



Project Call for:

**BIOlogical, Integrated, Novel, Silicon Photonics for Efficient
Characterization and Testing (BIO INSPECT)**

April 30, 2024



1. Research Opportunity

Funding Opportunity Title: BIOlogical, Integrated, Novel, Silicon Photonics for Efficient Characterization and Testing (BIO INSPECT)

Announcement Type: AIM Photonics Government Directed Project (GDP)

Submission Deadline: Electronic proposals must be received no later than 11:59 PM (EST) on **June 12, 2024**. Proposals received after the deadline will not be considered. A notice of intent is not required for this project call.

Submission Address: All proposals are to be submitted electronically to Maria Halepis at MHalepis@aimphotonics.com. **IMPORTANT NOTE:** Due to email size restrictions, either keep all proposals < 10 MB to ensure a successful submission or inquire about other options to submit an on-time proposal. A confirmation email will be sent to each team who submitted a proposal acknowledging the proposal was received within one business day. Following up after any submission with an email seeking submission confirmation is recommended prior to the submission deadline.

Points of Contact:

- Administrative POC: Maria Halepis, MHalepis@aimphotonics.com, (AIM Photonics)
- Financial POC: Nathan Bull, NBull@aimphotonics.com, (AIM Photonics)
- Technical POC: Nicholas Usechak, Nicholas.Usechak@us.af.mil, (Program Sponsor)

Available Federal Funding Profile: Multiple awards are anticipated under this program at a funding level of \$1,150,000.00 each. Additional Federal funding may become available in future years; however, it is expected that any future work will build on the results of this effort.

Funding Opportunity Description: This is a Government Directed Project Call soliciting proposals focused on a specific technical objective. Under AIM Photonics, Government Directed Projects (GDPs) offer a compelling way for the U.S. Government to take advantage of the capabilities developed by the AIM Photonics Manufacturing Innovation Institute (MII) and leverage the utility of the AIM Photonics Cooperative Agreement. GDPs enable the government to provide additional funding to accomplish specific work within the AIM Photonics ecosystem, beyond what is possible using the Government's base investment alone.

Whenever feasible, the Government favors taking advantage of the U.S.-based ecosystem AIM Photonics has been challenged to create in performing such work. This enables competitive procurement and, in so doing, helps to encourage and develop a wider range of ideas from the AIM Photonics ecosystem in responding to specific challenge problems. This approach also offers additional benefits for the Members of AIM Photonics — funding opportunities — and provides value back to the overall ecosystem not only via additional funding but in the ability of such work to help improve and enhance the overall capabilities of AIM Photonics.

Proposals for projects outside of this topic area (described below) will not be considered for additional funding at this time. Information on proposer eligibility and other requirements can be found in Section 2 below.

Background: Within the broad field of biology there have been many recent advancements that have sought to take advantage of modern scientific discoveries. For example, messenger Ribonucleic acid (mRNA) has recently been used, with great effect, in vaccines to instruct the human body to make specific proteins. When designed correctly, these proteins can subsequently trigger the immune system to create antibodies to protect patients from viruses. In this example, the body itself is used as the “factory” to create proteins in order to generate a specific response out of the acquired immune system. Of course, all biological research is not based on working with humans or other animals and recent work has sought to replace the “factory” in the above example with infrastructure that more closely resembles typical preconceived notions of what factories are.

Today there are two specific areas of interest in which The U.S. Government is supporting and exploring research via separate MIIs run out of the Office of the Under Secretary of Defense’s (OUSD’s) Manufacturing Technologies (ManTech) office:

- a. **BioFabUSA** – focuses on the scalable, consistent, and cost-effective manufacture human cells, tissues, and organs.
- b. **BioMade** – focuses on the creation of bioindustrial solutions for materials such as synthetic rubber.

