

Guidelines

Prevention,
Reporting and
Management of
Wrongdoing

Table of Contents

1. Purpose and Scope of Application	1
2. Supporting Role of WHO	1
3. How Unitaid Defines Wrongdoing	2
4. Responsibilities	3
5. Preventing and Detecting Wrongdoing	3
5.1. Ethical Organizational Culture	4
5.2. Role of an Effective Internal Control System.....	4
5.3. Aggravating Factors and other Considerations	4
6. Reporting of Wrongdoing	5
6.1. Obligation to Report	5
6.2. Reporting Channels	5
6.2.1. Reporting Directly to Unitaid	5
6.2.2 Reporting using the Integrity Hotline	6
7. Managing and Investigating Cases of Wrongdoing	7
7.1. Case Management Process.....	7
7.2. Investigation by the Lead Grantee	7
7.3. Right to Investigate by Unitaid	8
7.4. What happens After an investigation?	8
8. Conclusion	8

1. Purpose and Scope of Application

These Guidelines set out Unitaid's requirements and provide guidance regarding the prevention, detection, reporting and management of any wrongdoing in Unitaid grants. They also clarify the roles and responsibilities of Unitaid Grantees and any sub-recipients of Unitaid funding. Unitaid holds itself and its Grantees to the highest ethical standards and has no tolerance for acts of wrongdoing in projects that it funds. Unitaid expects its Grantees to take a proactive approach to detect, manage and report wrongdoing, in line with these Guidelines, with a view to ensuring high standards and confidence in this respect. For this purpose, a definition of wrongdoing is provided in paragraph 3 below.

2. Supporting Role of WHO

Unitaid is hosted by the World Health Organization (WHO) and to ensure the highest standards with respect to cases of wrongdoing, Unitaid leverages additional support where relevant from WHO's structures, policies and processes, as referred to below in these Guidelines.

The guidance and clarification set out in this document are provided in addition to any requirements included in the terms of grant agreements between Unitaid and its Grantees, including with respect to compliance with WHO's policies in this area. In this context, all Grantees are required to ensure they have read the following WHO policies:

- (i) the WHO Code of Ethics and Professional Conduct;
- (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response;
- (iii) the WHO Policy on Whistleblowing and Protection Against Retaliation; and
- (iv) the UN Supplier Code of Conduct.

These policies are publicly available on the WHO website at:

- <http://www.who.int/about/finances-accountability/procurement/en/> for the UN Supplier Code of Conduct and;
- <http://www.who.int/about/ethics/en/> for the other WHO policies.

Unitaid Grantees are required to comply with the provisions applicable to "WHO Collaborators" in the WHO policies (referred to as "non-staff" in the WHO Policy on Whistleblowing and Protection Against Retaliation and "UN Suppliers" in the UN Supplier Code of Conduct). All Unitaid Grantees are expected to take appropriate measures to prevent and respond to any violations of the standards of conduct by their own employees and any third-party recipients of project funding.

3. How Unitaid Defines Wrongdoing

Wrongdoing is intentional illegal or unethical misconduct and dishonest behaviours that can adversely affect the projects or activities that Unitaid funds. Unitaid defines wrongdoing broadly for the purposes of these Guidelines: in case of doubt or discrepancy in determining the intent or meaning of these Guidelines, an inclusive interpretation should be applied.

Wrongdoing comprises types of misconduct involving misuse of funds as well as sexual misconduct and abuse, or other violations of human rights¹ and practices that obstruct the protection of human rights.

