

PROJECT CALL



Sustainable Logistics for Advanced Manufacturing (SLAM)

MAY 2024



Table of Contents

1. Introduction to BioMADE	2
2. Project Call Overview and Focus Areas	3
3. Guidelines for Successful Proposals	5
4. Proposal Submission Process and Timeline.....	9
5. Proposal Evaluation Criteria	10
6. Reporting and Invoicing Requirements After Award	12
7. Contact Information	12
Appendix A: Bioindustrial Manufacturing Readiness Levels	13
Appendix B: Safety, Security, Sustainability, and Social Responsibility (4S)	15
Appendix C: Cost Share Guidelines.....	17

1. Introduction to BioMADE

BioMADE is a Manufacturing Innovation Institute (MII) sponsored by the U.S. Department of Defense (DoD) with a vision to build a sustainable, domestic, end-to-end bioindustrial manufacturing ecosystem. Our mission is to enable domestic bioindustrial manufacturing, develop technologies to enhance U.S. bioindustrial competitiveness, de-risk investment in relevant infrastructure, and expand the biomanufacturing workforce to realize the economic promise of industrial biotechnology.

BioMADE is building a robust bioindustrial manufacturing ecosystem and has a national network of over 280 members spanning industry, academia, and non-profit organizations. BioMADE's primary aim is to accelerate the commercialization of new bioindustrial manufacturing technologies by guiding them through the pilot-scale Biomanufacturing Readiness Levels (BioMRLs) 4-7 ([Smanski et al 2022](#)). The direct outcome of these efforts will be to develop and expand industrial and defense-related biomanufacturing in the United States. BioMADE will drive advances by leveraging DoD funds and in-kind support from member organizations to complete projects critical to domestic bioindustrial manufacturing.

BioMADE is committed to promoting and advancing greater diversity, equity, and inclusion within the biomanufacturing field. BioMADE seeks partners who have a demonstrated ability to achieve biomanufacturing innovation and a commitment to advancing opportunities that foster a diverse, inclusive, and equitable workforce. BioMADE partners are expected to demonstrate their commitment and strategy for achieving a diverse workforce through their proposed implementation plan. A core feature of BioMADE's mission is advancing and integrating the pillars of Safety, Security, Sustainability, and Social Responsibility (4S) throughout its work, detailed in [Appendix B](#).

Together with the DoD, BioMADE is interested in accelerating technology development related to mitigating the causes and consequences of global climate change, particularly when these intersect with bioindustrial manufacturing. In summer 2022, BioMADE solicited concepts from our member organizations. The Sustainable Logistics for Advanced Manufacturing (SLAM) Project Call focuses on innovation priority areas identified in these submitted concepts. Projects funded through this Project Call will require 1:1 cost share but be treated as Agency Driven Projects that fall under the invention sharing requirements in the Intellectual Property Management Plan, see additional details below. This packet describes the purpose, process, and eligibility criteria for the SLAM Project Call.

2. Project Call Overview and Focus Areas

Program Overview

Bioindustrial manufacturing offers the ability to create new molecules and materials with unique and desirable physicochemical properties, as well as cost-competitive drop-in replacements for petrochemicals with well-established markets. Further, it can leverage carbon-neutral or carbon-negative processes, thus mitigating the climate impact of manufacturing. Establishing the commercial viability of these product-markets is high risk, because vetting new material in an individual application can require 10-100 kg of material or more for testing and evaluation.

Successful proposals will describe projects with the potential to mitigate the causes or consequences of global climate change. Proposals must highlight their technology and a DoD-relevant use-case of the innovation in one of the Project Call focus areas.

The focus areas are:

- **Sustainable food production**
- **Converting waste to bioproducts**
- **Carbon capture technologies**
- **Lowering the resource requirements for processing steps**
- **Mitigating environmental impacts**

Successful proposals will focus on processes or technologies within BioMRLs 4-7 ([Appendix A](#)). Proposers must provide justification for the current MRL status and description of how the project will advance the MRL status for the given bioproduct or process.

Focus Areas

In summer 2022, BioMADE solicited concept ideas that would mitigate the causes or consequences of climate change. Submitted concepts were reviewed by the DoD Government Program Management Team to assess their relevance to advancing the DoD mission. Below is a summary description of research and development activities that have been approved as appropriate for this funding call. Submitters will be asked to identify the focus area relevant to their proposal when submitting their proposal. BioMADE encourages applicants to discuss their proposed idea with a BioMADE Program Manager prior to submission. Please contact proposals@biomade.org to schedule a meeting.

