

ENGAGEMENT WITH NON-STATE ACTORS, INCLUDING PRIVATE SECTOR ENTITIES, AND IARC'S ONGOING RESOURCE MOBILIZATION EFFORTS

Preamble

1. The purpose of this paper is twofold: (i) to inform the Governing Council about the new World Health Assembly (WHA) Resolution providing a Framework of Engagement with non-State Actors (FENSA), and seek guidance on its implementation at IARC; and (ii) to update the Governing Council about IARC's proactive resource mobilization efforts, and seek guidance on the way forward.
2. The two topics are inherently related, given that attracting additional extrabudgetary resources often entails engagement with non-State actors, including novel ways of partnering with private sector entities.

Implementation of FENSA

3. In May 2016, following extensive consultations and two years of intergovernmental negotiations, the Sixty-ninth World Health Assembly adopted the Framework of Engagement with non-State actors through Resolution WHA69.10 (2016)¹, referred to below as the "Framework".
4. The Framework covers engagements² with non-State actors at all levels of the World Health Organization (WHO), including Headquarters, Regional Offices and Country Offices, entities established under WHO (including IARC), as well as hosted partnerships.³
5. The Framework sets out the rationale, principles, benefits and risks of engagement, and defines four groups of non-State actors (nongovernmental organizations, private sector entities – including international business associations, philanthropic foundations and academic institutions) and five types of engagement (participation, resources, evidence, advocacy, and technical collaboration).
6. Management of conflict of interest and other risks of engagement are addressed through a process of due diligence, risk assessment, and risk management, with increased transparency via the creation of a Register of non-State actors.

¹ http://www.who.int/about/collaborations/non-state-actors/A69_R10-FENSA-en.pdf?ua=1

² As referred to in paragraph 49 of the Framework, not all engagements are covered, for instance procurement.

³ For hosted partnerships the framework of engagement with non-State actors will apply, subject to the policy on WHO engagement with global health partnerships and hosting arrangements (Resolution WHA63.10).

7. Resolution WHA69.10 (2016) defined the timelines and mandates for the implementation of the Framework. Specifically, the World Health Assembly requested the WHO Director-General to:

- (a) immediately start implementation;
- (b) report annually to the Executive Board through the Programme, Budget and Administration Committee;
- (c) fully establish the register of non-state actors by the Seventieth World Health Assembly;
- (d) fully operationalize implementation of the Framework within a two-year timeframe;
- (e) conduct an initial evaluation of the implementation of the Framework in 2019.

8. The WHO Independent Expert Oversight Advisory Committee (IEOAC) reviews the implementation of the Framework, and reports to the WHO Executive Board (EB) through the Programme, Budget, and Administration Committee at each of its January sessions. At the 2017 January EB session, the IEOAC cautioned against being too restrictive, and called for a balanced approach, carefully weighing benefits against risks. It was considered important to set up from the beginning a system across the Organization that would allow the application of rules and risk identification and management in a consistent and harmonized manner. Furthermore, the IEOAC strongly advised the Organization to create two levels of due diligence and risk assessment as foreseen by the Framework, by distinguishing between a regular and a low-risk procedure.

9. WHO is currently developing an integrated platform for global management of engagements, which will include an electronic workflow for clearing engagements with non-State actors, and will also support coordination of resource mobilization, as well as the management of declarations of interest of individual experts. A Guide for staff and a Handbook for non-State actors are also in preparation by WHO, together with a change management plan and training material for staff.

10. Following the adoption of Resolution WHA69.10, most WHO Regional Committees discussed the implementation of the Framework and all Regional Offices are actively planning for its implementation, including through briefings of Heads of WHO Country Offices and training sessions for staff.

11. The Framework replaces previous guidance documents, such as the 'Principles governing relations between the WHO and nongovernmental organizations' and the 'Guidelines on interaction with commercial enterprises to achieve health outcomes'. These previous WHO guidance documents were referenced by IARC in Governing Council document GC/49/14, and in Resolution GC/49/R13 titled "Acceptance of funds from industrial sources". They were also used to develop IARC's internal briefing document in 2009, entitled "IARC Guidelines on Working with the Private Sector".