Examples of wrongdoing include, but are not limited to:

- engaging in **fraud, bribery or corruption**, such as through theft of assets² or irregularities in contracting processes, paying kickbacks, using Unitaid funds for personal use or individual benefits, or misrepresenting or falsifying information in reports to Unitaid;
- **intentionally not declaring or not managing conflicts of interest**;
- **falsifying or counterfeiting pharmaceutical products** (including but not limited to active pharmaceutical ingredients and medical equipment), such as by falsifying representation of product identity, source or marketing authorizations or registrations needed to operate in the market; or modifying packages to intentionally supply medical products and medical devices that do not conform to applicable standards;
- **intentionally exploiting unauthorized intellectual property rights** of third parties or failing to register or renew intellectual property rights in a timely fashion;
- **engaging in unethical behaviour in clinical research**, such as failing to obtain informed consent of a patient/individual with a patient-centered approach or failing to enforce appropriate clinical practice standards;
- **intentionally not maintaining confidentiality of personal data**, including medical data; and not implementing information security measures according to the nature of the personal data collected, processed, stored or transferred in accordance with applicable international or national laws, standards and regulations;
- **intentional waste of resources or sabotage**;
- **intentionally engaging in activities causing substantial and specific danger to public health or safety**;
- **abusing power, authority or position**, including for personal gain;
- **sexual exploitation or abuse**³;
- **human rights violations and abuses** as well as practices that obstruct the protection of human rights;
- **knowingly engaging or associating with individuals or entities involved in terrorism, transnational organized crime or related activities**;
- knowingly directing or counselling a person to commit any of the wrongdoings set out above.

¹ As set out in the Universal Declaration on Human Rights (UDHR).

² This includes both cash and non-cash assets (e.g. commodities, laptops, tablets, mobile phones, fixtures and fittings, intangible assets).

³ 'Sexual exploitation' is an actual or attempted abuse of a position of vulnerability, differential power, or trust, for sexual purposes, including, but not limited to, threatening or profiting monetarily, socially or politically from the sexual exploitation of another. 'Sexual abuse' is the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions. WHO strictly forbids sexual activity with children (persons under the age of 18), regardless of the local age of consent or majority. More information can be found on the WHO website (http://www.who.int/about/ethics/sexual-exploitation_abuse-prevention_response_policy.pdf?ua=1) or the United Nations Glossary on Sexual Exploitation and Abuse (<https://hr.un.org/materials/un-glossary-sexual-exploitation-and-abuse-english>).

In addition to running counter to Unitaid's firm commitment to its ethical principles, wrongdoing may result in financial liabilities and can negatively affect the delivery and impact of the projects that Unitaid funds. Wrongdoing also has the potential to damage the reputation of Unitaid and its Grantees, as well as of their respective donors.

4. Responsibilities

Unitaid Grantees are responsible for taking all necessary measures to identify, prevent and manage risks and acts of wrongdoing and to proactively communicate and coordinate with Unitaid on such measures as further detailed in paragraphs 6 and 7 below. Unitaid requires its Grantees to immediately report any confirmed or suspected case of wrongdoing within a Unitaid-funded project or otherwise associated with Unitaid-funded work.

If a Unitaid-funded grant is implemented through sub-recipients that are also receiving Unitaid funding (e.g. Sub-Grantees, service providers or members of a consortium of Sub-Grantee organizations), Unitaid requires the Lead Grantee to:

- take all necessary measures to ensure that their personnel and personnel of other recipients involved in the implementation of the grant are aware of, and compliant with, the guidance and requirements detailed in these Guidelines. Grantees should effectively communicate the guidelines to third-party recipients of Unitaid funds, including where relevant through legal agreements with them;
- hold and maintain the overall responsibility for managing risks and reports of wrongdoings, as well as providing oversight of other sub-implementers and ensuring any potential financial liabilities are assessed and mitigated;
- reserve adequate rights of oversight (e.g. audit and investigation rights) to facilitate detection in the event of wrongdoing by or involving third-party recipients of Unitaid funds.

Unitaid reserves the right to request additional measures to further prevent and manage wrongdoing.

5. Preventing and Detecting Wrongdoing

Unitaid has no tolerance for acts of wrongdoing in projects that it funds or in activities it is associated with. This means that any instance of wrongdoing shall be given a timely, effective and adequate response when detected. For this purpose, Unitaid requires its Grantees to maintain an adequate control and risk management framework to prevent, detect and mitigate risks or acts of wrongdoing. This includes (i) promoting and enforcing an ethical organizational culture as well as (ii) maintaining an effective internal control system at all levels of project implementation.

