

Strategic Advisory Group of Experts (SAGE) Terms of reference

Functions

SAGE serves as the principal advisory group to the World Health Organization (WHO) for development of policy related to vaccines and immunization. SAGE is charged with advising WHO on overall global policies and strategies, ranging from vaccine and technology research and development, to delivery of immunization and linkages between immunization and other health interventions. The mandate of SAGE is to provide strategic advice rather than technical input, and is not restricted to childhood vaccines and immunization but extends to the control of all vaccine-preventable diseases.

SAGE advises the WHO Director-General specifically on the:

1. adequacy of progress towards the achievement of the goals of the Global Immunization Vision and Strategy (GIVS);
2. major issues and challenges to be addressed with respect to achieving the goals of GIVS;
3. immunization programme response to current public health priorities;
4. major general policies, goals and targets including those related to vaccine research and development;
5. adequacy of WHO's strategic plan and priority activities to achieve the GIVS goals consistent with its mandate and considering the comparative advantages and the respective roles of partner organizations;
6. cross-departmental activities and initiatives related to vaccine and immunization technologies and strategies and linkages with other health interventions;
7. engagement of WHO in partnerships that will enhance achievement of global immunization goals.

Membership

The SAGE comprises 15 members, who shall serve in their personal capacity and represent a broad range of disciplines encompassing many aspects of immunization and vaccines.

SAGE members are recruited and selected as acknowledged experts from around the world in the fields of epidemiology, public health, vaccinology, paediatrics, internal medicine, infectious diseases, immunology, drug regulation, programme management, immunization delivery, health-care administration, health economics, and vaccine safety.

The membership of SAGE shall seek to reflect a representation of:

1. professional affiliation (e.g., academia, medical profession, clinical practice, research institutes, and governmental bodies including national immunization programmes, public health departments and regulatory authorities);
2. major areas of expertise (e.g., influenza control, diarrhoeal diseases, respiratory diseases, research, biologics, and safety); and
3. the three major strategic areas of WHO's work relating to immunization (i.e., accelerating innovation, ensuring quality and safety, and maximizing access and links with other health interventions).

SAGE members, including the Chairperson, shall be nominated by the WHO IVB Director in consultation with WHO Regional Offices and other relevant WHO departments upon the proposal of an independent selection panel including representatives of key partner organizations. A public call for nominations is issued. After determination of eligibility, nominations are submitted to the selection panel. Members will be selected on the basis of their qualifications and ability to contribute to the accomplishment of SAGE's objectives.

SAGE members are appointed by the WHO Director-General; all nominations for new SAGE members, as well as renewals and discontinuation of appointments to SAGE, must be approved by the WHO Director-General. Consideration will be given to ensuring appropriate geographic representation and gender balance.

Members of SAGE, including the Chairperson, shall be appointed to serve for an initial term of three years. Such three-year terms may only be renewed once.

Prior to being appointed as SAGE members and prior to renewal of term, nominees and current SAGE members shall be required to complete a WHO declaration of interest as per the attached form (Annex 1).

In addition, prior to confirmation by WHO of their appointment as SAGE members, SAGE nominees shall be required to sign a confidentiality agreement (Annex 2). All papers presented to SAGE, which may include pre-publication copies of research reports or documents of commercial significance, shall be treated as confidential. SAGE deliberations are confidential and may not be publicly disclosed by SAGE members.

A register of members' interests and signed confidentiality agreements shall be maintained by WHO.

Membership in SAGE may be terminated for any of the following reasons:

- (1) failure to attend two consecutive SAGE meetings;
- (2) change in affiliation resulting in a conflict of interest; and
- (3) a lack of professionalism involving, for example, a breach of confidentiality.

Roles and responsibilities of SAGE members

Members of SAGE have a responsibility to provide WHO with high quality, well considered, advice and recommendations on matters described in the SAGE terms of reference. Members play a critical role in ensuring the reputation of SAGE as an internationally recognized advisory group in the field of immunization. In keeping with SAGE's mandate to provide strategic advice rather than technical input, members will be committed to the development and improvement of public health policies. Focused technical input will be solicited from identified experts and advisory scientific groups.

