New Jersey Department of Environmental Protection

Division of Science and Research
T-Dependent Antibody Response (TDAR) for Immunotoxicity

BIDS DUE April 21st, 2025, by 5:00 pm EST

Date Issued: April 3rd, 2025

Request for Proposals
Immune System Toxicity of select PFASs

The New Jersey Department of Environmental Protection (NJDEP) Division of Science and Research (DSR) seek a qualified entity to characterize *in vivo* functional immune response to an immunogen to evaluate the potential immunosuppressive effects of specific per- and polyfluoroalkyl substances (PFAS).

Project Award Cap: None Specified
Anticipated Start Date: June 1, 2025
Project Duration: May 31, 2027

PROPOSAL DEADLINE
All proposals in response to this Request for Proposals must be submitted via email to Dr. Greg Raspanti, project manager, at Greg.Raspanti@dep.nj.gov by **5:00 PM EST on April 21st, 2025**. Any questions can be submitted to the project manager until April 14th, 2025.

This investigator will be required to submit an electronic copy of the proposal as well as Form CC-120 ensuring it is signed, dated, and submitted prior to the submission deadline. The NJDEP reserves the right to not award this RFP if an adequate proposal is not received.

Please note: The winning bidder must complete the DPA paperwork and be registered in NJSTART before the execution of the purchase order. Both new and existing NJSTART contractors must register/update information at http://www.njstart.gov in order to process a purchase order. Assistance with NJSTART can be requested at njstart@treas.nj.gov or (609) 341-3500.

NJDEP reserves the right to reject any or all proposals based on scientific merit, proposed cost, or based on internal deliberations and considerations.

Schedule for Selection

1. Deadline for receipt of proposals by 5:00 PM EST on April 21st, 2025
2. Applicant will be notified when a contractor is selected
3. Work will commence upon execution of a purchase order or contract

Purpose of Solicitation

Introduction
In 2023, NJDEP reached a settlement with Solvay surrounding the environmental release of per- and polyfluoroalkyl substances (PFAS) at their West Deptford facility. As a result, funds have been allocated to NJDEP DSR to conduct toxicology studies into selected PFAS chemicals to fill critical knowledge gaps in the literature related to human health effects from specific PFAS exposure. More specifically, this proposed project will solicit external collaborators from academic or contract laboratories to conduct repeated dose mammalian studies into immune system effects of oral exposure to chloroperfluoropolyether carboxylates (ClPFPECAs) and perfluoropolyether dicarboxylic acids (PFPE-DCAs).

ClPFPECAs and PFPE-DCAs are PFAS compounds used at Solvay during chemical processes commonly utilized in complex mixtures of long-chain congeners of different carbon and oxygen chain lengths. These compounds have been recently detected in surface waters, ground water (including private wells), soil, and fish near the facility

which creates a potential for exposure to the public. In response, NJDEP has developed Interim Specific Ground Water Quality Criterion for the industrial mixtures based the limited available toxicology data.

ClPFPECAs are reported to be bioaccumulative in humans with a half-life of 2.5-3 years, similar to other bioaccumulative PFAS such as perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA). They are associated with numerous health endpoints in occupationally exposed workers, including increased serum lipids and liver enzymes, decreased immunoglobulins, changes in endocrine parameters, and others. For PFPE-DCAs, there is no information on toxicokinetics or health effects of PFPE-DCAs in humans, but they are known to be bioaccumulative and toxic in both male and female rats.

The toxicological database for both ClPFPECAs and PFPE-DCAs includes acute oral, dermal, and eye irritation studies and repeated dose oral studies of up to 13-week duration in rats, and several types of systemic toxicity (e.g., liver, blood, and/or lung) have been identified for both types of PFAS mixtures. Immune system effects have been observed in other PFAS compounds (specifically PFOA, PFNA, PFDA, and PFOS), however little is known about immune system effects of the ClPFPECAs and PFPE-DCAs industrial mixtures (Pachkowski et al., 2019).

Scope of Work

The selected contractor will begin by conducting a thorough review of the relevant scientific literature (including national/international guidance), as well as toxicological and chemical information of which include seven day, four week, and 13 week oral toxicity studies as well as chemical safety data sheets which are available on NJDEP DSR Alternative PFAS website.

