

Code of Conduct for responsible Research

November 2017



Code of Conduct for responsible Research

Acknowledgements

This document was prepared by the Office of Compliance, Risk Management and Ethics (CRE) of WHO. CRE's objective is to pursue excellence at all levels of WHO in an effective, efficient, transparent and accountable way by promoting and upholding the highest organizational standards, ethical principles and conduct.

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1. Glossary and links

[Clearance procedures for publications](#) – lays out the procedures for all proposals for publications to be issued by WHO to be cleared before development begins.

[Code of Ethics and Professional Conduct](#) - provides a standard to assist staff members and collaborators in carrying out WHO's mission while respecting WHO's basic principles of ethical behaviour. It provides guidance to ensure that the principles of integrity, accountability, independence/impartiality, respect and professional commitment are followed at all levels of the Organization.

Collaborators - individuals who work for WHO as non-staff members, including consultants, holders of Agreements for Performance of Work (APW), Technical Services Agreement (TSA) holders, Special Service Agreements (SSA) or letters of agreement, Temporary Advisers, Interns, and Volunteers, as well as third party entities such as vendors, contractors or technical partners who have a contractual relationship with WHO.

[Declaration of interest for staff members](#) – form that WHO staff members in designated functions are requested to complete annually to declare any interest that may conflict with their work at WHO.

[Declaration of interest for experts](#) – form that external experts are requested to complete before they can initiate their collaboration with WHO. External experts are asked to declare any circumstance that could represent a conflict of interest related to their expertise.

Fabrication of data - deliberate creation, recording and reporting of nonexistent results

Falsification - deliberate manipulation of data to change, or omit data, including the deceptive manipulation of images

[Financial regulations and financial rules](#) - The Financial Regulations govern the financial administration of the Organization. The Financial Rules are established by the Director-General, including relevant guidelines and limits for the implementation of the Financial Regulations, in order to ensure effective financial administration, the exercise of economy, and safeguard of the assets of the Organization.

[Framework of Engagement with Non State Actors](#) - is a process and instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity, reputation and public health mandate and thereby enables WHO's engagement with non state actors (nongovernmental organizations, private sector entities, philanthropic foundations, and academic institutions)

[Fraud Prevention Policy and Fraud Awareness Guidelines](#) – defines fraud as "misappropriation, irregularities and illegal acts characterized by deceit, concealment or violation of trust", and establishes an investigation process.

[Guidelines for Declaration of Interests](#) - explain the meaning of a "conflict of interest"; identify when an external expert must complete a declaration of interests form ("DOI Form"); explain how the WHO Secretariat through the relevant technical unit (the "Secretariat"), should assess the information disclosed; and describe what actions should be taken when a potential conflict appears to exist. The Guidelines also describe the Public Notice and Comment procedure and provide a listing of practical considerations relating to the selection of experts and the management of conflicts of interest

[Integrity Hotline](#) - a telephone number, email, or web tool providing a safe and independent mechanism to report any concerns about issues involving WHO or other partners (See below). Information about, and access to, the Hotline is available here: <http://www.who.int/about/ethics/en/#integrity>

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[Misconduct](#) - any improper action by a staff member in his official capacity; any conduct by a staff member, unconnected with his official duties, tending to bring the Organization into public discredit; any improper use or attempt to make use of his position as an official for his personal advantage; any conduct contrary to the terms of his oath or declaration.

Wrongdoing in research - intentional, fraudulent or grossly negligent behaviour such as fabrication, falsification, plagiarism, deliberate misrepresentation or other practices by a staff member or collaborator that seriously deviate from this *Code*

[Outside activities](#) - Engagement in outside occupation or employment, paid or unpaid, may interfere with exercise of the staff members' WHO functions. Some external activities may be incompatible with the status of World Health Organization employees, or conflict with the best interest of the Organization.

Plagiarism - the copying of ideas, data or text (or various combinations of the three) without proper acknowledgement and misappropriation as one's own;

Piracy - unauthorized use, reproduction, or sharing of intellectual property;

Policy on Misconduct in Research – outlines actions to be taken when reports of wrongdoing in research are brought against individuals working for or collaborating with WHO.

[Policy on open access](#) - Taking account of WHO's obligations as an intergovernmental organization (IGO), aiming to increase the reach and usage of WHO publications, and to maximizing access to WHO-authored and WHO-funded work published externally, this policy supports open access to the published output of its activities as a fundamental part of its mission and a public benefit to be encouraged wherever possible.

[Policy on Whistleblowing and Protection Against Retaliation](#) – Issued in 2015, WHO's policy aims to encourage staff members as well as the wider public to report concerns or suspicions of wrongdoing involving WHO, and defines protection against retaliation.

[Policy on Prevention of Harassment](#) - This policy: (a) seeks to promote a work environment free from harassment, in which staff members at all levels avoid behaviours that may create an atmosphere of hostility or intimidation; (b) provides a process for the consideration of claims of harassment and (c) provides for due process for all concerned.

[Policy on Sexual Exploitation and Abuse](#) – addresses sexual exploitation defined as any 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. It also addresses sexual abuse, defined as the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions. Sexual exploitation and abuse also includes sexual relations with a child, in any context¹.

[Publishing Policies](#) - Outline the different steps involved in publishing information products and links to the policies that apply during those steps

¹ This excludes situations where a WHO staff member is legally married to someone under the age of 18 but over the age of majority or consent in both the WHO staff member and spouse's country of citizenship.

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[Research](#): is defined as the development of knowledge with the aim of understanding health challenges and mounting an improved response to them. The term "research for health" reflects the fact that improving health outcomes requires the involvement of many sectors and disciplines. Research of this type seeks to perform the functions of understanding the impact on health of policies, programmes, processes, actions or events originating in any sector and of assisting in developing interventions that will help prevent or mitigate that impact².

[Research Ethics Review Committee \(ERC\)](#) - provides ethical oversight to health research involving human beings supported by WHO.

Sabotage - intentionally damaging, destroying, obstructing or otherwise harming a research project

[Staff regulations and Staff Rules](#) - The Staff Regulations embody the fundamental conditions of service and the basic rights, duties and obligations of the World Health Organization Secretariat staff. They are the broad principles of personnel policy for the guidance of the Director-General in the staffing and administration of the Secretariat. The Staff Rules implement the provisions of the Staff Regulations and govern the conditions of service of the World Health Organization.