When creating any new manufacturing capability, process control is required to develop a robust, repeatable, and reliable solution. This depends not only on being able to carefully tailor and control the process but also to better understand and optimize it. To aid such undertakings, myriad measurements and diagnostic tools help to equip scientists and engineers with the most accurate and actionable information possible. In addition to traditional measurements of things such as temperature and pressure, insight into the chemical processes, as they unfold, would help these Bio-related manufacturing activities rapidly advance and understand their manufacturing capabilities. As a result, the availability of a compact sensor solution able to provide insight into the concentration of proteins, metabolites, and other biologically relevant materials would be highly beneficial, not only for medical applications, but also for those seeking to develop and leverage biological processes for the manufacturing/healing of complex systems (via “regenerative medicine”) or for novel ways to create/synthesize materials and chemicals (via Bio Manufacturing).

Program Description: BIO INSPECT seeks proposals focused on creating a biological sensing solution which leverages integrated photonic circuits. This GDP will result in an AIM Photonics’ member working to develop a viable sensor prototype and highlighting its capability and functionality by demonstrating the final product, system, or prototype to the **BioFabUSA** MII. This GDP challenges proposers not only to develop a sensor solution able to identify the concentration of metabolites or proteins with clinical precision, but also to devise a system which can be used to perform in-situ, “real-time,” measurements.

Program Structure: BIO INSPECT is an 18-month single-phase, single technical area, GDP under AIM Photonics.

Technical Area(s): BIO INSPECT is comprised of a single Technical Area for which proposals are sought which will result in the creation of a prototype system able to perform measurements of relevant constituents such as metabolites and proteins. While interest exists for solutions that would better equip both **BioFabUSA** and **BioMade** with enhanced diagnostic capabilities, to focus the current project call, efforts related to medical applications serve as the focus. There is, however, the expectation that future work could leverage any capabilities developed under this project to address other applications (albeit such work may require additional non-recurring engineering costs to develop a solution to sense different constituents of interest). Therefore, while still generally applicable to **BioMade**, the remainder of this technical area will devote its focus more on topics of greater interest to the **BioFabUSA** MII.

BioFabUSA focuses on regenerative medicine, a field which seeks to develop new methodologies and treatments to heal organs and tissues that are defective, diseased, or in other ways damaged (see <https://www.armiusa.org/> for additional detail). The longer-term objectives for researchers working in this field would be to develop solutions to prolong and improve the quality of life for patients that are living with what have historically been debilitating conditions. The statistics here are staggering. For example, by 2030 there are predicted to be more than 550 million people living with diabetes [1]. Another example is chronic renal failure in kidneys which degrades quality of life and mandates more than 2 million patients undergo dialysis to prolong their life while ~10% or more of the world's population suffers from chronic kidney disease [2]. Here regenerative medicine offers perhaps the best hope to provide a substitute for dialysis [3].

Most of the Photonic Integrated Circuit (PIC)-based sensor research conducted to date has focused on one-time measurements of things such as COVID-19, Insulin levels, specific chemicals, etc. This GDP challenges researchers to make a series of measurements of significant interest to those working in bio manufacturing while also devising solutions able to provide many measurements without human intervention. To help focus this GDP we selected a specific example for proposers to consider addressing: the creation of stem-cell based β (SC- β) cells after Ref. [4]. While proposers can focus on other **BioFabUSA**-relevant differentiation protocols, they would need to be similar in complexity. This will not only ensure work undertaken within this GDP is of broad interest to **BioFabUSA**, but also to ensure all efforts would be taking on similarly difficult objectives.

Using this example, this GDP focuses on a recently reported differentiation protocol to develop SC- β cells to help develop an alternative treatment/solution for those living with diabetes. In Ref. [4] a specific differentiation protocol is carried out to generate SC- β cells as depicted in Fig. 1.

