



C-25-0434-07-08

DEPARTMENT OF THE NAVY
NAVAL HEALTH RESEARCH CENTER
140 SYLVESTER ROAD
SAN DIEGO CA 92106-3521

IN REPLY REFER TO:
3900
Ser 00/283
20 Jul 25

STANDARD
NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
BETWEEN
NAVAL HEALTH RESEARCH CENTER (NHRC)
AND
HIDALGO COUNTY HEALTH AND HUMAN SERVICES (HCHHS)

AGREEMENT TITLE: HCHHS Biosurveillance Sample and Data Exchange Agreement

AGREEMENT NUMBER: NCRADA - **NHRC- 25-12050**

AGREEMENT ADMINISTRATORS:

NHRC

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STANDARD
NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
BETWEEN
NAVAL HEALTH RESEARCH CENTER (NHRC)
AND
HIDLAGO COUNTY HEALTH AND HUMAN SERVICES (HCHHS)

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), the Department of the Navy Collaborator, Naval Health Research Center, 140 Sylvester Road, San Diego, CA 92106, and the Non-Navy Collaborator described below agree to and enter into this Cooperative Research and Development Agreement (CRADA).

Hidalgo County Health and Human Services (HCHHS), 1304 South 25th Avenue Edinburg, Texas 78542, is a political subdivision, organized under the laws of the State of Texas.

NHRC has extensive expertise, capabilities, and information in testing for infectious diseases and in accordance with the U.S. Federal Technology Transfer Act, desires to make this expertise and technology available for use in the public and private sectors.

HCHHS has the interest, resources, capabilities, and technical expertise to transition the results of Naval research and development for public use.

Article 1. DEFINITIONS

As used in this Agreement, the following terms shall have the meanings defined below, which are equally applicable to both the singular and plural forms of nouns or any tense of verbs.

1.1 "Agreement" means this Cooperative Research and Development Agreement (CRADA) with its Appendices.

1.2 "Classified Information (CI)" means all Information classified in accordance with the national security laws of the United States.

1.3 "Collaborator" means the Navy participant or the Non-Navy participant represented and bound by the signatories of this Agreement.

1.4 “Controlled Unclassified Information (CUI)” means information the Government creates or possesses, or that an entity creates or possesses for or on behalf of the Government, that a law, regulation, or Government-wide policy requires or permits an agency to handle using safeguarding or dissemination controls. CUI is further defined in 32 C.F.R § 2002.4.

1.5 “Cooperative Work” means research, development, engineering, or other tasks performed under this Agreement by NHRC or HCHHS working individually or together, pursuant to the Objectives (Article 2) and the Statement of Work (Appendix A).

1.6 “Data” means recorded information of any kind regardless of the form or method of the recording, including computer software.

1.7 “Effective Date” means the date of the last signature of the Collaborators executing this Agreement.

1.8 “Exclusive Commercial License” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell an Invention for commercial purposes.

1.90 “Government” means the Government of the United States of America.

1.10 “Government Purpose Rights” means the right of the Government to use, duplicate, or disclose Data, in whole or in part, and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes. Government Purpose Rights includes competitive procurement, but does not include the right to have or permit others to use Data for commercial purposes.

1.11 “Information” means all Data, trade secrets, and commercial and financial information.

1.12 “Intellectual Property” means the property of ideas, examples of which include, but are not limited to, patents, trademarks, copyrights, and trade secrets.

1.13 “Internal Use License” means the grant by the owner of Intellectual Property of the right to make, have made, use, and import, but not commercially sell, an Invention or a product or service made using an Invention.

1.14 “Invention” means any creation or discovery that is or may be patentable or otherwise protected under Title 35, United States Code, or any novel variety of plant that is or may be patentable under the Plant Variety Protection Act.

1.15 “Invention Disclosure” means the document identifying and describing to organizational management the Making of an Invention.

1.16 “Jointly Made Subject Invention” means any Invention Made jointly by the Collaborators.

1.17 "Limited Rights" means that each Collaborator of this Agreement may use, reproduce, and disclose to their employees properly marked Non-Subject Data provided by the other Collaborator(s) for use in support only of this Cooperative Work.

1.18 "Made" when used in conjunction with any Invention means the conception or first actual reduction to practice of such Invention.

1.19 "Nonexclusive Commercial License" means the grant by the owner of Intellectual Property of the nonexclusive right to make, use, or sell an Invention.

1.20 "Non-Subject Data" means any Data that are not Subject Data.

1.21 "Non-Subject Invention" means any Invention that is not a Subject Invention.

1.22 "Patent Application" means an application for patent protection for an Invention with any domestic or foreign patent-issuing authority.

