitive, and they have been satisfactorily peer reviewed to ensure that the questionnaire is likely to achieve the intended outcomes. For example: * Online and/or anonymous surveys where there is no direct contact with participants (i.e., recruitment is through generic email, mail or a social networking site link.) * Research interviews/focus groups that do not include highly sensitive topics or where accidental disclosure would not have serious consequence * Establishment of a data registry using non-identifiable data from existing data sets   ***b) Examples of projects involving the use of bio-specimens***  Research using existing bio-specimens already taken with unspecified (i.e., broad) or extended consent for research:   * Where the research does not involve any risks to the donors, their blood relatives or their community that are more serious than discomfort * Where the research cannot reveal information that may be important for the health of the donor(s), their blood relatives or their community * Where specific individuals cannot be identified from the bio-specimens used (i.e., the bio-specimens are non-identifiable to the researcher).   ***c) Examples of projects involving non-invasive or minimally invasive activities***   * Prospective research involving non-invasive or minimally invasive activities may be eligible for low-risk review. Examples might include research activities where participants are asked to read materials, review pictures or videos, play online games, solve puzzles, or perform cognitive tasks.   2 Inclusion on this list merely means that the activity is eligible for review through LNR processes when the specific circumstances of the proposed research involve no more than low risk to participants.  **4) Projects that may be exempt from ethics review**  Institutions may choose to exempt from ethics review, research that involves the use of existing collections of data or records that contain only non-identifiable data about human beings and is negligible risk research.  Institutions that do not have separate procedures for reviewing research that is exempt from ethics review are likely to review this sub-set of research under their established low risk review processes.  **Journal Requests for Ethics Review**  If required by a journal as a condition of publication, an HREC or other ethics review body may be willing to review a study. However, editors of most journals will usually accept a letter from the institution confirming that an appropriate ethics review process was used or that ethics review was not required.  **Figure 1** below provides an overview per the National Statement, including step-wise considerations to help institutions determine the appropriate level of review. |

1. *HREC review* means review by an HREC that is constituted and functioning in accordance with Section 5 of the National Statement. [↑](#footnote-ref-1)