HANDBOOK
FOR NON-STATE
ACTORS ON
ENGAGEMENT
WITH THE
WORLD HEALTH
ORGANIZATION

Handbook for non-state actors on engagement with the World Health Organization

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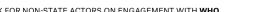
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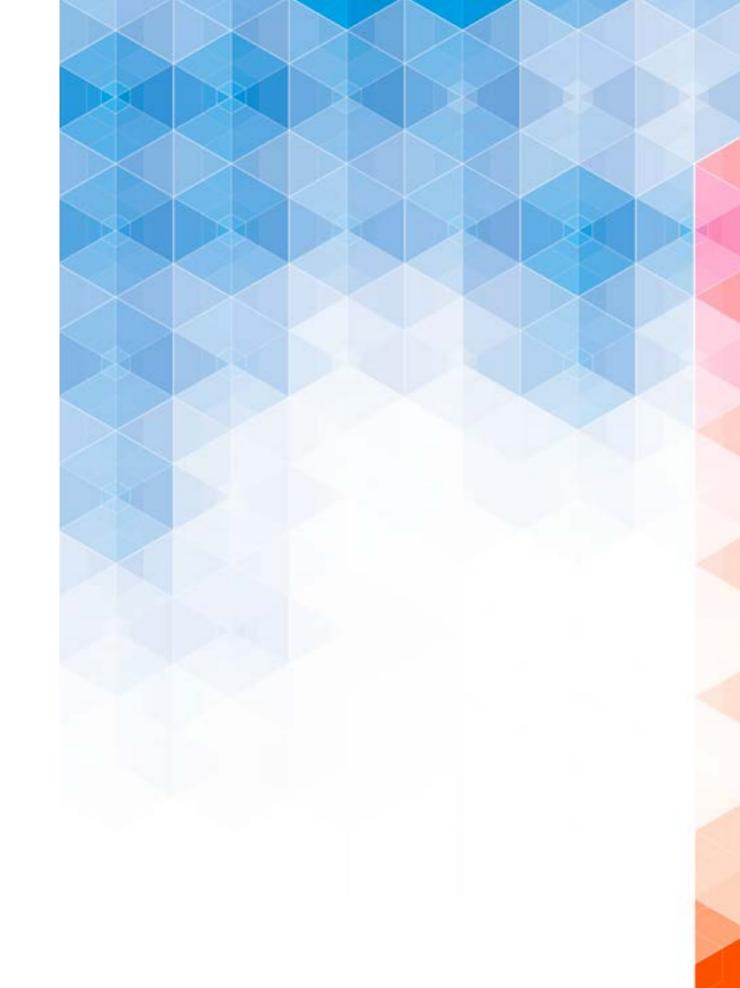


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RATIONALE

The purpose of this *Handbook* is to guide non-State actors in engaging with the World Health Organization (WHO) by walking them through The Framework of engagement with non-State actors' principles and processes and ensure smooth implementation of the Framework.

WHO's Framework of Engagement with Non-State Actors (FENSA) provides the guidance needed to engage with all types of non-State actors while maintaining the Organization's integrity and independence from interests detrimental to health. WHO will continue to strategically strengthen its engagement with non-State actors.

The *Handbook** does not replace the text of FENSA. The text adopted by WHO Member States will be applied by the WHO Secretariat when engaging with non-State actors. If there are information gaps in the *Handbook*, or any apparent inconsistencies between the *Handbook* and FENSA, FENSA and the WHO relevant rules and policies will apply. Non-State actors are encouraged to refer to the FENSA text.

In May 2016 the World Health Assembly adopted the Framework for Engagement with non-State actors, or FENSA, which is a set of rules governing WHO's engagement with non-State actors. Its overall goal is to strengthen WHO's engagement with non-State actors while preserving its integrity, reputation, mandate and work.

FENSA acknowledges that the global health landscape has become more complex, with an increasing number of players, including non-State actors. FENSA recognizes that non-State actors play a critical role in supporting WHO's work, and that inclusiveness, dialogue and engagement with them is key to its success.

FENSA also recognizes that WHO's engagement with non-State actors brings important benefits to both parties and that, this convergence of interests can benefit global public health.

^{*} The Handbook is a living document and will be updated based on the implementation of Framework of engagement with non-State actors

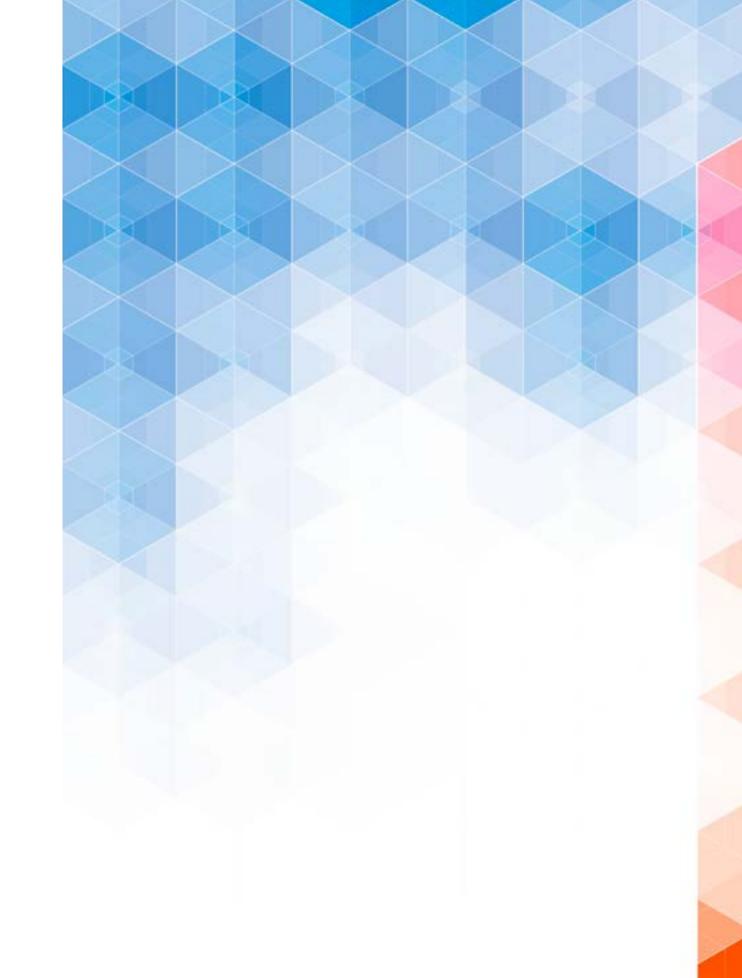
Benefits include:

- √ the contribution of non-State actors to the work of WHO;
- the additional resources that non-State actors can contribute to WHO's work;
- √ the wider dissemination of and adherence to WHO's policies, norms and standards by non-State actors;
- √ the influence that WHO can have on non-State actors to enhance their impact on global public health; and
- the influence that WHO can have on non-State actors' compliance with WHO's policies, norms and standards.

