National Institute of Standards and Technology
U.S. Department of Commerce

DIETARY SUPPLEMENT LABORATORY QUALITY ASSURANCE PROGRAM (DSQAP) CONSORTIUM
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

Article 1. Introduction

This Cooperative Research and Development Agreement ("**Agreement**" or "**CRADA**") is entered into by and between ("**Collaborator**")

and the National Institute of Standards and Technology ("**NIST**") (Collaborator and NIST referred to individually or collectively herein as "**Party**" or "**Parties**," as appropriate). This Agreement is effective on the date of the last authorized signature hereto ("**Effective Date**").

Article 2. Purpose and Authority

2.1 The purpose of the NIST Dietary Supplement Laboratory Quality Assurance Program ("**DSQAP**") Consortium ("**Consortium**") is to develop and evaluate measurement methods and standards, including reference materials, to support quality and safety for the dietary supplement testing community ("**Purpose**"). The Consortium's efforts are intended to advance dietary supplement measurement capabilities, provide measurement assurance strategies, support the development of dietary supplement reference materials, and collect data to support the development of best practices and standard methods. NIST does not endorse any of Collaborator's products or services that are used in the course of the Consortium. Notice of the Consortium was published in the Federal Register as 89 FR 105535 on December 27, 2024.

2.2 NIST enters into this Agreement pursuant to its authority granted under 15 U.S.C. 272(b) and (c), 272a, 273, and 3710a. Collaborator enters into this Agreement with the understanding that each participant in this Consortium (each individually, "**Consortium Member**," and two or more, "**Consortium Members**") that is legally permitted to enter into a CRADA will be bound by the terms and conditions enumerated herein. If Collaborator is an agency or department of the Federal Government (such Consortium Members referred to individually and collectively herein as the "**Federal Government**"), to the extent that the terms of the attached Appendix B conflict with the terms of this Agreement, the terms of Appendix B shall control and by this reference are made a part hereof and incorporated herein. Entities that are legally prohibited or not legally authorized to enter into a CRADA may, at NIST's discretion, be permitted to participate in the Consortium under an agreement other than a CRADA with terms that will differ, as necessary, from the terms of this Agreement. Foreign governmental entities may, at NIST's discretion, be permitted to participate in the Consortium under an appropriate international agreement.

Article 3. Membership and Collaborative Research

3.1 **Membership**. Collaborator shall be a Consortium Member as of the Effective Date. Collaborator acknowledges that NIST may publicly display Collaborator's name as a Consortium Member, including on NIST's website.

3.2 **Research Plan**. The research and development activities of the Consortium are detailed in the research plan at Part III of the attached Appendix A ("**Research Plan**"), which by this reference is made a part hereof and incorporated herein. The Research Plan shall be performed on a reasonable efforts basis.

3.3 **Contributions and Personnel**. NIST shall provide administrative and scientific supervision for the Consortium and the Research Plan, and the NIST individual responsible for managing the Consortium and the Research Plan ("**NIST Consortium Manager**") is identified at Appendix A. NIST's and Collaborator's respective contributions of material and equipment and/or any other property to the Consortium and the Research Plan (respectively, "**NIST Contributions**" and "**Collaborator Contributions**") are listed in Appendix A, as well as the respective personnel

of each Party who will contribute to the Research Plan (for each Party, its "**Project Team**"). NIST cannot contribute funds to Collaborator under this Agreement; however, Collaborator may contribute funds under this Agreement. Additional terms relating to the use of NIST Contributions and Collaborator Contributions are detailed at Article 3.4(i) and Article 5, below.

3.4 **NIST Contractors**.

i. Collaborator acknowledges and agrees that some or all of the research activities described in the Research Plan may be performed by the employees, subcontractors, or consultants of non-federal organizations funded by NIST to perform such activities ("NIST Contractors"). NIST Contractors are not employees of NIST. Collaborator hereby permits NIST to share with NIST Contractors any material Collaborator Contributions and information that Collaborator provides to NIST pursuant to this Agreement. In accordance with Article 4.1, below, no Proprietary Information is expected to be exchanged by the Parties under this Agreement. Collaborator agrees that NIST shall not be responsible to Collaborator for any loss, claim, damage, or liability resulting from NIST Contractors' use of any Collaborator Contributions or information of Collaborator.

ii. Any NIST Contractors are identified in Appendix A. NIST Contractors' individual personnel may vary throughout the performance of the Research Plan. The NIST Consortium Manager may periodically request an updated list of NIST Contractors' personnel throughout the performance of the Research Plan, and such information shall be available to Collaborator at Collaborator's request. NIST is not responsible for the conduct of any NIST Contractors.