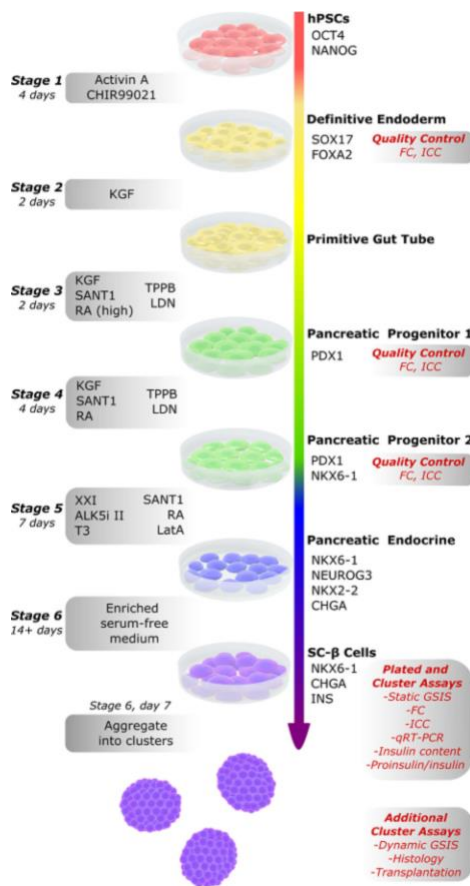


Figure 1: Figure highlighting one differentiation methodology used to develop stem-cell based β (SC- β) cells after Ref. [4]. Here the overall procedure has been broken up into multiple stages which last different periods of time (as noted) and require different inputs to ensure the successful development and conclusion of each stage. Because of the complexity associated with measuring the development of the SC- β cells, the careful measurement of the inputs represents the focus of this GDP.

The example differentiation protocol noted here requires several inputs which are detailed in Table 1. In lieu of a direct measurement of the output of each phase (something that is currently felt to be too complex an objective for this GDP) a diagnostic sensor able to measure the inputs has been determined to be a worthy goal for this GDP.

Media Component	Type	Reference
Activin A	Protein	R&D Systems, 338-AC
Keratinocyte Growth Factor/FGF-7	Protein	Peptotech, AF-100-19
bFGF/FGF-2 (basic Fibroblast Growth Factor)	Protein	Stemcell Technologies, 78003
Chir99021	Metabolite/Small Molecule	Stemgent, 04-0004
LDN193189	Metabolite/Small Molecule	Stemgent, 04-0074
TPPB	Metabolite/Small Molecule	Tocris, 5343

Retinoic Acid (RA)	Metabolite/Small Molecule	MilliporeSigma, R2625
SANT1	Metabolite/Small Molecule	MilliporeSigma, S4572
ALK5i II	Metabolite/Small Molecule	Enzo Life Sciences, ALX-270-445-M005
L-3,3',5-Triiodothyronine (T3)	Metabolite/Small Molecule	MilliporeSigma, 64245
γ-Secretase Inhibitor XXI, Compound E	Metabolite/Small Molecule	MilliporeSigma, 565790
Latrunculin A (LatA)	Metabolite/Small Molecule	Cayman Chemical,10010630

Table 1: Proposed Proteins and Metabolites to be targeted under this GDP.

The preceding discussion introduced a specific differentiation protocol to focus the proposed work under this GDP. As noted above, proposers can identify a comparable differentiation protocol if it is better aligned with their expertise, prior work, and/or commercial interests, provided it is similar in complexity (e.g. requires the identification of multiple proteins etc.). Note: If a different differentiation protocol is proposed its relevance to regenerative medicine would need to be introduced and discussed. Regardless of the targeted differentiation protocol, all proposers will be evaluated on their proposed solution’s ability to develop a system that can address the threshold metrics found in Table 2. The most compelling proposals will seek to address not only the threshold metrics but also the goals found in Table 2. While this effort seeks a sensor able to address the threshold metrics noted in this table, a solution able to address the goals would have wider applicability and proposals should comment on how they envision they could address the goals even if that would require future work and fall outside of what could be accomplished under their proposed GDP.

Metric	Threshold	Goal	Units
Minimum Inputs Sensed	4	12	Number of Different Inputs
Sample Volume	< 100	10	μL/Measurement
Volume Lost	< 10	1	μL/Measurement
Samples Required	> 10	1,000	Samples/run
Sample Rate	1	60	Samples/hour
Sample Sensitivity	2	0.1	ng/ml
Analysis Time	1,000	50	Seconds
System Size*	30U	< 5U	Rack Units
System Deliverable	60-day loan	Transfer	N/A

Table 2: Targeted metrics for a successful sensor system under this GDP. *Note: this applies to the “bulk” system. It does not apply to capturing the overall volume associated with interfacing the proposed solution with a specific **BioFabUSA** related differentiation protocol.