Along with promoting the benefits of WHO's engagement with non-State actors, FENSA aims to protect WHO's work and mandate from potential risks of engagement. The Framework reinforces that WHO does not engage with the tobacco industry or with non-State actors that represent the interests of the tobacco industry, or with the arms industry.

WHO exercises particular caution when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants.

While WHO will continue to strengthen its engagement with non-State actors and proactively seek such engagements to implement the priorities defined in its General Programme of Work, it is the sole prerogative of WHO to define the acceptability and terms of each proposed engagement.





SECTION 1 BASIC ELEMENTS

This Section gives a general introduction to "Framework of Engagement with non-State Actors" (FENSA).

WHAT IS FENSA?

FENSA stands for "Framework of Engagement with non-State Actors" and was adopted by the World Health Assembly in May 2016¹. It is a set of rules governing WHO's engagement with non-State actors.

As noted in the Rationale, FENSA aims to strengthen WHO's engagement with non-State actors to benefit global public health, while protecting its work from potential risks. (see paragraphs 7 and 33) Risks include conflicts of interest, reputational risks and undue influence. (see paragraph 22 to 26)

As described in greater detail in Section 4 of the Handbook, FENSA applies to all types of engagements between the WHO Secretariat² and non-State actors across all three levels of WHO: global, regional and country (see paragraph 1).

The Overarching Framework is complemented by **four separate polices and operational procedures** covering WHO's engagement with the four groups of non-State actors.

- √ WHO policy and operational procedures on engagement with nongovernmental organizations
- √ WHO policy and operational procedures on engagement with private sector entities
- Resolution WHA69.10. Framework of engagement with non-State actors. In: Sixty-ninth World Health Assembly, Geneva, 23–28 May 2016. Resolutions and decisions, annexes. Geneva: World Health Organization; 2016
- The WHO Secretariat includes entities established under WHO and hosted partnerships. For hosted partnerships FENSA will apply, subject to the policy on WHO's engagement with global health partnerships and hosting arrangements (resolution WHA63.10). Hosted, as well as external partnerships are explained in paragraph 49 of FENSA. (FENSA, paragraph 1, footnote 1)

- WHO policy and operational procedures on engagement with philanthropic foundations
- WHO policy and operational procedures on engagement with academic institutions

The scope of WHO's engagement with each non-State actor is defined by one of these four separate policies and operational procedures.

WHAT IS A NON-STATE ACTOR?

A non-State actor is an entity that falls into one of the following four groups: nongovernmental organizations (NGOs); private sector entities including international business associations; philanthropic foundations; and academic institutions. They are described in paragraphs 9 to 12 of FENSA.





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GROUPS OF NON-STATE ACTORS

SECTION 2 GROUPS OF NON-STATE ACTORS

As explained under Section 1 of the *Handbook*, there are four groups of non-State actors: NGOs, private sector entities, philanthropic foundations and academic institutions.

WHO's engagement with a particular non-State actor will be governed by one of the four policies and operational procedures in addition to the overarching framework. FENSA grouping allows WHO to determine which of its four separate policies and operational procedures will apply to its engagement with that non-State actor.

This grouping is specific to WHO and is not based on the legal status of the non-State actor under any national jurisdiction. Its only significance is for the purpose of WHO's engagement with the entity under FENSA.

Non-State actors are encouraged to carefully review the policy and operational procedures that apply to their group.

WHO DECIDES WHICH POLICY/OPERATIONAL PROCEDURE APPLIES TO A NON-STATE ACTOR? HOW IS THE DECISION MADE?

WHO's Secretariat decides (see paragraphs 12 to 32). As explained in more detail in Section 5 of the *Handbook*, as part of its screening and due diligence review, a decision is made as to which policy/operational procedure applies based on information provided by the non-State actor concerning, among other things, its nature, objectives, governance, funding, independence and membership. This information is included in the WHO Register of non-State actors.



This Section describes what is meant by WHO's "engagement" with non-State actors under FENSA. It also describes the five distinct types of engagement and refers to types of engagement not regulated by FENSA.

WHAT DOES "ENGAGEMENT WITH NON-STATE ACTORS" MEAN?

An "engagement" under FENSA is any formalized interaction between WHO and a non-State actor in one of the five types of engagements described in the next paragraph. "Engagement" covers a wide variety of activities, ranging from major, longer-term collaborations, to briefer interactions. Broadly, institutional engagements between WHO and non-State actors are covered by FENSA. Telephone exchanges, informal discussions and preliminary contacts are not considered as engagements but FENSA's principles apply.

TYPES OF ENGAGEMENT

FENSA categorizes engagements into five types of interaction. Each of these is described in FENSA's Overarching Framework and in each of the four separate policies and operational procedures, as indicated in the paragraphs below:

- **Participation**, which refers to non-State actors attending meetings organized by WHO, including meetings of the governing bodies; consultations; hearings; and other meetings; and WHO staff members attending meetings organized by non-State actors.
- **Resources**, which refers to financial or *in-kind* contributions, including donations of medicines and other goods and the free provision of services. Any engagement involving the transfer of resources is always governed by a contract between WHO and the non-State actor.



- Evidence, which refers to inputs based on up-to-date information, knowledge on technical issues, and consideration of scientific facts, independently analyzed by WHO.
- Advocacy, which refers to action to increase awareness of health issues; to change behaviours in the interest of public health; and to foster collaboration and greater coherence between non-State actors where joint action is required.
- √ Technical collaboration, which refers to other collaboration with non-State actors, as appropriate, in activities that fall within WHO's General Programme of Work. Examples include product development; capacity building; operational collaboration in emergencies; and contributions to the implementation of WHO's policies.

There are multiple different ways WHO engages with non-State actors, such as capacity building, emergency reponse, monitoring and services delivery. For the purpose of the FENSA's application, these are attributed to one or more of the five types of engagement as defined in FENSA.

ARE THERE TYPES OF ENGAGEMENTS THAT ARE NOT REGULATED BY FENSA?

FENSA does not apply to engagements with governmental entities or intergovernmental organizations. However, engagements with State-owned companies, foundations or universities are subject to FENSA.

FENSA regulates <u>institutional</u> engagements between WHO and non-State actors. FENSA's provisions do not apply for the following:

- Engagement between WHO and Members States, including their ministries, national agencies, subnational agencies such as regional or local governments, and other public entities that are directly reporting to the government.
- Engagement between WHO and global or regional intergovernmental organizations (United Nations and its funds, specialized agencies).
- Procurement of goods and services such as from non-State actors to WHO. In this case, the WHO procurement policy and WHO's financial Rules and Regulations apply (except pro-bono).
- √ Fees, payments, contributions received by WHO from non-State actors as a result of their use of WHO materials, information, data or other mechanisms or services.

- Engagement between WHO and individuals acting on their own behalf and not as a representative of a non-State actor. In this case, the WHO Rules and Regulations for individual experts apply.
- Engagement between the Codex Alimentarius Commission and non-State actors.

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FENSA does not apply for engagements where WHO is assessing individual products of companies.

