**Instructions:** The following Standard Operating Procedure (SOP) (alternatively also referred to as the NITAG ‘Charter’) provides a guidance template for all NITAGs to adapt. The sections marked with the “< >” are to provide guidance and must be erased and completed by the NITAG Secretariat to reflect the specific context of your NITAG. The NITAG SOP must be clearly defined and should include the rules and procedures for all operations.

*<Italicized>* examples in *blue* have also been added in some areas to reflect key recommendations that can guide and define your NITAG membership and functioning aspects. This can assist you to review, compare and develop or update the sections of your NITAG SOP. In addition, the following NITAG SOP country examples can be accessed to help as a reference point and for adaptation purposes: [Bahrain](https://www.nitag-resource.org/sites/default/files/9a8a000924df684744ca9c9868aff060d66058d5_1.pdf), [Nepal](https://www.nitag-resource.org/sites/default/files/4bf1afea4cb2a584d4614070bf37d6db0c9430a7_1.pdf), [USA](https://www.nitag-resource.org/sites/default/files/2020-09/acip-charter.pdf), [Chile](https://vacunas.minsal.cl/wp-content/uploads/2017/02/Reglamento-interno-CAVEI-2015.pdf), [Canada](https://www.nitag-resource.org/sites/default/files/40dbda9854dabf66e97a497d575622bbe1a8b110_2.pdf), [Cote d’Ivoire](https://www.nitag-resource.org/sites/default/files/a1d220d7de248969cd9f7a21c2dbddc19df7f603_1.pdf)

The NITAG Secretariat checklist, accessible [here](https://www.nitag-resource.org/training/maintaining-solid-secretariat-and-processes/how-run-nitag-secretariat) is another useful reference document that can assist you with detailed tips, suggestions and links to training resources to better understand the roles, responsibilities, functions and procedures enlisted below.

**<Insert NITAG Acronym>: Standard Operating Procedure**

**Terms of Reference:**

<Insert the purpose or mandate of your NITAG, state the objective and the scope of activities delineated by the Ministerial decree>

**Membership:**

<Insert the composition details and size of your NITAG. How many core and non-core members are present in your NITAG?>

*<The recommended number of core voting members in a NITAG should ideally be 10-15 members as it enables manageable discussion and allows functioning if all members are not present (quorum required by internal NITAG procedures is ideally half + one member). Having an odd number is useful for tie-breaking and having this limited number also helps minimize budget for meetings>*

<List the job titles of the core, ex-officio, and liaison members. Specify their technical expertise>

*<Core members should not be MoH or immunization programme employees (nor have a direct or indirect supervisory relationship with them). In addition, they must not be associated or employed by pharmaceutical companies.*

*Ex-officio members should be selected due to their key positions in government agencies that represent immunization aspects, i.e., MoH officials (heads of departments, specialists) vaccine licensing bodies, vaccine control laboratory, officials responsible for immunization programs, planning, education, finance.*

*Liaison members can represent important professional societies, other national advisory committee, and key technical partners (WHO, UNICEF).*

*Note: Industry should not be allowed in meetings and do not have the power to vote, but occasionally they can be invited to highly structured settings to provide specific information.*

*With respect to technical expertise, WHO recommends at least 5 areas of technical expertise to be represented from these areas: clinical medicine (paediatrics, adult medicine, geriatrics), epidemiology, infectious disease, microbiology, public health, immunology, vaccinology, immunization program, health systems and delivery, health economist, social scientist*

*Committee membership should be balanced in terms of points of view represented, the committee's function and diverse geographic areas to the extent possible. Members cannot be represented by alternates or substitutes.>*

<Define the membership terms and process for selection/nomination, rotation, voting and termination in your NITAG. Include similar membership terms for Work Groups if anticipated>

*<Selection/Nomination: Selection, nomination and appointment of core voting members should be done by senior government officials through a well-defined transparent process executed after a wide-open call.*

*Chair appointment: The NITAG Chair should be appointed for one period with the potential of an extension, especially to preserve continuation of NITAG duties during periods transitions. Selection will be based on a demonstrated ability to lead and work effectively with members.*

*Rotation: Rotation of membership is recommended as a limited duration of service for the core members (5-6 years). Staggering of members to provide continuity can ensure the terms of all members do not expire at the same time and can help with orientation of new members. Small countries with limited number of experts at the national level may choose not to rotate NITAG members. For members completing their final term, an additional extension may be considered upon agreement between the chairperson and the Secretariat to complete projects for which they are the lead.*

*Voting: Only core members have the power to vote NITAG’s recommendations. Members of the secretariat, ex-officio members, liaison members, invited experts can contribute to discussions but cannot vote on recommendations.*

*Termination: The SOP must specify the termination process method and the authority who can initiate the process. Possible reasons for termination of membership include not attending a specified number of consecutive meetings, conflict of interest, breach of confidentiality, resignation, etc.*

*Resignation: A core member may ask for early termination of his/her appointment. The procedure to make resignation effective should be described in the SOP.*

*Working groups: Working groups can be established for gathering, analysing, and preparing information to help NITAGs with decision making for which they receive secretariat support. It is generally comprised of 1-2 or more core NITAG voting members along with additional subject matter experts as deemed necessary.>*