As part of its grant development approach, Unitaid assesses those two elements and the capacity of future Grantees to identify, prevent, detect and manage any potential future risks of wrongdoing. During grant implementation, Unitaid periodically revisits this assessment to ensure that existing safeguards are maintained and that any weaknesses or exposures have been properly mitigated.

5.1. Ethical Organizational Culture

Essential components of a Grantee's ethical organizational culture include, but are not limited to, a clear corporate stance against acts of wrongdoing, emanating from and clearly reinforced by the senior management and governing bodies. Such a culture may be translated through actions that express these values, for example:

- the maintenance of policies covering the matters addressed in these Guidelines (including for instance, sexual exploitation or abuse);
- provision of these Guidelines to all personnel, stakeholders, subcontractors or outsourced companies operating with the Grantee and;
- roll-out and maintenance of training and education programs raising the awareness of personnel regarding the risks of wrongdoing. Unitaïd expects that, at a minimum, key personnel involved in the management of Unitaïd grants will complete adequate training regarding the detection, prevention and adequate reporting of wrongdoing (including training on corruption, together with sexual exploitation and abuse).

5.2. Role of an Effective Internal Control System

Essential components of an effective internal control system include, but are not limited to:

- well-established organizational policies, processes and procedures as well as appropriate allocation of tasks and separation of duties, especially in the areas of project, human resource, financial, procurement and legal management;
- effective internal control activities that minimize risks and detect acts of wrongdoing. At a minimum, Unitaïd requires that its Grantees ensure financial and operational controls on grant expenditures are in place (e.g. expenditure reviews and approvals, reconciliation of grant financial reports with statutory accounting systems);
- effective complaint mechanisms, enabling personnel and external stakeholders to report suspected or confirmed acts of wrongdoing, or other concerns, in full confidentiality;
- internal and external assurance and oversight mechanisms (including independent audits or verifications) to evaluate and improve the effectiveness of governance, risk management, control and compliance processes in accordance with applicable local and international anti-bribery/corruption laws and regulations.

5.3. Aggravating Factors and other Considerations

Some factors or situations are more conducive to the risk of wrongdoing. The following situations are regarded as aggravating factors, which may increase the likelihood, magnitude and gravity of acts of wrongdoing:

- ineffective or inadequate internal controls, absence of clear policies or ineffective policy enforcement and control procedures for risks and acts of wrongdoing;
- ineffective or inadequate oversight systems on project implementation;
- complex or unclear project implementation and funding arrangements, especially those pertaining to roles and responsibilities and the flow of funds between implementers or across countries and/or organizational layers of the consortium;

- project implementation in a high-risk environment (e.g. in politically unstable countries, countries scoring low in transparency and corruption indexes or in humanitarian and fragile settings);
- unclear or inappropriate data collection, consolidation, analysis and reporting processes between parties or across countries and/or organizational layers of a consortium or project implementers; and
- weak grant management capacity. This includes having limited track record, experience and knowledge in managing comparable, donor-funded projects. Grantees should have mechanisms in place to assess whether the parties involved in implementing Unitaid-funded activities have the necessary resources and skills, including sufficient knowledge of grant implementation and country settings.

Unitaid expects its Grantees to put in place mechanisms to identify and address such situations during implementation of a Unitaid-funded project.

6. Reporting of Wrongdoing

6.1. Obligation to Report

Grantees may have grounds to suspect wrongdoing before they have clear evidence of it or fully ascertain all the relevant details. Grantees should nonetheless contact their Unitaid counterparts as soon as a credible suspicion emerges. This first exchange would enable the Grantee and Unitaid to share a common understanding of the issue before entering into the formal reporting step as explained in paragraph 6.2.1 below. In all cases, Unitaid expects Grantees to apply the utmost professional standards and sense of urgency and to diligently report incidents as early and as comprehensively as possible.