² Research for health covers the full spectrum of research, which spans the following five generic areas of activity:

- measuring the magnitude and distribution of the health problem;
- understanding the diverse causes or the determinants of the problem, whether they are due to biological, behavioural, social or environmental factors;
- developing solutions or interventions that will help to prevent or mitigate the problem;
- implementing or delivering solutions through policies and programmes; and
- evaluating the impact of these solutions on the level and distribution of the problem.

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2. Introduction: fostering responsible research

- 1 The primary objective of the World Health Organization (WHO), as a specialized agency of the United Nations, is the attainment by all peoples of the highest possible level of health, by improving equity in health, reducing health risks, promoting healthy lifestyles and settings, and responding to the underlying determinants of health.
- 2 WHO considers research a fundamental instrument for the advancement and attainment of health, and is committed to the highest standards of scientific quality and ethical integrity. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge is one of WHO's core functions³.

2.1 Objectives

- 3 As delineated in its [Code of Ethics and Professional Conduct](#), WHO ensures that all of its public health and research interventions are founded upon a robust ethical framework and is committed to developing and promoting ethical, evidence- and human-rights-based guidance for the development of evidence-based health policies, and guidelines.
- 4 This *Code of Conduct for Responsible Research*⁴ ("Code") provides a standard to guide individuals working on all research associated with WHO, including non clinical research. The *Code* provides general principles and standards for good practice in the conduct of research, applicable to all individuals engaged in research associated with WHO
- 5 This *Code* is informed by existing WHO, international, national, institutional research guidance on best practices and codes of conduct for health research, and reflects WHO ethical principles as described in the [Code of Ethics and Professional Conduct](#). It is also guided by policies, guidance and academic and scientific communities' commonly accepted norms such as those promoted by the [Council for International Organizations of Medical Sciences](#). Particular emphasis is given to good research practice, conflict of interest, intellectual property, publication, and research wrongdoing.

2.2 Scope: defining research

- 6 This *Code* states key principles for research associated with WHO. It does not aim to be an exhaustive list of health ethics, but seeks to provide guidance to WHO staff and collaborators, as well as partner institutions engaging in research, by clarifying the requirements of the Organization. As such, this *Code* covers all research activities associated with WHO.
- 7 WHO defines [research](#)⁵ as the development of knowledge with the aim of understanding health challenges and mounting an improved response to them. This definition covers the full spectrum of research, which spans five generic areas of activity: measuring the problem; understanding its cause(s);

³ [Twelfth General Programme of work 2014-2019](#)

⁴ Referred to throughout this document as the "*Code*"

⁵ WHO eManual XV.1.1 Research Strategy for Health

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elaborating solutions; translating the solutions or evidence into policy, practice and products; and evaluating the effectiveness of proposed health solutions.

- 8 Applicable to the variety of ways through which WHO supports research (Figure 1), this *Code* ensures that WHO staff follow the right procedures in supporting WHO public health, guidelines and research interventions.

Figure 1: WHO's role in research projects/WHO's support to health research

WHO role in research project	WHO support to health research:	Level of responsibility
WHO is a <u>funder</u>	WHO <u>provides funding</u> to a research institution; research protocol is written by an external investigator. The research is conducted by the investigator under a contractual relationship established by WHO with the institution to which the investigator belongs, usually a TSA. The investigator and institution are legally bound to follow the terms of the contract. WHO staff are responsible for ensuring that the terms of the contract are fulfilled. It is the institution's responsibility to obtain adequate liability insurance.	It is the responsibility of WHO staff to: 1. Ensure that partner institutions have Codes of Conduct in place that uphold principles in line with this <i>Code</i>. 2. Report any suspicions of non adherence to the principles of this <i>Code</i> to their supervisors for action, or to the Integrity hotline as applicable. 3. Take action to address any suspicions that the principles have not been adhered to, including by terminating contractual engagements, or withdrawing from publication projects.
WHO <u>acts as a sponsor</u> of research	The funding may or may not be provided by WHO. In such cases, WHO usually ensures the conduct of the research through a contractual relationship with one or more research institutions through a TSA. In its role as a sponsor, WHO develops the research protocol, has responsibility for quality assurance in the conduct of the research (but does not actually conduct the research) (see ICH/GCP), and has responsibility for any mishap or wrongdoing during the research process. When required (e.g. clinical trial) and when not secured by another co-sponsor or third party, clinical trial liability insurance must be purchased. If a pharmaceutical product or a medical device is being tested, WHO staff conduct such projects under a Memorandum of Understanding (or collaborative R&D agreement) with the company whose product is being tested.	It is the responsibility of WHO staff to: 1. Ensure that partner institutions have Codes of Conduct in place that uphold principles in line with this <i>Code</i>. 2. Report any suspicions of non adherence to the principles of this <i>Code</i> to their supervisors for action, or to the Integrity hotline as applicable. 3. Take action to address any suspicions that the principles have not been adhered to, including by terminating contractual engagements⁶, or withdrawing from publication projects.
WHO is a <u>coordinator of</u>	Funding may or may not be provided by WHO. WHO may or may not be a sponsor. WHO staff are responsible for quality assurance during the	It is the responsibility of WHO staff to: 1. Uphold the principles outlined in this <i>Code</i>.

⁶ In consultation with the ERC in cases where terminating a trial early may have ethical implications.

