The United Stated Army Medical Research Acquisition Activity (USAMRAA) intends to negotiate, on a sole source basis under the authority as prescribed in FAR 13.106-1(b)(1), with Metabolon Inc 617 Davis Dr, Suite 400 Morrisville, NC 27560, as the only responsible source that can provide analytical services of blood (plasma/ serum), urine, saliva, fecal, and tissue samples for metabolomics analyses as defined herein. Samples will be provided by USARIEM. This acquisition is being conducted under FAR Part 12 Acquisition of Commercial Items. Provisions and clauses in effect through Federal Acquisition Circular 2024-07 are incorporated. The intended procurement will be classified under North American Industry Classification System (NAICS) 541380 with a Small Business Size Standard of \$19M.

The contractor shall provide metabolomics analyses. The contractor shall possess Laboratory Analysis Services must include the following, at minimum:

- 1. Must have ultra-high performance liquid chromatography-tandem-mass spectrometry (UPLC-MS/MS) with a heated electrospray ionization source and Orbitrap mass analyzer capability that can be operated in both positive and negative ion modes, and gas chromatography-mass spectrometry (GC-MS) capability for measuring metabolites derived from multiple biochemical pathways in human blood, urine, saliva, stool, and muscle.
- 2. Must have the capability to detect at least 8,000 novel metabolites and to validate and confidently identify at least 5,000 known metabolites using company-owned libraries.
- 3. Must use bioinformatics systems that include a Laboratory Information System (LIMS) that enables fully auditable laboratory automation through a secure, easy to use, and highly specialized system. This system must at least include sample accessioning, sample preparation, instrumental analysis and reporting, and must also be able to provide advanced data analysis. The system must enable data extraction and peak identification, utilize data processing tools for quality control and compound identification in accordance with Good Laboratory Practices (GLP), and contain, at a minimum, a collection of information interpretation and visualization tools used specifically for metabolomics data analysis.
- 4. Potential Offeror's must show detailed expertise in bioinformatics analysis of metabolomics data, ability to provide user-friendly web portals for exploring, analyzing, and visualizing metabolomics and electronic reports summarizing analytical results and their interpretation.
- 5. Contractor Staff must include PhD-level scientists available to assist USARIEM scientists in interpretation of study results such as analyzing, summarizing, and interpreting the generated untargeted and/or targeted metabolomics data for all samples. Contracting company and/or its scientists must show history of contributing to peer-reviewed publications using the above-mentioned technologies.
- 6. Must have the capability to conduct quantification of short-chain fatty acids and bile acids and their derivatives in multiple biological sample types.
- 7. Must have Laboratory Systems governed by Standard Operating Procedures (SOP's) that are reviewed and updated with adherence to Good Clinical Laboratory Practice (GLP) Standards and quality control for all analysis conducted.
- 8. Laboratory technicians trained on appropriate measurement procedures and validated equipment.

Data Analysis Services:

Data Analysis Services must include the following, at minimum:

- 1. Must be able to provide a list of biochemicals detected and identified by biochemical name, biochemical class (grouped by super pathway and sub pathway), platform used for measurement, KEGG identifier, HMDB identifier, PUBCHEM identifier, CHEMSPIDER identifier and CAS identifier.
- 2. Must include KEGG/HMBD links for all compounds having a KEGG or HMDB ID.
- 3. Must be able to show relative quantitation expressed as peak area (both raw and normalized with and without missing data imputed).
- 4. Must deliver results of all statistical analyses requested by the Primary Investigator (P.I.) including unadjusted p-values and false discovery rate adjusted p-values (q-value).
- 5. Must be able to provide box maps showing quantification of all detected compounds by study group and timepoint.
- 6. Must be able to provide a narrative summary of all results along with their interpretation within the context of the study design. Narrative summary will include visualizations, demonstrating results of statistical analyses and biochemical pathways, and methods sufficiently detailed to be used in peer-reviewed publications.
- 7. Must provide access to a web-based portal in which the USARIEM PI can continue to access, analyze, and visualize the generated metabolomics data using data analysis tools including principal components analysis, partial least squares discriminant analysis, volcano plots, hierarchical clustering, t-tests, and ANOVA.

Additional Comments for Analytical Support under this Effort:

1. Shall have a bioinformatics system consisting of a Laboratory Information Management System (LIMS) that enables fully auditable laboratory automation through a highly specialized system, access to a specialized library of purified standards or recurrent unknown entities and provide USARIEM scientists access to visualization and interpretation software to conduct analysis for this requirement. Previous and ongoing studies at the USARIEM have been performed under these systems and future analyses must utilize the same methods and equipment to allow for valid and accurate comparisons across studies.

This notice of intent is not a request for competitive proposals and no solicitation document will be posted for this requirement.

Any other firms desiring consideration must fully identify their interest and capability to provide these services no later than 13 March 2025 to the individual listed below. A determination by the Government not to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government. Interested persons may identify their interest in writing, to the Government Point of Contact. Responses to this notice must be received no later than 11:00am Eastern Standard Time, 13 March 2025. The point of contact for this action is Ms. Kasey Carroll, kasey.l.carroll.civ@health.mil. No telephone requests will be honored.