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1. INTRODUCTION

Medicines Development for Global Health (MDGH) does not tolerate child exploitation and/or abuse of any kind.

2. PURPOSE OF THE POLICY

The purpose of this policy is to inform MDGH employees and third parties of the principles guiding all MDGH activities.

3. SCOPE

This policy applies to our employees and consultants at all times. The procedures in the MDGH Child Protection Working Practice WP MDGH-028 also apply as relevant to the work being undertaken. If employees or consultants are engaged in activities that involve working with or contact with children, the MDGH Child Protection Code of Conduct (WP MDGH-028 Form 1) also applies.

This policy also applies to MDGH contractors we engage on activities involving working with or in contact with children. In these cases, it is expected contractors will have their own Child Protection Policy compliant with this policy. Alternatively, this policy must be adopted.

Contractors MDGH engages that are working with children or have contact with children as part of their normal operations, are required to have policies and procedures in place for the safeguarding and protection of children relevant to their jurisdiction that are aligned with the principles in this policy; and ensure their employees comply with those policies. This includes an obligation to meet the requirements of the Australian Government Department of Foreign Affairs and Trade (DFAT) ([DFAT Child Protection Policy](#)) and other funding bodies where relevant.

4. DEFINITIONS

Child or Children	In accordance with the United Nations Convention on the Rights of the Child, 'child' means every human being under the age of 18 years, unless national laws recognise adulthood earlier. For the purposes of this policy, MDGH considers a child to be a person under the age of 18 years.
Child abuse	Child abuse is defined as all forms of physical and emotional abuse, neglect, ill-treatment and exploitation, including sexual abuse.
Child Protection or Child Safety	Responsibilities and activities undertaken to prevent child abuse.
Contact with children	Contact with children means being part of an activity or in a position that involves or may involve contact with children, either under the position description or due to the nature of the work environment. This means physical contact, face-to-face contact, oral communication, written communication or electronic communication, including access to photographs.
Consultant	A Consultant is an individual or organisation who is employed for a specific task or role, typically employed under a consultancy agreement and subject to MDGH policy and process.
Contractor	A Contractor is an institution or organisation that is engaged to deliver a service. Arrangements are typically managed through a services agreement, purchase order or work order.
Electronic records	Refer to clinical trial participant files, meta data or text descriptions with information about a child as well as electronic images and videos.
DFAT	The Australian Government Department of Foreign Affairs and Trade.
Investigator	A person medically qualified undertaking a clinical trial at a trial site. The Principal Investigator is the responsible person for the activities at the site.

Responsible Employee	For the purpose of this policy, the Responsible Employee is the MDGH employee responsible for management and/or oversight of the delivery of a contracted service (e.g. clinical, regulatory, manufacturing or other) including management of the relationship with the relevant third parties.
Third Party	A Third Party is a broad term for any company or person contracted to perform a specific task for, or on behalf of, MDGH and includes consultants, contractors, institutions, their sub-contractors, or any other organisations engaged by or working in partnership/collaboration with MDGH.
Clinical Project Manager (CPM)	Person appointed by a Sponsor or Contract Research Organisation, with responsibility for set-up, coordination and oversight of a clinical study on behalf of the Sponsor. The CPM may also have study monitor responsibilities.
Study Monitor	Person appointed by a Sponsor or Contract Research Organisation, with responsibility for overseeing the progress of a clinical study at one or more sites on behalf of the Sponsor, and to ensure that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirements. For the purposes of this document, the term study monitor is used to denote the person responsible for identification and/or evaluation of investigators and investigation sites. This person could be the Study Monitor, Clinical Project Manager, or Development Manager (or delegate).
Working with children	Working with children means being engaged in an activity with a child where contact would reasonably be expected as a normal part of the activity and the contact is not incidental to the activity. The term working also includes volunteering or other unpaid work.

5. POLICY

MDGH has zero tolerance for child abuse, exploitation or harm and respects the rights outlined in the Convention on the Rights of the Child.

It is MDGH's policy that:

- Children have the right to be protected from harm and abuse in all its forms.
- It will protect the cultural safety of Indigenous children and make the organisation a safe place for Indigenous families, as well as promote the cultural safety of children from culturally and linguistically diverse backgrounds.
- All clinical trials, including those that involve children, must follow International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines, local laws and regulations, and the latest version of the World Medical Association Declaration of Helsinki.
- The organisation will promote children's rights to life, survival, development and non-discrimination, and work in the best interests of children in the studies it sponsors.
- Clinical trial staff and study participants are governed by their employing organisation, ethics committee/Institutional Review Board and regulatory authority oversight. MDGH will include contact details of the ethics committee/ Institutional Review Board in the consent form along with contact details of the sponsor by default, noting that the final decision of the consent form content is the ethics committee's/ Institutional Review Board's.
- The organisation will not knowingly engage people or organisations that pose an unacceptable risk to children and will ensure that all employees are aware of, and abide by, this policy. At a minimum, all employees working with or in contact with children must follow the MDGH Child Protection Code of Conduct at all times.
- The organisation will take disciplinary action and where appropriate seek prosecution against any person associated with MDGH who abuses or exploits children.

- Fair and appropriate procedures are in place when responding to concerns or allegations of child abuse and exploitation.

6. RELATED GUIDELINES AND LEGISLATION

This policy supports compliance with the:

- World Medical Association Declaration of Helsinki
- United Nations Convention on the Rights of the Child
- Australian Department of Foreign Affairs and Trade Child Protection Policy
- Child Wellbeing and Safety Act 2005 (Victoria)
- Crimes Act 1958 (Victoria)
- Victorian Charter of Human Rights and Responsibilities
- Victorian Child Safe Standards, and
- Working with Children Act 2005 (Victoria).

7. RELATED POLICIES

- WP MDGH-028 Child Protection
- POL MDGH-014 New Third Party Selection Policy
- WP MDGH -025 New Third Party Selection Process
- SOP MDGH-004 Investigational Site Selection
- SOP MDGH-009 Site Initiation and Approval
- SOP MDGH-003 Protocol Writing

8. POLICY AMENDMENT HISTORY

Version Number	Reason for Amendment	Summary of Change	Date
01	New	New policy	9 Dec 2020
02	Periodic review	Updates to ensure compliance with DFAT policy and inclusion of the new MDGH New Contractor Policy as a screening & compliance check for new contractors.	17 Mar 2023
03	Revised to reflect staff feedback on implementation of V02 and in response to company decision to separate overarching policy from implementation aspects.	Removal of implementation aspects of policy to be separate Working Practice. Updated to align with New Third Party Selection Policy and Working Practice. Updated to address staff feedback after implementation of V02.	13 Mar 2024