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the research project	conduct of research, and/or for managing and analyzing data, writing up the research report, and publication and dissemination. A contractual relationship (through a TSA) is established with one or more external institutions and principal investigators.	2. Ensure that partner institutions have Codes of Conduct in place that uphold principles in line with this <i>Code</i>. 3. Report any suspicions of non adherence to the principles of this <i>Code</i> to their supervisors for action, or to the Integrity hotline as applicable. 4. Take action to address any suspicions that the principles have not been adhered to, including where appropriate by terminating contractual engagements⁷, or withdrawing from publication projects.
WHO staff <u>conduct research</u>	WHO staff members do not normally act as principal investigators⁸. WHO staff members can participate in research by, for example: • carrying out literature reviews. • designing surveys, usually in collaboration with Ministries of Health, national organizations or associations • less frequently, undertaking field or laboratory research.	It is the responsibility of WHO staff to: 1. Ensure that partner institutions have Codes of Conduct in place that uphold principles in line with this <i>Code</i>. 2. Adhere to this <i>Code</i> in all their research activities 3. Report any suspicions of non adherence to the principles of this <i>Code</i> to their supervisors for action, or to the Integrity hotline as applicable Principal investigators have direct responsibility for the day-to-day running of the project, unless the responsibility has been delegated to another institution under a contractual relationship.
WHO staff <u>are advisors</u> and provide technical assistance to a research project.	This can include the following: • WHO staff provide technical assistance to a project sponsored by another entity by providing advice on how to conduct the research, being the repository of the data or advising on how to manage or analyze the results. • WHO staff provide advice or act as reviewers: ➤ WHO staff provide ongoing technical advice to a project through membership of a Scientific or Advisory Committee established for the conduct of a research project. ➤ WHO staff member provide technical or ethical review on a research project. ➤ WHO staff participate in advisory Boards such as Data Safety/Protection Committees	Responsibilities are commensurate with level of involvement - when acting as advisers, WHO staff members have an obligation to: 1. Ensure that partner institutions have Codes of Conduct in place that uphold principles in line with this <i>Code</i>. 2. Their advice is in line with the principles of this <i>Code</i>. 3. Report any suspicions of non adherence to the principles of this <i>Code</i> to their supervisors for action, or to the Integrity hotline as applicable

⁷ In consultation with the ERC in cases where terminating a trial early may have ethical implications.

⁸ In exceptional circumstances, WHO may decide to be involved in a research project as Principal Investigator

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- 9 WHO promotes high-quality research that is ethical, expertly reviewed, efficient, accessible, transparent, carefully monitored, and rigorously evaluated.

2.3 Coverage

- 10 This *Code* applies to all WHO staff members, independent of their location or grade, and including Temporary Appointment holders and Seconded⁹ In its spirit and principles, this *Code* also applies to all WHO collaborators, notwithstanding their contractual or remuneration status: i.e.: individuals who work for WHO as non-staff members including interns, volunteers, consultants, holders of Agreements for Performance of Work (APW), Technical Services Agreement (TSA) holders, Special Service Agreements (SSA) or letters of agreement, Temporary Advisers, as well as third party entities such as vendors, contractors or technical partners who have a contractual relationship with WHO.
- 11 Responsibility for ethical behaviour in research lies with all staff members at all levels, and forms the basis of WHO's reputation. The trust placed in WHO by Member States, its external stakeholders and the general public must never be taken for granted. WHO staff members and collaborators are committed to the highest standards of research conduct while striving for excellence in developing, carrying out, participating in, disseminating, and applying the results of state-of-the-art science.
- 12 WHO staff and collaborators are expected to demonstrate exemplary behaviour in research, reflecting personal commitment through responsible action. They must apply the highest standards of scientific integrity as detailed in this *Code*, and are responsible for ensuring adherence to WHO standards.
- 13 It is therefore essential that all staff members know and understand the *Code* and use it as a guide for thought and action. Moreover, as the *Code* is not intended to cover every situation or problem that may arise, staff members are encouraged to seek guidance and assistance from their supervisory channels, the Office of Compliance, Risk Management and Ethics (CRE), the Ethics Review Committee (ERC), and/or the Office of the Legal Counsel (LEG) as applicable in order to resolve issues and ensure the ethical performance and discharge of their professional responsibilities.

3. Guiding ethical principles for responsible research

- 14 WHO staff and collaborators, are required to adhere to and promote the principles of integrity, accountability, independence/impartiality, respect for persons and communities, and professionalism in their research engagements. WHO staff members must ensure the partner institutions they work with have Codes of Conduct in place that uphold principles in line with this *Code* and inform them that breaches may cause WHO to terminate any collaboration arrangement¹⁰. These principles underlie all WHO involvement with the scientific, ethical, and practical requirements and challenges that arise in health research:

⁹ Junior Professional Officers and individuals on loan from other entities are also bound by WHO's ethical principles.

¹⁰ In consultation with the ERC in cases where terminating a trial early may have ethical implications.

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Figure 2: WHO ethical principles to be followed in conducting/supporting research

Integrity	WHO staff members are required to demonstrate intellectual and moral honesty in proposing, conducting, and reporting research. Truthfulness and responsible conduct underlie the integrity of research proposals, information, data, analyses, reports, and publications.
Accountability:	WHO staff members must take responsibility for their actions and their commitments to research. They are expected to promote public transparency throughout the research process and adhere to applicable policies, including WHO's <i>Statement on Public Disclosure of Clinical Trial Results</i> and to WHO <i>Information Note 21/2016</i> . WHO staff conduct as well as the research in which they engage must be open to monitoring and verification.
Independence and impartiality	WHO staff members are expected to conduct themselves with the interests of WHO only in view and under the sole authority of the Director-General. Professional and ethical conduct requires that the international character of WHO is respected and that staff maintain their independence and not seek or receive instructions from any Government, external entity, or person external to WHO. WHO staff members must ensure that personal views, convictions, previous experiences or future ambitions do not compromise the objective scientific process, the performance of their official duties or the interests of WHO. Bias, prejudice, conflict of interest or undue influence must not be permitted to supersede the professionalism of their conduct. Staff members must exercise the utmost discretion in their actions, refrain from participating in any activity that is in conflict with the interests of WHO or might damage WHO's reputation, and respect and safeguard the confidentiality of information, which is available or known to them because of their official functions.
Respect for persons and communities	WHO staff members must engage in research based on the respect of the dignity of persons and communities. Alongside the health needs of individuals and communities, WHO staff must consider all factors that affect quality of life when designing, conducting, and reporting research. These factors include the social, economic, and psychological needs and expectations of individuals and communities. WHO staff must consider the cultures and environments in which people live, and promote culturally and environmentally responsible research. This means taking into account the underlying inequalities and the diversity of persons and communities, and to strive for equity and justice in health research. WHO staff must be mindful of the potential risks associated with specific research as well as the potential benefits for persons and communities, eliminating or limiting research risks wherever possible while enhancing and promoting research benefits whenever possible.
Professional commitment	WHO staff are required to build their professional competence on a foundation of integrity, scientific knowledge, and personal commitment to advancing health for all. Objectivity, accuracy, efficiency, and impartiality are expected when WHO staff are engaged in research.