1.23 "Principal Investigator (PI)" means that person having the responsibility for the performance of the Cooperative Work on behalf of a Collaborator.

1.24 "Proprietary Information" means Information that:

(i) embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information (a) is not known or available from other sources without obligations concerning its confidentiality, (b) has not been made available by the owners to others without obligation concerning its confidentiality, (c) is not already available to the Government without obligation concerning its confidentiality, and (d) has not been developed independently by persons who have had no access to the information; or

(ii) has been generated by the Navy Collaborator during the performance of this Agreement, and would have qualified as Proprietary Information under 1.24(i) above if it had been generated by the Non-Navy Collaborator, and that the Collaborators have agreed to treat as Proprietary Information for a term of up to five years from generation.

1.25 "Subject Data" means that Data first recorded in the performance of the Cooperative Work.

1.26 "Subject Invention" means any Invention Made in the performance of the Cooperative Work.

1.27 "Tangible Property" means personal or real property having or possessing physical form.

1.28 "Technical Data" means recorded Information relating to experimental or engineering works that can be used to define an engineering or manufacturing process or to design, procure, support, maintain, operate, repair or overhaul material, including, but not limited to graphic or pictorial delineations in media.

1.29 "Technical Document" means recorded Information that conveys scientific and Technical Information or Technical Data.

1.30 "Technical Information" means Information relating to research, development, engineering, test, evaluation, production, operation use, and maintenance of munitions and other military supplies and equipment.

1.31 "Unlimited Rights" means the right to use, modify, reproduce, release, disclose, perform, or display Data in whole or in part, in any manner and for any purpose whatsoever, and to have or permit others to do so.

Article 2. OBJECTIVES

The purpose of this agreement is to formalize collaborations between the Operational Infectious Diseases Directorate at the Naval Health Research Center (NHRC-OID) and Hidalgo County Health & Human Services. The goal of this joint effort is to develop and expand wastewater, respiratory, enteric, antimicrobial resistance and vector-borne biosurveillance in Texas and along the United States (US)/ Mexico border.

Article 3. RESPONSIBILITIES FOR PERSONNEL AND FACILITIES USE

3.1 Facilities and Supervision

The Collaborators shall provide personnel, facilities, and equipment necessary for, and shall perform, the Cooperative Work.

The Cooperative Work done by each Collaborator will be performed under the program guidance of its PI, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within that Collaborator's facilities or done on behalf of that Collaborator by third parties in support of this Agreement. Personnel who perform Cooperative Work at the other Collaborator's facilities will be supervised by their own PI.

3.2 Security Regulations and Directives

Each Collaborator will abide by the safety and security regulations and directives of the host facility in which the Cooperative Work is being performed.

Article 4. REPRESENTATIONS AND WARRANTIES

4.1 NHRC's Representations and Warranties

NHRC hereby warrants and represents to HCHHS that the performance of the activities specified by this Agreement is consistent with the mission to optimize operational readiness and warfighter health by informing DoD policy through research excellence and technology transfer missions of NHRC. NHRC is a Federal laboratory of the U.S. Department of the Navy, as defined by 15 U.S. Code § 3710a (d)(2)(A) and Department of Defense Instruction 5535.08, dated September 22, 2002.

4.2 HCHHS's Representations and Warranties

HCHHS hereby warrants and represents to NHRC as follows:

HCHHS, as of the Effective Date of this Agreement, is a political subdivision, organized under the laws of the State of Texas.

HCHHS is not a small business as defined in 15 U.S. Code § 632 and implementing regulations (13 C.F.R. 121.101 et seq.) of the Administrator of the Small Business Administration.

If HCHHS or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement of thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), the HCHHS or its successor or assignee shall promptly notify NHRC to that effect.

The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any agreement binding on HCHHS. Furthermore, the execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any valid order of any court, or any regulatory agency or other body having authority to which HCHHS is subject.

HCHHS is not currently subject to debarment or suspension by any agency of the Government. Should HCHHS be debarred or suspended during the term of this Agreement or thereafter, HCHHS will notify NHRC within thirty (30) days of receipt of a final notice. NHRC may then elect to terminate this Agreement and any licenses and options granted under this Agreement.

4.3 Joint Representations and Warranties

The Collaborators make the following Representations and Warranties:

There is no express or implied warranty as to any research, Invention, or product, whether tangible or intangible. In particular, the Collaborators make no express or implied warranty as to the merchantability or fitness for a particular purpose of any research, Invention, or product, whether tangible or intangible. Likewise, the Collaborators make no express or implied warranty as to any Cooperative Work, Subject Invention, Subject Data, or other product resulting from the Cooperative Work.

