

Health and Medical Cooperation

Specimen Sharing Agreement Between the Government of the
United States of America and the Government of Malawi through
the Ministry of Health

Signed at Lilongwe January 12, 2026.

Entered into Force February 11, 2026.



NOTE BY THE DEPARTMENT OF STATE

Pursuant to Public Law 89—497, approved July 8, 1966
(80 Stat. 271; 1 U.S.C. 113)—

“ . . . the Treaties and Other International Acts Series issued under the authority of the Secretary of State shall be competent evidence . . . of the treaties, international agreements other than treaties, and proclamations by the President of such treaties and international agreements other than treaties, as the case may be, therein contained, in all the courts of law and equity and of maritime jurisdiction, and in all the tribunals and public offices of the United States, and of the several States, without any further proof or authentication thereof.

SPECIMEN SHARING AGREEMENT
BETWEEN
THE GOVERNMENT OF THE UNITED STATES OF AMERICA
AND
THE GOVERNMENT OF MALAWI
THROUGH THE MINISTRY OF HEALTH

PREAMBLE

The United States of America (U.S. Government) and the Government of Malawi (together the “Parties”) seek to engage in a bilateral Specimen Sharing Agreement (“Agreement”).

Article 1. Purpose and Scope

a. The purpose of this Agreement is to promote global health security through the facilitation of the rapid sharing of specimens, samples, sequencing data, and any other associated data related to novel and emerging infectious diseases with epidemic or pandemic potential ("specimen and related data") between the U.S. Government and the Government of Malawi for legitimate public health purposes, including responding to outbreaks and the development of diagnostics and medical countermeasures.

Article 2. Specimen Sharing with the U.S. Government

a. Upon a request by the U.S. Government, the Government of Malawi agrees to initiate sharing specimen(s) and related data with the U.S. Government within seven (7) days of the Government of Malawi receiving such a request from the U.S. Government or on an alternative timeline as mutually agreed to between the U.S. Government and the Government of Malawi on a case-by-case basis. If requested by the U.S. Government, the Government of Malawi may provide sequencing data via sharing on a public database instead of or in addition to directly sharing specimens and related data with the U.S. Government.

b. The Government of Malawi agrees to authorize the U.S. Government sharing the specimen and related data for the purpose of developing diagnostics and medical countermeasures with up to ten (10) non-U.S. Government U.S. entities (“U.S. Recipients”), each of whom must have the capability to assist in

developing diagnostics and/or medical countermeasures. The U.S. Government will provide written notice when a specimen is shared with a U.S. Recipient.

Article 3. Benefits to Malawi

- a. In the event that a medical countermeasure is developed primarily from specimen and related data shared under this Agreement by the Government of Malawi, the U.S. Government, subject to the availability of funds and applicable law, shall prioritize any request by the Government of Malawi for the medical countermeasure immediately behind the U.S. Government's domestic need for such medical countermeasure and make best efforts to make such medical countermeasure available to the Government of Malawi at prices equal to or below those paid by the U.S. Government.
- b. The U.S. Government will explicitly acknowledge the contribution of the Government of Malawi and its relevant institutions in publications, presentations, and reports arising from the use of the specimens and related data.
- c. Where discoveries or other innovations generated through the use of specimens shared by the Government of Malawi offer broader benefits, such as improved surveillance methods, diagnostic approaches, or public health knowledge, the Parties shall consult in good faith on appropriate ways for the Government of Malawi to benefit from these advances, consistent with applicable laws, regulations and resource availability.

Article 4. Representations

- a. Each Party affirms that its participation in any multilateral agreement or arrangement, including surveillance and laboratory networks, governing access and benefit sharing of human and zoonotic specimens and related data shall not prejudice its compliance with this Agreement.
- b. The Government of Malawi acknowledges that, pursuant to Section 4.7 of the Memorandum of Understanding (MOU) between the Government of Malawi and the U.S. Government, of January 12, 2026, so long as the U.S. Government is providing any funding under the MOU, the U.S. Government has a significant and material interest in ensuring that the Government of Malawi fulfills the commitments for specimen and related data sharing set out in this Agreement and that failure by the Government of Malawi to fulfill these commitments could result in changes in U.S. Government planned assistance contemplated under the MOU, the discontinuation of the MOU, or the termination of this Agreement by the U.S. Government.

Article 5. Additional Terms

- a. **Duration:** This Agreement shall enter into force thirty (30) days after signature by both Parties and shall remain in force for seven (7) years.
- b. **Termination:** In the event the MOU is discontinued prior to December 31, 2030, either Party may terminate this Agreement upon giving one year's written notice to the other Party. If the MOU is no longer in effect, either Party may terminate this Agreement with one year's written notice to the other Party. In the event the Government of Malawi terminates this agreement, termination shall not affect the use by the U.S. Government of any specimens and related data previously shared under this Agreement or any U.S. benefit sharing obligations under this Agreement that arise from such use. The Parties agree to consult on any differences related to U.S. Government use and benefit sharing obligations for previously shared specimen and related data following the termination of the Agreement.
- c. **Amendments:** This Agreement may be amended by mutual written consent of the Parties.
- d. **Notices:** Any notice required under this Agreement is expected to be provided to:

For the U.S. Government
Melania Arreaga
Chargé d’Affaires
U.S. Embassy
16 Jomo Kenyatta Road
Lilongwe 3, Malawi

For the Malawi Government
Honourable Madalitso Baloyi, M.P.
Minister
Ministry of Health and Sanitation
P.O. Box 30377
Lilongwe 3, Malawi

Either Party may, by notice in writing to the other Party, designate additional representatives or substitute other representatives for those designated in this Section. The Parties intend any notice, request or other communication under this Agreement to be in writing and delivered to the address specified in this Agreement or such other address as either Party may provide to the other Party.

- e. **Procedures for Sharing:** The Parties agree that the transfer, use, management and control of specimens and related data shared under this Agreement will be carried out consistent with applicable domestic laws including personal data protection and privacy, protection of human subjects, and internationally recognized standards of specimen sharing, collection and handling. A document specifying characteristics of specimens and related data

may be completed at the time of specimen transfer between the sending entity in Malawi and the U.S. Government receiving entity. The Parties agree to develop a standard Material Transfer Agreement (SMTA) for sharing specimens. Until such time as the SMTA is agreed, the Parties will use existing documents (e.g., templates) for sharing specimens.

f. **Other Sharing Permitted:** This Agreement neither precludes new agreements nor negates or replaces existing agreements for sharing specimen and related data between the U.S. Government and the Government of Malawi.

g. **Privileges and Immunities of the Parties:** Nothing in or related to this Agreement shall be construed as a waiver, express or implied, of privileges and immunities accorded to either of the Parties, including the sovereign immunity of either of the Parties, under any applicable law or agreement.

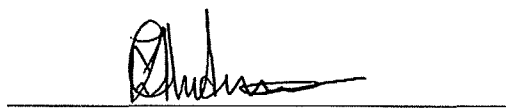
h. **Resolution of Differences:** The Parties agree to resolve any differences between them arising from or in connection with the interpretation or performance of this Agreement through consultations between themselves.

DONE at Lilongwe, on January 12, 2026, in duplicate, in the English language.

FOR THE GOVERNMENT OF THE
UNITED STATES OF AMERICA:


CHARGÉ D'AFFAIRES

FOR THE GOVERNMENT
OF MALAWI:


MINISTER OF HEALTH