- 15 The quality of the research and the value of the knowledge achieved depend intrinsically on the integrity of those performing the research. Honesty, truthfulness, and transparency not only contribute to the

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accuracy and reliability of the scientific activity and its outcomes, they also form the foundation for public trust and good health policy resulting from research.

- 16 WHO promotes an ethics of consciousness enriched by dialogue and supported by a careful awareness of the needs and sensitivities of persons, communities, and cultures. Staff need to be particularly sensitive to the expectations of persons and communities participating in research as well as the impact of the research on those persons and communities. WHO staff are expected to demonstrate exemplary behaviour in research, reflecting personal commitment through responsible action.

4. Wrongdoing in research and questionable or poor practice

- 17 The **non adherence to the principles laid out in this Code is considered wrongdoing** and, where established by an examination of facts, will, in the case of staff members, be found to amount to misconduct in accordance with [WHO rules and regulations](#), and will be treated in a manner commensurate with the potential seriousness of its implications on the health of the people the Organization serves.
- 18 In the case of WHO collaborators, specific measures will be devised on a case by case basis to address established wrongdoing.
- 19 The extent of the harmful consequences of wrongdoing in research is as difficult to estimate as it is to mitigate in terms of potential impact on the health of individual people, public health, the environment, the credibility of the Organization, and the wider public's general trust in science.
- 20 In this context, the term wrongdoing in research means **intentional, fraudulent or grossly negligent behaviour that breaches the principles of this Code. Such behaviour includes without being limited to:**
- Inappropriate development of research protocols;
 - Failure to disclosure or take action on declared conflict of interest;
 - Inadequate management of a research project;
 - Fabrication, falsification, plagiarism, deliberate misrepresentation or other practices that deviate from this Code and from the academic and scientific communities' commonly accepted norms¹¹ for proposing, conducting or reviewing research or for reporting research results.
- 21 WHO's policy on Misconduct in Research provides detailed procedures for reporting, screening, examining and taking action on reports of wrongdoing in research, based on the principle that:
- WHO staff and collaborators becoming aware of violations of this Code must report their concerns to their supervisors, and in instances where this may be problematic, must contact the [Integrity Hotline](#);
 - Individuals reporting suspicions of research wrongdoing in good faith will be considered whistleblowers and protected against retaliation as per WHO's [Policy on Whistleblowing and Protection against Retaliation](#).

¹¹ Including Declaration of Helsinki, and the Guideline for Good Clinical Practice (GCP) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

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22 Wrongdoing in research does not include honest errors or honest differences in interpretations or judgements of data. It also is different from other forms of questionable research practices, or poor practice, which can include inadequate data management and research procedures. To address this issue, and maintain the same standards, WHO staff are reminded of the importance of managing research contractual agreements with their partners and collaborators adequately.

23 Deviations from the standards of good practice listed in this *Code*, while not necessarily amounting to wrongdoing, may ultimately have similarly serious public health, moral or legal consequences and undermine public trust in WHO, and, more generally, in science. They must be reported to the immediate attention of their supervisors, and in instances where this may be problematic, can be reported through the [Integrity Hotline](#).

5. Applying standards of good practice in the conduct of research

24 WHO's good practice standards cover training and supervision, conflict of interest, research ethics, the management of research data, research procedures, contractual and other collaborative arrangements, publication, dissemination and authorship, and peer review.

5.1 Adherence to research standards

25 WHO staff members are required to be familiar with, appreciate, and adhere to high scientific and ethical standards when engaged in research. This also includes requiring institutions where the research is (to be) conducted, to have Code of Conducts that uphold principles in line with this *Code* and to adhere to their national scientific, ethical, and legal regulations and guidelines.

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26 Figure 3 lays out the responsibilities of WHO staff members with regard to adherence to research standards:

Figure 3: Responsibilities of staff members to adhere to research standards

WHO staff members are responsible for ensuring that:	
1	The research is responsive to the health needs of the population in which it is conducted;
2	The research is described in a protocol, including the medical, scientific, ethical, and monitoring aspects of the proposed study;
3	Research involving human subjects is reviewed by the WHO Ethics Review Committee¹² and other, non-human subjects research (for example, basic science or animal research) is reviewed by relevant WHO committee(s) ¹³ , as appropriate;
4	The protocol receives the appropriate and required ethical and regulatory clearances outside WHO;
5	There is a clear definition of the respective responsibilities of WHO and partner institutions in collaborative research in advance of the start of the research project; and
6	All members of the research team ¹⁴ recognize and accept their responsibilities as per established standards and best practices in their research field;
7	All members of the research team are aware of the requirement to comply with the principles of this <i>Code</i> and of their duty to report any departures from its principles, to their supervisors, to the leader of the research team, or through the Integrity Hotline in cases where this may be problematic.

5.2 Research training and supervision

27 WHO promotes an environment¹⁵ that supports research of high scientific and ethical standards, professionalism, cooperation, and the open and honest exchange of ideas. A culture of excellence in research underlies a large part of WHO's goal of achieving health for all. Training and mentoring WHO staff in research responsibilities and good research practices, including research ethics, are essential to achieving excellence in research, in both policy and practice.