The use and dissemination of Information and materials exchanged under this Agreement will be in accordance with all U.S. laws and regulations, including those pertaining to national security and export control. Nothing in this Agreement shall be construed as a license to export Information. The exporting Collaborator is responsible for obtaining any export licenses and/or foreign disclosure reviews that may be required by U.S. Federal law. HCHHS shall provide written notification to NHRC immediately upon their awareness that an export or disclosure has been made without the required export license or disclosure authorization.

The work proposed in the Statement of Work, Appendix A, may require the introduction or generation of CUI. All CUI that is introduced or generated in the performance of work under this Agreement shall be properly marked and safeguarded as provided herein and in all applicable U.S. Federal laws and regulations.

Article 5. FUNDING

Each Collaborator will fund its own efforts.

Article 6. REPORTS AND PUBLICATIONS

6.1 Interim Reports

The Collaborators shall submit yearly interim written reports to each other on the progress of the Cooperative Work.

6.2 Final Reports

The PIs shall submit to the NHRC Technology Transfer Office and HCHHS preferred contact a final report within four (4) months of the completion, termination, or expiration of this Agreement that includes the results obtained and a list of all Subject Inventions Made.

6.3 Agreement to Confer Prior to Publication or Public Disclosure of Information

For the purposes of this Article, the term “disclosure” shall include, but not be limited to, submission of any manuscript for peer review prior to publication.

The Collaborators agree to confer and consult prior to any publication or public disclosure of Subject Data to ensure that no Proprietary Information, Government CI, or CUI, is released and that patent rights are not compromised. Prior to any such publication or public disclosure of Subject Data, each Collaborator shall be offered a period not to exceed thirty (30) days, to review any proposed abstract, publication, presentation, or other document for public disclosure.

If a Collaborator objects to a proposed public disclosure, that Collaborator must so notify the other Collaborator within thirty (30) days of the date of notice of intent to disclose publicly. If no objection is received by the Collaborator intending to make public disclosure, concurrence is assumed.

If a Collaborator objects on the grounds that patent rights may be compromised, a Patent Application must be filed by the responsible Collaborator before the public disclosure or by another date mutually agreed to by the Collaborators.

If a Collaborator objects to the release of Information on the grounds that the Information is Proprietary Information, or Information whose dissemination is restricted by U.S. security laws or regulations, the disclosure shall be postponed until the Information no longer meets the definitions of Proprietary Information, or is no longer covered by U.S. security laws or regulations.

6.4 Public Presentation of Subject Data

Any public presentation that includes Subject Data that are CI or CUI must have prior review and approval by NHRC pursuant to the pertinent security laws, regulations, and directives.

Article 7. INTELLECTUAL PROPERTY

7.1 Rights Under Other Agreements

Nothing in this Agreement is intended to change the rights in Intellectual Property acquired by the Collaborators in any other contract or Agreement between the HCHHS and the Government.

7.2 Rights in Subject Data

7.2.1 Rights of Both Collaborators

Each Collaborator shall have title to all Subject Data generated by that Collaborator. Each Collaborator agrees to provide all Subject Data to the other Collaborator and hereby grants Unlimited Rights in Subject Data that does not contain Proprietary Information.

7.2.2 Rights of NHRC

For Subject Data that contains HCHHS's Proprietary Information, the Government has rights to: 1) Use, modify, reproduce, release, perform, display, or disclose Technical Data within the Government without restriction; and 2) Release or disclose Subject Data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that Subject Data for any U.S. Government purpose including competitive procurement.

7.2.3 Rights of HCHHS

For Subject Data that contains NHRC's Proprietary Information, HCHHS has rights to use, modify, reproduce, release, perform, display, or disclose Technical Data within HCHHS's organization, in whole or in part, and in any manner, for any internal purpose excluding commercial purposes. If HCHHS is subsequently awarded a Government contract that entails deliverables that incorporate the NHRC's Proprietary Information, such deliverables must be delivered with at least Government Purpose Rights, as defined in the DFARS § 252.227-7013.

HCHHS shall have a Limited Right to use, reproduce, or disclose Subject Data that may describe one or more Inventions in which the Government owns or may own a right, title, or interest, if such Subject Data are provided by NHRC under this Agreement. This Limited Right does not grant the HCHHS any License to any Invention in which the Government owns or may own a right, title, or interest. In accordance with Article 7.5 below, such Subject Data are to be held in confidence.

7.3 Rights in Non-Subject Data

7.3.1 Rights of Both Collaborators

The Collaborators shall have Unlimited Rights in any Non-Subject Data that are not Proprietary Information or protected under 35 U.S. Code § 205 provided under this Agreement.