For more information on the relationship between FENSA and other WHO policies, please refer to paragraphs 48 and 49 of FENSA. See also FENSA, paragraphs 23 and 21, footnote 1.

SECTION 4 PRINCIPLES OF ENGAGEMENT

This Section describes the overarching principles of engagement that WHO applies when managing risks under FENSA.

OVERARCHING PRINCIPLES OF ENGAGEMENT

FENSA includes eight overarching principles that all engagements between WHO and non-State actors must adhere to. Given the importance of these principles, it is worth setting them out exactly as they appear in FENSA (see paragraph 5):

"WHO's engagement with non-State actors is guided by the following overarching principles.

Any engagement must:

- demonstrate a clear benefit to public health;
- conform with WHO's Constitution, mandate and General Programme of Work;
- respect the intergovernmental nature of WHO and the decision-making authority of Member States as set out in WHO's Constitution;
- support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work;
- protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards³;
- not compromise WHO's integrity, independence, credibility and reputation;

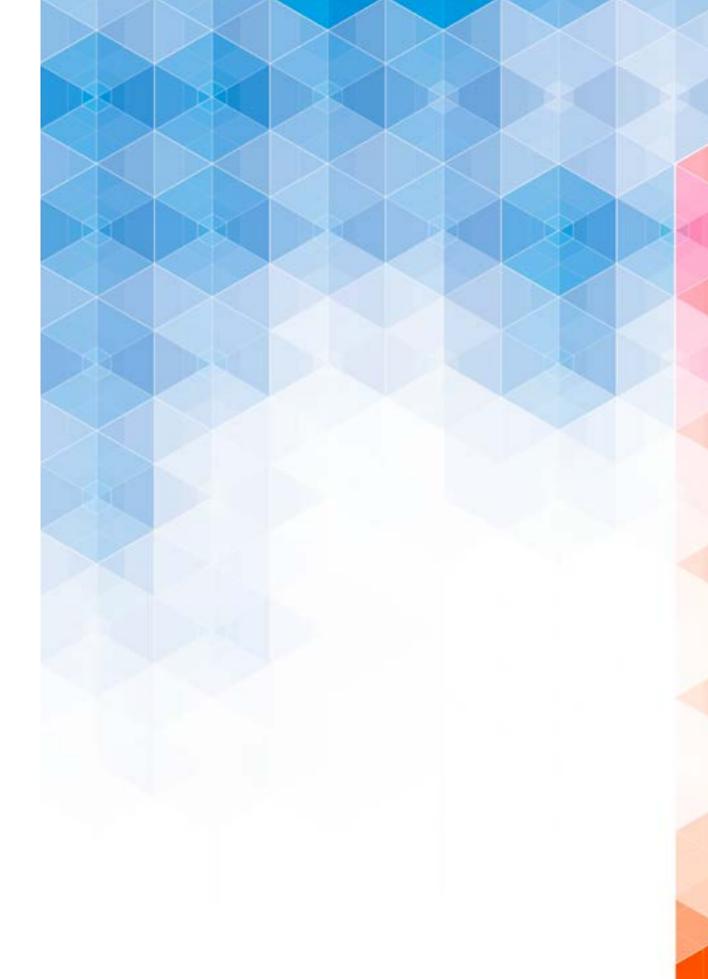


Policies, norms and standard setting include information gathering, preparation for, elaboration of and the decision on the normative text.

- be effectively managed, including by, where possible avoiding conflict of interest⁴ and other forms of risk to WHO;
- be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect."

These eight overarching principles guide the Secretariat's approach to managing and, where appropriate, avoiding conflicts of interest and other risks of engagement with non-State actors.







SECTION 5 ENGAGEMENT: STEP BY STEP PROCESS

This Section describes the process leading to an engagement with WHO. It focuses on those aspects of the process that involve non-State actors directly or that non-State actors should be aware of.

INITIAL STEP: INFORMAL EXCHANGES

Many engagements are preceded by an informal exploratory phase where the technical department (that is, the WHO department that would engage with the non-State actor) and the non-State actor, discuss the possibility of engagement. At this initial and exploratory stage, there is no requirement to initiate an assessment review under FENSA, although its principles apply. Some initial contacts with non-State actors remain as informal exchanges and do not necessarily proceed to a formal engagement as described below.

STEP ONE: INITIATION OF PROPOSAL FOR ENGAGEMENT

When a proposal for engagement becomes more concrete, the WHO Secretariat will consider whether the engagement would be in WHO's interest and in line with the eight overarching principles. The Secretariat also considers whether the engagement would be in line with WHO's priorities contained in the General Programme of Work and Programme budget.

If the engagement seems to meet these requirements, the technical department sends an invitation to the non-State actor asking it to enter basic information about itself into the WHO Register of Non-State Actors, "the Register", either for the full or simplified profile subject to the type of engagement planned.

STEP TWO: ENTRY OF INFORMATION IN THE REGISTER OF NON-STATE ACTORS⁵

The non-State actor designates its **focal point**, whose name and title must be communicated to the technical department. (The focal point's identity is not included in the information that is publicly available in the Register). The focal point is responsible for the initial entry of information into the Register and for keeping the information up-to-date. For more information, please refer to FENSA paragraphs 38 and 42.

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The Register is an internet-based, publicly available, electronic mechanism used by the WHO Secretariat to document and coordinate engagements with non-State actors. It is designed to increase the transparency and accountability of WHO's engagement with non-State actors.

THE REGISTER HAS THREE SECTIONS:

- a non-State actor profile section which is filled in by the non-State actor. It contains information about each non-State actor that engages with WHO;
- 2 | a "WHO Engagements" section, which is filled in by the WHO Secretariat, and contains a high-level description of WHO's engagements with non-State actors; and
- a section on non-State actors in official relations with WHO, which is filled in by the WHO Secretariat. It includes the plans for collaboration between WHO and non-State actors in official relations with agreed objectives and outlining activities for the relevant period, structured according to the General Programme of Work and programme budget and consistent with FENSA. This section also includes annual reports on the implementation of the collaboration plans.

Each of the non-State actor's focal point fills in the "non-State actor profile" section of the Register; this information is made publicly available.

The following information is included:

- · Name of the non-State actor
- Contact details
- Membership
- Legal status
- Objective
- Governance structure
- Composition of main decision-making bodies
- Assets
- Annual income
- Funding sources
- Main relevant affiliations
- Webpage
- Disclosure and declaration of links with tobacco, arms and other industries

In addition, the following information must be provided which will not be made publicly available:

- · At least one non-State actor focal point for WHO contacts
- Founding and supporting documents that validate the information provided in the Register
- · Any other information that WHO may request on a case-by-case basis.

In cases where the Secretariat requests the entity to fill in a simplified profile/entry in the Register the following information is required:

- · Name of the non-State actor
- Contact details
- Funding sources
- Disclosure and declaration of links with tobacco, arms and other industries.
- Webpage
- At least one non-State actor focal point for WHO contacts

To note, either the simplified or standard profile and procedures are made at the WHO's sole assessment and discretion.