The Committee has no executive or regulatory function. Its role is solely to provide advice and recommendations to the Director-General of WHO, and includes providing advice and recommendations on urgent matters as needed.

SAGE members may be approached by non-WHO sources for their views, comments and statements on particular matters of public health concern and asked to state the views of SAGE. SAGE members shall refer such enquiries to WHO.

Meetings and operational procedures

SAGE will normally meet twice annually. The frequency of meetings may, however, be adjusted as necessary. Decisions or recommendations will, as a rule, be taken by consensus.

UNICEF, the Secretariat of the Global Alliance for Vaccines and Immunization (GAVI), and WHO Regional Offices will participate as observers in SAGE meetings and deliberations.

WHO may also invite other observers to SAGE meetings, including representatives from WHO regional technical advisory groups, non-governmental organizations (NGO), international professional organizations, technical agencies, donor organizations and associations of manufacturers of vaccines and immunization technologies.

Additional experts may be invited to meetings, as appropriate, to further contribute to specific agenda items.

SAGE will work with WHO to develop its priorities of work and meeting agendas.

SAGE will be kept informed by WHO and partner agencies of progress in implementation of strategies and the attainment of objectives at country and regional level. SAGE will also be informed of policies and recommendations set by the WHO regional technical advisory groups. WHO, with advice from SAGE, will determine which policy recommendation issues and information from other WHO technical advisory groups should be brought to the attention of SAGE.

SAGE Working Groups are established as resources intended to increase the effectiveness of SAGE deliberations by reviewing and providing evidence based information and options for recommendations together

with implications of the various options to be discussed by the full SAGE in an open public forum. These Working Groups are established on a time limited basis in exceptional situations to help address specific questions identified by SAGE when the issue is particularly complicated and could not be addressed by existing standing WHO advisory committees. The need and charge for a working group is discussed and agreed during SAGE meetings. The purpose, structure and functioning of the Working Groups is described in detail in Annex 3.

In addition to attendance of meetings, active participations will be expected from all SAGE members throughout the year, including participation in SAGE working groups, video and telephone conferences as well as interactions via e-mail. Review of documents may also be solicited. SAGE members may be requested to participate as observers in other important WHO departmental or cross-departmental meetings.

SAGE members will not be remunerated for their participation in SAGE; however, reasonable expenses such as travel expenses incurred by attendance at SAGE or related meetings will be compensated by WHO.

SAGE reports to the WHO Director-General (or designee(s)). The SAGE chairperson will debrief the Director-General (or designee) and the IVB Director following each SAGE meeting. Minutes of SAGE meetings will be taken and circulated among SAGE members. The recommendations/conclusions of SAGE meeting shall be published, with the prior approval of WHO, in the Weekly Epidemiological Record and posted on the IVB Departmental website within two months of each SAGE meeting. In addition these recommendations and conclusions will be further translated and posted on the IVB Departmental website.

DECLARATION OF INTERESTS FOR WHO EXPERTS

The assistance of distinguished authorities knowledgeable in a variety of medical and scientific fields is essential to WHO's work on global health issues. **It is expected that individuals who are qualified to serve as an expert for WHO may have private interests related to their expertise. But, at the same time, it is imperative that situations are avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality.**

To assure the highest integrity, and hence public confidence, in its activities, WHO policies require that all experts serving in an advisory role agree to disclose any circumstances which could give rise to a **potential conflict of interest** (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Since you have been selected as a WHO expert in the activity described below, you are requested to disclose in this Declaration of Interest (DoI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you will be involved and any interest that could be significantly affected by the outcome of the meeting or work. You are also asked to declare relevant interests of others who may, or may be perceived to, unduly influence your judgment (such as immediate family members, employers, close professional associates or any others with whom you have a substantial common personal, financial or professional interest.)

Kindly complete this form and submit it to WHO Secretariat, well in advance of the meeting or work. You are also asked to inform the Secretariat if any change in this information occurs before or during the course of the meeting or work. Non-completion of a DoI form at any stage precludes participating as an expert.