7.3.2 Rights of NHRC

NHRC has a Limited Right to use, reproduce, and disclose only to Government employees for use in support of the Cooperative Work any Non-Subject Data that are properly marked as Proprietary Information and are provided by HCHHS under this Agreement. Such Proprietary Information can be used only for the purpose of performing the Cooperative Work unless written consent to other use or disclosure is obtained from HCHHS.

7.3.3 Rights of HCHHS

HCHHS shall have a Limited Right to use, reproduce, or disclose Non-Subject Data that may describe one or more Inventions in which the Government owns or may own a right, title or interest, if such Non-Subject Data are provided by NHRC under this Agreement. Such Non-Subject Data shall be properly marked by NHRC.

7.4 No Implied License

Unless otherwise specifically provided, the Collaborators agree that the exchange of Data of any kind does not confer a license to any Non-Subject Invention claimed in any patent or Patent Application or to the subject matter of any copyright, trademark/service mark, or other form of Intellectual Property protection.

7.5 Protection of Data

Except for the rights granted in Article 7.1 and Article 7.2, Data shall be protected in accordance with the proper markings of its owner and as provided by, at a minimum, the requirements of 15 U.S. Code § 3710a. Proprietary Information will be protected only if it is properly marked as such. Information provided in intangible form that is Proprietary Information must be designated Proprietary Information at the time it is provided, followed within fifteen (15) days by a writing summarizing the exact information to be protected. The Collaborator receiving Information in an intangible form that is designated as Proprietary Information shall be responsible for protecting the Information as Proprietary Information during the fifteen (15) day notification. After the fifteen (15) day period, if no written summary has been received, the receiving Collaborator need not continue to protect the Information received in intangible form.

Data that is provided by HCHHS in the performance of this Agreement, and is appropriately marked as a trade secret or commercial or financial information that is privileged or confidential under 5 U.S. Code § 552(b)(4), shall not be disclosed by NHRC. HCHHS shall agree to not disclose, for five (5) years, Data that is produced by NHRC and that would have been considered a trade secret, business commercial, or financial information that is privileged or confidential if it had been produce by HCHHS.

CI, CUI or otherwise restricted information shall be protected in accordance with the security laws of the U.S.

7.6 Release of Data Under the Freedom of Information Act

NHRC will comply with the Freedom of Information Act and Executive Order 12600.

7.7 Marking of Data

7.7.1 Markings Required for Both Collaborators

7.7.1.1 Data Provided with Less than Unlimited Rights

Each Collaborator shall mark all Data that it provides with less than Unlimited Rights with a marking that clearly identifies the Limited Rights.

7.7.1.2 Data that are CI, CUI, or Otherwise Restricted

Each Collaborator shall mark all Data that are CI, CUI or otherwise restricted by U.S. security or export control laws or regulations that it provides under this Agreement.

7.7.2 Markings Required for NHRC

7.7.2.1 Data that are Subject to 35 U.S. Code § 205

NHRC shall mark Data it provides under this Agreement that disclose one or more Inventions in which the Government owns or may own a right, title or interest, and that are subject to confidentiality under 35 U.S. Code § 205. Such Data shall be marked:

“NHRC DATA PROTECTED FROM RELEASE OR DISCLOSURE UNDER 35 U.S. Code § 205.”

7.7.2.2 Data Protected Under Article 7.5

NHRC shall place a proprietary marking on each medium used for recording Data that NHRC provides to HCHHS, where the Collaborators have agreed, under second paragraph of Article 7.5 of this Agreement, to protect such Data for up to five (5) years. The marking shall state:

“NHRC DATA SHALL BE PROTECTED BY THE HCHHS FOR A PERIOD OF [state a number up to five years] FROM [state the date of generation].”

7.7.3 Markings Required for HCHHS

7.7.3.1 Data that are Proprietary Information

HCHHS shall place a proprietary marking on each medium used for recording Data that HCHHS provides to NHRC under this Agreement that HCHHS asserts is Proprietary Information.

For Non-Subject Data that are Proprietary Information the Marking shall state:

“PROPRIETARY INFORMATION OF HCHHS – NHRC MAY USE ONLY FOR PURPOSE OF CRADA NUMBER NCRADA – NHRC – 25-12050”

For Subject Data that are Proprietary Information the Marking shall state:

“PROPRIETARY INFORMATION OF HCHHS – GOVERNMENT HAS CERTAIN RIGHTS UNDER CRADA NUMBER NCRADA – NHRC –25-12050.”