In line with the requirements in paragraph 4 above, Grantees must ensure that the scope of the obligation to report is clearly communicated to all third-party recipients of grant funds. Any other party associated with the implementation of the Unitaid-funded project—such as key stakeholders and partners—must be reminded to report both suspected and confirmed acts of wrongdoing.

Grantees must take all necessary measures to ensure that all parties involved in the implementation of Unitaid-funded projects (e.g. personnel and patients, Sub-Grantees or contractors and their personnel and patients) are aware of the reporting channels made available as detailed below.

6.2. Reporting Channels

Two channels are available to report suspected or confirmed cases of wrongdoing to Unitaid.

6.2.1. Reporting Directly to Unitaid

Unitaid Grantees must report suspected and/or confirmed acts of wrongdoing within the Unitaid-funded project using the standard Unitaid Fraud and Loss Report Form (also called an “Incident Report” form).

The Incident Report form should be sent to the designated Unitaid Programme Manager. If the form cannot be completed in full, Grantees should explain why and provide an estimated date for when a new, complete version of the report will be shared with Unitaid.

It is the role of the Grantee to ensure that sub-implementers or other third-party recipients of Unitaid funds report and follow up on incidents on a timely basis, providing the appropriate supporting documentation. Grantees are responsible for proactively sharing regular updates on the resolution of reported incidents, including on corrective actions, and to diligently follow up on these until such incidents are considered as closed by Unitaid. In addition, Grantees should also share a formal update as part of regular annual and semi-annual reports submitted to Unitaid.

Unitaid reserves the right to request additional information from Grantees after evaluating the circumstances and/or nature of each case.

6.2.2 Reporting using the Integrity Hotline

Suspected acts of wrongdoing can be reported anonymously through Unitaid's Integrity Hotline. The Integrity Hotline can be accessed at the following Internet address: <http://unitaid.org/report-fraud-abuse>.

The Integrity Hotline is available for individuals or entities who are concerned that they may be subject to retaliation or prejudice because of providing their report or who have no formal direct relationship with Unitaid enabling them to submit an Incident Report (as described in paragraph 6.2.1 above).

The hotline service is managed by Expolink, a professional, independent organization with impartial staff trained to handle anonymous reports. Expolink is contracted by the WHO to provide a safe and secure mechanism for individuals to report concerns related to Unitaid-funded projects or activities. The hotline service is always available. Reports received are then transmitted to WHO's Office of Compliance, Risk Management and Ethics (CRE).

Sub-Grantees should ensure that their Lead Grantees are aware of any suspected and/or confirmed acts of wrongdoing associated with the Unitaid-funded project. They also have the option of using the Integrity Hotline to report their concerns in confidentiality.

Confidentiality and Protection against Retaliation

The identity of individuals contacting the Integrity Hotline will be protected. Confidentiality will only be waived with the express informed consent of the individual, unless CRE and/or other persons involved in the investigation deem it a case of clear and imminent danger to the individual in question or another person. Their name will not be revealed to the person(s) potentially implicated in the suspected wrongdoing or to any other person unless the individual personally authorizes the disclosure of their identity as required by subsequent investigative processes, or by law.

Any retaliatory measures⁴ against a Grantee or its personnel, agents or representatives or any other individual reporting wrongdoing will constitute misconduct and be dealt with by Unitaid's investigative bodies (see paragraph 7, below) as a separate act of wrongdoing. However, it is important to note that protective measures against retaliation cannot be assured if the individuals reporting concerns remain anonymous.

When using the Integrity Hotline, whistleblowers⁵ may choose to remain anonymous when reporting suspected and/or confirmed acts of wrongdoing. In such cases, the whistleblower will be provided with a reference number, to enable future interactions with CRE and/or investigators. In the event that the identity

⁴ Retaliation is defined as any direct or indirect adverse action recommended, threatened or taken towards an individual who has in good faith reported, wrongdoing or cooperated with a duly authorized audit or investigation of a report of wrongdoing.

