

### **1. INTRODUCTION**

This Research Code of Conduct Policy (the Code) provides the foundation for responsible, ethical and high-quality research at The George Institute for Global Health (TGI).

The purpose of the Code is to describe the guiding principles for research conducted by TGI and to outline the responsibilities that flow from those principles. The Code is supplemented by a number of Standard Operating Procedures (SOPs) and Associated Documents (ADs), that express the practical application of this policy in the day-to-day operation of the organisation.

This policy is based on the relevant Research Codes of Conduct or equivalent publications for Australia (as allowed under Creative Commons Attribution 4.0 Licence), China, India and the United Kingdom. These references are recorded in section 5 below. Excerpts may not be specifically referenced in each instance.

## 2. SCOPE

All individuals undertaking any research-related work in any capacity for, or on behalf of, The George Institute (TGI) must comply with the Code. This includes all permanent or temporary employees, students, consultants, contractors, secondees, volunteers, and any other associates undertaking work for or on behalf of TGI.

It should be noted that researchers with appointments at other institutions/universities may have additional responsibilities and obligations in relation to their respective institution/university. It is the individual's responsibility to be aware of and uphold those obligations.

## 3. RESPONSIBLE RESEARCH AT TGI

All TGI research must be conducted according to established ethical principles, guidelines for research conduct, relevant legislation and regulations. Research must also adhere to TGI policies and SOPs. This ensures that TGI can:

- safeguard the individuals participating in our research;
- protect researchers/investigators (by providing a clear framework to work within);
- uphold ethical and scientific quality;
- identify and manage risk;
- promote good research practice and culture; and
- maintain the credibility of, and community trust in, research activities.



# 3.1. Principles of Responsible Research Conduct

The guiding principles for responsible research conduct at TGI are:

Hawaata	in the development undertaking and rementing of recorded		
Honesty	in the development, undertaking and reporting of research.		
	Present information truthfully and accurately in proposing, conducting and reporting research.		
Rigour	in the development, undertaking and reporting of research.		
	Underpin research by attention to detail and robust methodology, avoiding or acknowledging biases.		
Transparency	in declaring interests and reporting research methodology, data and findings.		
	Share and communicate research methodology, data and findings openly, responsibly and accurately.		
	Disclose and manage conflicts of interest in accordance with TGI's Conflict of Interest Policy.		
Fairness	in the treatment of others.		
	Treat fellow researchers and others involved in the research fairly and with respect.		
	Appropriately reference and cite the work of others.		
	Give credit, including authorship where appropriate, to those who have contributed to the research in accordance with TGI's Authorship Policy.		
Respect	for research participants, the wider community and the environment.		
	Treat human participants and communities that are affected by the research with care and respect, giving appropriate consideration to the needs of underserved or marginalised people.		
	Minimise adverse effects of the research on the environment.		
Recognition	of the rights of all peoples to be engaged in research that affects or is of particular significance to them.		
	This includes but is not limited to First Peoples, diverse ethnic groups, people from a refugee background, people with disabilities and LGBTQI+ people.		
	Recognise that factors such as social and historical circumstances, diversity, knowledge, ability, cultural property and connection to land must be considered in shaping how research is undertaken. This includes engaging with communities prior to research so that they freely make decisions about their involvement, and reporting the outcomes of research to those communities.		
Accountability	for the development, undertaking and reporting of research.		
	Comply with relevant legislation, policies and guidelines.		
	Ensure good stewardship of public and TGI resources used to conduct research.		
	Consider the consequences and outcomes of research prior to its communication.		
Promotion	of responsible research practices.		
	Maintain knowledge of current best practices in research.		
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T	Promote and foster a research culture and environment that supports the responsible
	conduct of research.