¹² WHO eManual>VIII.7.4 Research involving human subjects

¹³ WHO eManual>XV.3.1 WHO Research Ethics Review Committee

¹⁴ A research team includes all persons involved with the initiation, planning, conducting, and reporting of a research project or projects

¹⁵ For example, Global Information Full Text (GIFT) program that provides WHO staff worldwide with 24/7 online access to major journals and databases in the medical and biomedical field

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- 28 Figure 4 lists the role of WHO staff members involved in research and of the Organization with regards to training and supervision:

Figure 4: Research training and supervision

The role of staff	The role of the Organization
1 Take responsibility for becoming familiar with the principles of this <i>Code</i>, and guidance related to research, and public health ethics. 2 Ensure that skills/experience support the responsibilities they assume in engaging with research and undertake proactive steps to maintain, update or complement competences; 3 Ensure that all research teams undergo initial and continuous training in research ethics and receive adequate guidance; 4 Ensure sufficient training, availability of necessary tools and mentoring for updating and improving the knowledge and skills required to review, design, conduct and report state-of-the-art research; 5 Understand when to seek guidance and do so pro-actively when in an unfamiliar or challenging situation; 6 Require acceptance of WHO standards and procedures for the conduct of research with or by collaborative research institutions; and 7 Agree with funders that the research to which they are contributing, is conducted in accordance with WHO standards and procedures.	1 Set standards to ensure that staff and collaborators involved in research are supervised by a qualified, trained and available supervisor; 2 Make available training to cover this <i>Code</i> and relevant subjects to maintain professional research competence; 3 Ensure training to maintain and update research and technical competencies; and 4 Make available the policies, guidelines, rules and procedures that relate to the conduct of research including this <i>Code</i> and information on mechanisms to report research wrongdoing

5.3 Conflict of interest and bias

- 29 A [conflict of interest](#) (COI) arises in research when the objectivity, accuracy, efficiency, and/or impartiality of an individual or group engaged in the research is threatened by an interest outside the scientific and ethical interests of the research. Figure 5 shows potential situations that may give rise to a COI in research.
- 30 Individuals engaging in research may have some degree of “intellectual bias” in relation to a particular topic. Individuals engaging in different research projects must assess their vulnerability to conflict of interest/bias anew for every different topic and/or level of involvement as conflict of interest is situation-specific. WHO expects all its staff and collaborators to maintain high standards of independence and impartiality. This entails keeping the ability to put aside their own views, opinions, beliefs, past positions, or past research results, and future personal ambitions to look at data objectively

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with an open and critical mind, particularly so when emerging data may not confirm the results of previous professional endeavours.

Figure 5: Conflict of interest and bias situations

Conflict of interest or bias situations	
1	A WHO staff member or research team member may gain, directly or indirectly, significant personal benefit or professional advantage from the research outcomes (including financial gain and/or professional advancement);
2	A study is initiated, designed, and/or financed by a person or organization (public or private) with a significant interest in the research outcomes, and direct access to research results can lead them to undue gain/advantage;
3	WHO staff and research teams are required to demonstrate readiness to acknowledge newly generated data, and accept to revise their views, opinions, and past positions based on the availability of new information.

31 WHO staff are responsible for proactively taking the steps described in Figure 6:

Figure 6: Requirements vis a vis conflicts of interest and bias

WHO staff members are expected to:	
1	Keep a critical and honest view of themselves and any private interest, and bias that they may have with regards to a particular research project;
2	Identify and assess the type and severity of each conflict of interest or bias they may feel towards a project;
3	Consult CRE concerning the conflict of interest or bias they have identified, and how to address it;
4	Disclose any real or potential conflict of interest or bias among themselves and in their research teams prior to the start of the research and as and when it may arise during the course of the research;
5	Document the conflict of interest as part of the study documents and declare any conflict of interest to the WHO Ethical Review Committee (ERC) as well as all other ethics committees or regulatory agencies reviewing the research; and
6	Withdraw from any engagement with research where a conflict of interest or bias could potentially compromise the integrity or validity of the research.

32 Staff members and collaborators who find themselves in a situation of conflict of interest or recognize facing certain bias with regards to a particular subject can consult CRE at ethicsoffice@who.int confidentially for advice. They must disclose their interest or bias by completing or updating CRE's declaration of interest form for [staff](#) or [for consultants/experts](#) respectively. Such disclosure does not automatically disqualify them from participating in the project but enables them and the Organization to manage the said conflict of interest or bias to maintain independence and impartiality.

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- 33 WHO staff members must request that all prospective collaborators and contractual partners complete the WHO [Declaration of Interest for experts](#)¹⁶. WHO staff must also require that partner institutions have Codes of Conduct in place that uphold principles in line with this *Code*, and adhere to their national requirements relating to conflicts of interest.

5.4 Managing collaboration in research

- 34 Managing collaboration with other institutions or researchers is essential to good research practice. WHO has established policies and procedures to assist in selection, procurement and development of contracts¹⁷ for research. Particular attention to conflict of interest is required, and declarations of interest must be completed, reviewed, where necessary with the advice of CRE, prior to finalizing an agreement with an external researcher. The WHO Technical Services Agreement (TSA)¹⁸ structure provides the strongest safeguards for scientific research contracts with research institutions. Other types of WHO-approved contracts¹⁹ that are used in association with research purposes also require careful preparation and monitoring. LEG can be consulted for legal advice at any time.

Figure 7: Requirements for managing research collaboration arrangements

WHO staff are expected to:	
1	Ensure that WHO rules and regulations are applied in selection/procurement processes, with particular attention to requirements for adherence to this <i>Code</i> , and to WHO's requirements regarding conflict of interest ;
2	Prepare and review contracts to assure that the research is clearly described, including the roles, and responsibilities of the contract participants;
3	Ensure contracts adequately define research requirements and that all parties have access to the necessary capacities and resources;
4	Address issues of confidentiality, ownership of the research results, intellectual property, etc. in consultation with LEG where necessary, and ensure that contracts properly reflect the required arrangements;
5	Follow contract clearance procedures ²⁰ ;
6	Monitor contract compliance; and
7	Ensure amendments to a contract are appropriately reviewed in consultation with LEG, and are fully reflected in the research activities.

5.5 The financial management of research

- 35 Good financial management of research projects is essential to the support and integrity of research and its outcomes.

¹⁶ WHO Guidelines for Declaration of Interests

¹⁷ The term 'contract' refers here to Technical Services Agreements (TSAs), Direct Financial Cooperation arrangements, Letters of Agreement, Agreements for Performance of Work, and Consultant Contracts

¹⁸ [WHO eManual. XVI.1 Technical Services Agreements](#)

¹⁹ For further clarification see [WHO eManual VI.2.3 Procurement of Services](#)

²⁰ [WHO eManual. XVI Contractual Arrangements for Programme Implementation](#)

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- 36 The financial terms and conditions of research funding need to be defined clearly in all research contracts.