⁵ Individuals reporting concerns through the Integrity Hotline.

of a whistleblower is disclosed when making the report or during subsequent exchanges through the Hotline service, it will be treated confidentially. No details will be disclosed to third-parties external to the investigation without the whistleblower's authorization. In all cases, the contents of reports submitted through the Integrity Hotline will also remain confidential vis-a-vis third-parties external to the investigation, unless the whistleblower authorizes such a disclosure.

7. Managing and Investigating Cases of Wrongdoing

7.1. Case Management Process

Once a concern is reported, Unitaid follows its internal processes, which include a pre-assessment of the reported concern. In cases where this pre-assessment warrants the need for Unitaid to launch its own investigation, Unitaid will consult the Lead Grantee where relevant or appropriate and as needed. Where the assessment concludes that Unitaid agrees to rely on the Grantee's own investigation resources, this will be communicated in writing by Unitaid – in such case the investigation report will be shared with Unitaid within one week of its issuance.

For reports submitted through the Integrity Hotline, CRE will transmit the full details of the case to Unitaid for preliminary assessment and investigation only if authorized to do so by the whistleblower. In the event that the whistleblower does not provide this authority, CRE will manage the matter, together with relevant third parties and WHO's Internal Oversight Services (IOS) if necessary⁶.

7.2. Investigation by the Lead Grantee

As part of its pre-assessment of reports received (paragraph 7.1 above), Unitaid determines what the best investigation approach should be. For example, Unitaid determines the robustness of the Grantee's systems, processes and procedures for managing suspicion of wrongdoing as part of its pre-grant capacity assessment. Based on the results of this capacity assessment, Unitaid may agree to rely exclusively on the Grantee's own investigation resources. In such case, the Grantee must ensure that:

- Unitaid agrees to the scope of the investigation (e.g. in terms of timelines, investigation terms of reference, access to information);
- any information relating to the investigation is shared in a timely manner with Unitaid; and
- the final investigation report is shared with Unitaid within one week of its issuance.

⁶ WHO IOS is responsible for conducting (or subcontracting) investigations to respond to suspicion of wrongdoing received.

7.3. Right to Investigate by Unitaid

As a result of its pre-assessment of reports received (paragraph 7.1 above) or at any time during the process, Unitaid may decide to launch its own parallel investigation, irrespective of any other investigations. The WHO IOS, or any firm contracted under the technical supervision of IOS, may be requested to carry out the investigation on behalf of Unitaid.

7.4. What happens after an investigation?

Investigations help to substantiate the suspected acts of wrongdoing and evaluate responsibilities and possible losses resulting from the acts. Upon receipt of an investigation report, Unitaid will communicate back to the Grantee in writing the necessary course of actions. Where relevant, this would include a reminder of the Grantee's obligations to reimburse the possible financial loss affecting Unitaid funded assets.

For that reason, it is therefore recommended to Grantees to ensure that adequate safeguards are in place to ensure they are in a position to reimburse any resulting liabilities to Unitaid (including but not limited to securing adequate rights of recovery against Sub-Grantees and other third-party recipients, as well as taking the necessary insurance arrangements).

Once an investigation substantiates wrongdoing, it is important that Unitaid and its Grantee discuss lessons learnt and actions implemented to minimize the case of wrongdoing occurring again. This may for example include strengthening of internal controls and/or raising awareness of staff through dissemination of lessons learnt and work tools.

On Unitaid's side, this would lead to greater communication between Unitaid and the Grantee on the area of wrongdoing and could potentially lead to the introduction of new reporting/monitoring requirements, the establishment of conditions to future funding, the reporting of the case to the relevant national authorities, or—in an extreme situation—Unitaid having to reconsider its future contractual relationship with the Grantee.

8. Conclusion

As explained above, wrongdoing comprises types of misconduct involving misuse of funds as well as sexual misconduct and abuse, or other violations of human rights and practices that obstruct the protection of human rights. Wrongdoing can negatively affect the delivery and impact of Unitaid-funded projects and has the potential to harm individuals, the reputation of Unitaid, its partners and their respective donors. For this reason, preventing, detecting and effectively managing wrongdoing is a shared responsibility that relies upon open and regular communication and collaboration among all.

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