The profiles in the Register can only be created at the request of WHO and on the basis of an engagement with WHO. Each non-State actor is solely responsible for the accuracy and completeness of the information it enters in the Register, and for keeping the information up-to-date⁶. The inclusion of information in the Register does not constitute any form of endorsement by WHO (see paragraph 40). Non-State actors cannot use the fact that their information appears in the Register for, or in conjunction with, commercial, promotional marketing and advertisement purposes. Further

The Register of non-State actors is currently containing all non-State actors in official relations. The functionality of registering other non-State actors WHO engages with is currently being built and will then be rolled out step by step. Therefore these descriptions will only apply when the tool is ready and a non-State actor receives an invitation to provide information.

Information in the Register will be dated. Information on non-State actors that are no longer engaged with WHO or that have not updated their information will be marked "archived". Archived information can be considered in relation to any future applications for engagement (FENSA, paragraph 41).

details concerning the terms and conditions that govern the use of the Register and its contents are found here.

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Once the non-State actor focal point has completed the information in the profile section of the Register, the WHO Secretariat complements the information with a description of the engagement.

STEP THREE: SCREENING, DUE DILIGENCE AND RISK ASSESSMENT

SCREENING AND DUE DILIGENCE

The WHO Secretariat carries out a screening or due diligence review which involves finding and verifying information about a non-State actor to reach a clear understanding of its nature. Along with reviewing information provided by the non-State actor, information is sought from other sources, for example media sources, analyst reports and various public and legal directories and reports.

The outcome of the due diligence review guides the WHO Secretariat in deciding which of the four policies/operational procedures will apply to a particular non-State actor (that is: NGOs; private sector entities; philanthropic foundations; and academic institutions).

Another important part of the due diligence review is to consider whether the engagement would breach the following strict FENSA provisions and, therefore, engagement would be prohibited:

- a WHO does not engage with the **tobacco industry** or with non-State actors that work to further the interests of the tobacco industry. The latter includes but is not limited to:
 - entities and subsidiaries engaged in the manufacturing, distribution and/or sale of tobacco or tobacco-related products;
 - entities working to specifically further the interests of the tobacco industry through lobbying, advertising, legal advice or similar activities;
 - entities being funded, supported or influenced in their governance by tobacco-related entities; and
 - entities having tobacco industry or their representatives among their members.
- b WHO does not engage with the <u>arms industry</u>. For entities receiving funding from entities linked to the arms industry, a case-by-case assessment is made on the acceptability of receiving funding from such entities.

WHO also exercises **particular caution** when considering possible engagements with non-State actors whose policies or activities negatively affect human health and which are not in line with WHO's policies, norms and standards. This is especially the case in the area of noncommunicable diseases and their determinants (see paragraph 45).

RISK ASSESSMENT

At the same time as the Secretariat conducts a screening or due diligence review, it does a risk assessment. It is easy to confuse the two.

Whereas screening and due diligence refer to the steps taken by WHO to find and verify relevant information on a non-State actor and to reach a clear understanding of its profile, risk assessment refers to the assessment of potential <u>benefits</u> and *risks* associated with a specific proposed engagement with that non-State actor. Risks are the expression of the likelihood and potential impact of an event that would affect WHO's ability to achieve its objectives.

In considering possible risks of engagement, WHO examines *conflict of interest*; improper influence exercised by a non-State actor on WHO's work, especially in policy setting, norms and standards; and an engagement that would negatively affect WHO's integrity, independence, credibility and reputation, and public health mandate.

The identification of possible conflicts of interest is a central part of a risk assessment. In general, it involves WHO deciding whether there is a potential for a secondary interest (that is, a vested interest in the outcome of WHO's work in a given area) to unduly influence, or be reasonably perceived to undue influence, either the independence or objectivity of professional judgment or actions regarding a primary interest (WHO's work). Conflicts of interest are not only financial, but can take other forms as well. The existence of a conflict of interest does not necessarily mean that there has been an improper action. Instead, it means that there is a risk of such improper action occurring.

The identification and management of conflicts of interest is not always straightforward. Non-State actors that would like more information should consult <u>paragraphs</u> 22 to 26 of FENSA.

DETERMINING APPLICABLE POLICY/OPERATIONAL PROCEDURE

As noted above, the outcome of the screening or due diligence review and risk assessment guides the WHO Secretariat in deciding which of the four policies/operational procedures will apply to a particular non-State actor. It is possible that, based on the review, a non-State actor will be placed in a group that is different from what it considers itself, or some of the provisions of one group may apply in a particular situation.

For instance, WHO may determine through its screening or due diligence whether a non-State actor is subject to the specific policy and operational procedures for private sector entities, and whether the entity is or is not considered to be at arm's length from private sector.

A case-by-case approach is considered based on the provisions set in FENSA and taking into account the following general considerations:

- Any entity having an important proportion of its funding from private sector entities, especially if those private sector entities have a commercial interest and are active in the same field as the non-State actor and if funds are coming from a single or small number of private sector entities.
- Entities being influenced by private sector entities through representation in their governing bodies, especially by representatives of private sector entities active in the same field as the non-State actor.
- c Any other method of relevant influence by private sector entities on the non-State actor.

It is important to remember that a determination of which of the four policies applies to a particular non-State actor, following a screening or due diligence review and risk assessment, is solely for the purpose of FENSA at WHO's discretion. For example, applying the NGO policy to a non-State actor does not mean that the non-State actor is an NGO for all purposes. Rather, it is simply a determination under FENSA that the NGO policy and operational procedures will apply to WHO's engagement with that non-State actor.

STEP FOUR: DECISION ON ENGAGEMENT

Once the screening or due diligence review and risk assessment are completed, the WHO Secretariat decides on the proposed engagement.

WHO will only enter into an engagement when the benefit of the engagement, in terms of direct or indirect contributions to public health and the fulfillment of WHO's mandate, outweigh any risks of engagement, as well as the time and expense involved in establishing and maintaining the engagement.

A decision is taken to:

√ enter into the engagement;

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- √ continue the engagement;
- √ engage with measures to mitigate *risks*; or
- decide not to carry out, or to stop carrying out, a particular engagement. (see paragraph 34)

If a proposed engagement is approved, the WHO Secretariat fills in the "WHO Engagement" section of the WHO Register of non-State Actors. This contains a high-level description of the engagement and is publicly available (paragraphs 40).

STEP FIVE: IMPLEMENTATION, MANAGING AND MONITORING ENGAGEMENTS

One of FENSA's overarching principles is that engagements with non-State actors must be effectively managed. FENSA also provides that WHO's interaction with non-State actors be managed transparently, for example by including information about non-State actors and their engagements with WHO in the Register of non-State actors.

On a day-to-day basis, the WHO department with which the non-State actor engages is responsible for managing and monitoring the engagements. Any problems encountered should be addressed, in the first instance, by the non-State actor and the WHO focal point responsible for the engagement.