7.8 Subject Inventions

7.8.1 Reporting of Subject Inventions

Within sixty (60) days of Making an Invention resulting from the Cooperative Work, and prior to disclosure of the Invention to any third parties, unless a shorter time period is required by circumstances, the inventor(s) shall submit an Invention Disclosure to their employer. In the case of an Invention Made jointly by inventors from both Collaborators, the inventors of each Collaborator shall submit an Invention Disclosure to their respective employer. Each Collaborator shall provide the other Collaborator with a copy of each Invention Disclosure reporting a Subject Invention within sixty (60) days of receiving the Invention Disclosure from its inventor(s).

7.8.2 Determination of Subject Inventions

The Collaborators shall review each Invention Disclosure resulting from the Collaborative Work and shall confer and consult to determine whether an Invention Disclosure represents a Subject Invention.

7.8.3 Title to and Ownership of Subject Inventions

Each Collaborator shall be entitled to solely own the Subject Inventions Made solely by its employees. For any Jointly Made Subject Invention, each Collaborator shall have ownership of the Subject Invention in the form of an undivided interest, without a right of accounting.

Each Collaborator shall cooperate with the other Collaborator to obtain inventor signatures on Patent Applications, assignments or other documents required to secure Intellectual Property protection.

7.9 Non-Subject Inventions

7.9.1 Ownership of Non-Subject Inventions

Each Collaborator owns its Non-Subject Inventions.

7.9.2 Preexisting Non-Subject Inventions Pertinent to the Cooperative Work

Non-Subject Inventions Made prior to the Effective Date of this Agreement and pertinent to the Cooperative Work that are specifically identified as property of **NHRC** include but are not limited to the following:

None.

Non-Subject Inventions Made prior to the Effective Date of this Agreement and pertinent to the Cooperative Work that are specifically identified as property of **HCHHS** include but are not limited to the following:

None.

7.10 Filing of Patent Applications

By mutual agreement, the Collaborators shall identify which Collaborator shall file a Patent Application on any Subject Invention. The Collaborator responsible for filing of a Patent Application on any Subject Invention shall file such Patent Application at least sixty (60) days prior to any bar date and prior to publication, or one year from the date the Invention Disclosure was received, whichever comes first. In the case of a Jointly Made Subject Invention, if no Patent Application is filed within the specified time period by the responsible Collaborator, the other Collaborator may assume control of filing the Patent Application and take title to the Jointly Made Subject Invention on ten (10) days written notification. The Collaborator that relinquished the responsibility to file shall retain a nonexclusive, irrevocable, paid-up license to practice the Jointly Made Subject Invention or have the Jointly Made Subject Invention practiced throughout the world by or on its behalf.

7.10.1 Patent Filing

The Collaborator responsible for filing any Patent Application for a Subject Invention shall notify the other Collaborator of all filing deadlines for prosecution of any Patent Application and maintenance of any Patents on the Subject Invention. Notwithstanding the primary responsibility defined in Article 7.10, sixty (60) days prior to any filing deadline, the Collaborators shall confer to determine if the filing Collaborator intends to respond to the filing deadline. The non-filing Collaborator has the right to take action if the filing Collaborator declines.

7.10.2 Copies and Inspection

Each Collaborator filing a Patent Application on a Subject Invention shall provide the other Collaborator with a copy of any communication relating to prosecution of said Patent Application within thirty (30) days of receipt of such request. The filing Collaborator shall give the other Collaborator a limited power to inspect, with authorization to access the Patent Application, make copies, and, in the event that the filing Collaborator declines continued prosecution of the Patent Application, do all that is necessary to secure patent protection for the Jointly Made Subject Invention.

7.10.3 Rights of Inventors if the Collaborators Decline to File a Patent Application

In the event both Collaborators decline to file a Patent Application on a Subject Invention, the Government will renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

In the event both Collaborators decline to file a Patent Application on a Subject Invention, HCHHS may, at its sole discretion, renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

7.11 Licenses to Subject Inventions

7.11.1 Internal Use License to HCHHS

Government grants to the HCHHS a nonexclusive, irrevocable, paid-up Internal Use License to a Subject Invention Made solely by employees of NHRC. No Internal Use License granted under this Agreement shall permit licensee to grant sublicenses. No Internal Use License granted under this Agreement shall be assigned, licensed or otherwise disposed of except to the successor in interest of that part of HCHHS business to which such license pertains.

