IEDB3 Statement of Work

Contract Number

75N93019C00001

Project Period

Y1: 15 December 2018 to 14 December 2019

Options 1-6 extend the project period until 2025

Options 7-104 increase the amount of effort and tasking by up to 14 units per year

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Statement of Work – Scope

This contract will provide for further development and enhancement, as well as population and maintenance, of the IEDB containing a comprehensive immune epitope database and epitope analysis tools.

Note the following will NOT be supported under this contract: IEDB systems development, immune epitope discovery through direct experimentation, and/or any laboratory-based basic or clinical research or any phase clinical trial.

Statement of Work – Excerpt of Technical Requirements

Specifically, the Contractor shall:

1. Maintain and further enhance a central web-based source of information on T cell epitopes and linear and conformational antibody/B cell epitopes (e.g., carbohydrates, lipids, and modified peptides) through curation of existing literature and direct submissions by the broader research community.
2. Maintain and further enhance a central web-based source of data on ligand binding to MHC class I, class II, non-classical, and MHC-related molecules, including ligands shown experimentally not to bind to any of these molecules (i.e., negative binding data).
3. Maintain and further enhance a central source of data on BCR and TCR repertoire information associated with T cell and antibody/B cell epitopes located within the IEDB.
4. Foster further development of an Analysis Resource within the IEDB composed of more robust algorithms, mathematical models, and other predictive tools that support:
    a. Identification of novel antibody/B cell and T cell epitopes from genome or protein sequence information and predicting host responses to specific pathogens or immune-mediated diseases
    b. Draw connections between both BCR and/or TCR repertoire sequence data, epitope binding and computational identification of epitopes from TCR/BCR sequence; and/or
    c. Facilitate identification of antibody and T cell epitopes associated with infectious or immune-mediated diseases for their use as targets for vaccine candidates and/or immune-based therapies.

TASK A: Immune Epitope Database

Maintain, further develop, and improve the IEDB's web-based relational database populated with antibody/B cell epitope and T cell epitope information. The IEDB will be freely accessible to the scientific community via an Internet website. Immune epitope information will be obtained primarily through curation of the scientific literature (relevant journal articles), but will also include curation of direct submissions from the broader research community. Epitopes shall be derived from infectious agents, allergens, alloantigens, autoantigens, and model antigens. HIV and cancer epitopes are NOT to be considered at the time of initial contract award but may be added at any time during the contract period with additional level of effort using options.

Specifically the Contractor shall:

1. Continue to provide for the further enhancement, collection, storage, analysis, archive, and exchange of immune epitope data and accompanying information from multiple sources including;
    a. an organized compilation of amino acid or other molecular sequences of linear and conformational antibody epitopes, and an organized compilation of T cell epitopes consisting of peptide amino acid and/or other ligand sequences known to bind to various MHC class I, class II, non-classical, and MHC-related molecules of human, non-human primate, and other animal origin, including enough HLA alleles to cover the human population worldwide;
    b. inclusion of the most current information available concerning each of the identified antibody and T cell epitopes, such as its three-dimensional structure, immunogenicity, neutralization capacity, receptor repertoire information, other biological activities, source (pathogen or commensal; autologous, allogeneic, or xenogeneic sources; plant or animal derived allergens; etc.), and methods of epitope discovery and validation;
    c. curation of immune epitopes and accompanying biological information from the scientific literature;
    d. free access of all information within the IEDB as well as all the contractor-generated materials (e.g., documentation, software source codes, analysis tools and algorithms), to the research community; and
    e. accessibility to the IEDB for investigators from the broader research community to submit immune epitope data and accompanying biological information for inclusion in the system.
2. Provide, upgrade, and maintain hardware and networking architecture for the collection, storage and exchange of immune epitope information for a widely-distributed user network. Users are located internationally and do not necessarily have the same hardware or network configurations. The architecture shall accommodate this variability in hardware and/or network configurations among users located at domestic and foreign sites.
3. In consultation with the Contracting Officer Representative (COR), provide for the integration of system updates to accommodate future technological advances and user needs such as an increase in the number of users, number and types of user-generated queries, or increases in system capabilities.
4. Web portal:

a. Maintain, optimize and further enhance uniform, intelligent web-based interfaces for making data accessible to end users. The interface shall minimally include complex query; semantic query; download; epitope submission; epitope prediction, visualization and analysis tools; links to related resources; and reports, manuscripts, and compendia.
b. Test interfaces for practical flow and usability with the scientific community. Interfaces developed shall be clear and intuitive.
c. Establish and track performance metrics to determine utilization and utility of the web portal within the scientific community. Relevant metrics shall include analysis tool utilization, frequency of data downloads, characterization of users and other usage statistics. Utilization reports shall be generated and sent to the COR in the quarterly and annual progress reports.