To meet these objectives, it is anticipated that proposers would need to develop one or more customized PIC designs, get those designs fabricated by AIM Photonics, functionalize the PICs if/as needed, package the PICs, and interface the resulting sensor with a laser, tunable laser, or other light source. The system would then need to collect and process a signal using some detection methodology and interface these measurements with a computer or other intelligent machine that is able to analyze the samples with the

specificity desired and store and/or display the data back to **BioFabUSA** researchers. While this already presents a challenge, the requirement to take multiple samples without human intervention adds another level of complexity to the effort.

Since this is a research effort there is no need to develop a final commercial-ready prototype and there is not a stringent metric on the size and no requirements on the weight or power consumption. As a consequence, systems can be developed which take advantage of bulky commercial off-the-shelf components (e.g. a tunable laser) provided they can be interfaced to capture useful data. Most of metrics are felt to be clear however additional comment is provided here to avoid any confusion.

Minimum Inputs Sensed: The number of different differentiation protocol inputs (from Table 1 or equivalent) able to be sensed by the proposed solution.

Sample Volume: Refers to the volume of material that can be used by the sensor to make a single measurement.

Volume Lost: Refers to the volume of material that can be consumed during a single measurement.

Samples Required: Refers to the number of samples the overall system can take, while meeting the other metrics, before any human intervention is required.

Sample Rate: Refers to how frequently samples can be taken.

Sample Sensitivity: Since this effort seeks to create a sensing capability the sensitivity and accuracy of that sensor is important and is captured here. The numbers provided in the table relate to the strength of the samples added to the differentiation protocol to drive its progression while ensuring meaningful data can be collected.

Analysis Time: This refers to how long the system needs to analyze the data once it is acquired. We note that the sample rate will be limited by the sensor while the analysis time relates to the overall system which interrogates the actual sensor. As a result, these numbers can be drastically different depending on the overall system methodology used etc.

System Deliverable: Denotes how long the proposer should be prepared to loan the system developed under this effort to **BioFabUSA** for testing.

System Size: Denotes the size for the sensor solution in standard “rack units”.

Scope:

This effort includes all activities focused on further developing biological sensors and sensor solutions using PICs. This includes work needed to ensure that the recipients of any hardware have sufficient training/knowledge on how to use the resulting prototype(s).

Tasks/Technical Requirements:

The proposer or proposing team must clearly define the tasks and methods to be utilized to address the threshold metrics associated with this project call. These tasks and the associated deliverables should be clearly stated and must incrementally lead toward the creation of a PIC-based sensing capability. Tasks fall to the discretion of the proposer but are currently envisioned to include:

PIC Sensor Design, Fabrication, and Testing — to include not only design and testing but any functionalization work.

System Design, Construction, and Testing — to include the creation of the overall system topology, PIC interacting, PIC packaging, some form of interrogator, and system testing.

System Delivery — to capture the delivery of a functional prototype as noted in the Deliverable section below.

Training — Ideally any prototype developed under this effort would be almost turnkey. However, this is an aggressive effort and so while it is hoped that minimal hands-on training would be needed any training will be as proposed.

The proposers should provide a compelling approach to address the threshold metrics and, whenever possible, proposers should discuss how they would address not only the threshold metrics, but the overall goals found in Table 2. Compelling proposals will highlight any unique capabilities held by the proposing team and any relevant prior work which would speak to their ability to perform the work and help to establish the level of risk associated with their proposal.

Deliverables:

BIO INSPECT awardees will be required to:

1. Host a kickoff meeting with AIM Photonics, the government, and a representative from BioFabUSA after the award of a Project Award Agreement (PAA).
2. Provide quarterly reports summarizing the work conducted during the prior quarter of the effort.
3. Hold quarterly review meetings summarizing the work conducted during the prior quarter of the effort. Note: AIM Photonics runs quarterly review meetings that would be an ideal venue for these review meetings and participating in these meetings is the preferred way to meet this requirement. However, if concerns over proprietary information exist, additional accommodations may be requested but should be discussed in any proposal.
4. Submit a final report summarizing the work and accomplishments made under the effort.
5. Provide any of the following if/when applicable: journal papers, patents, success stories, any news coverage related to work associated with this effort.
6. Deliver hardware as noted below.