1. Sustainable food production

Innovations in food production that reduce the CO₂ footprint of food production at and/or transport to DoD operational environments are solicited. These could include, but are not limited to, production of nutrient-dense military rations via fermentation processes, utilizing

one carbon molecule (C1) feedstocks for food production, and novel cell culture methods suitable for the production of cultivated meat/protein.

2. Converting waste to bioproducts

Valorizing waste streams by directly using them as feedstocks for bioindustrial manufacturing is within scope for this project call. Bioproducts produced should have relevant applications within the DoD, and higher priority will be given to projects that will develop technologies to displace current manufacturing pipelines with large carbon footprints.

3. Carbon capture technologies

Processes that convert greenhouse gases including CO₂ or methane into bioproducts that are of industrial use and are recalcitrant to degradation are encouraged through this project call. Priority will be given to projects that produce materials used in large quantities. These could include but are not limited to biocement, biochar, and bioplastics.

4. Lowering the resource requirements for processing steps

Bioindustrial manufacturing often relies on unit operations that require substantial energy or utility inputs. Projects that develop innovations in scale-up production or downstream processing steps that substantially reduce these resource requirements to improve the net sustainability of biomanufacturing are eligible for this funding call. For example, downstream processing steps that replace energy-intensive distillation processes with separation methods that work well in ambient temperatures. For projects in this category, proposers must provide preliminary results or modeling that quantify the predicted resource savings afforded by their innovation during industrial-scale manufacturing.

5. Mitigating Environmental Impacts

Projects that develop bioproducts useful in mitigating the negative environmental impacts either regionally or globally, are encouraged. Proposers should state in their application the particular region(s) that will benefit from the technology. For example, bioproducts that can be used to prevent or slow coastal erosion, or bioproducts that mitigate the impact of drought or fluctuating weather patterns are encouraged. Innovations that decrease the water footprint of biomanufacturing processes or allow for biomanufacturing using saline or brackish water fit into this category. Higher priority will be given to proposals that outline the specific benefit to DoD interests or operations of the climate change impact mitigation technology.

3. Guidelines for Successful Proposals

The intent with of this Project Call is to solicit proposals that directly address research and development priorities that will have a direct impact on building sustainable logistics for advanced manufacturing. Innovation areas that are within scope for this project call are listed above. Compliant proposals must identify which priority focus area(s) is being addressed (e.g., sustainable production of military rations) and a specific description of the focus area impact realized by successful completion of the project. Projects may address one or multiple areas.

All successful projects will need to include tasks with intermediate BioMRLs 4-7 ([Appendix A](#)). It is acceptable for a project to contain some tasks that contribute fundamental knowledge or specialized measurement or modeling capabilities, but the overall project must focus on advancing an intermediate BioMRL process to a higher level of manufacturing readiness.

A. Eligibility and Membership Requirements

The proposal eligibility requirements are detailed below. Failure to comply with these requirements may result in disqualification of the proposal. Contact BioMADE staff at proposals@biomade.org with questions. Membership inquiries should be directed to membership@biomade.org.

To request an exception to any of the requirements, please complete and submit this [form](#) to proposals@biomade.org at least five (5) business days prior to the proposal submission deadline. Exception requests will be reviewed and approval or denial of any such requests is at BioMADE's discretion.

- The lead submitting organization must be a member in good standing, with a signed membership agreement, at the time of white paper submission (no later than July 1, 2024).
- All partner organization(s) must be members in good standing, with a signed membership agreement at the time of white paper submission (no later than July 1, 2024).
- If an organization is not a current BioMADE member, it will need to return a signed membership agreement to BioMADE by June 28, 2024. This deadline applies to lead and partner organizations.
- To meet the eligibility requirements of being a “member in good standing,” the lead and all partner organizations must be current members, with signed membership agreements and cash membership dues paid in full, at the time of white paper submission (no later than July 1, 2024).
 - *For current term members and renewing members:* If an organization's membership lapses following the white paper submission, following the full proposal submission, or during subaward negotiation, cash membership dues for the membership renewal term must be paid within 15 days of notice or prior to subaward execution (if applicable) – whichever comes first.