**Mode of operation:**

<insert the interest prevention and management policy of your NITAG>

*< Conflicts of interest (CoIs) can occur at any stage of the recommendation-making process: setting of the NITAG agenda, preparation of background documents, presentation and discussion during the NITAG plenary assembly, and voting or consensus-reaching. CoIs should therefore be prevented at every stage of this process.*

*For this purpose, an interest management policy should not apply only to the NITAG Chair and core members but also to the Secretariat and any experts invited to contribute to the working groups.*

*Declaration of interests: All members (chairperson, core members, ex-officio, liaison as well as special invitees) should declare in writing their relevant interests before their official appointment and verbally before each meeting or recommendation decision, and/or proactively if there is any change or update to their initial interests and affiliations. NITAGs should develop a policy to prevent and manage interests>*

<insert the confidentiality agreement procedure for your NITAG>

*<Confidentiality agreement: Annually, all members (chairperson, core members, ex-officio, liaison as well as special invitees) should sign an agreement stating that they will keep information confidential>*

<insert the defined role and support from the core members, non-core members and secretariat>

*<Core member roles: attending meetings, documentation revision, participation in working groups, NITAG advocacy, spokesperson, and communications, etc. according to what has been delineated by the Ministerial decree.*

*Liaison members: to bring knowledge and input into the NITAG discussions; express the views of the societies or associations they represent, and communicate NITAG's recommendation to them, as appropriate.*

*Secretariat role and support: The Secretariat shall provide the means for NITAG functioning as well as actively participate in NITAG meeting bringing knowledge and inputs into discussions. The Secretariat is responsible for drafting the NITAG’s SOP, Terms of reference as well as the meeting agenda. It should circulate the agenda to the members two weeks prior to the meetings along with background information / technical documents collected by the secretariat (or the working groups) to assist NITAGs with their deliberation. All documentation of the NITAG including meeting minutes, recommendations to the Ministry of Health, overseeing the NITAG website (if available), must be undertaken by the secretariat. If desired the secretariat can also establish a work plan for their NITAG and can lead, co-lead or support NITAG assessments and evaluations. More detailed information on all these aspects, can be accessed on the secretariat checklist available* [*here*](https://www.nitag-resource.org/training/maintaining-solid-secretariat-and-processes/how-run-nitag-secretariat)*.*

*Executive Secretary: It provides leadership and strategic advice for achieving the mandate of the NITAG, including its management. This position works closely with the NITAG Chair and the Secretariat to ensure the NITAG's mandate is met in an effective and efficient manner. This position provides advice to the Ministry of Health on NITAG related issues and keeps the NITAG informed of issues that may impact its operation. The Executive Secretary may be nested within the Secretariat and responsible for implementing the Secretariat’s tasks associated with NITAG operation, including meetings preparation, recommendation crafting, and NITAG evaluation.>*

<insert the meeting rules and format for NITAG members to follow>

*<Meeting rules and frequency: NITAGs must meet at least once a year, with flexibility for additional meetings as needed. Emergency or ad hoc meetings may be called by the chairperson as needed to address emerging issues. Reference materials along with the agenda should be provided in advance of ordinary, extraordinary, and emergency meetings The meetings can be open or closed. Countries can select either of the option appropriate for them. Open meetings increase transparency and may improve public acceptance but may make the process less efficient or be difficult to implement in terms of infrastructure. Industry do not have the power to vote, but occasionally they can be invited to highly structured settings to provide specific information. >*

<insert the decision-making process to be followed by your NITAG>

*<Process for agenda development: Items should come from the Ministry of Health, but NITAG chair, secretariat and stakeholders may suggest issues.*

*Process to review and share evidence: Prior to meetings, specific questions should be articulated to the NITAG. Agenda and background documents must be circulated by the Secretariat at least 2 weeks in advance of meetings.*

*NITAG decision making process: The NITAG must have a well-defined decision-making framework for formulating recommendations. This must be stated in the SOP of each NITAG. The decision-making process should be an evidence-informed, independent process undertaken by defining and adopting a generic set of criteria for decision-making.*

*Decision by vote or consensus: NITAGs need to decide if decisions of its core members will be made by majority vote or by consensus, and how many members need to be present (quorum) to formulate recommendations>*

<insert the recordkeeping procedure for your NITAG>

*<Recordkeeping and communications: Summary minutes of each meeting focusing on main conclusions and recommendations should be available and endorsed by NITAG within a maximum of 60 days of meeting and ideally shortly after the meeting (two weeks). Minutes can be public or private. Publication of minutes increase transparency and may improve public trust, as well as help with immunisation policy information dissemination.*

*Clear process and format for communicating the minutes to the members as well as the drafted recommendations to the Ministry of Health and decision makers (who, to whom, when, and how) must be established>*

<Insert the estimated annual operating costs or official terms of funding for your NITAG. All NITAG activities should be sustainable through secured and adequate funding>

*<Estimated annual operating costs: The NITAG must develop an annual budget that covers NITAG activities (meetings, documentation, recommendation crafting, training, NITAG experience exchanges, etc.) and costs related to NITAG functioning (travel and accommodation expenses, meeting locations, etc.) which are specified in the work plan. The activities should be accompanied by the specific sources of funding.*

*A senior level Ministry of Health staff should receive the annual budget and a budget line for NITAG activities should appear in the overall Ministry of Health budget>*

<insert date and signature / stamp of the secretariat>

Note: Updated SOP must be shared with all members of your NITAG.