BIO INSPECT will result in the creation of at least one prototype system addressing the sensing of the items listed in Table 1 while satisfying the metrics found in Table 2. This system will be loaned* to BioFabUSA for testing at the end of the GDP for a period of at least 60 days.

This GDP involves both AIM Photonics and **BioFabUSA** MII and can be viewed as a joint Institute project. Nevertheless, because this effort does not mandate intense collaboration between members of both MIIs, and instead focuses on creating a new capability that would benefit **BioFabUSA**, **BioFabUSA** has the role of an end user in this effort. While it may prove advantageous for other work, this does not require the GDP participant join, or be a member of, the **BioFabUSA** MII.



That said, the proposer must be willing to provide at least one prototype system to **BioFabUSA** at the conclusion of this effort. The hardware deliverable shall be provided **BioFabUSA** via:

Dr. Tom Bollenbach
CTO, Advanced Regenerative Manufacturing Institute
400 Commercial Street
Manchester, NH 03101
tbollenbach@armiusa.org

*Note: AIM Photonics and the Government sponsor are aware of the cost of the equipment needed to deliver a functional system and the current funding available to support this GDP. Therefore, to keep the effort focused on technical capability, while not incurring excessive costs, it has been determined to be sufficient to provide a prototype system to **BioFabUSA** for on-site testing for a period of no less than 60 days. This will enable **BioFabUSA** to gain some experience working with the prototype system but will not require the proposing teams purchase excessive contractor acquired property (CAP) and they would obtain their hardware back.

Government Furnished Equipment, Property, or Information:

No Government Furnished Equipment, Property, or Information is envisioned to be provided under this effort.

2. Proposal Preparation and Submission

2.a Required Forms and Documents: Technical Volume

Proposers are recommended to use the Project Proposal Template which accompanies this call for proposals to facilitate proposal preparation. This document provides a template that adheres to the guidance set forth in this document and contains additional information. All proposals must be submitted using either MSWord or *.pdf format. Proposals submitted against this topic call must be limited to 25 pages or fewer. **Note:** neither the cover page, any references included at the end of the proposal, nor a section that discusses how CUI or export controlled information will be handled (if/when applicable or required) count against this page limit. Any documents received whose technical proposal section exceeds this page count will have their content truncated by the administrative POC before they are distributed for review.

The technical volume must include a discussion of how the proposer intends to address the overall objectives associated with this call for proposals. In addition to any background information and a discussion of the technical approach to be undertaken the proposal must also include a proposed statement of work as delineated in the Project Proposal Template.

2.b Required Forms and Documents: Cost Volume

Proposers must complete the Project Budget Estimator which accompanies this call for proposals and is provided as a *.xlsx document. While this documentation is sufficient for the initial review of proposals (see Section 3 below) additional information seeking to substantiate things such as rates etc. may be required by the government before any down-selected effort can be awarded. Additional information is provided below on each funding request category:

Personnel-Fringe (Labor): Capture all costs associated with the anticipated labor required to perform this work. This should include a breakout in hours or by % full-time equivalent (FTE) and by job type of the individuals proposed to support the effort.

Equipment: Equipment* purchases are not envisioned by the government under this effort but, may be approved if adequately justified. Note that any equipment purchased by a company would become Government Furnished Property at the end of the effort and would need to be delivered back to the government. Any effort that envisions an equipment need must provide a justification for why such an item is required and why this need cannot be met any other way (to include renting the item).

*Note: for the purposes of this opportunity “Equipment” is defined as any item with a cost > \$5,000 that has a durable nature and is not consumed or damaged in performing the proposed work. As an example: function generators, oscilloscopes, and voltage sources are obvious equipment items. Items such as lensed fibers and microwave probes (which often degrade with use) can be viewed as material items if properly justified.



Supplies (Materials): List all requested materials purchases required to support this work. A justification must be provided for all purchases. Any items that could be viewed as equipment but are felt to be material by the proposing team should include the rationale for such a determination.