3.5 **Steering Committee**. For the purpose of discussing and planning the Research Plan and to guide and track the Consortium's technical progress, a steering committee made up of at least one representative of NIST and at least one representative of each Consortium Member ("**Steering Committee**") shall be formed. It is anticipated that each member of the Steering Committee will serve a term of one year, and members may be reappointed. The Steering Committee will meet and confer with the NIST Consortium Manager in order to aid in the planning and coordination of the performance of the Research Plan, and the NIST Consortium Manager shall have final authority in all decisions.

3.6 **Conduct.** Collaborator agrees that each member of its Project Team will abide by all applicable regulations, policies, and procedures relating to safety, security, and conduct and adhere to all applicable building and restricted area access controls while on NIST premises.

Article 4. Proprietary Information and Publication of Results

4.1 **Proprietary Information**. The Parties agree that no Proprietary Information will be exchanged between the Parties under this Agreement. "**Proprietary Information**" means scientific, business, or financial information, which may embody trade secrets, when such information is developed exclusively at private expense, except if such information:

i. was in the possession of NIST and/or the Federal Government before receipt from Collaborator; or
ii. is or becomes a matter of public knowledge through no fault of NIST and/or the Federal Government; or
iii. is received by NIST and/or the Federal Government from a third party without a duty of confidentiality; or
iv. is disclosed by Collaborator to a third party without a duty of confidentiality on the third party; or
v. is independently disclosed by NIST and/or the Federal Government with Collaborator's prior written approval; or
vi. is independently developed by NIST and/or the Federal Government without reference to information disclosed hereunder.

4.2 **Whistleblower Protection Act.** These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General or the Office of Special Counsel of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this Agreement and are controlling.

4.3 **Research Results**. The Parties agree that all recorded data first produced by Collaborator and/or NIST in the performance of the Research Plan and during the term of this Agreement ("**Research Results**") shall be exchanged between Collaborator and NIST. NIST and Collaborator shall each have the right to use and disclose the Research Results in accordance with the terms of this Agreement and agree only to those delays in the public disclosure of the Research Results that are provided for herein. NIST intends to assign a unique code to Collaborator to associate with the Research Results in lieu of Collaborator's identity.

4.4 **Publication of Research Results and Collective Results.** The Parties intend to publish the Research Results collectively with the research results of all Consortium Members ("**Collective Results**"). In any such publication of Collective Results, Collaborator will be tied to the Research Results by its unique code. Likewise, the other Consortium Members will be tied to their own research results by their own unique codes assigned by NIST, thus anonymizing the Collective Results. Until the date of the first public disclosure of the Collective Results, Collaborator agrees not to disclose the Research Results, the Collective Results, or any other data or report provided to Collaborator under the terms of this Agreement to any third party who is not also a Consortium Member. NIST will provide Collaborator with at least thirty (30) days to review the proposed publication of the Collective Results to ensure that no Proprietary Information is contained therein. Collaborator may publish Collaborator's own Research Results after the first publication of the Collective Results, provided that Collaborator's publication references the Consortium.

4.5 **Protected CRADA Information.** Information and data generated by NIST in the performance of the Research Plan, including Research Results generated by NIST, that is also specifically related to one or more of Collaborator Contributions, e.g., is generated through the use of one or more of Collaborator Contributions, and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-federal Party participating in the Consortium under a CRADA ("**Protected CRADA Information**"),shall not be disclosed by NIST to any third party without the written permission of Collaborator for a period of five (5) years from the date of generation of the Protected CRADA Information. NIST will treat the Protected CRADA Information as exempt from disclosure for the designated period under the provisions of s5 U.S.C. 551, *et seq*.