For its part, to facilitate a successful engagement, the non-State actor is required to:

- √ comply with FENSA and WHO's policies and standards;
- √ implement all agreed activities in a timely way;
- ensure information in the profile section of the Register of non-State actors is complete, accurate and up-to-date;
- ensure WHO's name and emblem are not used without WHO's prior written authorization (this is addressed in Section 6 of the Handbook);
- use the Register according to the Terms and Conditions of its use, which can be found here.

PARTICULAR SITUATIONS

SECTION 6 PARTICULAR SITUATIONS

This Section addresses particular situations under FENSA: the application of FENSA's procedures during health emergencies; the secondment of individuals to WHO; the use of WHO's name and emblem; and WHO participation at and co-sponsorship of meetings organized by non-State actors.

HEALTH EMERGENCIES

WHO's Director-General may exercise flexibility in the application of the procedures of FENSA when responding to acute public health events described in the International Health Regulations (2005) or other emergencies with health consequences. For details, please refer to paragraph 73.

SECONDMENTS

A "secondment" is the assignment to WHO of an individual already employed by another entity, for a fixed period, under an agreement concluded by the three parties - namely WHO, the entity that employs the individual, and the employee.

WHO accepts secondments from non-State actors, except from private sector entitie. Secondments from NGOs, philanthropic foundations and academic institutions are accepted according to the criteria and principles.

USE OF WHO NAME AND EMBLEM

The World Health Organization's name and emblem are recognized symbols of integrity and quality assurance. WHO's name, emblem, and acronym ("WHO") may not be used for commercial, promotional, marketing or advertising purposes. This includes



the display of WHO's name, acronym and emblem on any premises or space, communication material, social media, or any other publication/advertisement issued by the non-State actor.

Any use of WHO's name or emblem requires the prior written authorization of WHO's Director-General (see paragraph 46). Additional information can be found on the following web link.

WHO PARTICIPATION AT MEETINGS AND CO-SPONSORSHIP OF MEETINGS ORGANIZED BY NON-STATE ACTORS

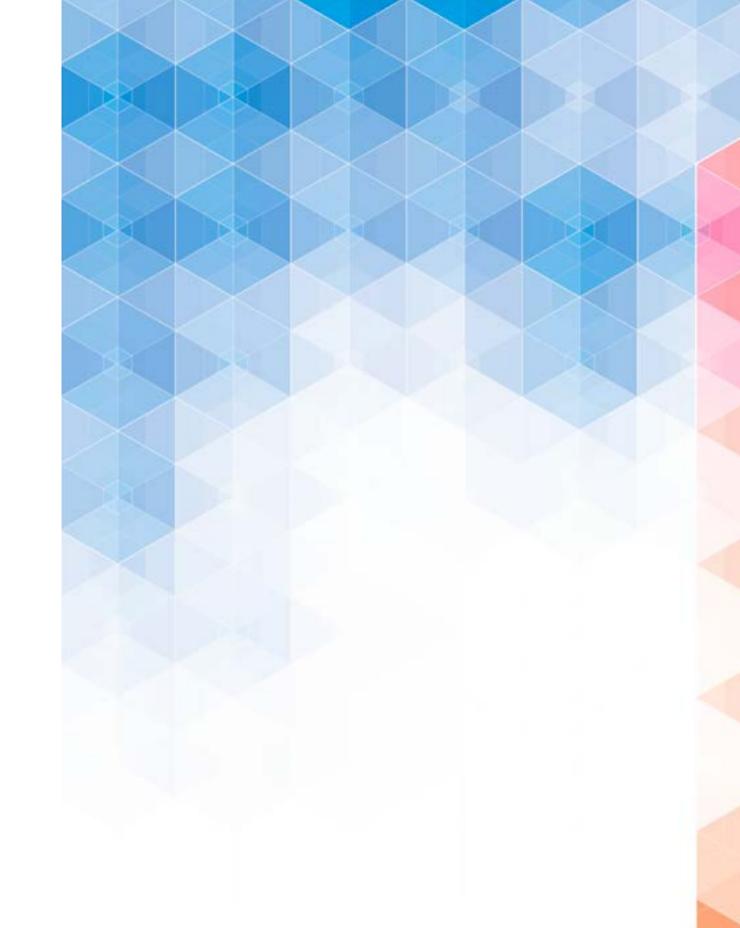
In the event WHO participates in meetings organized by non-State actors where the role of WHO staff is limited to being participants or speakers, such participation will not be considered as an event co-sponsored, jointly organized, or endorsed by WHO, nor should it be considered as an endorsement of the activities, name, brand, products, or views of the non-State actors involved.

Therefore, the WHO emblem and name will not appear on any material related to this event/meeting nor on the host entity's social media platforms, press releases or other material related to this event/meeting, and there will be no commitments expected from WHO such as signing a "Declaration", implementation plan, recommendations, endorsement of any roadmap or strategy, partnerships, etc., at the meeting/event.

WHO involvement in co-sponsorship of meeting and/or co-organization of meetings with non-State actors is subject to FENSA provisions.

In accordance to FENSA, WHO does not co-sponsor meetings organized by private sector entities. Co-sponsorship of meetings organized by other actors where non health-related private sector entities are also co-sponsors are decided on a caseby-case basis.

There shall be no commercial exhibitions on WHO premises and at WHO's meetings. WHO does not co-sponsor commercial exhibitions, whether as part of meetings organized by private sector entities or as part of meetings organized by other actors.



NON-STATE ACTORS IN OFFICIAL RELATIONS

SECTION 7 **NON-STATE ACTORS IN OFFICIAL RELATIONS**

This Section describes FENSA's provisions on non-State actors in "official relations" with WHO, which have replaced the "Principles Governing Relations between WHO and Nongovernmental Organizations", and provides detailed practical information on such things as eligibility criteria, the official relations application process and the triennial review of official relations.

Non-State actors who are eligible and want to learn more about "official relations" should review paragraphs 50 to 66 of FENSA.

WHAT DOES BEING IN OFFICIAL RELATIONS WITH WHO MEAN?

"Official relations" is a privilege that may be granted by WHO's Executive Board to those non-State actors that fulfill the eligibility criteria and that have had and continue to have a systematic and sustained engagement with WHO.

This privilege includes inter alia:

- A special agreed collaborative arrangement of three-years with WHO, supporting WHO's work;
- Possibility to participate in WHO governing body meetings as observers and delivering statements on technical matters. Further details of what attending such meetings involves, in practice, are found in FENSA, paragraph 55;
- Possibility to organize side events during the World Health Assembly.

The status of official relations is not a condition for WHO to engage with non-State actors.



ARE ALL NON-STATE ACTORS ELIGIBLE FOR OFFICIAL RELATIONS?

Three groups of non-State actors are eligible for official relations: NGOs; international business associations; and philanthropic foundations, as defined in FENSA (see paragraph 50).

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Non-State actors in the private sector group (excluding international business associations) and academic institution group are not eligible for official relations. Academic institutions or departments thereof can however apply for a designation as WHO collaborating centers.