Travel: Capture all anticipated travel required to support the proposed effort. In so doing note that it is anticipated that award recipients would participate in one in-person AIM Photonics meeting (the AIM Photonics Members Meeting) per year. These meetings typically alternate between the East and West Coast. For budgeting purposes, it is recommended that locations of Santa Barbara, CA; Rochester, NY; and Boston, MA are assumed. Additional travel, e.g. related to visiting proposed team members, can be included but must be justified.

Contractual: Include the costs associated with all proposed sub recipients, subcontractors, and/or consultants broken down by expenditure type.

Other Miscellaneous: Services provided by AIM Photonics such as MPW or TAP services are to be included within the other cost category. The cost of MPW offerings can be found at the following web address: <https://www.aimphotonics.com/mpw-pricing>. For TAP services cost proposers are directed to <https://www.aimphotonics.com/tap>. Other direct costs can also include things such as certain costs related to graduate students, software licenses, or service agreements.

Indirect Costs: The indirect cost base must be shown as a calculation identifying which expenditures are included. A copy of an indirect rate agreement must be provided to AIM Photonics or the Government in cases where proprietary information is included. If an indirect rate agreement is not available, the 10% de minimis indirect cost rate may be applicable.

Flow of Funds: Funds will flow from the Government to AIM Photonics via Cooperative Agreement FA8650-21-2-1000. AIM Photonics will then issue a PAA to the awardee. The awardee will be expected to pay all project costs from these funds including any AIM Photonics' related multi-project wafer costs or any costs associated with test assembly and packaging. All costs must be included in the proposal budget and be budgeted in the year the costs are incurred. Only in cases where information cannot be shared directly with AIM Photonics (for example if ITAR work is involved), AIM Photonics may pay project participants directly only after AIM Photonics receives an "Approval to Pay" notice from the Government funding agent however this would be clarified prior to any PAA and is not anticipated under this GDP.

Cost Match Requirement: No specific cost matching requirement has been identified for this project however cost matching is always desirable, and proposers are encouraged to propose cost matching whenever possible. Any cost matching must be from non-Federal funding sources. Please note that quantity and quality of the cost match is not a strict requirement for this GDP but will be considered as



part of the evaluation process. Any cost matching may be eligible to be applied to a proposer's AIM Photonics membership fee but should be clarified with AIM Photonics ahead of time.

Period of Performance: A 18-month effort is anticipated for this project with an estimated start date of **1 September 2024**, and a project conclusion date of **28 February 2026**.

Questions: Questions regarding this topic should be submitted to the Administrative POC before **May 28, 2024**. The question(s) will be distributed to the appropriate person for a response. The questions and their answers will then be provided to all potential proposers by posting them on the **AIM Photonics** website under the page associated with this project call.

Proposer Eligibility

To address the objectives of this GDP, AIM Photonics strongly encourages proposers to develop teams which enable proposals that build on the unique capabilities of the team members and offer the best combination of performance, cost, and timeline. AIM Photonics will recognize team arrangements provided that:

- The lead proposer and all participating organizations are or agree to become members of AIM Photonics prior to the project being awarded. To be eligible for an award, participating organizations, of a proposal team, must be Full Active members of AIM Photonics prior to the commencement of the project. **Note: To avoid extensive delays in commencing the project, a grace period of 1 month after the tentative award will be given to become an AIM Photonics member. After this time the Government/AIM Photonics reserves the right to withdraw its tentative award selection and make an award to a different proposer (who responded to the original solicitation).** Information on how to join AIM Photonics is available at: <https://www.aimphotonics.com/become-a-member>. Any cost match incurred by each organization participating in this project may be able to be applied towards the membership of that organization but should be discussed with AIM Photonics ahead of time.
- Proposal team arrangements must be identified and fully disclosed in the proposal.
- The lead proposer is fully responsible for all project and subcontract performance, reporting requirements, and budget execution.
- When proposing, note that vendors and organizations providing services (e.g. machine shops) to the lead proposer are not required to be members of AIM Photonics.
- Proposing teams acknowledge that any reliability information from this project will be shared with AIM Photonics members in accordance with the AIM Photonics Membership Agreement and may also be used to focus future projects.
- All proposal participants acknowledge that any intellectual property (IP) generated within this project will be available to the Government at no cost for both developmental and production purposes, while any process developments that result from this effort are anticipated to be made available to all AIM Photonics members. Should any IP generated under this effort be used for commercial (non-Government) purposes, licensing from the IP owner will be required if applicable.