## 3.2. The George Institute's Responsibilities

TGI is committed to the principles and practice of responsible research, including the following:

- the provision of the Code and related documents;
- provision of ongoing training to promote responsible research conduct and integrity amongst all staff involved in research, including trainees and those who supervise trainees;
- provision of a Quality, Risk and Compliance Coordinator across TGI offices to assist in the promotion and fostering of responsible research culture and conduct;
- the provision of clear, transparent, fair and timely processes to receive and investigate complaints about potential breaches of the Code;
- ensuring that those processes are publicised within the organisation and easily accessible to anyone to whom they apply, including making a summary of complaint processes available on the TGI public website.

#### 3.3. The George Institute as Sponsor

The Sponsor of a project has particular obligations regarding responsible research. The Sponsor is the individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a research project in an affiliation, collaboration or partnership.

TGI will be a Sponsor in the following scenarios:

- Peer-review funded projects where the Principal Investigator is employed by TGI
- Peer-review funded projects where the Principal Investigator is not employed by TGI, but there is an agreement between the Principal Investigator's organisation and TGI delegating the Sponsor role to TGI.
- Non peer-review funded projects where the funding body has delegated the Sponsor role to TGI.

All individuals undertaking research activities at TGI where TGI is the Sponsor must ensure that they are fulfilling Sponsor responsibilities.

Sponsor responsibilities are outlined below. ICH-GCP E6(R2) (2016) can be used as a guide to explain the details.

- Quality management, assurance and control
- Medical oversight (if applicable)
- Research project design



- Research Project management including conflict of interests
- Data handling and record keeping
- Investigator selection
- Allocation of responsibilities
- Insurance and indemnity
- Contracting
- Ethics and Regulatory
- Intervention management (with or without interventional product)
- Record access and monitoring
- Safety reporting
- Audits and compliance
- Manage premature termination or suspension of a project if required
- Research project reports

#### 3.4. Breach of the Code

TGI recognises that TGI researchers demonstrate behaviours consistent with the principles set out in the Code. A failure to meet the principles and responsibilities set out in the Code is a breach of the Code. Any suspected or potential breach of the Code will be managed in accordance with *GE*-SOP-07 Managing Potential Breaches of the Research Code of Conduct.

Breaches occur along a spectrum. The seriousness of a breach will be determined during the processes described in *GE-SOP-07*. Serious breaches that are "also intentional, reckless or negligent" may be deemed Research Misconduct. Consequential actions for breaches will be determined according to the circumstances and seriousness of the breach.

#### 3.5. References

#### International

Singapore Statement on Research Integrity (2010). World Conference on Research Integrity.

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013). *World Conference on Research Integrity.* 

Good Clinical Practice E6(R2) (2016). International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

#### China

Code for the Responsible Conduct of Medical Research (2014) (医学科研诚信和相关行为规范). *National Health Commission*.



China Good Clinical Practice (2020) (药物临床试验质量管理规范). National State Drug Administration and National State Health Commission.

#### India

Ethical Guidelines for Biomedical Research on Human Participants (2017). *Indian Council for Medical Research*.

India Code of Conduct for Research Scientists Engaged in the Field of Life Sciences (2014). *Indian Council for Medical Research*.

#### **United Kingdom**

The Concordat to Support Research Integrity (2019).

Good Research Practice Principles and Guidelines (2014). Medical Research Council.

Code of Practice for Research (2009). UK Research Integrity Office.

#### Australia

Australian Code for the Responsible Conduct of Research (2018). *National Health and Medical Research Council.* 

Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018). *National Health and Medical Research Council.* 

Research Integrity and Misconduct Policy (2019). National Health and Medical Research Council.

### 4. REVISION HISTORY

Version number	Replaces	Reason/description of change
V1.0 (27 October 2020)	Research Misconduct Policy (2013) Global Research Policy	Substantially rewritten in line with new requirements from funding bodies and to reflect new/updated research integrity publications released after 2013 in all four countries. Change of emphasis from misconduct to research integrity and responsible conduct, incorporating research principles and
	(2017)	processes