Article 5. Material and Equipment

5.1 **Ownership & Use of Collaborator Contributions.**

i. **Collaborator Contributions**. Collaborator Contributions, as detailed in Appendix A, may include, inter alia, material and equipment contributed by Collaborator to the Consortium for use in the Research Plan. Collaborator grants to NIST and the Federal Government, and to other Consortium Members as NIST determines necessary, the right to use Collaborator Contributions for the purpose of the Consortium in the performance of the Research Plan. The U.S. Government shall not be responsible for damage to Collaborator Contributions or other property acquired by NIST for the purpose of the Consortium in the performance of the Research Plan. Any equipment or material purchased by NIST with funds paid by Collaborator under this Agreement shall be the property of NIST.

i. **Equipment**. Collaborator Contributions in the form of equipment are and will at all times remain the property of Collaborator, unless the Parties agree in writing on an alternative disposition of the same. At the earlier of the conclusion of the Consortium, the expiration or termination of this Agreement, or the relevant amendment or updating of Appendix A, NIST and/or the Federal Government will return to Collaborator or request Collaborator's retrieval of all equipment at Collaborator's sole risk and expense.

ii. **Material**. Collaborator Contributions in the form of material are provided under this Agreement with no expectation of being restored to Collaborator. NIST agrees to retain control over such material, and NIST shall use, store, and dispose of the same in accordance with all applicable laws and regulations. Notwithstanding the foregoing and as detailed in the Research Plan, NIST may transfer Collaborator's material to third parties for non-profit research purposes, including the development of NIST standards and reference materials, NIST may use such material in the development of NIST standards and reference materials, and NIST may distribute such standards and reference materials that incorporate Collaborator's material. Should Collaborator wish to provide material for use in the Research Plan but prevent it from being used and distributed by NIST in the development of standards and reference materials, Collaborator must specifically identify that material to which Collaborator wishes this exception to apply in the list of Collaborator Contributions in Appendix A. NIST shall be under no obligation to accept any such excepted material from Collaborator. Should NIST accept such excepted material,

Collaborator should provide it separate from any other of Collaborator Contributions and label it accordingly. At the earlier of the conclusion of the Consortium, the expiration or termination of this Agreement, or the relevant amendment or updating of Appendix A, NIST and/or the Federal Government will return to Collaborator or destroy any excepted material of Collaborator not already expended in the performance of the Research Plan.

5.2 **Ownership & Use of NIST Contributions - Material.** At its discretion, NIST Contributions may include providing to Collaborator certain material, including blinded samples of NIST Standard Reference Materials® ("**SRMs**"), in accordance with the Research Plan. NIST will identify any such material NIST Contributions in writing at the time they are provided to Collaborator. Collaborator shall use such material only in the performance of the Research Plan and not for any commercial purposes, such as screening, production, or sale, for which a commercialization license may be required. Collaborator agrees to retain control over such material and not to transfer it to others, including other Consortium Members. Collaborator shall not use the material NIST Contributions in human or animal subjects or for any clinical purposes, and Collaborator agrees to comply with all federal rules and regulations applicable to the Research Plan and the handling of such material. NIST reserves the right to distribute any material NIST Contributions to third parties and to use them for its own purposes. At the earlier of the conclusion of the Consortium or the expiration or termination of this Agreement, Collaborator shall return, destroy, or otherwise dispose of NIST's material as mutually agreed by the Parties.

5.3 **Contributions of Consortium Members.** Collaborator and NIST agree not to sell, distribute, sublicense, modify, disassemble, reverse engineer, or otherwise alter the equipment and/or material contributed to the Consortium by one another and/or other Consortium Members, except as explicitly provided for herein.

Article 6. Intellectual Property

6.1 **Copyright in Research Results**. Any compilations or publications of Research Results or Collective Results that are prepared by federal employees are not subject to copyright in the United States, in accordance with 17 U.S.C. 105. Should Collaborator independently prepare any compilation of Research Results or other written work relating to the Consortium and/or the Research Plan, Collaborator hereby grants to the U.S. Government a paid-up, non-exclusive, irrevocable, world-wide license to reproduce or have reproduced, prepare or have prepared in derivative form, and distribute or have distributed copies of such compilation or written work for Government purposes.

