

1. Purpose

The purpose of this policy is to provide a framework to facilitate the ethical planning and management of risks associated with:

- the use of animals or humans in research pertaining to DMTC activities; and
- exposure to biohazards as part of DMTC activities.

This policy articulates related requirements including that research be undertaken in a structured, efficient and ethical manner, and in accordance with relevant laws and standards including the *Australian Code for the Responsible Conduct of Research*, the *Australian Code for the Care and Use of Animals for Scientific Purposes* and the *National Statement on Ethical Conduct in Human Research*.

Additionally, this policy articulates requirements for DMTC activities that concern work with or exposure to biological hazards and regulated biological material.

This policy represents an assurance that DMTC's related internal risks are contained within acceptable levels as determined by DMTC's management and the Board of Directors.

2. Policy Scope/Coverage

This policy is applicable to all DMTC activities involving:

- animal research;
- human research; or
- organic substances that pose a risk to human and/or animal health or the environment such as biological risk group agents and regulated biological materials (hereinafter collectively referred to as '**Biohazards**').

This policy is intended to bind:

- members of the DMTC organisation; and
- members of all organisations that carry out work with or on behalf of DMTC in relation to DMTC activities (**DMTC partners**).

3. Policy Statement

3.1. Policy Overview – Research Ethics

DMTC maintains a strict expectation that all members of the DMTC organisation and every DMTC partner comply with all ethical requirements for conducting animal and human research. This expectation relates to requirements arising out of applicable laws and regulations (at both State/Territory and Commonwealth levels), and best practices.

- Where research procedures involve humans or animals as research subjects, approval must be sought from the appropriate Human Research Ethics Committee (or Human Research Advisory Panel) (**HREC**) or the Animal Care and Ethics

Committee (**ACEC**) of an accredited institution. The design and conduct of research projects must take account of relevant ethical guidelines published by the National Health and Medical Research Council (**NHMRC**) including:

- the National Statement on Ethical Conduct in Research involving Humans (**The National Statement**);
 - the Australian Code for the Responsible Conduct of Research; and
 - the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (**The Code**).
- Research involving Aboriginal and Torres Strait Islander peoples must be conducted in accordance with guidelines published by the NHMRC and Australian Institute of Aboriginal and Torres Strait Islander Studies (**AIATSIS**) respectively including:
 - the NHMRC guidelines document titled '*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018*'; and
 - the *AIATSIS Guidelines for Ethical Research in Australian Indigenous Studies*.

DMTC will accept ethics approval from DMTC partners that are also accredited institutions in accordance with The Code and/or The National Statement.

DMTC partners must provide DMTC with the relevant ethics approval documentation for any research project utilising humans or animals before the relevant research work can begin.

Subject to advice from advisory, stakeholder or governance groups, DMTC may choose to request a review of the approved ethics documentation by independent bodies including, but not limited to the Department of Defence and Veteran's Affairs Human Research Ethics Committee or the Australian Defence Force – Malaria and Infectious Disease Institute.

If a DMTC project team does not have an accredited institution participating in the project, the DMTC project team must outsource an ethics assessment to an institution accredited under the relevant framework.

The viability of the relevant DMTC project will be reviewed if ethics approval from the appropriate accredited institution cannot be obtained. DMTC reserves its right to cancel or substantially modify funding arrangements where relevant ethics approvals cannot be obtained.

3.2. Policy Overview – Biorisk Management

DMTC is committed to protecting the health and safety of people, animals and the environment by identifying and managing risks posed by Biohazards.

All members of the DMTC organisation and every DMTC partner must comply with legal requirements and best practice guidelines for conducting work involving exposure to Biohazards. This obligation extends to requirements arising out of or made pursuant to:

- relevant state and territory occupational health and safety laws (such as, for

example, the *Occupational Health and Safety Act 2004* (Vic));

- the *Biosecurity Act 2015* (Cth);
- the *Gene Technology Act 2000* (Cth);
- the *National Health Security Act 2007* (Cth);
- the *National Health Security Regulations 2018* (Cth); and
- other laws and regulations as applicable.

Where activities involve exposure to Biohazards, DMTC strongly encourages consideration of:

- relevant Australian Standards including AS/NZS 2243.3-2010 - Safety in laboratories Part 3: Microbiological safety and containment;
- the World Health Organization's *Laboratory Biosafety Manual*; and
- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

If requested, DMTC partners must provide DMTC with relevant risk prevention, management and response plans and policies and evidence of controls in relation to occupational health and safety, and risks posed by Biohazards.

If requested, DMTC partners must cooperate with DMTC to facilitate any requested audit or inspection of records or physical facilities (such as laboratories) where required to ascertain compliance with matters arising out of this policy.

DMTC reserves the right to review the viability of the relevant DMTC project and cancel or substantially modify funding arrangements in relation to the relevant DMTC project where DMTC perceives that this policy has not been complied with or there is a risk that this policy will not be complied with for any reason.

3.3. Responsibilities and Authorities

The Chief Executive Officer is responsible for:

- reviewing the approved ethics documentation received from the relevant DMTC project team;
- conducting due diligence on the ethics and occupational health and safety record of any new partner seeking to work with DMTC, as part of DMTC's standard Quality Assurance framework; and
- monitoring DMTC activities which involve Biohazards to ensure that such activities have appropriate controls in place to achieve compliance with this policy and applicable laws.

In conducting these reviews, due diligence and monitoring duties, the CEO may delegate or seek external advice as needed.



4. Linked Documentation

- [Procedure – Admission of a New DMTC Partner](#)
- <https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes>
- <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2007>
- <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018><https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples>
- <https://aiatsis.gov.au/sites/default/files/docs/research-and-guides/ethics/gerais.pdf>
- https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/
- <https://www.standards.org.au/standards-catalogue/sa-snz/publicsafety/ch-026/as-slash-nzs--2243-dot-3-2010>
- <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32000L0054>