This specific project will investigate the potential immunotoxicity of repeated exposure to ClPFPECAs and PFPE-DCAs in mice and will follow USEPA Guidelines set forth in USEPA Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Test Guidelines Immunotoxicity 870.7800 (1998).

The study objectives are as follows:

- Investigate the immune system effects of repeated dose exposure to ClPFPECAs and PFPE-DCAs in mice as measured by Plaque Forming Cell (PFC) assay and/or Natural Killer (NK) cell assay to fill critical knowledge gaps in scientific literature.
- Investigate the dose-response relationship using sequentially increasing dose levels in order to determine effect levels amenable to Benchmark Dose modeling which can inform human health risk assessors when determining human health Reference Dose levels.

Study design should be similar to that used in Dong et al. (2009). Briefly, male and female mice (at least eight mice/sex/dose) will be orally administered either ClPFPECAs or PFPE-DCAs at varying doses, including a negative and positive control (e.g., immunosuppressive chemical cyclophosphamide) group, for at least 28 days. Immunization with Sheep Red Blood Cells (SRBCs), in order to elicit an immune system response, will occur four days prior to sacrifice. ClPFPECA and PFPE-DCA compounds will be provided by NJDEP to the contracted laboratory.

The primary endpoints are as follows:

- PFC assay will be conducted to determine splenic anti-SRBC (IgM) immune response.
    - If IgM response is suppressed, phenotypic markers of major lymphocyte populations (total T, total B, CD4, and CD8) will be measured.
    - If IgM response is not suppressed, NK cell assay will be conducted to determine non-specific immune response.

- Daily observations of animal behavior, body weight, food/water intake, mortality, and morbidity will be conducted.
- Spleen, liver, and thymus weights will be measured.
- Blood serum will be collected from all animals for PFPE-DCA and ClPFPECA to better understand internal dose levels. These samples may be sent to either NJDEP or USEPA ORD for analysis if analysis cannot be completed by the contract laboratory.

The first major task for the contractor will be to develop a Quality Assurance Project Plan (QAPP), which includes and details the methodology of the project. This QAPP must be approved by the project manager and the NJDEP Office of Quality Assurance (OQA). Contained in this QAPP shall be a thorough standard operating procedure (SOP) which details precise study protocols, procedures, data output, and data reporting. As a counterpart to this effort, the contractor will also be expected to submit a provisional report in the first year that summarizes the literature and the progress of the study. Once the QAPP has been approved and the provisional report reviewed by NJDEP, the contractor will address comments and guidance to proceed with finalizing the remaining deliverables.

Proposal Specifications

All proposals should include:

- A basic statement of qualifications, including experience, background, skills, and degree of expertise in the specific areas outlined in this RFP. A minimum of five years of experience conducting mammalian toxicologic studies and in particular immune system toxicology in accordance with EPA guidelines and methods.
- Financial proposal for the project, including cost for personnel, must be submitted using the CC-120 Form. **Note**: NJDEP reserves the right to reject any or all proposals based on scientific merit, proposed cost, or based on internal deliberations and considerations.
- Applicants should additionally provide a project description outlining their plan (using the budget template below) for the requested funding. Cost estimate should be provided per deliverable. This information will support review of the proposed work to ensure it is in compliance with national/international guidance required by USEPA.
- Any other relevant contractual language for NJDEP consideration. The successful applicant's final proposal will become part of any signed agreement.

Please note: Eligibility for funding depends on the qualifications of the applicants and adherence to details outlined in this RFP. If there are concerns about understanding the terminology specified in this RFP, you can contact the project manager at Greg.Raspanti@dep.nj.gov.

This request for proposals does not commit the State of New Jersey to engaging the services of any firm for any of the items either within or outside the outlined scope of work.

Deliverables

The following items must be submitted prior to the completion of this project. Sub-bullets are intended to provide additional context for deliverables.

1. Develop QAPP for approval.
2. Submit Progress Reports
    - May be subject to public comment period
    - Summarizes the literature review
    - Considers the references listed at the bottom of this RFP
    - Provides rationale for the proposed method
    - **Progress reports shall be submitted every six months**
3. Submit Draft Final Report
    - DSR will review and provide feedback/edits to be incorporated into the final report.
4. Submit Final Report
    - Summarizes all deliverables
    - Provide all raw and summary data
5. Presents a project overview and key results to DEP staff
6. Submit final invoice

Data Format: All raw, and created summary data, shall be provided to NJDEP. The data provided to NJDEP shall be in an editable format (.csv, .xlsx, or equivalent) which includes all measurements, dose timing, and summary statistics made on each individual animal. A detailed description of each measurement/variable shall be provided, which includes units, in the form of a data dictionary (i.e., metadata).