6.2 **CRADA Inventions**. The Parties do not intend to conceive of any inventions in the performance of the Research Plan. The Parties agree that any invention conceived by the Parties and/or the Federal Government in the performance of the Research Plan ("**CRADA Invention**") shall be dedicated to the public domain to be freely used by all. Collaborator hereby acknowledges that NIST and/or the Federal Government, pursuant to any applicable requirements of 15 U.S.C. 3710a(b), has offered Collaborator the option to obtain a license to NIST's and/or the Federal Government's ownership in any CRADA Invention conceived by employees of NIST and/or the Federal Government, and that Collaborator affirmatively declines the option to license or acquire any interest in any such CRADA Invention. Although neither Party shall seek patent protection for any CRADA Invention, Collaborator grants to NIST and the Federal Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced any CRADA Invention that is conceived solely by Collaborator throughout the world by or on behalf of the U.S. Government.

6.3 **Intellectual Property Protection.** The Parties agree to neither seek intellectual property protection for nor attempt to enforce any intellectual property rights, including copyright, in either any CRADA Invention or any work authored in the performance of the Research Plan, including any publication of the Research Results or Collective Results, or in any other intellectual property resulting from the performance of the Research Plan. Both Parties agree not to seek patent protection for any CRADA Invention, any of which shall instead be dedicated to the public domain to be freely used by all.

6.4 **Inventions of NIST Contractors.** NIST Contractors have the right under 35 U.S.C. 200 *et seq.* to elect to retain title to their interest in any invention created by NIST Contractors' employees in accordance with 35 U.S.C. 202(c). Ownership rights stemming from any of NIST Contractors' elections are not subject to the provisions of this Agreement.

6.5 **No Other Rights.** Except as explicitly provided herein, no rights in the intellectual property of either Party that preexists this Agreement or is created outside and independent of this Agreement are transferred or conveyed hereunder.

Article 7. Expiration, Termination and Amendments

7.1 **Expiration.** This Agreement is effective as of the Effective Date and shall expire on the date listed in Appendix A.

7.2 **Termination.** Collaborator and NIST shall each have the right to terminate this Agreement, without or without cause. Termination by one Party will be effective upon thirty (30) days' written notice to the other Party. NIST may terminate this Agreement immediately in the event of either: (i) direct or indirect control of Collaborator is transferred to a foreign company or government; or (ii) if Collaborator is already controlled by a foreign company or government, that control is transferred to another foreign company or government.

7.3 **Amendments.** Should a need arise for NIST to modify the terms and conditions of this Agreement, the details of the Research Plan, or any other NIST information contained in Appendix A, NIST may propose to each Consortium Member that has signed a CRADA identical modifications in the form of a CRADA amendment. NIST will require all Consortium Members that have signed a CRADA to accept the same modified terms and conditions. NIST may terminate this Agreement immediately if such an amendment is not signed by Collaborator within the time prescribed by NIST. Except for changes to Collaborator's Project Team, should Collaborator need to modify any of the Collaborator Information at Part II of Appendix A, including a need to modify Collaborator's named Principal Investigator, Collaborator should notify the NIST Consortium Manager of the need for such modification, and NIST will prepare an amendment to effectuate the modification. No amendment to this Agreement will be effective until fully signed by both Parties.

7.4 **Project Team Modifications.** If either Party wishes to remove and/or add personnel from/to its Project Team, such Party may request such an update using the instructions and form set forth at Appendix C, which is attached hereto. The process set forth at Appendix C is solely for changes to a Party's Project Team and does **not** include changes to either Party's Principal Investigator, the latter of which must accomplished via the amendment process set forth above. Updates to a Party's Project Team are **not** amendments to this Agreement, and as such, the individual signing a proposed Project Team update on behalf of either Party need not be an individual who is authorized to legally bind the relevant Party. The proposed changes to the Project Team may only be implemented **after** the Party requesting the change has received a countersigned acknowledgement of the proposed change from the other Party in the form set forth at Appendix C.