- While this call is open to all Full Active members of AIM Photonics, the government funds available to support this activity require the effort address the creation of a more vibrant US-based PIC ecosystem and the creation of US capabilities in this technology sector. Any team proposing to include foreign organizations would be required to justify why no US-based capabilities exist to meet the objectives AND how the collaboration with the proposed foreign team member would advance the objectives of AIM Photonics beyond what would be possible teaming up with a US-based organization.
- Requests for a Fundamental Research Exemption (FREs) by some academic or not-for-profit organizations. The proposed effort will be funded with Advanced Technology Development (6.3) funds and focus on the creation of one or more prototype systems. Nevertheless, if a proposing organization seeks a PAA that would be awarded as fundamental research a justification must be provided, and accepted, as to why the work is consistent with fundamental research.
- Should any Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), and/or Controlled Unclassified Information (CUI) restricted work or information be involved in the contemplated effort, the proposal must identify how any/all such information will be protected, per the regulations which govern it in an Appendix (which does not count against the overall page count).
 - **Note 1:** At this time AIM Photonics is unable to accept proposals that contain ITAR information. Should the proposed effort itself involve such information it may still be eligible for submission but would require prior coordination. In such cases, please contact the Administrative POC as soon as possible.
 - **Note 2:** If proposals involve EAR or CUI information the proposer must coordinate this with AIM Photonics ahead of time to ensure the proposal is handled in accordance with the associated regulations (e.g. transmitted via encrypted means and only accessed/stored on a NIST 800-171 compliant IT system/network).

All project team members must sign an agreement with the lead proposer, obligating them to their agreed project role, cost match, and the flow-down requirements of the over-arching contract before any awards will be made.

Proposal Submission

Proposals must be submitted to the Administrative POC noted in Section 1 of the call for proposal prior to the submission deadline. As noted in Section 3, PAAs will be based upon the most responsive proposal(s) whose offer is the most advantageous in terms of evaluation criteria (see below).

As with all GDP project calls, AIM Photonics reserves the right to:

- Reject any or all offers and discontinue this project call process without obligation or liability to any potential proposer.
- Accept proposals other than the lowest price.
- Award a contract to an alternate recipient should the originally selected proposal originate from a non-AIM Photonics member who is either unwilling or unable to sign up as an AIM Photonics member within a reasonable time frame (1 month).



Export-Controlled Technologies

Should any of the information used/generated from this project contain technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., Sec 2751, et seq.) and/or the Export Administration Act of 1979 as amended Title 50 U.S.C., App. 4201 et seq) this must be clearly indicated on the cover page of subsequent communications with AIM Photonics and the Government. At the present time ITAR-controlled information cannot be communicated to AIM Photonics. Violations of these export laws are subject to severe criminal penalties. The proposer must be International Traffic in Arms Regulations (ITAR) compliant to handle and protect ITAR protected technical information needed to conduct and generated by this project. Due to export controls, foreign persons as defined by the U.S. Department of State, under Title 22, Foreign Relation, section 120.16, are prohibited from handling information that is deemed ITAR on this project.

3. Evaluation Criteria and Review Process

Introduction: As a Government Directed Project, all proposals will be subjected to a two-tier review process. All proposals received by the published due date will be reviewed by the Administrative POC for compliance and then internally reviewed within AIM Photonics. AIM Photonics will then forward only those proposals that were down selected by this process (those recommended for funding by AIM) on to the government for a formal evaluation. This process will result in a contract modification to the AIM Photonics' Cooperative Agreement which will provide funding for those proposals (via AIM Photonics' PAAs) that have been approved. Until such a contract modification occurs, any proposals selected for funding by AIM Photonics must be understood to represent AIM's recommendations and not a guarantee of funding or funding at the level requested.