12. In summary, the Framework is expected to result in increased transparency and accountability of non-State actors; in open access to information on potential donors, experts and potential partners; and in an enhanced oversight role of WHO Member States.

Impact of FENSA on IARC

13. The IARC Governing Council, in its 49th session held in May 2007, recognized that some cases may occur where “no other source of funds than from industrial sources appears likely to finance a particular research opportunity which lies within the IARC research programme.” The adoption of Resolution GC/49/R13 followed, outlining the procedure for the “Acceptance of funds from industrial sources”.

14. Although the procedure outlined in Resolution GC/49/R13 is meant to cover the acceptance of financial contributions from industrial sources, the same overall procedure has been applied for in-kind contributions from all private sector entities to research projects. According to this procedure the following steps should apply when accepting funding from industrial sources: (i) the Director assesses the risk of a conflict of interest arising and seeks the views of the Office of the Director-General and the Legal Counsel; (ii) the Director reports his assessment and those received from WHO to the Chairperson and Vice-Chairperson of the Governing Council in order to discuss the opportunity; (iii) if WHO considers that the proposed receipt of funds is incompatible with the ‘Guidelines on interaction with commercial enterprises to achieve health outcomes’ the question has to be referred to the Governing Council for decision; (iv) only Unrestricted Research Grants shall be considered under this mechanism, whereby IARC has the sole responsibility for developing the study protocol, organizing the study, collecting and collating the data, interpreting the findings, and publishing them as scientific literature; (v) a Scientific Committee will be appointed to oversee and follow the study; (vi) a formal request for acceptance of funds should be presented to the Governing Council with reporting requirements laid down in the IARC Financial Regulations; (vii) any such project should be subject to the normal IARC scientific review process (GC/47/R10); and (viii) a minimum overhead charge of 20% shall be levied on such funding.

15. Under the Framework, all instances where IARC works with a non-State actor¹ in any of the five areas mentioned in paragraph 5 (i.e., participation, resources, evidence, advocacy, and technical collaboration) would be subject to due diligence and risk assessment, including new activities with previous partners. The scope of the Framework includes partnerships and collaborations even in the absence of exchange of funds.

16. The Framework applies to IARC as an “entity established under WHO” (Footnote 1 of Annex to Resolution WHA69.10, refers). The implementation of the Framework at IARC is complex and requires careful assessment over the above-mentioned two-year timeframe because of the nature of IARC’s work, and of its governance and management structure.

17. In order to explore the implementation of the Framework at IARC, the Director invited the WHO Director of Partnerships and Non-State Actors Department (PNA) to visit IARC in November 2016 to brief staff and answer questions in a Town Hall meeting. IARC participated in the Framework’s focal points meeting held in Geneva in September 2016, and sent two staff members from the IARC Resource Mobilization and Grants Office for a one-day briefing with the WHO Partnerships and Non-State Actors Department in February 2017.

¹ Except the areas referred to under paragraph 49 of the Framework, as mentioned above, for instance procurement.

18. The initial phase of implementation of the Framework at IARC has presented a number of difficulties, not in relation to private sector entities, which remain limited in number and have always been subject to a comprehensive due diligence and risk assessment process, but in relation to (a) timing for conducting due diligence and risk assessment prior to submitting competitive grant applications, and (b) frequent (almost daily) engagements with academic institutions, non-governmental organizations, and philanthropies (through research collaborations, often including material and data transfers).

19. WHO engages differently with non-State actors than does IARC. Their work is not primarily scientific, but more operational or normative. IARC's engagement also appears to differ in scale. IARC estimates that the number of non-State actor engagements annually, taking account of research collaborations, participation in consortia, participation in grant applications, exchanges of biological samples and data, and other forms of collaborative work would necessitate more than 1000 assessments each year¹ (compared to an average of 200 assessments received from each major WHO Regional Office² per annum, of which the majority refers to recurring engagements). Currently, IARC would be required to submit all these through WHO PNA, with a risk of significantly extending the time required for clearance of grant submissions. Therefore the nature and scale of IARC's requirement appear to be different than those of WHO HQ and Regional Offices, with major resource implications. Thus, the implementation of the Framework needs to be done in a way which does not comprise IARC's ability to fulfill its purpose.