It should be clarified that the giving of affirmative answers to questions in a DoI form would not automatically disqualify or limit your participation as an expert. Rather, your answers will be screened by the Secretariat to determine if a potential conflict of interest may exist or may be perceived to exist. One of several outcomes can occur, depending on the circumstances (i.e., the nature and magnitude of the interest, its timeframe, the availability of sufficient measures to safeguard the integrity of the decision-making process if the expert is permitted to participate).

After reviewing the disclosures in the DoI form, the Secretariat may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If it appears that a conflict of interest exists and is potentially or clearly significant (or may be reasonably perceived to be so), one of the following three options, or a combination of these options, may be applied by the Secretariat: (i) you may be invited to continue to participate in the meeting or work, provided that your interest would be publicly disclosed; (ii) you may be asked not to take part in the portion of the meeting, discussion or work related to your interest, or not participate in related decisions; or (iii) you may be asked not to take part in the meeting or work altogether.

Any relevant conflicts will be **publicly disclosed** to other participants at the start of the activity and in the resulting report or other work product. The Secretariat will assume that you consent to such a disclosure, unless you check "no" in the space provided on the last page of this form. In a **later audit or investigation**, the contents of your DoI form may be made available to persons outside of WHO if the objectivity of the work or meeting in which you are involved is questioned and the Director-General considers disclosure to be in the best interests of the Organization, although only after discussion with you. By completing this DoI form, it is assumed that you agree to these conditions.

Name: Institution: Email:

Date and title of meeting or work, including description of subject-matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children). "Commercial entity" includes any

commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.

	EMPLOYMENT AND CONSULTING Within the past 3 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or negotiation for future work.	
1a	Employment	Yes <input type="checkbox"/> No <input type="checkbox"/>
1b	Consulting, including service as a technical or other advisor	Yes <input type="checkbox"/> No <input type="checkbox"/>
	RESEARCH SUPPORT Within the past 3 years, have you or your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application for future research support.	
2a	Research support, including grants, collaborations, sponsorships, and other funding	Yes <input type="checkbox"/> No <input type="checkbox"/>
2b	Non-monetary support valued at more than US\$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
	INVESTMENT INTERESTS Do you have current investments (valued at more than US\$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified.	
3a	Stocks, bonds, stock options, other securities (e.g., short sales)	Yes <input type="checkbox"/> No <input type="checkbox"/>
3b	Commercial business interests (e.g., proprietorships, partnerships, joint ventures)	Yes <input type="checkbox"/> No <input type="checkbox"/>
	INTELLECTUAL PROPERTY Do you have any current intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?	
4a	Patents, trademarks, or copyrights (also include pending applications)	Yes <input type="checkbox"/> No <input type="checkbox"/>
4b	Proprietary know-how in a substance, technology or process	Yes <input type="checkbox"/> No <input type="checkbox"/>
	PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)	
5a	As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5b	Have you held an office or other position, paid or unpaid, where you may be expected to represent interests or defend a position related to the subject of the meeting or work?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ADDITIONAL INFORMATION	
6a	If not already disclosed above, have you worked for the competitor of a product which is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a financial or commercial competitive advantage?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6b	To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, financial or professional interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?	Yes <input type="checkbox"/> No <input type="checkbox"/>

6c	Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	TOBACCO OR TOBACCO PRODUCTS (answer without regard to relevancy to the subject of the meeting or work) Within the past 3 years, have you had employment or received research support or other funding from the tobacco industry or had any other professional relationship with an entity, directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity?	Yes <input type="checkbox"/> No <input type="checkbox"/>

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not provide, the amount or value of the interest, where requested, it will be assumed to be significant.

Nos. 1 - 4: 7 Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) <u>and</u> basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)
Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details				

CONSENT TO DISCLOSURE. The Secretariat will assume that you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product, unless you check "no" in the space provided here. If you check "no", the Secretariat will not disclose the information without your prior approval, although this may result in your not being able to participate in the meeting or conference. **No:**

DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of WHO and complete a new declaration of interests which describes the changes. This includes any change which occurs before or during the meeting or work itself and through the period up to the publication of the final results.