Furthermore, "partnerships", "collaborative arrangements" and "public-private partnerships" are not considered eligible for official relations. Instead, WHO includes such entities in its list of "Partnerships and Collaborative Arrangements with WHO involvement", which is regularly updated and where these entities are recognized for their work with WHO.

WHAT ARE THE ELIGIBILITY CRITERIA FOR OFFICIAL RELATIONS?

The non-State actor must have had, and is continuing to have, a *sustained and systematic engagement* with WHO; when submitting the application for official relations the non-State actor is expected to have had at least two full years of systematic engagement which goes beyond participation in each other's meetings.

Additionally, the non-State actor is expected to:

- have aims and activities that are in conformity with the spirit, purposes and principles of WHO's Constitution;
- √ contribute significantly to the advancement of public health;
- √ be international in membership and/or scope;
- √ have a constitution or similar basic document;
- have an established headquarters, governing body and administrative structure; and
- have a regularly updated entry in the WHO Register of non-State actors. (see paragraph 51)

In particular cases when NGOs are working on global health issues, sustained and systematic engagement could include research and active advocacy around WHO meetings and WHO's policies, norms and standards. Official relations may be considered for such NGOs based on at least three years of their activities and a future work plan based on research and advocacy on global public health issues (see paragraph 53).

ARE POTENTIAL ENGAGEMENTS WITH NON-STATE ACTORS IN OFFICIAL RELATIONS APPROVED AUTOMATICALLY?

No. All potential engagements with non-State actors, whether or not in official relations, are reviewed under the same *due diligence* and *risk* assessment process. All non-State actors are also subject to the same rules under FENSA when engaging with WHO.

HOW DOES A NON-STATE ACTOR APPLY FOR OFFICIAL RELATIONS?

First, the non-State actor should review <u>paragraphs 50</u> to <u>66</u> of FENSA and this Section of the *Handbook* to consider whether, in its view, it may qualify for official relations.

The non-State actor should consult with a WHO technical department, with which it must have had a sustained and systematic engagement for at least two years when submitting its application, whether, there is an interest on WHO's side pursuing official relations.

If a non-State actor considers that it may qualify for official relations, and there is the necessary interest on WHO's side, the non-State actor's focal point should:

- liaise with his or her counterpart in the WHO technical department, known as a Designated Technical Officer (DTO), so as to finalize its application;
- work with the WHO Designated Technical Officer, to prepare a report⁸ on collaboration with WHO over the past three years and a proposed plan for collaboration for the next three years. (see paragraph 52).
- Once these developed, to submit to the DTO, the final drafts of both the report and plan for collaboration with the letter of expression of interest.
- keep the DTO informed of events and projects the non-State actor may develop, which are relevant to its cooperation with WHO (FENSA, paragraph 63); and
- keep the entity's profile in the WHO Register on non-State actors up-to-date.

CAN A REGIONAL OR NATIONAL NON-STATE ACTOR BE IN OFFICIAL RELATIONS WITH WHO?

No. Official relations are possible if the non-State actor concerned is international in its membership and/or scope. However, single region or national non-State actors can be accredited for regional committees according to existing rules and practices in the relevant WHO region⁹. As FENSA's <u>paragraph 57</u> mentions, regional committees may also decide on a procedure granting accreditation to their meetings to other international, regional, and national non-State actors not in official relations with WHO as long as the procedure is managed in accordance with this Framework. For instance the WHO Regional Committee¹⁰ for Europe has an example of such a procedure of accreditation.

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TIMING OF APPLICATIONS AND ROLE OF WHO SECRETARIAT AND GOVERNING BODIES

New full applications for official relations, must reach WHO headquarters no later than the end of July, for submission to the WHO Executive Board at its session the following January (see paragraph 59). The application shall be submitted through the WHO Designated Technical Officer.

A full application consists on the following elements:

- a complete or up-to-date profile into the WHO Register of non-State actors, providing all the necessary information as requested by FENSA¹¹. The non-State actor is responsible for completing the Register and ensuring that it is up-to-date;
- a three-year plan for collaboration with WHO. The plan is developed and agreed on jointly by the non-State actor and WHO, through the focal point and the DTO respectively. The plan for collaboration needs to highlight how the collaborative activities will support the work of WHO as per the General Programme of Work and Programme Budget
- a report on past collaboration. This document is drafted jointly between the non-State actor and WHO;
- 9 Framework of engagement with non-State actors, paragraph 57
- Procedure for accreditation of regional non-State actors not in official relations with WHO to attend meetings of the WHO Regional Committee for Europe: http://www.euro.who.int/en/about-us/partners/non-state-actors/ procedure-for-accreditation-of-regional-non-state-actors-not-in-official-relations-with-who-to-attend-meetings-of-the-who-regional-committee-for-europe
- 11 Framework of engagement with non-State actors, paragraph 39

 a signed letter from the Head or Deputy of the non-State actor expressing interest in applying for official relations, providing the contact details of the person in the entity that has been identified by the non-State actor as the focal point for the official relations with WHO.

Once the non-State actor has submitted to the technical department all necessary information, applications for official relations are reviewed by WHO's Secretariat to ensure that established criteria and other requirements of FENSA appear to be satisfied. This includes the Secretariat's verification of entries in the Register and conducting a due diligence and risk assessment, based on information in the Register and other sources, including the report on past collaboration and the proposed three-year collaboration plan described above.

During its annual January session, the Executive Board's Programme, Budget and Administration Committee (PBAC) considers new applications and makes recommendations to the Executive Board, which decides on applications. The PBAC's report, and the record of the Board's decisions, are publicly available in all languages here.

For those non-State actors that are admitted into official relations, the agreed plan for collaboration will be made available to the public through the <u>WHO Register of non-State actors</u>.

WHAT CAN A NON-STATE ACTOR DO TO INCREASE THE LIKELIHOOD THAT IT WILL BE MAINTAINED IN OFFICIAL RELATIONS?

The non-State actor should:

- √ implement the collaboration plan in an efficient and a timely manner;
- ensure information in the profile section of the Register of non-State actors is complete, accurate and up-to-date, including any change in the non-State actor's focal point;
- √ ensure it does not abuse the privileges conferred by official relations;
- complete, with the DTO, an annual report of activities/relations, including at the time of the triennial review of the relations;
- keep the DTO informed of events and projects the non-State actor may develop, including with other entities, that are relevant to its official relations with WHO;
- contribute with its work to WHO's the priorities defined in the General Programme of Work;

- √ comply with FENSA and WHO's rules and policies; and
- refrain from using and displaying WHO's name and emblem without requesting written authorization as per the terms governing the use of WHO's name and emblem. This includes the display of WHO's logo on any premises, webpage, visual/communication/training materials, social media tools or publications from the non-State actor.

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IS OFFICIAL RELATIONS A PERMANENT PRIVILEGE?

The Executive Board, working through its Programme, Budget and Administration Committee (PBAC), reviews collaboration with each non-State actor in official relations every three years. This means that one-third of non-State actors in official relations are reviewed each year (see paragraph 64).