All proposals submitted to AIM Photonics before the published deadline will be evaluated by an independent review committee which will be convened specifically to address the review of proposals associated with this opportunity. This group of 3-to-6 individuals will be comprised of representatives from the RF SUNY, the Government, and the AIM Photonics ecosystem. The reviewers will be selected based on their background, expertise, lack of conflict of interest (e.g. they cannot have submitted a proposal to this topic), willingness to participate, and agreement to hold the proposals, any intellectual property or background intellectual property in confidence. Aside from the administrative POC associated with this effort, proposals will only be shared with the review committee.

The evaluated strengths and weaknesses found in each category will be used to facilitate discussion and prioritization of proposal impact, including technical strengths and weaknesses, and suitability of goals and the project team. For this funding opportunity proposals will be evaluated against the evaluation criteria noted below.

NOTE: All proposals will be treated as confidential. Proposals not selected for funding will not be released or discussed outside of the review team. AIM Photonics and/or the government sponsor may use some of the non-proprietary information from the proposals selected for funding to describe the planned work to be done under this GDP.

Evaluation Criteria:

- 1. Overall Technical Merit:** The proposed technical approach is found to be innovative, feasible, achievable, and complete. The proposed technical team has the expertise and experience to accomplish the proposed tasks. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that the final program outcome is anticipated to achieve the stated objectives. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

2. Potential Contribution to the Capabilities of AIM Photonics: The proposer clearly demonstrates its plans and capabilities to contribute to AIM Photonics, U.S. national security, and U.S. technological capabilities in general. The evaluation may consider the proposer's history of transitioning or plans to transition technologies to foreign governments or to companies that are foreign owned, controlled, or influenced. The evaluation will also consider the proposer's plans and capabilities for the results of their proposed program to benefit the overall AIM Photonics ecosystem. This can occur several ways to include the proposed effort resulting in improved AIM capabilities and/or via a solution closer to a product which would result in patronage of AIM Photonics in the future and, in so doing, help to address AIM Photonics' sustainability objectives. In addition, the evaluation will take into consideration the extent to which any proposed intellectual property (IP) rights would limit the impact on AIM Photonics and its associated ecosystem.

Note: To maximize the benefit associated with this funding opportunity for the AIM Photonics overall ecosystem, when all things are found to be equal and there are not concerns associated with undue risk, new work will be prioritized over teams with existing funding/sponsorship seeking to address very similar objectives.

3. The Proposers Capabilities and Related Experience: The proposer's prior experience in similar efforts must clearly demonstrate the ability to perform the proposed work as this applies not only to the proposed technical performance but also addresses their ability to do this work within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer and by key members of the proposed team in this area can be described to help establish this.

4. Cost Realism: The proposed costs are realistic for the technical and management approach and accurately reflect the technical goals and objectives of the solicitation. The proposed costs are consistent with the proposer's Statement of Work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed sub awardees are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates).

* **Cost Matching:** Since cost matching is not mandated under this GDP, it will not be evaluated as its own category. Instead, cost matching will be considered as a strength under evaluation criteria 2, 3, and 4 as it bolsters those existing activities.

Evaluation Determinations: For each evaluation criteria each proposal will use the following rating definitions in the evaluation of the proposals.

- Outstanding - Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
- Good - Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
- Acceptable - Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
- Marginal - Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
- Unacceptable - Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

4. References

[1] L. Yuen, *et al.*, “Projections if the prevalence of hypoglycemia in pregnancy in 2019 and beyond: Results from the international diabetes federation diabetes atlas, 9th edition” *Diabetes Res Clin Pract.* 2019, 157: 107841.

[2] <https://www.kidney.org/kidneydisease/global-facts-about-kidney-disease>

[3] T. Yokoo, A. Fukui, and E. Kobayashi, “Application of Regenerative Medicine for Kidney Diseases,” *Organogenesis*, Vol 3 Issues 1 (2007).

[4] N. J. Hoglebe, K. G. Maxwell, P. Augsornworawat, and J. R. Millman, “Generation of insulin-producing pancreatic β cells from multiple human stem cell lines,” *Nat. Protocols* **16**, 4109-4143 (2021).