20. IARC's challenge is how to manage the reputational risk of non-State actor engagements, while retaining scientific flexibility, and formally complying with the Framework within the limited human resources currently available. The strong advice of the WHO Independent Expert Oversight Advisory Committee (IEOAC), to create two levels of due diligence and risk assessment as mandated by the Framework, offers the potential for a pragmatic approach to complying with the implementation of the Framework at IARC, distinguishing between a regular and a low-risk procedure. The former could be handled through the central platform for management of engagements developed by WHO, whereas the latter could be locally processed and independently evaluated by IARC.

IARC's Resource Mobilization Efforts

21. IARC has faced severe constraints on assessed contributions from its existing Participating States for the past eight years. Modest increases of its regular budget to cover for statutory staff cost increases and inflation were achieved through assessed contributions levied on new IARC Participating States, and subsidy from the Governing Council Special Fund. In addition, the Agency has been successful in securing extrabudgetary contributions mainly through competitive grants to implement additional scientific activities.

¹ WHO PNA estimates a full due diligence and risk assessment to take between one hour to three days, depending on complexity. With an estimated workload of one hour per preliminary risk assessment carried out by IARC prior to sending the file to WHO PNA, IARC would require a minimum of one full time staff, exclusively dedicated to carry out this function.

² Estimates are based on WHO's two largest Regional Offices, i.e., EMRO and AFRO.

22. The Governing Council is empowered to accept grants or special contributions from any individual, body or government. The special projects of the Agency shall be financed from such grants or special contributions (IARC Statute, Article VIII, paragraph 7, refers). Where such grants or special contributions are specifically earmarked by the donor for financing a special project or projects, the Governing Council shall decide on acceptance after having received the advice of the Scientific Council. Such funds shall be accounted for separately (IARC Financial Regulations, Article V, paragraph 5.6, refers). The Governing Council Special Fund is a case in point.

23. Given the wider context of the difficult donor climate since the 2008 financial crisis, IARC has been exploring innovative ways to raise additional funds in order to fulfill the Medium-Term Strategy 2016–2020.

24. The Director has established a Resource Mobilization Task Force in 2016 to discuss and explore potential sources of additional funding for IARC. Among other activities, the Task Force is working on establishing a 'Friends of IARC' Group who could support the Agency in organizing a Partners' Meeting, with the aim of establishing new funding agreements for priority projects. Furthermore, the Task Force is exploring options to attract funds from the public through a 'contribution button' on the website, and other novel opportunities to receive un-earmarked extrabudgetary contributions.

25. The Scientific Council in January 2017 supported IARC's efforts to secure additional extrabudgetary contributions through a more proactive and innovative resource mobilization approach.

Requests to Governing Council

26. The Governing Council is requested to note this document and establish a Governing Council Working Group to explore ways to meet new requirements and obligations set out in Resolution WHA69.10 (2016), and how best to approach the operationalization of the Framework over the transition period of the next two years. The Working Group may take account of IARC's unique governance structure, the nature of its work and the resource implications of implementing the Framework.

27. The Governing Council is requested to note that the Framework supersedes document GC/49/14, Resolution GC/49/R13 titled "Acceptance of funds from industrial sources", and IARC's internal document, entitled "IARC Guidelines on Working with the Private Sector".

28. The Governing Council is requested to support the Secretariat's innovative resource mobilization efforts to secure additional extrabudgetary funds, including the organization of a Partners' Conference and attracting funds from the public through a 'contribution button' on the IARC website. The Governing Council is also requested to consider other opportunities to receive un-earmarked extrabudgetary contributions and advise the Secretariat on the next steps in exploring such options.