Date: _____

Signature _____

CONFIDENTIALITY UNDERTAKING

1. Commercial, academic and other research institutions and individual scientists often submit or present for discussion by committees or groups of the WHO Department of Immunization, Vaccines and Biologicals on research, products and processes (hereafter referred to as "Information") which the institutions and individuals consider proprietary. To help ensure the appropriate use by WHO of such Information whilst protecting the institutions' or individual's proprietary rights, WHO undertakes to release such Information only to persons who have signed this agreement.
2. Information submitted by such institutions or individuals through WHO to committees or groups for review, discussion or comment, whether at meetings, on internet-based collaborative workspaces, during telephone conferences or otherwise, shall be regarded by the Undersigned as confidential, unless clearly stated otherwise, by the institution, individual concerned and/or the WHO Secretariat.
3. The Undersigned undertakes to treat such confidential Information as proprietary information and agrees not to make copies of it, nor to disclose or use the same in whole or in part.
4. If requested to do so, the Undersigned agrees to return to WHO any and all Information identified as confidential.
5. The Undersigned shall not be bound by confidentiality if he/she is able to demonstrate that the Information:
 - (a) was known to him/her prior to any disclosure to him/her by the institution or individual or WHO;
 - (b) was in the public domain at the time of disclosure by the institution or individual;
 - (c) becomes part of the public domain through no fault of the Undersigned; or
 - (d) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality to the institution, individual or WHO.
6. This Confidentiality Undertaking is valid during the entire time the Undersigned participates in the work of the committee or group, in whatever capacity, and for a period of ten (10) years thereafter.

Signed:

Signature.....

Name.....
(print or type)

CONFIDENTIALITY1.

Purpose, structure and functioning of the Strategic Advisory Group of Experts on Immunization (SAGE) Working Groups

Working Group Purpose and decision to establish SAGE Working Groups

SAGE Working Groups are established as resources intended to increase the effectiveness of SAGE deliberations by reviewing and providing evidence based information and options for recommendations together with implications of the various options to be discussed by the full SAGE in an open public forum.

These Working Groups are established on a time limited basis in exceptional situations to help address specific questions identified by SAGE when the issue is particularly complicated and could not be addressed by existing standing WHO advisory committees.

The need and charge for a working group is discussed and agreed during SAGE meetings.

Terms of reference of the Working Groups and identification of needed expertise to serve on the working group

Each Working Group operates under specific terms of reference (TORs). These TORs need to be defined within 30 days of the SAGE meeting leading to the establishment of the working group.

TORs and proposed related expertise to serve on the Working Group are developed jointly by the SAGE member serving as Working group Chair and the Lead WHO technical staff. Final decision is taken jointly by the SAGE Chair and the Director of the Department of Immunization, Vaccines and Biologicals.

Working Group Composition and selection of membership

Each Working Group should include two SAGE members (one of whom functions as chair), WHO staff (one of whom functions as the Working Group technical lead), and additional subject matter experts serving in their own individual capacity and with a view to meet the identified needed expertise for the group. This may include organizations representatives, and members of regional technical consultative groups. SAGE members and other experts who have identified conflicts of interest cannot serve on the Working Groups charged with responsibility in the identified areas of conflict.

The size of the Working Groups should not exceed 10 members and will be adjusted based on the need for expertise and representation.

A public call for nomination of Working group members will be posted on the SAGE website together with the relevant terms of reference of the Working Group and indication of the desirable expertise. SAGE members, regional offices, WHO staff and key partner organization will also be approached for potential nominations. From the pool of nominees, the Working Group Chair and Lead WHO staff will propose a Working Group composition for endorsement by the SAGE Chair and the Director of the Department of Immunization, Vaccines and Biologicals. The proposed list should also identify other names and rationale for proposed selection.

Individuals other than SAGE members and organization representatives may participate in SAGE Working Groups meetings only by secretarial invitation in consultation with either Chairs of SAGE or of the Working Group. Occasionally the Working Group Chair, in consultation with the Lead WHO staff and the SAGE Chair, may request the participation of additional disease / vaccine experts who are not members of the working group. These may include SAGE members, organization representatives, industry representatives/experts, public health officials and faculty of academic institutions. Other experts, including representatives of vaccine manufacturers may be asked to provide information to the Working Groups on an ad hoc basis and as needed.