5. Documentation:
    a. Document all system components, software and databases in accordance with industry best practices and in a manner that will allow another Contractor or user to understand and utilize the system.
    b. Provide a high-level overview of functions and features of the system, including system architecture, hardware and software design, database design and data models. This compendium of functions and features shall be updated semi-annually or as requested by the COR or Contracting Officer.
    c. Establish and deliver to the COR a schedule of system updates and releases. The release schedule shall be updated semi-annually.
6. System Service Levels: Make available all systems based on the following service levels. The service level shall be 99.5% up time with online support provided live 8 hours per day 5 days per week. Weekend issues with the database or analysis tools shall be addressed with an email from the contractor within 5 hours of being alerted.
7. Populate the IEDB with data and supporting information obtained from studies reported in the literature, direct web-based submissions by the broader research community, and other databases. The data and supporting information shall minimally include the following:
    a. Antibody epitopes and mimetopes (structural or functional antigen mimics) including linear and conformational sites, identifiable by their epitope sequence (i.e., amino acid, carbohydrate, or lipid composition for linear and conformational antibody epitopes) as well as other key information currently available, such as their antibody isotype; pathogen, antigen or disease source; composition of natural, artificial, and modified amino acids (as may occur during post-translational modifications of whole molecules or ligands); and haptens associated with the epitope/mimetope.
    b. T cell epitopes and mimetopes consisting of peptide and non-peptide ligands identifiable by their epitope sequence (i.e., amino acid, carbohydrate, or lipid composition) including the composition of natural, artificial, and modified amino acids as may occur during post-translational modifications of peptide ligands, as well as other key information currently available, such as their MHC binding motif; MHC molecule; pathogen, antigen or disease source; and haptens associated with the epitope/mimetope.
    c. For both antibody and T cell epitopes, nucleotide and amino acid sequences shall be aligned per standard practices and procedures as exemplified in major scientific journals and/or existing databases.

d. Extensive annotation/curation for each antibody/B cell and T cell epitope, which shall minimally include:
    i. Size and three-dimensional structure of the antigen from which the epitope derives, as well as the MHC-ligand or antigen-antibody complexes, where available.
    ii. Epitope location on the whole antigen (where available).
    iii. Background information about the epitope, including: identification methods; validation of immunogenicity and/or antigenicity in vivo and in vitro (e.g, protection studies in vivo, in vitro cytotoxicity, The Enzyme-Linked Immunosorbent Assayelisa (ELISA), The Enzyme-Linked ImmunoSpot (ELISPOT) assay, pathogen neutralization); receptor repertoire sequence information (if available); methods to generate and test antibodies; antibody/antigen binding affinity and immunogenicity; post-translational modifications; and MHC binding affinity.
    iv. BCR and TCR repertoire information associated with T cell and antibody/B cell epitopes located within the IEDB.
    v. Full references (i.e., the PubMed identification number, source, and link to the PubMed website).

8. Annotate the IEDB and curate epitope information using widely accepted, appropriate biological reference ontologies, as can be found in the Open Biological and Biomedical Ontologies Foundry (http://www.obofoundry.org/), Ontology for Biomedical Investigation (http://obi-ontology.org/page/Main_Page), and Ontology for Immune Epitopes (ONTIE: http://ontology.iedb.org/), or through Contractor-developed ontologies for areas in which no reference or domain-specific ontology is available. Domain experts in immunology shall perform the data annotation and curation. Minimally, the domain experts shall comprise a group of scientists with expertise in the fields of antigen processing and presentation for generation of T cell epitopes, antibody production, antibody-antigen binding, and B and T cell activation.
9. Provide capabilities that allow users to query the IEDB. Domain experts shall work closely with database development and software engineering staff to ensure that the scientific information is catalogued and organized in a manner that permits users to access the data through data searches and queries, to minimally include retrieval of data based on one or combinations of the following areas:
    a. Type of immune epitope
    b. Type of immune response
    c. Host species
    d. Epitope source organism
    e. Disease
    f. Immune assay type
    g. MHC restriction