Deliverable Due Dates and Payment Schedule

The anticipated timeline for completion of tasks and submitting deliverables to NJDEP is outlined in Table 1. Deliverable due dates and payments will follow as outlined in Table 2 and will be adjusted based on date of award. Progress payments shall be made upon receipt and approval of each deliverable. Once a deliverable is received and accepted by the Project Manager, the Contractor will submit their invoice and a signed State of New Jersey Payment Voucher to the Project Manager. The Project Manager will certify the Payment Voucher officially accepting the deliverable. The payment package is then forwarded to the DEP's Central Procurement Unit to process the payment. Final payment shall be withheld pending receipt of all final reports. The Contractor will either receive a check or the payment will be processed electronically depending on their remittance setup in NJSTART. The invoice for completed work and all report package deliverables must be submitted **by the end of the task timeline.**

Table 1. Anticipated deliverable task timeline. Anticipated timeline for completion of tasks and submitting deliverables to NJDEP.

Fiscal Year	**2025**	**2026**				**2027**		
	Q4	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**
Award								
Grant Contracting								
Develop QAPP for approval								
Initial Progress Report (subsequent progress reports shall be submitted every 6 months)								
Conduct immune system toxicity study								
Submit Draft Final Report DSR Review of Draft Report Submit Final Report								
Submit all raw and summary data								
Presentation to NJDEP Staff								

Table 2. Payment schedule is deliverables-based. Payments will be provided upon the review and approval by the project manager of the indicated tasks.

Deliverable Task	Payment	% of Award Amount	Date (months from start)
Develop QAPP for approval	#1	25	6
Conduct Immune System Toxicity Study Submit Progress Report	#2	25	9
Complete study Submit Draft Final	#3	25	18
Submit Final Report including all raw and summary data Presentation to DEP	#4	25	23

References

Dong, G-H et al. (2009). Chronic effects of perfluorooctanesulfonate exposure on immunotoxicity in adult male C57BL/6 mice. *Archives of Toxicology*. 83(9): 805-815.

Pachkowski, B., Post, G., and Stern, A. (2019). The derivation of a Reference Dose (RfD) for perfluorooctane sulfonate (PFOS) based on immune suppression. *Environmental Research*. 171: 452-469.

United States Environmental Protection Agency. (1998). OPPTS Harmonized Test Guidelines Series 870 Health Effects. Health Effects Test Guidelines OPPTS 870.7800 Immunotoxicity. Office of Prevention, Pesticides, and Toxic Substances.

Budget Detail

Applicant(s) must include an itemized budget and associated justification. The budget must be itemized as shown below and associated justification provided. Note that the State is limiting the maximum allowable overhead to 15% and a maximum of 50% of the final budget can be allocated to subcontracts. Personnel costs (line item "a") can be provided as *either* a percentage of time (i.e., percentage of annual salary) *or* as an hourly rate and dedicated number of project hours. The budget template below is for a two-year project duration and two research personnel, add or remove years and research personnel as needed. If fields do not apply, then leave them blank or remove them from the budget table included in the submitted proposal.

Budget Object	**Salary:** Annual or Hourly Rate	**Year 1:** % of Time or # Hours	**Year 2:** % of Time or # Hours	**Year 1 Cost:** Annual Salary x % of Time or Hourly Rate x # Hours	**Year 2 Cost:** Annual Salary x % of Time or Hourly Rate x # Hours	**Total**
Personnel:						
Cost Researcher 1				$	$	$
Cost Researcher 2				$	$	$
a. Total Personnel				$	$	$
Fringe Researcher 1				$	$	$
Fringe Researcher 2				$	$	$
b. Total Fringe				$	$	$
c. Travel				$	$	$
d. Equipment						$
e. Supplies						$
f. Contractual						$
g. Construction						$
h. Other						$
i. Total Direct				$	$	$
j. Modified Total Direct Costs				$	$	$
k. Total Indirect				$	$	$
l. Total Cost						$

a) Personnel: $-

Researcher 1 – If annual salary ($- salary x % of time = $- Year 1)

