NIS Considerations - Australia
An overview of the considerations when conducting Non-interventional Studies in Australia

Stuart McCully • CHCUK Ltd • NIS-C-AU-2014
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DATA PRIVACY

Australian Privacy Legislation

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Disclaimer

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to non-interventional studies. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.
## SUMMARY OF CHANGES SINCE PREVIOUS VERSION

Summary of country-specific changes implemented since the publication of NIS-C-AU-2013_Version 2 (Dec 2013)

**NOTE:** Look for the sections highlighted in the colour on the left. This is a visual indication that a section has been updated or is new.

<table>
<thead>
<tr>
<th>Area Impacted</th>
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<tr>
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<td><strong>REC Requirements</strong></td>
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<td><strong>Data Privacy Requirements</strong></td>
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<tr>
<td><strong>Pharmaceutical Association Requirements</strong></td>
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## Study Classification

### MARKET HEALTH RESEARCH OR NON-INTERVENTIONAL STUDY?

#### REGULATORY BODIES

<table>
<thead>
<tr>
<th>Category</th>
<th>Body</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Competent Authority</td>
<td>Therapeutic Goods Administration</td>
<td>TGA</td>
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<td>Human Research Ethics Committees</td>
<td>HRECs</td>
</tr>
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<td>Data Protection Agency</td>
<td>The Office of the Australian Information Commissioner</td>
<td>OAIC</td>
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<tr>
<td>Market Research Self-Regulation Body</td>
<td>Australian Market &amp; Social Research Society</td>
<td>AMSRS</td>
</tr>
<tr>
<td>Market Research Code of Practice</td>
<td>AMSRS Code of Professional Behaviour</td>
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<td>Pharmaceutical Self-Regulation Body</td>
<td>Medicines Australia</td>
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</table>
**Applicable Legislation and Guidance**

The laws and guidelines which are applicable to the management and conduct of Investigator Surveys in Australia include (but are not limited to):

<table>
<thead>
<tr>
<th>Regulations Applicable to Human research</th>
<th>Therapeutic Goods Act 1989</th>
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<tbody>
<tr>
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<td></td>
<td>Therapeutic Goods Regulations 1990</td>
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<td>National, State &amp; Territory Legislative Framework for the Ethical Review of Multi-centre Research</td>
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<td>The National Health and Medical Research Council Act 1992 (NHMRC Act)</td>
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<tr>
<th>Data Protection Regulations</th>
<th>Privacy Act 1988</th>
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<td></td>
<td>Privacy Amendment (Enhancing Privacy Protection) Act 2012</td>
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<td></td>
<td>OAIG Guidance on Health and Medical Research</td>
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<td>OAIG Guidance on Health and Genetic Information</td>
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<table>
<thead>
<tr>
<th>Ethical Standards and Codes of Practice</th>
<th>National Statement on Ethical Conduct in Human Research</th>
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<td>Human Research Ethics Portal (HREP)</td>
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<td>AMSRS Code of Professional Behaviour</td>
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<td>Medicines Australia Code of Conduct Guidelines (Version 4 - Feb 2014)</td>
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<td>Australian Code for the Responsible Conduct of Research</td>
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</table>
STUDY CLASSIFICATION

Summary

Prior to conducting any research that involves interaction with, or information from, human participants, researchers must determine what type of research it is that they wish to conduct and what level of risk the research presents to the participants (see table below). This in turn, directs the approval and notification requirements.

<table>
<thead>
<tr>
<th>Study Type?</th>
<th>Research Risk</th>
<th>Regulatory Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-marketing Surveillance study (PMS)</td>
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<td>• Notify TGA</td>
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<td></td>
<td></td>
<td>• HREC Approval</td>
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<tr>
<td>Other’ Non-interventional Human Research</td>
<td>More than low risk (see link)</td>
<td>• HREC approval</td>
</tr>
<tr>
<td></td>
<td>No more than low risk (see link)</td>
<td>• Non-HREC ethical approval</td>
</tr>
<tr>
<td></td>
<td>Negligible risk (see link)*</td>
<td>• No ethical review required</td>
</tr>
</tbody>
</table>

* e.g., market health research using non-identifiable participant information

What is human research?

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

• taking part in surveys, interviews or focus groups;

• undergoing psychological, physiological or medical testing or treatment;

• being observed by researchers;

• researchers having access to their personal documents or other materials;

• the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
# Regulatory Requirements

## COUNTRY-SPECIFIC REGULATORY REQUIREMENTS

### REGULATORY BODIES

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<tr>
<th>Category</th>
<th>Description</th>
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<tr>
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<td>Pharmaceutical Self-Regulation Body</td>
<td>Medicines Australia</td>
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</tbody>
</table>
DEFINITIONS

Adverse Drug Reaction
Any noxious and unintended response to an unapproved medicinal product, related to any dose. The phrase “response to an unapproved medicinal product” means that a causal relationship between the product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. ('Unapproved medicinal product’ here includes approved products used at levels or in ways that are unapproved).

or

A noxious and unintended response to a drug that occurs at doses of marketed medical products normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

(as per the Glossary of the National Statement on Ethical Conduct in Human Research).