Article 8. Miscellaneous

8.1 **Entire Agreement**. This Agreement constitutes the entire agreement of the Parties with respect to the matters set forth herein and supersedes and replaces in the entirety any prior understanding, written or oral, between the Parties concerning such matters.

8.2 **Counterparts.** This Agreement may be signed in one or more counterparts, each of which shall be deemed to be an original and all of which when taken together shall constitute the same Agreement. Any signed copy of this Agreement made by photocopy, facsimile, or PDF Adobe format shall be considered an original.

8.3 **NO WARRANTY. ANY MATERIAL, EQUIPMENT, SOFTWARE, SERVICE, AND/OR OTHER PROPERTY PROVIDED BY EITHER PARTY UNDER THIS AGREEMENT IS PROVIDED "AS IS" WITHOUT ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, OR AS TO THE CONDITION OR OWNERSHIP OF ANY RESEARCH OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER THIS AGREEMENT**.

8.4 **Advertising and Use of Name.** Each Party agrees not to use the name of the other Party on any commercial advertisement or promotional material for any product or service that is directly or indirectly related to this Agreement or to the Consortium without prior written approval by the other Party, except that NIST may use, disclose, and publicly display Collaborator's name to identify the Consortium Members to third parties. For the avoidance of doubt, Collaborator shall be free to display or reference any Research Results made publicly available by NIST as long as such display or reference by Collaborator does not imply endorsement by NIST, the Department of Commerce, the U.S. Government, or any subunit of the foregoing entities.

8.5 **Public Statements by Collaborator.** Collaborator may use the following text on its websites, publications, and promotional material without further approval by NIST.

"[Collaborator] is collaborating with the National Institute of Standards and Technology (NIST) in the Dietary Supplement Laboratory Quality Assurance Program (DSQAP) Consortium to develop and evaluate methods and reference materials in support of quality and safety in the dietary supplement testing community. NIST does not evaluate commercial products under this Consortium and does not endorse any product or service used. Additional information on this Consortium can be found via Federal Register Notice 89 FR 105535."

8.6 **Export Control**. NIST and the Federal Government comply with, and Collaborator agrees to comply with, all applicable export laws and regulations, including but not limited to the International Traffic in Arms Regulations (22 C.F.R. Part 121 *et seq.*) and the Export Administration Regulations (15 C.F.R. Part 730 *et seq.*), for all equipment, materials, and information shared under this Agreement. Without limitation, Collaborator agrees that it will not in any form export, re-export, resell, ship, or divert, or cause to be exported, re-exported, resold, shipped, or diverted, directly or indirectly, and product or technical data or software furnished under this Agreement or the direct product of such technical data or software to any foreign national, firm, or country, including foreign nationals employed by Collaborator, for which the U.S. Government or any agency thereof at the time of the conduct requires an export license or other governmental approval without first obtaining such license or approval.

8.7 **Assignment**. Except as explicitly provided for herein, neither this Agreement nor any rights or obligations of either Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

8.8 **Liability & Indemnification.**

i. The U.S. Government shall not be responsible for any damage to any equipment, material, or other property, tangible or otherwise, contributed by Collaborator under this Agreement.

ii. Collaborator shall indemnify and hold harmless the U.S. Government for any loss, claim, damage, or liability of any kind caused to or by Collaborator's Project Team arising in connection with this Agreement, except to the extent that such loss, claim, damage, or liability arises from the gross negligence or wrongful acts of NIST and/or the Federal Government and/or their employees. NIST and the Federal Government's responsibility for payment of tort claims in connection with the performance of the Research Plan is governed by, *inter alia*, the Federal Tort Claims Act, the Federal Employees Compensation Act, and the Antideficiency Act.

iii. Collaborator shall indemnify and hold harmless the U.S. Government for any loss, claim, damage, or liability of any kind arising out of the use by Collaborator, or others acting on its behalf or under its authorization, of the research results of NIST and/or the Consortium Members, the Collective Results, or any other research and/or technical development or product arising from the Research Plan and/or received by Collaborator under this Agreement or out of any use, sale, or other disposition of the same by Collaborator or others acting on its behalf or with its authorization.

iv. IN NO EVENT WILL EITHER PARTY BE HELD LIABLE FOR ANY LOST REVENUES, LOST PROFITS, OR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES OF ANY KIND ARISING OUT OF THIS AGREEMENT, PARTICIPATION IN THE CONSORTIUM, OR THE PERFORMANCE OF THE RESEARCH PLAN. Collaborator enters into this Agreement with the understanding that each Consortium Member has agreed or will agree to the preceding statement.