If hourly rate ($- rate x # hours = $- Year 1)

Researcher 2 – If annual salary ($- salary x % of time = $- Year 1)

If hourly rate ($- rate x # hours = $- Year 1)

+ researcher as needed

b) Fringe Benefits: $-

Apply appropriate Fringe rate for type of personnel (i.e., PI may have different fringe than a Tech)

Researcher 1 – Year 1 cost x fringe rate

Year 2 cost x fringe rate

Researcher 2 – Year 1 cost x fringe rate

Year 2 cost x fringe rate

+ researcher as needed

c) Travel: $-

Include details of estimated costs for flights, accommodation, registration, etc.

d) Equipment: $-

List equipment and estimated cost of each item

e) Supplies: $-

List supplies and estimated cost of each item

f) Contractual: $-

Subcontracts cannot exceed 50% of total budget

g) Construction: $-

often $0

h) Other Costs: $-

Laboratory Analysis (for example)

costs for _____ and miscellaneous parameters from contracted laboratories.

(# samples x $ per sample)

Other parameters - # samples x $ per sample

i) Direct Charges: $-
(a+b+c+d+e+f+g+h)

j) Modified Total Direct Costs (MTDC): $-

MTDC is used to calculate indirect costs. Please refer to the following table for eligible and ineligible costs:

Yes (include in MTDC)	**No (not allowed as part of MTDC)**
Direct Salaries and Wages	Tuition Remission
Fringe	Scholarships and Fellowships
Equipment Rental Fees (for example boat rental fees)	Facility Rental Costs

Materials (consumable items, for example: testing kits and sample bags)	Equipment Purchases (larger, more permanent purchased items such as computers or submersible vehicles)
Supplies (smaller items that may or may not be permanent)	Capital Expenditures
Services	Charges for Patient Care
Travel	Participant Support Costs
The first $50,000 of each subcontract	The portion of each subcontract over $50,000

k) Indirect Charges: $-
Indirect cost is calculated as MTDC (j) x %

l) Total Project Costs $_____ (Max).
Year 1: Total Direct(i) + Total Indirect(k) = $-
Year 2: Total Direct(i) + Total Indirect(k) = $-
Total Project = Year 1(i+k) + Year 2(i+k)

DPA Requirements:
The project award will be contingent upon the contractor being registered with the State of New Jersey, Division of Revenue, and possessing a valid Business Registration Certificate at time of project work. Contractor must also provide a copy of their New Jersey certificate of Employee Information or a copy of the Federal Letter of Approval verifying it is operation under a federally approved or sanctioned Affirmative Action program. Please see weblink below to obtain AA/EEOC forms:
http://www.state.nj.us/treasury/contract_compliance

To check Proof of Business Registration and print certificate:
https://www1.state.nj.us/TYTR_BRC/jsp/BRCLoginJsp.jsp

Contractors that are not registered with the Division of Revenue can complete Business Registration Application, found at:
http://www.state.nj.us/treasury/revenue/busregcert.shtml

Note: All contractors must register on NJ Start (this is where contractors will submit W-9 information)
https://www.state.nj.us/treasury/purchase/pdf/doingbusinessinnj.pdf

In addition to the above, the contractor must complete all the required DPA documentation on the checklist below:
https://www.state.nj.us/treasury/purchase/forms/Waiver%20and%20DPA%20Contract%20Checklist.pdf

Additional Terms and Conditions

Patent and Copyright Liability:
The Contractor shall hold and save the Department, its officers, servants, and employees, harmless from liability of any nature or kind including but not limited to actual use, perceived use, or threatened use for or on account of the use of any copyrighted or uncopyrighted composition, patented or unpatented invention, article, or appliance furnished or used in the performance of this project. This is in addition to and in no way limits any other indemnification provision in the project, including but not limited to Paragraph IV, Indemnification of the General Terms and Conditions.