Figure 8: Financial management requirements

WHO staff members are required to:	
1	Follow WHO's Framework of Engagement with non State Actors when engaging in donation agreements for research with third parties, including public and private sources of funding;
2	Review and consider the appropriateness of requirements and/or rules from research funders and collaborators prior to committing to receive funds or agreeing to collaborate in a research undertaking;
3	Identify clearly in research contracts how the research resources are to be allocated regarding personnel, equipment, materials, events, and subcontracting;
4	Ensure the appropriate management of resources and provide accountability for the use made of financial resources throughout the research;
5	Report in a timely and transparent way any deviations or irregularities regarding the use of research funding; and
6	Facilitate the monitoring and audit of finances related to the research.

5.6 Quality management in research

- 37 WHO is committed to research-quality management as an essential way to achieve excellence in research in line with academic and scientific communities' commonly accepted norms²¹. This includes assuring:
- the quality of the questions posed;
 - the quality of the design, conduct, and reporting of the research;
 - the quality of oversight of the research; and
 - the quality of the scientific, ethical, contract, and financial management of the research.

Figure 9: Quality management in research

WHO staff members are expected to:	The role of the Organization
1 Ensure that the research questions address the rationale of the project and are appropriate to the health condition, population, and health outcomes of interest;	1 Maintain relevant policies for the retention, management and dissemination of research data.
2 Ensure an appropriate study design with a research methodology capable of addressing and responding to the research question(s) posed;	2 Make available mechanisms for staff members and collaborators to be able to report issues of compliance with this <i>Code</i> , poor research
3 Ensure that the scientific, ethical, regulatory, and peer reviews of proposed, ongoing, and completed research are undertaken;	
4 Register clinical trials in a publicly accessible trial registry;	

²¹ Including Declaration of Helsinki, and the [Guideline for Good Clinical Practice \(GCP\)](#) of the [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use \(ICH\)](#)

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5 Ensure the research team has the necessary skills, training, resources, and support to carry out the proposed research; 6 Anticipate issues that may arise as a result of working collaboratively and decide in advance how such issues will be addressed, including in the contract and/or protocol and communicating the outcome to the members of the research team; 7 Ensure that the correct contract format is used and consult LEG as appropriate (including as to whether any amendments to the general conditions of any standard contract are needed). LEG must be consulted for any non-standard contractual arrangements, and amendments to standard contract. Define clearly in the contract the parties' responsibilities regarding the research; 8 Ensure that the needed and required insurance and indemnity policies covering WHO, the research participants and researchers are in place prior to commencing the research; 9 Ensure the highest scientific and ethical conduct of the study; 10 Ensure good data management, including the planning, generation, documentation, analysis, use, storage, and appropriate destruction of data; 11 Ensure that action is taken when there is evidence for severe non adherence to this <i>Code</i>, wrongdoing or poor practice, and if needed, terminate site participation when situation requires; 12 Ensure the timely and public dissemination of the research and its main outcomes (subject always to the protection of confidential information and proprietary rights); and 13 Maintain and make available research documentation for scientific, ethical, and regulatory review as well as for peer review and publications review procedures.	practice or malpractice through normal supervisory channels or through the Integrity Hotline in sensitive cases 3 Protect individuals reporting issues of adherence to the principles of this <i>Code</i> in good faith from retaliation. 4 Take action to resolve issues of non-adherence to the principles of this <i>Code</i>, or of poor research practice.
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5.7 Managing and monitoring research data

- 38 WHO promotes good data management practices in all research. This includes the appropriate collection, retention, use, dissemination, and destruction of research data. WHO supports good research oversight practices, including the monitoring and auditing of ongoing and completed research.

Figure 10: Managing and monitoring research data

The role of staff members	The role of the Organization
1 Be mindful of WHO guidelines and practices^{22,23,24} regarding research data, as well as international and national regulations and guidance; 2 Ensure adequate procedures, resources, and support for the appropriate, accurate, complete, and efficient collection, use, storage, and access to data during and after the research; 3 Ensure the proper security of confidential data, as well as the appropriate access to non-confidential data by interested parties and the public; 4 Ensure that the need for monitoring is addressed at the outset of the research, and describe specific requirements in audit plans; 5 Ensure that audits are facilitated by all members of the research team; 6 Ensure that appropriately trained monitors and auditors are assigned to the research; 7 Ensure that the reports and findings of monitors and auditors are addressed in a timely manner; and 8 Ensure that preventive and/or corrective actions are undertaken, as applicable.	1 Maintain and support WHO's guidelines, practices and policies on data management ²⁵; 2 Ensure secure storage of research data and record keeping facilities; 3 Maintain adequate policies on information disclosure policy, data sharing and access to data²⁶.

²² WHO Handbook for Good Clinical Research Practice: Guidance for Implementation (2005), <http://apps.who.int/iris/handle/10665/43392>

²³ WHO/TDR Handbook: Good Laboratory Practice GLP. Quality practices for regulated non-clinical research and development 2nd edition (2009) <http://www.who.int/tdr/publications/documents/glp-handbook.pdf?ua=1>

²⁴ WHO eManual>VIII.7.3 Use of data relating to patients or participants in research studies

²⁵ [Information Classification](#), [Archives](#) and [Records Management](#), and [Information Disclosure](#) Policies

²⁶ Policy statement on data sharing by WHO in the context of a Public Health Emergency of International Concern (as of 13 April 2016), <http://www.who.int/wer/2016/wer9118/en/>. Policy on use and sharing of data collected in Member States by WHO outside the context of public health emergencies, and policy on open access (<http://www.who.int/about/policy/en/>).

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5.8 Peer review

- 39 WHO promotes the peer review of health research, whether the Organization undertakes the research directly or indirectly.