8.9 **Governing Law.** The construction validity, performance, and effect of this Agreement for all purposes shall be governed by and construed in accordance with the laws of the United States. Any legal action concerning this Agreement shall be brought in the federal district courts of the United States.

[Signatures Follow on Next Page]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

Signatory for Collaborator:

_____ _____

Date

Contact Information for Notices:

Signatory for NIST:

_____ _____

Jeffrey DiVietro, PhD Date
Deputy Director, NIST Technology Partnerships Office

Contact Information for Notices:

NIST Technology Partnerships Office
Consortia Agreements Officer
100 Bureau Drive, Gaithersburg, MD 20899-2200
Agreements@nist.gov

Appendix A
RESEARCH PLAN AND RELATED INFORMATION

PART I. Project & NIST Information

1. **Consortium Title:** Dietary Supplement Laboratory Quality Assurance Program (DSQAP) Consortium. (*Parties may use this title for public disclosure and management reporting.*)

2. **NIST's Principal Investigator (PI) and Consortium Manager**: (*NIST PI may change at NIST management's sole discretion.*)

   Dr. Melissa Phillips
   NIST Chemical Sciences Division
   100 Bureau Drive, Gaithersburg, Maryland 20899
   Telephone: (301) 975-4134
   Email: melissa.phillips@nist.gov

3. **Duration of Agreement:** From the Effective Date through September 30, 2029.

4. **NIST Project Team and Services, Facilities, Intellectual Property, Material, and/or Equipment Contributions**:

   NIST Project Team (NIST Federal Employees):
   - Melissa Phillips
   - Hugh Hayes
   - Jenna Klingsick
   - Kate Rimmer
   - John Molloy

   NIST Contributions: NIST will contribute measurement expertise, experimental design expertise, statistical analysis expertise, personnel, facilities, and instrumentation.

5. **Other Participants**:

   NIST Contractors:
   - University of Maryland

Part II. Collaborator Information

PLEASE CHECK ALL THE APPROPRIATE BOX(ES) BELOW.

1. **Collaborator Eligibility.** Collaborator certifies the following to NIST, and the Collaborator agrees to notify NIST within thirty (30) days of any change in the following:

   ☐ Collaborator certifies that it is incorporated or organized under the laws of one of the states or territories of the United States.

   ☐ Collaborator certifies that it is **not** subject to the control of any foreign government or foreign company.

   ☐ Collaborator certifies that it is partially or wholly owned by the following foreign government: ___

   ☐ Collaborator certifies that it is not owned by any foreign government, but it is organized under the laws of the following foreign country: .

☐ Collaborator certifies that it **is** subject to the control of the following foreign parent company in the following foreign country:

☐ Collaborator certifies that it has a manufacturing presence in the United States.

2. **Participation in other Federally Funded Projects.** Collaborator certifies that:

   ☐ Collaborator's participation in this Consortium is **not** related to any research supported by other Federal or NIST Funds.

   ☐ Collaborator's participation in this Consortium **is** related to research supported by Federal (including NIST) funding, which is identified as follows:

   (*attach additional pages as necessary*)

3. **Collaborator's DUNs/UEI/TIN**:

4. **Collaborator's Principal Investigator(s)**:

5. **Collaborator Project Team and Services, Facilities, Intellectual Property, Material, and/or Equipment Contributions**:

   Collaborator Project Team (include each individual's name):

   All of the above-named individuals are full-time employees of Collaborator. ☐ Yes ☐ No
   If no, identify non-employees and their affiliations:

   If no, NIST TPO & NIST OCC consult.