TASK B: Analysis Resource

Maintain, enhance, further develop, and optimize the Analysis Resource for the IEDB. This includes online access to: (1) tools to help researchers locate and analyze information contained in the IEDB; (2) other relevant databases and related information; (3) data mining algorithms, mathematical models, and other sophisticated analytical tools to help researchers identify and/or visualize novel antibody/B cell and T cell epitopes from genome or protein/ligand sequence information, conduct analyses of TCR and/or BCR sequences and associated metadata, predict the immunogenicity and/or antigenicity of epitopes from different sources, and extrapolate host immune responses to particular epitopes from existing information. Note: The identification of more robust algorithms, mathematical models, and other predictive tools for identifying novel antibody/B cell and T cell epitopes associated with HIV are NOT to be considered at the time of initial contract award but may be added with additional level of effort in future options at any time during the contract period.

Specifically, the Contractor shall:

1. Provide online access, through links on the IEDB, to standard analytical tools to help researchers locate and analyze information contained in the database, minimally including:
    a. Software tools for data mining and analysis of antibody/B cell and T cell epitope information.
    b. Algorithms, mathematical models, and other prediction tools for identifying novel antibody and T cell epitopes from genome and protein/ligand sequence information, analyzing TCR and/or BCR sequences and associated metadata, predicting the immunogenicity and/or antigenicity of epitopes from different sources, and extrapolating host immune responses to epitopes from existing information. Provide information to the user community on the reliability and accuracy of these tools, including their strengths and weaknesses.
    c. Provide for the continued maintenance, enhancement and optimization of applications and tools for the prediction and analysis of immune epitopes and immune epitope related information.
2. Provide online access to other relevant databases and related information. These links shall be checked monthly by the Contractor for accessibility to the intended web site. The links shall minimally include:
    a. Genome sequence databases for mammalian and non-mammalian organisms (including prokaryotes).
    b. Protein databases.
    c. Other MHC-peptide databases, such as the HIV Molecular Immunology Database, that contain information not found in the Immune Epitope and Analysis Resource Program.
3. Provide ad hoc reports to the COR on subsets of data within the IEDB. These reports may not be for public use, but the information contained within the reports may be provided to various branches of the Government and/or other public health – related agencies upon request. The COR will specify the report format at the time of request.

TASK C: Community Outreach

Specifically, the Contractor shall interact with the scientific community by:

1. Promoting awareness throughout the scientific community of the data and tools available through the IEDB. At a minimum, information should be disseminated via electronic and print media and presentations at scientific meetings, symposia, and workshops.
2. Sponsoring an annual workshop to improve the contents of the database portion of the IEDB; standardize methodologies (e.g., antibody and T cell epitope identification, binding assays, validation of epitope antigenicity in vitro and in vivo); develop improved data mining and analysis tools and more robust algorithms; and promote technology transfer. In consultation with the COR, the Contractor shall identify key contributors to the fields of immunology, microbiology, biochemistry, computational biology, and bioinformatics whose contributions are relevant to the IEDB, and invite them to participate in the next workshop. Within eight (8) weeks of the completion of the workshop, the Contractor shall provide the COR with a hard copy and electronic version of a detailed summary of the workshop, including an executive summary highlighting participants' contributions and the recommendations that emerged from the meeting. After COR approval, the Contractor shall post the executive summary on the central website.
3. Interacting with investigators on an ongoing basis to solicit feedback from users and address questions that arise. These interactions shall include web-based discussions (offered through the central website) and participation at scientific meetings, symposia, and workshops.
4. Provide user support for data submission. Provide online and direct support to users to facilitate their submission of immune epitopes and accompanying biological information to the IEDB.

TASK D: Database

The contractor shall, provide an annual compendium of data in the IEDB and all analysis tools developed during the previous year. The compendium shall be an on-line publication available at the central website. An electronic copy of the compendium shall be sent to the COR for review fourteen (14) business days prior to posting at the website.

The annual compendium shall minimally include:

a. A comprehensive list and description of the antibody and T cell epitope information in the IEDB, identifying new epitopes added since publication of the previous compendium.
b. A comprehensive list and description of the various features of the website, particularly the analytical tools available through the Analysis Resource, identifying new features added since publication of the previous compendium.
c. A comprehensive list and description of major scientific publications and breakthroughs for which: i) the IEDB played a contributory role; or ii) had a direct impact on the database that occurred since publication of the previous compendium.