Figure 11: Peer review

The role of staff members	The role of the Organization
1 Facilitate the peer review of research prior to its implementation, taking into account and addressing the findings of peer reviewers; 2 Participate themselves in peer review when asked, according to their background, experience, and engagement in similar research²⁷; 3 Declare any conflicts of interest (financial, professional, or personal) regarding the research itself, its reporting, and/or outcomes they are asked to review; 4 Decline invitations for peer review, or withdraw from an ongoing review, where they have a real or perceived conflict of interest; 5 Follow WHO and other appropriate guidance for carrying out a peer review; and 6 Provide their peer reviews with the highest standards of thoroughness, objectivity, impartiality, confidentiality, and timeliness.	1. Establish standards for peer review and make them available to peer reviewers. 2. Ensure that peer reviewers are independent. 3. Institute processes to encourage and support staff members to participate in peer reviews

5.9 Intellectual property and authorship

- 40 WHO is committed to upholding intellectual property regulations in research, and not to violate third party intellectual property rights. This includes research ideas, processes, and materials as well as research data, reporting, and publications. WHO follows the [authorship criteria](#) of the International Committee of Medical Journal Editors (ICMJE), which establish the basis for the [status of authorship](#)²⁸:
- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
 - Drafting the work or revising it critically for important intellectual content; AND
 - Final approval of the version to be published; AND
 - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

²⁷ Participating in a peer review of research conducted by an outside institution would constitute an outside activity for which approval would need to be sought with the Office of Compliance Risk Management and Ethics at ethicsoffice@who.int

²⁸ ICMJE. <http://icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> . Accessed on 4 October 2017

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- 41 The criteria articulate the role and responsibilities of authors with particular attention to the issue of conflict of interest. Staff members and collaborators can get advice from CRE regarding conflicts of interest/bias.

Figure 12: ICMJE author responsibilities and conflicts of interest²⁹

Participants	Responsibilities	Reporting conflict of interest
Authors	When submitting a manuscript, responsible for disclosing all financial and personal relationships that might bias or be seen or bias their work.	• Authors' conflicts of interest; • Sources of support for the work, including sponsor names along with explanations of the role of those sources if any in study design; collection, analysis, and interpretation of data; writing of the report; the decision to submit the report for publication; or a statement declaring that the supporting source had no such involvement; • Whether the authors had access to the study data, with an explanation of the nature and extent of access, including whether access is on-going.
Peer Reviewers	When asked to review a manuscript, responsible for disclosing any conflicts of interest that could bias their opinions of the manuscript, and for undertaking to recuse themselves from reviewing specific manuscripts if the potential for bias exists. Reviewers must not use knowledge of the work they're reviewing before its publication to further their own interests	
Editors	When making final decisions about manuscripts, responsible for undertaking to recuse themselves from editorial decisions if they have conflicts of interest/bias or relationships that pose potential conflicts related to articles under consideration. Editors must not use information gained through working with manuscripts for private gain	

²⁹ Drawn from ICMJE "Author responsibilities – conflict of interest". <http://icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html>. Accessed on 3 October 2017

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- 42 WHO expects its staff to include provisions clarifying the ownership and/or use of intellectual property in contracts relating to research, seeking guidance and assistance from LEG as appropriate.

Figure 13: Requirements vis à vis intellectual property rights

The role of WHO staff members	The role of the Organization
1 Require the institutions conducting the research to comply with intellectual property regulations in the countries in which the research, reporting, and/or publications are carried out; 2 Anticipate intellectual property issues that may arise in the research and provide appropriate and adequate ways to address these issues during the research; 3 Work with the research team (and, where necessary, research funders) to develop a clear understanding of intellectual property ownership and its use within the research project; 4 Obtain the appropriate permissions before making use of pre-existing intellectual property in research; 5 Acknowledge the use of pre-existing intellectual property when reporting and publishing research; 6 Consult with collaborative partners prior to the disclosure of research or the findings of research (always subject to the protection of confidential information and proprietary rights).; and 7 After leaving WHO, staff members are required to obtain the written permission of CRE for the use of any intellectual property and/or information that belongs to WHO or parties collaborating with WHO and may have become known to them during their employment with the Organization.	1. Maintain a policy with clear criteria for authorship in the Organization's publications; 2. Make available information and training on intellectual property and authorship; 3. Address disputes about authorship; 4. Clarify the responsibility of the Organization in being mentioned as an author in a publication; 5. Withdraw from publication projects if there is discomfort about the extent to which the principles of this <i>Code</i> have been followed or about the actual level of involvement of individual authors in the research itself.

5.10 Publication and dissemination of research findings

- 43 WHO promotes the highest standards for the publication and dissemination of research and its outcomes³⁰. Subject to the protection of confidential information³¹ and proprietary rights, WHO clinical trial research and its main outcomes will be made publicly and freely available in accordance with WHO's [Statement on Public Disclosure of Clinical Trial Results](#)³². It is the duty of researchers to publish and

³⁰ [Code of Ethics and Professional Conduct](#)

³¹ Policy statement on data sharing by WHO in the context of a Public Health Emergency of International Concern (as of 13 April 2016), <http://www.who.int/wer/2016/wer9118/en/>. Policy on use and sharing of data collected in Member States by WHO outside the context of public health emergencies, and policy on open access (<http://www.who.int/about/policy/en/>).

³² And WHO *Information Note 21/2016*

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disseminate the main findings of research in an accurate, timely and complete manner that is ethically responsible and publicly accountable. Specifically, WHO staff members are required to ensure that:

- all clinical trials which WHO either funds, sponsors or coordinates are prospectively registered in a clinical trial registry complying with WHO standards (<http://who.int/ictrp/en/>); and that
- methods (ie the final clinical trial protocol) and summary results of clinical trials are made publicly within 12 months following study completion.

44 There are two main modalities for this to occur: by posting to the results section of the clinical trial registry (e.g. clinicaltrials.gov) and/or by journal publication. Doing either one is considered to fulfil WHO dissemination requirements.