HREC
Human Research Ethics Committee (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

Identifier
Details attached to data, such as name and/or contact information, that identify an individual. (It may remain possible to identify an individual even after all identifiers have been removed, if a code number has been assigned and there is access to the code, or if the data or tissue can be cross-linked to other data or tissue banks) (as per the Glossary of the National Statement on Ethical Conduct in Human Research).
Low Risk (Research)
Research in which the only foreseeable risk is one of discomfort (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

Monitoring (of research)
The process of verifying that the conduct of research conforms to the approved proposal (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

Negligible Risk
Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

Non-identifiable Data
Data that have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known they are about the same date subject, although the person’s identity remains unknown (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

Qualitative Research
Research involving the studied use of empirical materials such as case studies, personal experience, life stories, interviews, observations, and cultural texts (as per the Glossary of the National Statement on Ethical Conduct in Human Research).
**Re-identifiable Data**

Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

**Research**

Includes at least investigation undertaken to gain knowledge and understanding or to train researchers (as per the Glossary of the National Statement on Ethical Conduct in Human Research).

Research is defined as that which:

‘... includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.

(as per the Australian Code for the Responsible Conduct of Research).
Study Conduct Considerations

CONSIDERATIONS WHEN CONDUCTING NIS IN AUSTRALIA

CONTRACTS

Sponsors of clinical research studies should use the clinical trials research agreements/contract templates that have been developed and approved by Medicines Australia

Refer to:

- Medicines Australia Clinical Trials Research Agreements

Note - Sponsors will need a contract signatory to be present in Australia.

POST-MARKETING SURVEILLANCE (PMS) STUDIES

Post-Marketing Surveillance Studies must have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise (as per Section 10.1 of the Medicines Australia Code of Conduct - 2013).

- Companies’ attention is also directed to the Joint TGA-Medicines Australia Guidelines for the Design and Conduct of Company Sponsored Post-Marketing Surveillance (PMS) Studies.

Joint TGA-Medicines Australia guidelines for the design and conduct of company-sponsored post-marketing surveillance (PMS) studies

These guidelines apply to company-sponsored post-marketing surveillance studies of drug safety and toxicity. Most of these have been observational studies employing a cohort design. However, the guidelines apply equally to other types of study including case control studies, intensified monitoring and
various forms of recorded release (as per the Joint TGA-Medicines Australia guidelines for the design and conduct of company-sponsored post-marketing surveillance (PMS) studies - April 2012).

The term "post-marketing surveillance (PMS) study" implies a scientifically rigorous study of a product that is approved for registration in Australia designed to produce reliable information about drug safety. It is not appropriate to apply the term to clinical trials of registered products or to studies designed primarily for marketing purposes regardless of the scientific validity of the study design (as per the Joint TGA-Medicines Australia guidelines for the design and conduct of company-sponsored post-marketing surveillance (PMS) studies - April 2012).

PMS studies are generally performed on the initiative of the sponsoring company, but may be suggested or requested by other parties. They should generally be designed to address a specific drug safety question or hypothesis (the latter often identified initially by voluntary reporting) (as per the Joint TGA-Medicines Australia guidelines for the design and conduct of company-sponsored post-marketing surveillance (PMS) studies - April 2012).

These guidelines have been formulated:

- to encourage the design and conduct of scientifically sound and ethical studies;
- in an attempt, therefore, to maximise the possibility that the results of PMS studies may have scientific validity and offer new and useful information on the drugs being studied;
- to minimise the generation of large volumes of poor-quality adverse event or "experience" reports which may be resource- and time-intensive to analyse and may diminish the voluntary reporting scheme’s ability to generate true drug safety signals by diluting the database.

(as per the Joint TGA-Medicines Australia guidelines for the design and conduct of company-sponsored post-marketing surveillance (PMS) studies - April 2012).
DATA PRIVACY AND DATA PROTECTION CONSIDERATIONS WHEN CONDUCTING NIS IN AUSTRALIA

DATA PRIVACY

The Office of the Australian Information Commissioner (OAIC) is a statutory authority that sits in the portfolio of the Department of Prime Minister and Cabinet. Although the Office is a government agency, it is independent in the exercise of its regulatory and policy advising functions.

The Australian Privacy Commissioner is the national privacy regulator.

The Commissioner performs key functions under the Privacy Act 1988, such as providing information and advice about privacy and the law, handling complaints, conducting audits, and undertaking promotional and educational activities.

Australian Privacy Legislation

The Privacy Act covers the collection, use and disclosure, access to, quality and security of personal information in Australia. As well as providing principles to regulate these areas (see below), the Privacy Act, among other things, provides a framework for complaints about breaches of the Act, and
CONSIDERATIONS WHEN CONDUCTING STUDIES WITH HUMAN SAMPLES AND DATA IN AUSTRALIA

HUMAN GENETIC RESEARCH

The genome is an individual’s biological inheritance. An individual’s biological characteristics are determined by the interaction of his or her genome with the environment. An individual’s genome contains all of his or her genes (as per Chapter 3.5 of the National Statement on Ethical Conduct in Human Research).