   Collaborator Contributions:

Part III. Research Plan

Background Information:

The DSQAP will focus on improving the measurement methodologies and capabilities of the dietary supplement and natural product testing communities. Dietary supplement and natural product stakeholders are interested in evaluating in-house methods on various challenging, real-world matrices to demonstrate that their performance is comparable to that of the broader community and that their methods provide accurate results. Few consensus or official methods have been fully recognized or evaluated in this area, and the DSQAP will be a unique tool for assessing the quality of measurements and providing educational feedback about performance that can assist participants in improving laboratory operations, such as proposing method adjustments to improve accuracy or precision. Additionally, industry stakeholders can observe community-wide measurement challenges that can be addressed through further collaborative efforts, and NIST will benefit from industry participation and knowledge to guide the production and maintenance of reference materials.

Research Plan:

The objective of the DSQAP is to develop and evaluate measurement methods and standards to support quality and safety for the dietary supplement testing community. Approximately 75% of the U.S. population takes dietary supplements, including vitamins and mineral supplements, representing an annual expenditure of more than $20 billion. Regulations, driven by reported cases of inaccurate labeling, adulteration, contamination (with pesticides, heavy metals, or toxic botanicals), and drug interactions, are now in place that require manufacturers to evaluate the identity, purity, and composition of their ingredients and finished products. The plethora of unique products on the market has led to an uptick in published methods but limited outlets for external method evaluation and validation.

The focus of this Consortium is to evaluate and standardize methods to characterize and quantify nutrients, marker compounds, and/or contaminants in dietary supplement ingredients and finished products, improving overall comparability within the community and enabling Consortium Members to improve the accuracy and precision of their own, internal measurements. The DSQAP Consortium will organize at least two interlaboratory exercises annually based on candidate reference materials and/or commercial products with the following goals:

- Evaluate the suitability of current published methods, including standard methods, to measure nutrients, marker compounds, and/or contaminants in dietary supplement ingredients and finished products.
- Utilize common materials to collect reproducibility data in support of measurement assurance and standards development.
- Propose tests(s) that can be standardized through the AOAC or similar consensus process, using outcomes from Consortium efforts as a foundation.
- Evaluate the applicability of current reference materials for dietary supplement ingredient and finished product testing. If needed, develop new reference materials to support advancement of the dietary supplement testing industry.

Consortium Members will contribute expertise related to product development and testing, regulatory perspectives related to testing challenges and needs, and related goals for human health research.

In part, NIST promotes the generation and use of accurate and comparable measurement methods by certifying and providing over 1100 NIST Standard Reference Materials® ("**SRMs**") with well-characterized compositions or properties or both. SRMs are used to perform instrument calibrations in units as part of overall quality assurance programs, to verify the accuracy of specific measurements, and to support the development of new measurement methods.

In support of the Consortium's goals, NIST may, at its discretion, share with certain Consortium Members blinded samples of NIST SRMs, at no cost to the member. With such SRMs, the Consortium Members may undertake analyses using their own facilities and equipment. The results of such analyses will in turn be shared with NIST, and the aggregation of analyses will form part of the Collective Results.

In addition or in the alternative, certain Consortium Members may share with NIST, at their discretion, their own materials for purposes of the Research Plan, including for composition or property characterization. In furtherance of its standards development pursuits and the goals of this Consortium, NIST may transfer such material of Consortium Members to third parties for non-profit research purposes, NIST may use such material of Consortium Members in the development of NIST

standards, NIST SRMs, NIST reference materials, and NIST research grade test materials, and NIST may distribute to third parties the standards, SRMs, reference materials, and research grade test materials that incorporate the material of Consortium Members.

This Consortium directly advances NIST's mission to support U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. The Consortium enables NIST to work directly with industry on emerging dietary supplement products being developed to ensure standards maintain pace with the ever-changing marketplace.

Consortium Members will benefit from standardized methods and fit-for-purpose reference materials that help ensure trade of only safe and effective products in the marketplace.

Appendix B
FEDERAL AGENCY & DEPARTMENT COLLABORATOR ADDENDUM

If Collaborator is an agency or department of the Federal Government, Collaborator is entering into this Consortium through this Agreement with NIST and one or more non-federal entities. Collaborator enters into this Agreement subject to the following additional terms:

1. The NIST Consortium Manager is responsible for the scientific and technical conduct of the Research Plan on behalf of NIST. Collaborator's designated Principal Investigator(s) is responsible for the scientific and technical conduct of the Research Plan on behalf of Collaborator.