WHO staff perform, coordinate, or identify scientific studies and outbreak investigations to address questions that arise regarding appropriate vaccine policy decisions; conduct analysis of data addressing efficacy, effectiveness, safety, feasibility, and economic aspects of immunization policy.

Modus Operandi

SAGE Working Groups are not allowed to render consensus advice or recommendations directly to the WHO DG. SAGE Working Group Chairs, other Working Group representatives, or the Working Groups *per se* are not empowered to speak on behalf of SAGE. Rather, they are utilized by the SAGE to gather and organize information upon which the SAGE can deliberate and act. Thus, while SAGE Working Groups can and should

examine an area in detail and define the issues, including development of options for recommendations, the actual processes of group deliberation terminating in development of group consensus and recommendations must occur in the open public forum of SAGE meetings.

Working Group Process.

Effective communication and a strong working collaboration between the Working Group Chair and the Lead WHO staff are significant determinants of the effectiveness of a Working Group. The development of a brief (1-2 pages) summary of each Working Group meeting by one of these people will facilitate the function of the Working Group. Summaries should be provided to the SAGE Executive secretary so that IVB senior staff, immunization Regional Advisers and SAGE members can be informed in real time of progress and issues.

With the Lead WHO Staff, the Chair of the Working Group develops a plan for routine operations of the Group. Working Groups accomplish most of their work through teleconferences. A set day and time for routine monthly teleconferences may be established, in order to allow standing teleconferences to be arranged and Working Group members to anticipate and reserve time for these teleconferences. The frequency of Working Group teleconferences may be changed depending on the urgency of issues being considered by the group and the amount of preparatory work needed prior to a topic being brought up for plenary discussion and decision making at SAGE. Some Working Groups may more effectively achieve their purpose through exchange of e-mail communications with intermittent teleconferences.

In-person meetings of Working Groups may facilitate progress. If possible, they should be scheduled in association with SAGE meetings and should be anticipated at least 2 months in advance of the SAGE meeting. WHO routinely supports travel costs for the duration of SAGE meetings for SAGE members, chairs of regional technical advisory groups, WHO Regional Advisers and any experts invited to present at SAGE. WHO may support travel for additional persons for the purpose of a WG meeting. Such requests should be brought to the SAGE Executive Secretary for consideration on a case by case basis, with justification for the increased costs.

As issues mature, proposals for presentation to the SAGE should be submitted to the SAGE Executive secretary at least 10 weeks ahead of each SAGE meeting for circulation to SAGE members and to WHO staff. At this stage, formal interaction between the SAGE Working Group Chair, lead WHO staff, SAGE Executive secretary and the SAGE Chair should occur allowing for a briefing on the issue at hand and ensuring that areas of potential conflict are recognized prior to the meeting itself.

Decision to proceed with tabling the issue at the next SAGE meeting will then be taken jointly by the Chair of SAGE and IVB Director after consideration of issues raised during the consultative process.

Management of Conflict of Interest / Undue Influence

When a SAGE Working Group is formed, and at the start of each Working Group meeting, participants should respond to a request to report conflicts of interest relevant to the focus of the Working Group. This is done using the eDOI. SAGE members, organization representatives or WHO staff who have conflicts of interest may not participate in the Working Group. Persons who serve as consultants, may participate in the Working Group despite conflicts of interest if, in the judgment of the SAGE Chair, SAGE Executive Secretary, Working Group Chair and lead WHO staff they bring specific expertise that is essential to the efforts of the Working Group. However, conflicts, both personal and those of their liaison organization (in the case of liaison representatives), must be declared and recorded at the beginning of each Working Group meeting. Participation of all persons with declared conflicts will be restricted by the Working Group Chair and lead WHO staff to that necessary for the Working Group to benefit from the expertise provided by the consultant. No person with an identified conflict of interest should participate in drafting policy options or policy recommendations.

All consultants participate in Working Groups at the discretion of the Working Group Chair and lead WHO staff. The value and impact of SAGE recommendations and WHO policies and recommendations are critically dependent upon public trust in the integrity of the process. Thus, participation of any consultant may be curtailed, even in the absence of a declared conflict of interest, if in the judgment of the Working Group Chair and the lead WHO staff a potential for the appearance of undue influence exists.