Genetics is the study of the structure, location, function, expression, interaction, abnormalities and effects of the genes or genetic material and their products, including but not limited to studies of the structure of the nucleic acids and other molecules that make up the genetic material (as per Chapter 3.5 of the National Statement on Ethical Conduct in Human Research).

Genes and genetic information are being studied increasingly in clinical, epidemiological and social research, as well as in basic research (as per Chapter 3.5 of the National Statement on Ethical Conduct in Human Research).

Genetic research may involve study of:

- single or multiple genes, gene-to-gene interaction or gene-environment interaction;
- acquired somatic variation;
- inherited gene sequences, and their variants or their products;
• gene expression, including the influence on those genes of environmental factors, pharmaceutics and other therapeutic products;
• the genes of individuals, families or populations;
• epigenetics;
• use of informatics and genetic information; and
• clinical phenotypes.

Some research that falls within this broad description of genetic research does not involve information that is relevant to the future health of the individual participant and does not generate sensitivities for the individual, or his or her family or community. The guidelines in this chapter differentiate between research that necessitates special precautions in that respect, and research that is unlikely to be of concern to individual participants, their families or their communities (as per Chapter 3.5 of the National Statement on Ethical Conduct in Human Research).

For genetic research using stored data, see also Chapter 3.2: Databanks; and for genetic research using human tissue samples, see Chapter 3.4: Human tissue samples (as per Chapter 3.5 of the National Statement on Ethical Conduct in Human Research).

There are ethical issues specific to genetic research because:

• many of an individual’s genes are shared with close genetic relatives (commonly called ‘blood relatives’) and with unrelated people in the population; and
• genetic research can reveal information about predispositions to disease. Although people with such a predisposition may not develop the disease, the information may have implications for their access to employment and education and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have similar implications for blood relatives.

Research results and genetic material and information collected for genetic research may be significant for blood relatives of research participants. These
Best Practice Considerations

BEST PRACTICE CONSIDERATIONS WHEN CONDUCTING NIS IN AUSTRALIA

RESEARCH

The following provisions apply to Post-Market Surveillance Studies and market research conducted by or on behalf of a company, whether the research is carried out directly by the company or by an organisation acting under its direction (as per Section 10 of the Medicines Australia Code of Conduct Guidelines - 2013).

The conduct of clinical research such as Phase I, II and III clinical trials is governed by the Commonwealth therapeutic goods legislation; the ethical principles described in the NHMRC National Statement on Ethical Conduct in Human Research; and a number of Guidelines and Policies issued by State and Territory Health Departments (as per Section 10 of the Medicines Australia Code of Conduct Guidelines - 2013).

The Sections of the Code of Conduct that describe the appropriate interactions between a company and healthcare professionals providing consulting services also apply to interactions that occur when conducting clinical research. Any remuneration for services rendered should not exceed that which is commensurate with the services supplied. A company may provide reasonable travel, accommodation or hospitality to clinical research personnel engaged in conducting research. Interactions between companies and these clinical research personnel must not include entertainment. A
company must not subsidise or pay for the travel, hospitality, accommodation or other expenses for any guest, family, companions or other persons associated with the research (as per Section 10 of the Medicines Australia Code of Conduct Guidelines - 2013).

Companies must ensure that the requirements of Australia’s privacy legislation are complied with during any research activity and that all research is undertaken by suitably qualified and experienced individuals or organisations (as per Section 10 of the Medicines Australia Code of Conduct Guidelines - 2013).

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Common NIS Terminology

COMMONLY USED NIS TERMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Term</th>
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<tbody>
<tr>
<td>AE</td>
<td>Adverse Event</td>
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<td>AR</td>
<td>Adverse Reaction</td>
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<tr>
<td>CA</td>
<td>Competent Authority (e.g., MHRA)</td>
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<tr>
<td>CI</td>
<td>Chief Investigator</td>
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<td>CRA</td>
<td>Clinical Research Associate</td>
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<td>Case Report Form</td>
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<td>Contract Research Organisation</td>
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<td>CSR</td>
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<td>DPA</td>
<td>Data Protection Agency</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<td>Good Pharmacoepidemiology Practice</td>
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<td>GVP</td>
<td>Good Pharmacovigilance Practice</td>
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<td>ICF</td>
<td>Informed Consent Form</td>
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<td>ICH</td>
<td>The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</td>
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<td>Post-authorisation Safety Study</td>
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<td>Principal Investigator</td>
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<td>Patient Information Leaflet</td>
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<td>SmPC</td>
<td>Summary of Product Characteristics</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>SUSAR</td>
<td>Suspected Unexpected Serious Adverse Reaction</td>
</tr>
<tr>
<td>TMF</td>
<td>Trial Master File</td>
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<tr>
<td>Acronym</td>
<td>Term</td>
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<td>WMA</td>
<td>World Medical Association</td>
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