2. Neither NIST nor Collaborator may contribute funds to Consortium Members that are not part of the U.S. Government under this Agreement. If applicable, Collaborator may either provide funds or in-kind contributions to NIST, and Collaborator will be invoiced according to the schedule in Appendix A. Where applicable, at NIST's discretion, an in-kind contribution of equivalent value may be substituted for all or part of the membership fee. An in-kind contribution is a non-monetary contribution that may take the form of personal property (e.g., equipment and supplies), capital equipment, real property, work to be performed at either Party's facilities, and/or services that are directly beneficial, specifically identifiable, and necessary for the successful performance of the Research Plan.

3. Collaborator may terminate this Agreement immediately upon written notice to NIST.

4. The obligations to indemnify and hold harmless NIST identified at Article 8.8 do not apply to Collaborator.

5. **Collaborator need not provide responses at sections 1, 2, and 3 of Part II of Appendix A.**

Appendix C
UPDATES TO NIST OR COLLABORATOR PROJECT TEAM

*To request a change to its Project Team, either Party may complete the template on the following page using the step-by-step instructions below. This template **may not** be used to update any portion of Appendix A or Appendix B or the terms and conditions of the Agreement **other than** the Project Team; specifically, it may **not** be used to update either Party's Principal Investigator or to update the list of NIST Contractors.*

Background Information

Step A. Identify Collaborator using the same name found in the original Agreement.

Step B. Identify the NIST Agreement number associated with the original Agreement (typically a sequence of numbers and letters beginning with "CN").

Step C. Identify the date on which the request is being sent to the non-requesting Party.

Requesting Party & Changes

Step D. Identify the Party requesting the update ("Requesting Party") by checking the relevant box.

Step E. Identify the change to Requesting Party's Project Team, i.e., an addition of personnel, a removal of personnel, or both, by checking the relevant box.

Step F. List the personnel that are being added to and/or removed from Requesting Party's Project Team.

Step G. List all personnel on Requesting Party's proposed updated Project Team, including each individual's name, email address, and affiliation if not a full-time employee of the requesting Party.
NOTE: NIST's Project Team will **not** include any individuals other than NIST federal employees.

Implementing Changes

Step H. Requesting Party signs and dates form to memorialize request.
NOTE: This is **not** an Amendment to the Agreement; instead, it is an update to one Party's Project Team.

Step I. Requesting Party sends completed and signed form to the non-requesting Party ("Non-Requesting Party") via email using the information provided on the signatory page of the Agreement.

Step J. Non-Requesting Party receives partially-executed form from Requesting Party. If Non-Requesting Party has no objections, Non-Requesting Party countersigns form and returns it to Requesting Party via email.
NOTE: If Non-Requesting Party objects to changes to Requesting Party's Project Team, has questions about the changes, or fails to respond Requesting Party's email with a countersigned copy of the form, the requested changes to the Project Team may **NOT** be implemented. Requesting Party may **ONLY** implement the proposed changes to its Project Team **AFTER** it is in possession of a fully-executed copy of the form.

Step K. Requesting Party receives countersigned form from Non-Requesting Party and implements acknowledged changes to Requesting Party's Project Team.

CRADA Identification Number:

Collaborator:

Notice of Project Team Update

NIST Dietary Supplement Laboratory Quality Assurance Program (DSQAP) Consortium

Agreement Details	
Collaborator	
NIST Agreement #	
Date of Request	

Party Requesting Change: ☐ NIST ☐ Collaborator

Change to Personnel: ☐ Addition ☐ Removal ☐ Both

Added Individuals	Removed Individuals
Updated Project Team	
All of the above-named individuals are full-time employees of Requesting Party. ☐ Yes . ☐ No If no, identify non-employees and their affiliations: ***If no, NIST TPO & NIST OCC consult.***	

☐ Requesting Change on Behalf of
☐ Acknowledging Change on Behalf of

NIST

Signature

Date

Name

Title

☐ Requesting Change on Behalf of
☐ Acknowledging Change on Behalf of

COLLABORATOR

Signature

Date

Name

Title