

WHO Advisory Committee on Variola Virus Research (WHO ACVVR) Terms of Reference

In 1980, the World Health Assembly declared the global eradication of smallpox following two years of intense surveillance after the last naturally occurring case was reported in October 1977 in Somalia. Since then all remaining stocks of variola virus were moved to and are retained in two WHO global repositories, one in the Russian Federation and the other in the United States of America. The World Health Organization (WHO) is mandated by the World Health Assembly (WHA) to oversee the safe and secure management of variola virus stocks by undertaking biennial biosafety inspections of the two repositories. WHO also oversees all research using live variola virus with the support of the WHO Advisory Committee on Variola Virus Research (WHO ACVVR).

The WHO Advisory Committee on Variola Virus Research (WHO ACVVR) was established in 1999 with expert members appointed by the Director-General upon the request of the Health Assembly as set out in Resolution WHA52.10 (1999). The WHO ACVVR was asked to consider what research should be carried out in order to reach global consensus on the timing for the destruction of variola virus stocks and to develop a research plan for priority work with the virus. The WHO ACVVR has met annually since 1999 to continue oversight of this research agenda.

In May 2002, in Resolution WHA55.15, the Health Assembly authorized research to continue on the understanding that a new date for destruction of variola virus stocks would be set when research outcomes would allow consensus to be reached. In May 2007, in Resolution WHA 60.1, the Health Assembly requested the WHO Director-General (DG) to review the membership of the WHO ACVVR in order to ensure balanced geographical representation, substantial participation of public-health experts, and independence of the members from any conflict of interest. In this resolution, the Health Assembly also requested the DG to ensure that the benefits of approved research, including antiviral agents, vaccines and diagnostics, be made widely and equitably available to all Member States. In 2011, in Decision WHA64(11), the Health Assembly reaffirmed the need to reach consensus on a new date for the destruction of the variola virus stocks, when research outcomes crucial to public health response to an outbreak would so permit. In 2016, a review of the public health implications of synthetic biology technology, presented to the WHA, concluded that the risk of smallpox re-emergence had risen. In 2019, the Health Assembly endorsed continuation of countermeasures development and requested an update within five years.

This document outlines the work of the WHO Advisory Committee on Variola Virus Research (WHO ACVVR) in this context. The WHO ACVVR will act as an advisory body to WHO in this field.

I. Functions

In compliance with Resolution WHA52.10 (1999) and in its capacity as an advisory body, the WHO Advisory Committee on Variola Virus Research shall have the following functions and make recommendations on these topics:

1. *To advise WHO on all actions to be taken with respect to variola virus;*
2. *To develop a research plan for priority work on the variola virus;*
3. *To devise a mechanism for reporting of research results to the world health community; and*
4. *To outline an inspection schedule to confirm the strict containment of existing stocks and to assure a safe and secure research environment for work on the variola virus*

In compliance with Resolution WHA55.15 (2002), a new date for destruction of variola virus stocks should be proposed when research outcomes allow consensus to be reached on the timing of destruction.

II. Composition

1. The WHO ACVVR shall have up to 25 members¹, who shall serve in their personal capacities to represent the broad range of disciplines relevant to variola virus research. In the selection of the WHO ACVVR members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.
2. Members of the AG, including the Chairperson (and the Vice-Chairperson, if any), shall be selected and appointed by WHO following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the AG;
 - to liaise with the WHO Secretariat between meetings.

In appointing a Chairperson (and a Vice-Chairperson, if any), consideration shall be given to gender and geographical representation.

3. Members of the WHO ACVVR shall be appointed to serve for a period of 3 years and shall be eligible for reappointment. A Chairperson (and a Vice-Chairperson, if any) is eligible for reappointment as a member of the WHO ACVVR, and is permitted to serve as Chairperson (or Vice-Chairperson, if any) for one term, renewable once. Their appointment and/or designation as Chairperson (or Vice-Chairperson, if any) may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a member's appointment is terminated, WHO may decide to appoint a replacement member.
4. WHO ACVVR members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests (DOI) form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, and confirmation that their participation would not give rise to a real, potential or apparent conflict of interest.
5. Following a determination that a proposed member's participation in the WHO ACVVR would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the WHO ACVVR. Their appointment to the WHO ACVVR is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, WHO ACVVR members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.
6. As contemplated in paragraph II.4 above, WHO will, from time to time, request WHO ACVVR members to complete a new declaration of interest form. This may be before a WHO ACVVR meeting or any other WHO ACVVR related activity or engagement, as decided by WHO. Where WHO has made such a request, the WHO ACVVR member's participation in the activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.

¹ Members serve as full participants in the decision-making process of the meeting in which they are involved.

7. Where a WHO ACVVR member is invited by WHO to travel to an in-person meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter'). WHO shall not authorize travel, until a countersigned Temporary Adviser Letter is received from the invitee.
8. WHO ACVVR members do not receive any remuneration from the Organization for any work related to the WHO ACVVR. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.
9. One representative from each of the two WHO global variola virus repository institutions will be invited as permanent representative to the WHO ACCVR. Permanent representatives will be proposed by their respective institutions and appointed by WHO. They will receive a letter of appointment and will be eligible for reappointment. Permanent representatives will be required to recuse themselves from discussions of, and recommendations regarding, the research being proposed by their respective repository institutions, except to answer questions for clarification as required.

III. Operation

1. The WHO ACVVR shall normally meet each year. WHO may convene additional meetings. WHO ACVVR meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

WHO ACVVR meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

- (a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views and may be attended by Observers (as defined in paragraph III.3 below).
 - (b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the AG and essential WHO Secretariat staff.
2. The quorum for WHO ACVVR meetings shall be two thirds of the members.
3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as "observers", which category will include invited presenters and persons invited in an ad hoc capacity for their specific technical expertise. Invited presenters from the variola virus repository institutions will also be considered as observers. Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-state actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the WHO ACVVR. Invitations to observers attending as representatives from non-state actors will be subject to internal due diligence and conflict of interest considerations in accordance with FENSA. Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the WHO ACVVR at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting decisions and recommendations of the WHO ACVVR.

4. The WHO ACVVR may decide to establish smaller working groups (sub-groups of WHO ACVVR to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the WHO ACVVR for review at one of its meetings.
5. WHO ACVVR members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the WHO ACVVR.
6. A yearly report shall be submitted by the WHO ACVVR to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from the WHO ACVVR are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the WHO ACVVR.
7. The WHO ACVVR shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.
8. Active participation is expected from all WHO ACVVR members, including in working groups, teleconferences, and interaction over email. WHO ACVVR members may, in advance of WHO ACVVR meetings, be requested to review meeting documentation and to provide their views for consideration WHO ACVVR.
9. WHO shall determine the modes of communication of and by the WHO ACVVR, including between WHO and WHO ACVVR members.
10. WHO ACVVR members shall not speak on behalf of, or represent, the WHO ACVVR or WHO to any third party, except by express and written agreement with the WHO.

IV. Secretariat

WHO shall provide the secretariat for the WHO ACVVR, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

V. Information and documentation

1. Information and documentation to which members may gain access in performing WHO ACVVR related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter-signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, WHO ACVVR members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their WHO ACVVR - related activities shall be exclusively vested in WHO.
2. WHO ACVVR members and observers shall not quote from, circulate or use ACVVR documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.
3. WHO retains full control over the publication of the reports of the WHO ACVVR, including deciding whether or not to publish them.