45 WHO requires its staff and collaborative researchers, authors, editors, and publishers to follow [WHO policy on publication](#) and international and applicable national guidance for publishing the results of health research. WHO staff are expected to:

Figure 14: Publication and dissemination of research findings

The role of staff members	The role of the Organization
1 Address issues relating to publication and authorship jointly with all members of the research team, including the roles of collaborators and contributors, at an early stage of the design of a project; 2 Ensure that research participants and communities are appropriately informed of the main outcomes of the research at an early stage; 3 Facilitate the publication of research and its main outcomes without inappropriate influence on the publications from funders or other interested parties; 4 Ensure an accurate and complete statement of authorship regarding reports and publications of research and its outcomes; 5 Ensure the timely publication and dissemination of the research methods and its main outcomes, with appropriate attention given to the confidentiality of research participants, and the potential impact on public health; 6 Ensure that reports and publications of research and/or its main findings clearly acknowledge all funders and collaborators in the research and include a listing of any conflicts of interests; 7 Declare any real or perceived conflicts of interests in relation to research when reporting the research and its outcomes at meetings, in reports, or in publications; and 8 Ensure the public and open access availability of the research methods and its main outcomes (International clinical trials Registry Platform).	1 Maintain an environment of transparency, honesty, integrity and responsibility in the dissemination of research; 2 Disseminate information with due respect to confidentiality of sensitive information³³; 3 Support and make available assistance to researchers in communication with the media; 4 Acknowledge contributions of institutional partners, sponsors and others.

³³ Information dissemination will respect contractual arrangements and WHO's approach to contracting will ensure no contradiction with the WHO policy on public disclosure of results from clinical trials

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6. Final note

- 46 This *Code* supports WHO's commitment to the highest scientific and ethical conduct of responsible health research. This guidance is not intended to be exhaustive, but rather to remind staff members engaged in research of the principles of ethical behaviour and standards of conduct that should guide their decisions and actions. All WHO staff members are required to follow this *Code* conscientiously, promote it in all research-related settings, and to know when to seek advice in cases of uncertainty.
- 47 WHO is responsible to ensure that appropriate research oversight mechanisms are in place and functioning. This includes ethical review, compliance with this *Code* and WHO 's Code of Ethics and Professional Conduct, the Policy on Misconduct in Research, compliance with legal requirements and public transparency.
- 48 WHO Department Directors engaged in research are responsible for ensuring that their Departments adhere to this *Code*, requiring partner institutions to have Codes of Conducts that uphold principles in line with this *Code* and to adhere to their own national requirements, and facilitating the resolution of and taking relevant action to address reports of suspicions of wrongdoing in research promptly. WHO Research Managers/Coordinators are responsible for ensuring that WHO staff engaged in research projects have been properly trained in the implementation of this *Code* and demonstrate commitment to it throughout their research activities.
- 49 This *Code* is a living document and will be updated by CRE on a regular basis to reflect on-going policy changes and developments. It will be made public (published on the [WHO Website](#)). Related internal policies, procedures, and contractual documents with WHO collaborators and partner institutions will be amended to reflect the principles of this *Code*.

7. Selected resources

The following is a selected short listing of supporting documentation to this *Code*.

- 1 European Science Foundation and ALLEA (All European Academies) 2011. *The European Code of Conduct for Research Integrity*. (<http://www.allea.org/wp-content/uploads/2017/03/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017-1.pdf>) Accessed 13 December 2016.).
- 2 Steneck NH, 2007. The Office of Research Integrity. *Introduction to the Responsible Conduct of Research*. Revised edition. Washington DC: United States Department of Health and Human Services. (<https://ori.hhs.gov/sites/default/files/rcrintro.pdf>) Accessed 13 December 2016.
- 3 UK Research Integrity Office, 2009. *Code of Practice for Research. Promoting good practice and preventing misconduct* (<http://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf>) Accessed 13 December 2016.
- 4 World Health Organization, 2017, Code of Ethics and Professional Conduct (http://www.who.int/about/ethics/code_of_ethics_full_version.pdf?ua=1). Access on 4 September 2017.

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- 5 World Health Organization, 2015. WHO Whistleblowing and Protection against Retaliation: Policy and Procedures, 2009. <http://www.who.int/about/ethics/WHOwhistleblowerpolicy.pdf?ua=1> Accessed 4 September, 2017.
- 6 World Health Organization, 2017. Sexual Exploitation and Abuse Prevention and Response, Policy and Procedures. http://www.who.int/about/ethics/sexual-exploitation_abuse-prevention_response_policy.pdf?ua=1. Accessed 4 September 2017.
- 7 World Health Organization, 2006. WHO Accountability Framework: A Policy Paper. (http://www.who.int/about/who_reform/managerial/accountability-framework.pdf?ua=1 - Accessed: August 2, 2011).
- 8 World Health Organization, 2010. Guidelines for Declaration of Interest. <http://www.who.int/about/ethics/doi-guide-EN.pdf?ua=1> Accessed: August 2, 2011).
- 9 World Health Organization, 2010 Implementation of the WHO publications policy (<http://intranet.who.int/homes/whp/whopublishingpolicies/policygroups/ppcg11agendaitem5a.shtml> Accessed: February 23, 2012).
- 10 World Health Organization, 2016. WHO's Framework of Engagement with Non State Actors. <http://www.who.int/about/collaborations/non-state-actors/en/> Accessed 14 September 2017.
- 11 World Health Organization, 2010. WHO's Role and Responsibilities in Health Research: WHO Strategy on Research for Health. Report by the Secretariat to the Sixty-Third World Health Assembly. (<http://hinfo.humaninfo.ro/gsd/healthtechdocs/documents/s17733en/s17733en.pdf> Accessed: November 7, 2011).
- 12 World Health Organization, 2017, Information Disclosure Policy, <http://www.who.int/suggestions/InfoDisclosurePolicy.pdf?ua=1>. Accessed 4 September 2017.
- 13 World Health Organization, 2016. Policy statement on data sharing by WHO in the context of a Public Health Emergency of International Concern. <http://www.who.int/wer/2016/wer9118/en/>. Accessed 14 September 2017
- 14 World Health Organization, 2015. Statement on Public Disclosure of Clinical Trial Results. <http://www.who.int/ictrp/results/reporting/en/>. Accessed 28 September 2017
- 15 World Health Organization, 2005. Fraud Prevention Policy and Fraud Awareness. ([https://intranet.who.int/homes/ios/documents/fraudpolicyguidelines\[1\].pdf](https://intranet.who.int/homes/ios/documents/fraudpolicyguidelines[1].pdf) - Accessed: August 2, 2011).
- 16 World Health Organization, 2016. Policy on use and sharing of data collected in Member States by WHO outside the context of public health emergencies, and policy on open access (<http://www.who.int/about/policy/en/>. Accessed 14 September 2017