TASK E: Interaction with NIAID Programs

As directed by the COR, the Contractor shall:

1. Interact with both current and future NIAID contractors, as specified by the COR to ensure submission and exchange of data to include immune epitopes and biological information into the IEDB and facilitation of system operability.
2. Foster community outreach activities to expand the user-base and utility of the IEDB resource for the broader research community; and
3. Foster interaction with existing and future NIAID programs, which minimally include:
    a. B cell Epitope Discovery and Mechanisms of Action;
    b. Large–scale T cell Epitope Discovery;
    c. Allergen Epitope Discovery programs;

    NOTE: Contractors supported under these three programs are required to submit the novel immune epitopes and accompanying biological information discovered within their programs to the IEDB.

    d. Bioinformatics Support Contract (BISC)/ImmPort Database;
    e. Bioinformatics Resource Centers (BRCs);
    f. HIV Molecular Immunology Database, and;
    g. Other databases specified by the COR.

    NOTE: Interactions with these four programs minimally are to ensure exchange of relevant data and analysis tools and facilitate system interoperability.

TASK F: Project Management

The Contractor shall:

1. Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts.
2. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract and effective communications with the COR and the Contracting Officer.
3. Provide for a Principal Investigator and Project Manager with responsibilities for overall project management and communications for tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.

Meetings and Teleconferences

1. Contract Initiation Meeting: Within 60 calendar days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the COR, the Contracting Officer and other NIAID personnel, to be held at the Contractor's site. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NIAID contract procedures.
2. Monthly Meetings/Teleconferences: Plan and conduct meetings of the Contractor's Principal Investigator and Project Manager with the COR and Contracting Officer at least monthly, either in person or via teleconference, to review overall progress, the status of approved and pending projects, and to discuss any matters relevant to the scientific and financial administration of the contract and future activities. The schedule for those meetings will be established by the COR and Contracting Officer after contract award.
    a. Prepare and distribute the agenda and meeting/teleconference materials to all participants five (5) business days prior to the meeting.
    b. Provide a summary of all meetings and teleconferences within five (5) business days of the meeting to all participants.
3. Annual Site Visit: Arrange for and conduct annual site visits for NIAID contract and program staff to review and discuss: project progress; problems and obstacles and approaches to overcoming identified problems and obstacles; recommendations for modifications in project timelines, objectives, and research approaches/methodologies based on outcomes to date; and plans. These site visits shall be attended by the Principal Investigator, the Contractor's business representative, and all key personnel. The Contractor shall be responsible for:
    a. Planning and submitting the agenda to the COR for approval;
    b. Developing written and oral presentation materials;
    c. Arranging for the logistics associated with the site visits and for travel costs for all non-Government site visit attendees; and
    d. Preparing and submitting Annual Site Visit reports to the COR and Contracting Officer within fifteen (15) business days of completion of each annual site visit.

TASK G: Information Technology (IT) Resources, Facilities and Security

1. The Contractor shall provide and maintain secure IT systems and network architecture, development and production environments, and computational infrastructure to support the activities and resources provided to the users. IT systems shall be housed in an environment with an adequate level of redundancy in power, connectivity, and cooling. The IT system shall contain:
    a. An IT System Security Plan (ITSSP) that meets the OMB Circular A-130, NIST guidelines and NIH guidelines for IT system security. The ITSSP shall provide a summary of the security requirements for the system and describe the security controls in place or planned for meeting those requirements. The ITSSP must be reviewed and approved by the NIAID Information Systems Security Officer (ISSO) within 30 calendar days after the effective date of the contract.
    b. IT System protection measures that meet Department of Health and Human Services (DHHS) requirements by complying with the HHS Automated Information Systems Security Program Handbook (http://ftp.fas.org/sgp/othergov/hhs-infosec.pdf).
    c. Continuity of Operations Plan - a comprehensive Operational Recovery Plan (ORP) and Disaster Recovery Plan (DRP) that specifies the procedures used to restore operations following a natural or man-made disaster shall be provided to the COR for approval within 30 days after the effective date of the contract.
    d. Security against catastrophic loss of data or important software, including an off-site, separate, secure and access-controlled facility for storage of back-ups of all IEDB files and programs. A comprehensive Backup Plan (BP) that specifies the procedures used to insure against data loss shall be provided to the COR for approval within 30 days after the effective date of the contract.
    e. Provision of uninterrupted access and service to the IEDB user community, including procedures to minimize interruptions during hardware and software upgrades.
    f. Capability of being transferred to the NIAID or subsequent contractor without interruption.
    g. Provision for the appropriate labeling, storage, handling, and disposal of sensitive or confidential data, media, and output.
2. The contractor shall provide and maintain the following facilities, equipment, resources and security systems necessary to perform the technical requirements set forth in the Statement of Work for the entire contract period of performance in compliance with all NIH, Federal, state and local regulations and guidelines, including:
    a. One or more facilities to house all computer equipment, hardware, software, servers and other resources required to provide for the receipt, storage, retrieval, quality control, query, and analysis of immune epitope data. If multiple sites are used, sites must be electronically linked together for efficient access, exchange and retrieval of information.
    b. Resources for the provision of secure electronic communication linkages with the COR.