7.11.2 Government License

Pursuant to 15 U.S. Code § 3710a(b)(2), for Subject Inventions Made solely by an employee of HCHHS, HCHHS grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the Subject Invention or have the Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

7.11.3 Option for Commercial License to Subject Inventions

NHRC gives HCHHS the option of acquiring an Exclusive or Nonexclusive Commercial License for the field of wastewater sample testing for viral pathogens in the Government's rights in any Subject Invention Made in whole or in part by a NHRC employee. The license shall be for reasonable consideration. In order to exercise this option, HCHHS must notify NHRC in writing within six (6) months of the filing of a Patent Application. HCHHS must execute an Exclusive Commercial or Nonexclusive Commercial License to the Subject Invention within six (6) months of election to exercise the option, or the Invention shall be made available for licensing by the public in accordance with 37 C.F.R. Part 404.

7.11.4 Termination of Licenses Granted and Cancellation of License Option to Subject Inventions

NHRC may cancel the Exclusive or Nonexclusive Commercial License option and terminate any Exclusive or Nonexclusive Commercial Licenses and Internal Use Licenses provided for above made in whole or in part by Government employees in the event that:

- (a) HCHHS is in default for failure to make payment as agreed in Article 5; or
- (b) The Agreement is terminated unilaterally by HCHHS under Article 11.2; or
- (c) HCHHS fails to perform according to the Statement of Work (Appendix A); or

- (d) HCHHS becomes a foreign owned, controlled, or influenced (FOCI) organization that is reasonably determined by NHRC not to qualify under the requirements of Executive Order 12591, Section 4(a); or
- (e) HCHHS which was a FOCI organization when the Agreement was signed has now become a different FOCI organization that is reasonably determined by NHRC not to qualify under the requirements of Executive Order 12591, Section 4(a).

7.12 License to Non-Subject Inventions

Each Collaborator shall allow the other Collaborator to practice any of its Non-Subject Inventions for the purpose of performing the Cooperative Work. No license, express or implied, for commercial application(s) is granted to either Collaborator in Non-Subject Inventions by performing the Cooperative Work. For commercial applications of Non-Subject Inventions, the HCHHS must obtain a License from the NHRC, in accordance with applicable laws and regulations (including, but not limited to, 37 C.F.R. Part 404).

7.13 Copyrights

HCHHS may copyright works of authorship prepared pursuant to this Agreement if eligible for copyright protection under Title 17, U.S. Code § 106 HCHHS grants to the Government a nonexclusive, irrevocable, paid-up license in copyrighted works of authorship, including software, prepared pursuant to this Agreement for any purpose that is consistent with the rights in Data described in Article 7.2 and Article 7.3. HCHHS shall affix the applicable copyright notice of Title 17, U.S. Code §§ 401-403, and an acknowledgment of the scientific and technical contributions of NHRC. HCHHS grants to the U.S. Government a paid-up, non-exclusive, irrevocable, worldwide license to reproduce or have reproduced, prepare or have prepared in derivative form, and distribute or have distributed copies of publications and solely or jointly created Subject Data for Government purposes.

Article 8. TANGIBLE PROPERTY

8.1 Ownership of Tangible Property

Each Collaborator shall retain title to its Tangible Property. All Tangible Property owned and provided by one Collaborator shall remain the property of that Collaborator. Tangible Property having any component purchased or supplied by the Government shall be the property of the Government, unless such tangible Government components reasonably can be separated from non-Government components without damage to any of the individual components comprising the Tangible Property. These separated components shall remain the property of the Collaborator that purchased them. After termination of this Agreement the collaborators may, by mutual consent, separate the Tangible Property into its components and the separated components shall remain the property of the Collaborator that originally owned the property.

8.2 Tangible Property Operational and Disposition Costs

Each Collaborator shall be responsible for all costs of maintenance, removal, storage, repair, disposal and shipping of all Tangible Property to which it has title.

8.3 Disposal of Tangible Property

Unless otherwise agreed, each Collaborator shall take possession of its respective Tangible Property within sixty (60) days of termination of this Agreement. Each Collaborator shall cooperate with the other Collaborator in the recovery or disposition of the other Collaborator's property. Disposal of Tangible Property shall be in accordance with applicable U.S. Federal, State, and local property disposal laws, environmental laws, and regulations.

Article 9. LIABILITY

9.1 Extent of Government Liability

The Government shall be liable for the negligent or wrongful acts of its officers and employees solely to the extent provided for in the Federal Tort Claims Act (28 U.S. Code § 2671 et. seq.) and in other applicable laws and regulations of the U.S. that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the U.S.

9.2 Extent of HCHHS Liability

HCHHS shall be liable for the negligent or wrongful acts of its officers and employees solely to the extent provided for in the Texas Tort Claims Act (Tex. Civ. Prac. & Rem. Code Ann. §101) and the Federal Tort Claims Act (28 U.S. Code § 2671 et. seq.) and in other applicable laws and regulations of the U.S. that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the County. Further, HCHHS agrees that in any suit, action or claim brought by anyone not a Collaborator to this Agreement based on actions of [HCHHS, HCHHS shall not pursue any actions to enter the Government as a Collaborator in such suit, action or claim unless the Government has some liability under the Federal Tort Claims Act. This provision shall survive termination of this Agreement.