- *For new members:* If the organization signs their initial membership agreement less than 15 days prior to white paper submission, the organization has 15 days from the effective date of the initial membership agreement to pay cash membership dues for a proposal to meet the eligibility requirements.
- If the eligibility requirements detailed above are not met, the proposal will not be eligible for further review or consideration.
- The lead organization is responsible for ensuring the membership compliance of their project partners.
- BioMADE encourages the lead organization to contact BioMADE's membership team at membership@biomade.org as soon as it identifies partner organizations that are not current BioMADE members in good standing to allow adequate time to formalize the membership agreement by June 28, 2024.
- The process to formalize the BioMADE Membership Agreement requires that the organization review the BioMADE Membership Terms & Conditions and IP Management Plan, which are community documents that all members agree to, and to complete and return a signed copy of the membership agreement. Any organizations, lead or partners, that are not current BioMADE members in good standing should allow adequate time for their organization's internal process to review and sign the membership agreement and return it to BioMADE for full execution.
- All project participants must agree to remain members in good standing through the life of the project.
- White papers must meet the minimum requirements of this project call to be considered eligible for full proposal consideration.
- Submitted proposals must be responsive to focus area(s) of the Project Call and clearly indicate DoD relevance.
- All submitted materials must be completed in full on the provided forms and/or templates; including, but not limited to, the Budget Template, Subrecipient Profile Questionnaire, Current and Pending Support, Statement of Work (SOW), Project Timeline, and Technical Narrative.
- Proposals must be submitted via BioMADE's Proposal Submission Platform on the [Member Portal](#)
- BioMADE Members in the Training Tier are not eligible to lead a Tech project and/or contribute to technology development efforts. Training tier members may participate in a Tech project by contributing in EWD-related capacities.

Find more details about eligibility in the [FAQ section on BioMADE's website](#).

B. Funding Levels

BioMADE desires to fund collaborative projects that bring together team members from multiple organizations to address the project call focus areas. Total project costs including funded and cost-share contributions are generally between \$500,000 and \$2,000,000; however, variations outside of that range will be considered with justification. BioMADE generally funds projects with a period of performance of 18-24 months. Longer project periods will only be considered with sufficient justification. Budget

requests and timelines should match the scope of the proposed project and have a clear justification based on the impact of the proposed work. White papers must meet the minimum requirements of this call to be eligible for full proposal consideration. BioMADE reserves the right to make one, multiple, or no awards for this solicitation. BioMADE cannot fund every proposal. BioMADE reserves the right to review unfunded proposals and reevaluate funding decisions, should availability of funds or research priorities change.

C. Cost Share Requirements

BioMADE funded projects must include a minimum of 1:1 cost share from awarded teams. Cost Share of greater than 1:1 is strongly encouraged and will be judged favorably in review. Cost sharing includes cash and third-party in-kind contributions such as equipment use, facilities, and labor. State and Local funds, as well as private industry funding, can be used as cost share; however, federal funds or funds used for cost share for any other effort may not. Cost share can be divided between partnering entities at their discretion. More detailed cost share guidelines are attached in [Appendix C](#).

D. Indirect Cost Rates

Organizations with a federally negotiated Indirect Cost (IDC) rate must use this rate in their proposed budgets. BioMADE encourages organizations without a current federally negotiated IDC to negotiate an IDC rate directly with BioMADE. If approved, this rate is applicable to BioMADE projects for a period of two years. IDC rate negotiations must be complete at the time of full proposal submission. If an organization does not have a negotiated rate, a 10% de minimis rate is allowable. (Please note: If a federal rate is negotiated after a rate is approved by BioMADE, the federally negotiated rate will be used for all future BioMADE projects). If negotiating an IDC rate with BioMADE, a request must be initiated no later than August 14, 2024. Requests made after August 14, 2024 will not be considered. Queries regarding IDC negotiations should be directed to finrequest@biomade.org.

E. Relevance to the Department of Defense

Successful proposals will identify a possible DoD use-case for the technology, process, or bioproduct developed as part of their project. Collaboration with a DoD-related laboratory or testing facility is not a requirement but is allowed under the terms of this project, however work done in DoD labs must come from a separate budget (i.e., it cannot use project funds nor be counted towards project cost-share). Relevance to the DoD is a scoring criterium during white paper and proposal review.

F. Intellectual Property (IP) Policy

Terms for IP generated under this solicitation must be clearly articulated as part of the full proposal submission and proposers are encouraged to include such terms in the white paper proposal submission. This project call is distinct from typical BioMADE Project Calls and funded projects will be treated as “Agency Driven Projects” that do not fall under the invention sharing requirements in the Intellectual Property Management Plan. Specifically, new IP generated on projects funded under this solicitation will

not be accessible to other BioMADE members as described in the IPMP unless the project specifically proposes to share selected IP with the BioMADE community. Project-specific IP considerations will be determined during contracting. Further details on BioMADE's IP policy are found in our Membership Agreement documents, or on the [BioMADE Member Portal](#).

G. Compliance Requirements

To receive funding, project participants must have a Unique Entity Identifier (UEI). Members can register for free at SAM.gov.