The Director-General may also propose an earlier review, for example if a non-State actor does not fulfill its part in the collaboration plan; if it ceases to fulfill the criteria for admission; or if potential new *risks* for collaboration are identified (see paragraph 65).

The non-State actor in official relations shall provide annually a short report ¹² on the progress made in implementing the plan of collaboration and other related activities which will also be published in the Register (see paragraph 52).

Every year and prior to the triennial review, the non-State actor must update its entry in the WHO Register. In preparation to the triennial review, and based on the annual reporting on the implementation of the agreed plan for collaboration (see paragraph 52), the non-State actor's focal point and the WHO Designated Technical Officer will make an assessment of the collaboration over the past three years.

If both parties intend to further continue with the official relations, the focal point of the entity under review and the WHO Designated Technical Officer (DTO) are invited to jointly draft and agree upon a new three year plan for collaboration that would serve as the basis for the triennial review. These collaboration plans, after ensuring compliance with FENSA, are published in the WHO register of non-State actors.

The Executive Board may decide to maintain the non-State actor in *official relations*. It may also recommend the deferral of the review for one year or to discontinue official relations. Non-State actors are informed of the decision, which is also publicly available on WHO's website.

Template provided upon request by the WHO technical department

IF WHO DECIDES NOT TO ADMIT A NON-STATE ACTOR INTO OFFICIAL RELATIONS, OR TO DISCONTINUE OFFICIAL RELATIONS, IS ENGAGEMENT UNDER FENSA STILL POSSIBLE?

Subject to screening or due diligence and risk assessment, FENSA engagements would still be possible. A decision not to admit a non-State actor into official relations, or to discontinue official relations, would in principle not affect engagements under FENSA.

That said, if a non-State actor was not admitted into official relations, or if official relations were discontinued, because of information that came to light in a due diligence review (for example, if the non-State actor were to pose a reputational risk for WHO such as engagement with tobacco) – this could negatively affect decisions on other engagement.

CAN A NON-STATE ACTOR IN OFFICIAL RELATIONS WITH WHO ALSO BE A WHO COLLABORATING CENTRE?

WHO Collaborating Centres and non-State actors in official relations with WHO are subject to different rules and policies, which are mutually exclusive, and therefore an entity cannot be both.

A WHO Collaborating Centre is an institution designated by WHO's Director-General to form part of an international collaborative network carrying out agreed activities in support of the Organization's programmes at all levels. WHO Collaborating Centres are normally parts of universities, research institutes, hospitals and academies. The designation is time-limited (normally four years).

WHO Collaborating Centres are subject to WHO's Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration¹³. Non-State actors in official relations with WHO, on the other hand, are governed by FENSA.

Non-State actors that require more information about WHO Collaborating Centres should consult the detailed Guide for WHO Collaborating Centres.



This Section explains ways in which a non-State actor could fail to comply with FENSA, and the consequences of non-compliance. It also addresses whether a non-State actor may report possible non-compliance by another non-State actor, and whether non-State actors may challenge FENSA decisions.

Non-compliance with FENSA includes: "significant delays in the provision of information to the WHO Register of non-State actors; provision of wrong information; use of the engagement with WHO for purposes other than protecting and promoting health, such as for commercial, promotional, marketing and advertisement purposes; misuse of WHO's name and emblem; attempt at undue influence; and abuse of the privileges conferred by official relations" (see paragraph 69).

Non-compliance by a non-State actor may result in, for example, a reminder, warning, cease-and-desist letter, a rejection of renewal of engagement, and termination of engagement (see paragraph 70).

For non-State actors in *official relations* with WHO, the review of the status of official relations may occur earlier than the normal triennial review. As well, non-compliance may result in discontinuation of official relations (see paragraph 70).

Any financial contribution received by WHO that is later found to be non-compliant with FENSA will be returned to the contributor (see paragraph 71). For example, if WHO were to discover after-the-fact that a grant of funds from a non-State actor as part of an engagement with WHO in fact originated with a tobacco industry, the funds would be returned.

REPORTING POSSIBLE NON-COMPLIANCE

FENSA's mechanisms of transparency and accountability, and the conducting of rigorous due diligence and risk assessments, should reduce the possibility of FENSA non-compliance. Should cases arise, it will be WHO's responsibility to take appropriate action.

At the same time, a non-State actor, acting in good faith, may become aware of information concerning another non-State actor that could affect, in a material way, WHO's decisions on engagement. In any such case, the non-State actor that becomes aware of the information may inform WHO, through its first point of contact with the Organization. WHO will deal with any such reports appropriately. It will not be possible for the non-State actor who made the report to be contacted or informed of the outcome.



NON-STATE ACTOR CHALLENGING DECISIONS UNDER FENSA

A non-State actor that disagrees with a decision taken under FENSA has no right to formally challenge the decision. There is no appeal mechanism, or similar avenue, to formally contest decisions taken by the WHO Secretariat or by WHO Member States in the application of FENSA. WHO retains discretion in deciding whether to engage with any non-State actor for any proposed activity.

Before taking any action or decision under FENSA, in particular when information is not clear or there is the possibility of different interpretations, the Secretariat may, in its sole discretion, consult the non-State actor concerned. However, in the end, the final decision will rest with the Secretariat alone.





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TRANSITIONAL MEASURES

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SECTION 9 TRANSITIONAL MEASURES

When adopting FENSA in May 2016, WHO Member States referred to its full operationalization within a two-year time frame (WHA69.R10). All tools and background material on FENSA will be available by this time-frame, while the roll-out of the Register for non-State actors will continue beyond this time frame. It follows that transitional measures are required. These include:

- On-going engagements with non-State actors that existed when the Register of non-State actors became operational will continue without being included retroactively in the Register of non-State actors. Nevertheless, the policy provisions of FENSA apply to the continuation of these engagements. Newly initiated or renewed engagements will be included in the Register, even in cases where there have been many previous interactions with the non-State actor concerned.
- The Register will become fully operational using a phased approach. As
 a first step, non-State actors will be invited to enter/update their profile
 in the Register when a new engagement is initiated and be requested
 to ensure the information is complete and kept current. Focal points
 should be identified and communicated to the WHO technical officer.
- Profiles in the Register can only be created on the basis of an engagement with WHO. Non-State actors cannot apply to be listed in the Register of non-State actors. Listing will only occur when the WHO Secretariat request to the non-State actor to provide its information in view of a planned new engagement and the engagement has been approved.



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GLOSSARY

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GLOSSARY

This glossary lists terms defined in FENSA using the exact text of FENSA.

ACADEMIC INSTITUTIONS

Academic institutions are entities engaged in the pursuit and dissemination of knowledge through research, education and training.

(FENSA, paragraph 12)

ADVOCACY

Advocacy is action to increase awareness of health issues, including issues that receive insufficient attention; to change behaviors in the interest of public health; and to foster collaboration and greater coherence between non-State actors where joint action is required.

(FENSA, paragraph 19)

ARM'S LENGTH

An entity is "at arm's length" from another entity if it is independent from the other entity, does not take instructions and is clearly not influenced or clearly not reasonably perceived to be influenced in its decisions and work by the other entity.