9.3 *Force Majeure*

No Collaborator shall be liable for the consequences of any *force majeure* that (1) is beyond its reasonable control; (2) is not caused by the fault or negligence of such Collaborator; (3) causes such Collaborator to be unable to perform its obligations under this Agreement; and (4) cannot be overcome by the exercise of due diligence. In the event of the occurrence of a *force majeure*, the Collaborator unable to perform shall promptly notify the other Collaborator. The Collaborators shall suspend performance only for such period of time as is necessary to overcome the result(s) of the *force majeure* and shall use their best efforts to resume performance as quickly as possible.

Article 10. GENERAL PROVISIONS

10.1 Entire Agreement

This Agreement constitutes the entire agreement between the Collaborators concerning the Cooperative Work and supersedes any prior understanding or written or oral agreement relative to the Cooperative Work.

10.2 Severability

The illegality or invalidity of any Article of this Agreement shall not impair, affect, or invalidate any other Article of this Agreement.

10.3 Interpretation of Headings

Headings of the Articles of this Agreement are for convenience of reference only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

10.4 Governing Laws

U.S. Federal laws shall govern this Agreement for all purposes.

10.5 Independent Parties/Entities

The relationship of the Collaborators to this Agreement is that of independent parties and not as agents of each other, partners, or participants in a joint venture.

10.6 Subcontracting

Neither Collaborator may allow third parties to perform any part of the Cooperative Work under this Agreement without express written consent of the other Collaborator. If consent is obtained, the Collaborator requesting such consent shall remain fully responsible for the portion of the Cooperative Work to be accomplished under a third-party agreement, and the third-party is not a Collaborator of this Agreement. Any third-party agreement to perform a portion of the Cooperative Work shall contain terms consistent with this Agreement.

10.7 Assignment

This Agreement shall not be assigned or otherwise transferred by either Collaborator without the prior written consent of the other Collaborator, except to the successor of that part of HCHHS's business to which this Agreement pertains.

10.8 Disputes

NHRC and HCHHS agree to use reasonable efforts to reach a fair settlement of any dispute. If such efforts are unsuccessful, remaining issues in dispute will be referred to the signatories or their successors for resolution. If a dispute continues, the remaining issues may be submitted to the Chief of Naval Research (CNR), or the CNR designee, for resolution. This Agreement does not prevent any Collaborator from pursuing disputes in a U.S. Federal court of competent jurisdiction. No Collaborator will pursue litigation in a U.S. Federal court until after the CNR, or the CNR designee, decides the dispute, or until sixty (60) days after the dispute was first submitted to the CNR, or the CNR designee, whichever comes first.

10.9 Use of Name or Endorsements

HCHHS shall not use the name of NHRC or any other Government entity on any product or service that is directly or indirectly related to either this Agreement or any patent license or assignment associated with this Agreement without the prior approval of NHRC. By entering into this Agreement, NHRC does not directly or indirectly endorse any product or service provided, or to be provided, by HCHHS, its successors, assignees, or licensees. HCHHS shall not in any way imply that the Department of the Navy endorses any such product or service.

10.10 Public Release Announcements of This Agreement

Information regarding this Agreement, excluding funding information (Article 5), the Statement of Work, and associated Appendices, may be released to the public.

10.11 Environment, Safety, and Health

Each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste in its custody during the course of this Agreement. At the conclusion of this Agreement, each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste still in its possession. Each Collaborator shall obtain at its own expense all necessary permits and licenses as required by U.S. Federal, State, and local law and shall conduct such handling, control, and disposition in a lawful and environmentally responsible manner. Each Collaborator is responsible for all required environmental, safety, and health compliance, notice, and monitoring related to its facility in accordance with U.S. Federal, State, and local law and regulations. Collaborators shall abide by the environmental, safety, and health directives of the host facility in which the Cooperative Work is being performed, and any U.S. Federal, State, or local laws and regulations pertaining to environment, safety, and health that are applicable to the host facility.

10.12 U.S. Competitiveness

HCHHS agrees that any product, process, or service using Intellectual Property arising from the performance of this Agreement shall be manufactured substantially in the U.S.