TASK H: Transition Plans

1. Initial Transition: In the event of transition to a new contractor, ensure an orderly, secure, and efficient transition of activities from the predecessor contractor, as follows: In collaboration with the COR the Contractor shall plan and implement an orderly, secure and efficient transition of contract activities and data, systems, analytical tools, and other documents and materials as follows:
    a. Plan, coordinate, and implement an efficient transition from the incumbent contractor (www.iedb.org) of all relevant data as determined by the COR to include:
        i. data management system(s),
        ii. websites,
        iii. software applications and source code,
        iv. analytical tools and methodologies, ontologies, and other resources and
        v. user manuals and documentation.
    b. Within ten (10) business days of the effective date of the contract, the COR will provide to the Contractor a copy of the Final Transition Plan from the incumbent IEDB contractor.
    c. Within thirty (30) business days of the effective date of the contract, the Contractor shall develop and submit the Initial Transition Plan to the COR review and approval. This Plan shall specify which resources of the incumbent contractor are to be retained, modified, replaced, or discarded and which require new development, as well as proposed timelines and milestones to ensure an efficient and orderly transition of contract data, systems and activities. In addition, the Plan shall specify the staff responsible for implementing the initial transition with defined roles and responsibilities.
    d. After approval by the Contracting Officer and COR, implement and complete the Initial Transition Plan within the first 3 months from the effective date of the contract. During the implementation phase of the Initial Transition Plan, the Contractor shall on a biweekly basis update the COR about the progress of the transition either in writing or through teleconferences.
2. Final Transition: The Contractor shall ensure an orderly, secure, and efficient transition of contract-related materials and activities to the successor contractor or to the Government. A description of transition activities, timelines, and assigned staff shall be provided in a Draft and Final Transition Plan, which will be reviewed and approved by the COR and Contracting Officer. Instructions are as follows:
    a. Draft and Final Transition Plans
    b. No later than 12 months prior to the completion date of the contract, prepare and submit, for review and approval by the COR and the Contracting Officer, a Draft Final Transition Plan. The Draft Final Transition Plan shall detail the transition activities to be carried out, provide a timeline for the implementation of each transition activity, and describe the capabilities and responsibilities of Contractor staff who shall be assigned to implement the plan.
    c. Revise the Draft Final Transition Plan as necessary to accommodate COR and Contracting Officer comments, and submit the Final Transition Plan (approved by the COR and Contracting Officer) no later than 6 months prior to the completion date of the contract.
    d. The Contractor shall maintain full operational capacity until the expiration date of the contract.

Option(s)

In addition to the services/quantities outlined above to be provided for the base requirement, Options(s) for additional services/quantities under the contract may be exercised at the discretion of the Government and are defined as follows:

OPTION 1-6: Extend the Term of the Contract: The Government may include options to extend the contract period of the performance in twelve-month periods beyond the base year. The total period of performance resulting from the base period plus all potential Term Options is 7 years. If a Term Option is exercised, the services required will be the same as provided during the base year.

OPTION 7-104: Increase in Level of Effort: The Government may exercise options for increased level of effort in each year of the contract period of performance. Level of effort may be increased in increments of 1040 hours up to a total of 14,560 hours (~7 FTEs) in the contract base year and in each additional year in which Options 1-6 have been exercised.