Delay of Project:
The Contractor is responsible for completing the project as required by the Scope of Services and according to any approved project work schedules. However, a project schedule may be extended for delays caused by events which could not reasonably be anticipated, and which are reasonably beyond the control of the Contractor. Such causes include but are not limited to action by employees or other contractors employed by the Department, unanticipated work changes ordered by the Department, strikes, lockouts, fire, delays caused by common carriers, unavoidable casualties, work stoppage orders and suspension riders. If such an event occurs, the Contractor shall submit written documentation to the Department ’s project manager detailing the reason why the work was not completed within the required timeframe. Project extensions shall be requested at 6-month intervals for no more than 12 months.

Dissemination of Information:
During the course of this project and for two (2) years following submission of an approved final report, the Contractor shall not print, publish, disclose or otherwise make known to third parties the content of any data, information, studies, computation, memoranda, graphs, reports or other material arising from this project without at least thirty (30) days prior written notification to the Department, and without informing the Department of the nature of such disclosures. The Contractor shall coordinate all such disclosures with the Department and shall permit the Department to preview any such disclosure prior to its release. Contractor agrees to seriously consider the comments and suggestions of the Department in the final drafting of all publications. During the above thirty (30) day period, the Department may request a delay of any disclosure for up to one (I) year, if necessary, in order to protect the public interest. If the Contractor is publishing materials that the Department has reviewed and found unsatisfactory, inadequate, or unacceptable, at the request of the Department, the Contractor shall include in any publication of materials resulting from this project a statement, conspicuously placed, that the Department finds the material inadequate or unsatisfactory, that the Department disagrees with the analyses, interpretations, or conclusions contained therein, or both.

Acknowledge/Co-Authorship:
Publication by the Contractor of any work or portion of work arising from this Project must include a written acknowledgment of the Department's assistance (e.g., financial, equipment, manpower). Also, where a Department employee has contributed substantive work on the project, the appropriate State employees (Project Manager or other significant Department participants) shall be named as co-authors on publications arising from this Project.

Access to Material:
Unless otherwise specified in this Project, the Department shall have access to all data, samples, material, evidence, and documentation gathered, originated, or prepared for the Department by the Contractor during the performance of contractual responsibilities for a period of five (5) years from the submission of the approved Final Report. During that time period, any such data, samples, material, evidence and documentation shall be provided to the Department in a reasonably timely manner upon request by the Department.

Substitutions of Personnel and Subcontractors:
If, during the course of the Project, the Contractor cannot provide the personnel or subcontractors identified in this Project, and desires to substitute personnel or subcontractors, the Contractor first must request in writing from the Department permission to substitute personnel or subcontractors. Such written requests must:
1. Explain the reasons why the original persons cannot be provided;
2. Demonstrate that the qualifications of the substitution are equal to or better than the originally proposed persons; and
3. Warrant that the substitution will be provided at no additional cost to the Department.

Preliminary Data
Any written or verbal disclosure of information that is based on preliminary data (i.e., data that has not been accepted by the Department as being part of a defined final deliverable) must be clearly marked/identified as “preliminary” by the Contractor. All requests to use preliminary data in an abstract, presentation, or similar form must be reviewed and approved by DEP/Division of Science and Research Project Manager at least two weeks before submittal.

Intellectual Property and Data Ownership

All data and other intellectual property created generated, delivered, or otherwise prepared for or resulting from this Agreement, including but not limited to all papers, reports, surveys, plans, charts, records, analyses, or publications produced, regardless of State of completion, shall be jointly owned by the DEP and Contractor. Each party shall have a perpetual, irrevocable, royalty-free, non-exclusive worldwide right and license to freely use, make, have made, reproduce, disseminate, display, perform, and create derivative works, in all media and all forms, such data.

Quality Assurance Project Plan (QAPP)

For any scope of work that requires a QAPP, the QAPP must be approved by the Department in writing and prior to the initiation of any project activities including monitoring, measurements, or data generation. However, upon a showing of extraordinary circumstances and with the prior, written approval of the Department project manager, certain authorized project activities may begin before receipt of QAPP approval. In the event the contractor engages in project activities prior to receipt of a Department-approved QAPP or written approval to proceed under extraordinary circumstances, the associated costs of such unauthorized project activities may not be reimbursed by the Department. Any revisions or changes that occur to the approved sampling plan/QAPP during the contract working period will require an amendment to the approved QAPP and additional review and approval by the Department project manager.

PLEASE NOTE:

This request for proposal does not commit the State of New Jersey to engage the services of any contractor for any of the items either within or outside the outlined scope of work.