10.13 Waivers

None of the provisions of this Agreement shall be considered waived by either Collaborator unless such waiver is given in writing to the other Collaborator, signed by the executing official of this Agreement or the official's successor having the authority to bind the Collaborator making the waiver. The failure of either Collaborator to insist upon strict performance of any of the terms and conditions herein, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any right of either Collaborator under this Agreement.

Article 11. MODIFICATIONS AND NOTICES

11.1 Amendments

Any modifications to this Agreement shall be jointly agreed upon and shall not be effective until a written amendment is signed by both executing officials of this Agreement or their successors.

11.2 Unilateral Termination

HCHHS and NHRC each have the right to unilaterally terminate this Agreement upon thirty (30) days written notice to the other Collaborator.

11.3 Notices

All notices pertaining to or required by Articles of this Agreement, except those pertaining solely to the prosecution of any patent, trademark, or service mark, shall be in writing and shall be signed by an authorized representative of the Technology Transfer Office for NHRC or the preferred contact for HCHHS. All such notices shall be delivered in a manner that ensures confirmation of receipt.

If to NHRC:

ORTA
503 Robert Grant Ave
Silver Spring, MD 20910
usn.detrick.navmedrshcensvsmd.mbx.technology-transfer@health.mil

If to HCHHS:

Hidalgo County Health and Human Services
1304 S. 25th Ave
Edinburg, TX 78542
hidalgocountyhhs@hchd.org

A Collaborator shall notify the other Collaborator of a change of address in the manner set forth above.

Notices pertaining solely to the prosecution of any patent, trademark, or service mark related to this Agreement shall be in writing and shall be signed by and sent to the Collaborator's legal counsel for Intellectual Property. Legal counsel for Intellectual Property for each Collaborator shall send a copy of any such notice to the Technology Transfer Office for NHRC. If either Collaborator fails to identify such counsel upon request, then such notices shall be sent to the points of contact specified above.

Article 12. SURVIVING PROVISIONS

The Articles covering Definitions, Representations and Warranties, Funding, Reports and Publications, Intellectual Property, Tangible Property, Liability, General Provisions, Modifications and Notices, and Surviving Provisions shall survive the completion, termination, or expiration of this Agreement.

Article 13. DURATION

This Agreement expires four (4) years after its Effective Date, unless otherwise extended in writing according to the provisions of Article 11.

Signatures for the Agreement follow on next page

Article 14. SIGNATURES

For HCHHS:

I, the undersigned, am duly authorized to bind HCHHS to this Agreement and do so by affixing my signature hereto.

Entered into this 8th day of July, 2025. (AI-99931)

By: Dairen S Rangel

Name : Dairen Sarmiento Rangel
Title: Health & Human Services Director

For the Department of the Navy:

I, the undersigned, by 15 U.S. Code § 3710a and Navy regulations, am duly authorized to bind the U.S. Navy to this Agreement and do so by affixing my signature hereto.

Entered into this 21st day of July 2025.

By: MCMULLEN.KELLIE.LU GENBEEL.1269656626
Digitally signed by
MCMULLEN.KELLIE.LUGENBEEL.
1269656626
Date: 2025.07.21 04:55:35 -07'00'

Name: Kellie L. McMullen
Title: Commanding Officer
Navy Organization: Naval Health Research Center

APPENDIX A - STATEMENT OF WORK

BETWEEN

NHRC

AND

HCHHS

The Collaborators agree to perform the following tasks:

NHRC will be responsible for the following tasks (list as applicable):

1. Test wastewater, enteric, respiratory, and vector-borne samples for viral and bacterial pathogens, as well as antimicrobial resistance (AMR).
2. After testing, NHRC will provide the laboratory results to the partner via email. NHRC will cover the shipping costs associated with the samples through a prepaid label (no reimbursements will be made) and the testing and supplies cost.
3. Destroy the remaining samples.

HCHHS will be responsible for the following tasks (list as applicable):

1. Provide wastewater samples to undergo PCR testing. Wastewater samples are anticipated to be collected and shipped to NHRC weekly, but this may vary based on partner staffing and the staffing of their local wastewater processing facility. This workflow will continue for 52 weeks to establish a baseline for data analysis. Beyond this initial 52 week period, NHRC and the partner will discuss progress and make changes to the workflow as needed.
2. Collect enteric, respiratory, and vector-borne samples via stool sample, nasal swab, and blood draw, respectively, de-identify all samples in accordance with 45 CFR § 164.514, and provide these de-identified samples to NHRC for testing. Ideally, these samples will be collected and shipped bi-weekly, but this will depend on partner staffing and sample volume.

NHRC and HCHHS will be responsible for the following joint tasks:

1. Collaborate to analyze the aggregate sample data associated with each study.
2. Collaborate on publishing a manuscript to discuss findings.