(FENSA, paragraph 7, footnote 2)

BENEFITS OF ENGAGEMENT

WHO's engagement with non-State actors can bring important benefits to global public health and to the Organization itself in fulfilment of its constitutional principles and objectives, including its directing and coordinating role in global health.

(FENSA, paragraph 6)

CONFLICT OF INTEREST

A conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of WHO's work in a given area) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary influence (WHO's work). The existence of conflict of interest in all its

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forms does not as such mean that improper action has occurred, but rather the risk of such improper action occurring. Conflicts of interest are not only financial, but can take other forms of well.

(FENSA, paragraph 22)

INDIVIDUAL CONFLICT OF INTEREST

Individual conflicts of interest within WHO are those involving experts, regardless of their status, and staff members; these are addressed in accordance with the policies listed under paragraph 49 of the present framework.

(FENSA, paragraph 23)

INSTITUTIONAL CONFLICT OF INTEREST

All institutions have multiple interests, which means that in engaging with non-State actors WHO is often faced with a combination of converging and conflicting interests. An institutional conflict of interest is a situation where WHO's primary interest as reflected in its Constitution may be unduly influenced by the conflicting interest of a non-State actor in a way that affects, or may reasonably be perceived to affect, the independence and objectivity of WHO's work.

(FENSA, paragraph 24)

CO-SPONSORSHIP OF MEETING

Co-sponsorship of a meeting means (1) another entity has the primary responsibility for organizing the meeting; and (2) WHO supports and contributes to the meeting and its proceedings; and (3) WHO reserves the right to clear the agenda of the meeting, the list of participants and the outcome documents of the meeting.

(FENSA, paragraph 16, footnote 1)

DUE DILIGENCE

Due diligence refers to the steps taken by WHO to find and verify relevant information on a non-State actor and to reach a clear understanding of its profile. ... Due diligence combines a review of the information provided by the non-State actor, a search for information about the entity concerned from other sources and an analysis of all the information obtained. This includes a screening of different public, legal and commercial sources of information, including: media; the entity's website, companies' analyst reports, directories and profiles; and public, legal and governmental sources.

(FENSA, paragraphs 29, 30)

EVIDENCE

For the purposes of FENSA, evidence refers to inputs based on up-to-date information, knowledge on technical issues, and consideration of scientific facts, independently analyzed by WHO. Evidence generation by WHO includes information gathering, analysis, generation of information and the management of knowledge and research. Non-State actors may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of this framework, its four specific policies and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

(FENSA, paragraph 18)

IN-KIND CONTRIBUTIONS

In-kind contributions include donations of medicines and other goods and free provision of services on a contractual basis.

(FENSA, paragraph 17)

INTERNATIONAL BUSINESS ASSOCIATION

International business associations are private sector entities that do not intend to make a profit for themselves but represent the interests of their members, which are commercial enterprises and/or national or other business associations. For the purposes of this framework, they shall have the authority to speak for their members through their authorized representatives. Their members shall exercise voting rights in relation to the policies of the international business association.

(FENSA, paragraph 10)

NON-COMPLIANCE (WITH FENSA)

Non-compliance can include *inter alia* the following: significant delays in the provision of information to the WHO register of non-State actors; provision of wrong information; use of the engagement with WHO for purposes other than protecting and promoting public health, such as for commercial promotional, marketing and advertisement purposes; misuse of WHO's name and emblem; attempt at undue influence; and abuse of the privileges conferred by official relations.

(FENSA, paragraph 69)

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NONGOVERNMENTAL ORGANIZATION (NGO)

Non-governmental organizations are non-profit entities that operate independently of governments. They are usually membership-based, with non-profit entities or individuals as members exercising voting rights in relation to the policies of the nongovernmental organization, or are otherwise constituted with non-profit, public-interest goals. They are free form concerns which are primarily of a private, commercial or profit-making nature. They could include, for example, grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific gropes, and patient groups.

(FENSA, paragraph 9)

NON-STATE ACTOR

For the purpose of this framework, non-State actors are nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

(FENSA, paragraph 8)

OFFICIAL RELATIONS

"Official relations" is a privilege that the Executive Board may grant to nongovernmental organizations, international business associations and philanthropic foundations that have had and continue to have sustained and systematic engagement in the interest of the Organization. The aims and activities of all these entities shall be in conformity with the spirit, purposes and principles of WHO's Constitution, and they shall contribute significantly to the advancement of public health. Organizations in official relations can attend governing body meetings of WHO but are otherwise subject to the same rules as other non-State actors when engaging with WHO.

(FENSA, paragraph 50)

PARTICIPATION

Non-State actors may attend various types of meetings organized by WHO. The nature of their participation depends on the type of meeting concerned. The format, modalities, and the participation of non-State actors in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing body or by the Secretariat.

(FENSA, paragraph 15)

PHILANTHROPIC FOUNDATIONS

Philanthropic foundations are non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. They shall be clearly independent from any private sector entity in their governance and decision-making.

(FENSA, paragraph 11)

PRIVATE SECTOR

Private sector entities are commercial enterprises, that is to say businesses that are intended to make a profit for their owners. The term also refers to entities that represent, or are governed or controlled by, private sector entities. This group includes (but is not limited to) business associations representing commercial enterprises, entities not "at arm's length" from their commercial sponsors and partially or fully State-owned commercial enterprises acting like private sector entities.

(FENSA, paragraph 10)

RESOURCES

Resources are financial or in-kind contributions.

RISKS

Risks are the expression of the likelihood and potential impact of an event that would affect the Organization's ability to achieve its objectives.

(FENSA, paragraph 33)

RISK ASSESSMENT

Risk assessment refers to the assessment of a specific proposed engagement with a non-State actor.

(FENSA, paragraph 29)

A risk assessment on a proposed engagement [...] involves the assessment of risks associated with an engagement with a non-State actor, in particular the risks described in paragraph 7 [of the Overarching Framework of Engagement with Non-State Actors] and is to be conducted without prejudice to the type of non-State actor.

(FENSA, paragraph 33)

RISK MANAGEMENT

Risk management concerns the process leading to a management decision whereby the Secretariat decides explicitly and justifiably on entry into engagement, continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with non-State actors.

(FENSA, paragraph 34)

SUSTAINED AND SYSTEMATIC ENGAGEMENT

At least two years of systematic engagement as documented in the WHO register of non-State actors, assessed by both parties to be mutually beneficial. Participation in each other's meetings alone is not considered to be a systematic engagement.

(FENSA, paragraph 50, footnote 3)

For nongovernmental organizations working on global health issues, sustained and systematic engagement could include research and active advocacy around WHO meetings and WHO's policies, norms and standards.

(FENSA, paragraph 53)

TECHNICAL COLLABORATION

For the purpose of this framework, technical collaboration refers to other collaboration with non-State actors, as appropriate, in activities that fall within the General Programme of Work, including: product development; capacity building; operational collaboration in emergencies; contributing to the implementation of WHO's policies.

(FENSA, paragraph 20)