H. Cross-Institute Collaboration

BioMADE is one of 17 [Manufacturing Innovation Institutes](#) (MIIs) that span across several manufacturing sectors. Proposals that address intersectional areas between BioMADE and another MII should be highlighted in the full proposal. In such cases, leveraging funding from both Institutes is allowable and encouraged, but cost share requirements and the requirements of collaborating institutions must still be met. For cross-institute collaborations, the proposed work needs to specify distinct projects and clear Statements of Work (assigned to each collaborator) to ensure proper use of federal funding and to prevent redundancies for time and effort reporting. The budget justification must document funds from all sources and how these funds will support distinct lines of work. We strongly encourage members with cross-institute proposals to contact a BioMADE program manager for review and approval prior to submission to ensure that the project meets compliance and guidelines.

I. Team Composition

BioMADE is focused on growing domestic manufacturing capabilities, including industry capacity, workforce development, and socially relevant considerations. The SLAM Project Call is specifically designed to promote projects that combine two or more of these programmatic aspects. Depending on the project focus proposal teams are strongly encouraged to include at least one industry organization, and appropriate academic, government or non-profit partners. International organizations may be eligible to participate, however any team seeking to spend funds outside the U.S. or planning to incorporate foreign organizations as team members are required to discuss the plan and justification with a BioMADE Program Manager prior to submitting a full proposal, as foreign participation requires DoD approval. Details on what additional information will need to be included in the full proposal will be provided at that point.

Letters of Commitment from project partners and Letters of Support from contractors/vendors are required at full proposal stage and are encouraged at white paper stage. These letters indicate the signatory's intent to commit resources to the funded project as specified in the letter, should the proposal be funded. They can also include the partner's rationale for supporting the project and point to the strengths of the organization that could be of value in implementing or sustaining the project.

United States Government entities are not eligible to apply or participate in this Project Call.

4. Proposal Submission Process and Timeline

Concept Summary and Full Proposal Submission

BioMADE will use a two-step solicitation process: a white paper submission followed by invitations to full proposals. Submission of a white paper or full proposal does not guarantee project funding. White papers may be reviewed with DoD SMEs to help ensure DoD relevance. Additionally, proposers should ensure submitted materials are complete and include all requested materials according to instructions to avoid disqualification. Make note of all deadlines, as late submissions will not be accepted. Before submitting a white paper to this call, BioMADE encourages project teams to reach out to a BioMADE Program Manager to discuss project viability and alignment to the mission of the project call. Reach out to proposals@biomade.org with a brief description of your project to schedule a meeting.

Timeline

Key dates for proposal submission and decisions for this SLAM Project Call are as follows:

- **June 3, 2024:** Sustainable Logistics for Advanced Manufacturing (SLAM) Project Call is released
- **June 12, 2024 at 1:00pm CT/11:00 am PT:** Proposer's Day & Teaming webinar
- **July 1, 2024:** White Papers due by 5:00pm PT
- **Week of August 5, 2024:** Notification of advancement or decline to full proposal
- **September 18, 2024:** Full proposals due by 5:00pm PT
- **Week of November 1, 2024:** Notification of funding decision
- **February 2025:** Anticipated start date of projects

Submission of Materials

White papers should be submitted electronically via BioMADE's Proposal Submission Platform. Instructions and templates for submission are provided on the SLAM Project Call page on BioMADE's website, [found here](#), as well as [BioMADE's Member Portal](#). Late submissions will not be considered. Project leads are responsible for collecting details on the budget and cost-share for all proposed team members. If invited to submit a full proposal, submission materials and instructions will be provided at that time. Please contact proposals@biomade.org should any issues with document submission arise, submission instructions and FAQ can be found on the [Member Portal](#).

Proposal Formatting Requirements

White paper materials should be submitted electronically as a .docx file. Pages should be formatted with 1" margins on each side, single spaced, with 11-point minimum Arial font. Smaller font size can be used

in figures and figure legends. White Papers have a 5-page maximum. Supporting materials such as Letters of Support and Letters of Commitment are not included in the page count.

5. Proposal Evaluation Criteria

White Papers

White papers (pre-proposals) will be evaluated on several criteria areas including but not limited to adherence to the project call focus areas, eligibility requirements, the BioMADE mission, and budget and cost share requirements. Detailed scoring criteria is provided below. White papers that are deemed competitive for funding will be invited to submit a full proposal. Invitation to submit a full proposal is dependent on the debrief with the BioMADE Program Manager. Prior to full proposal submission, a BioMADE Program Manager will be made available for up to an hour to meet with the proposers and other key personnel to discuss the approach for the full proposal. An invitation to submit a full proposal does not guarantee funding.

Full Proposals

Full proposals are evaluated by a panel of reviewers and will receive section scores and overall scores based on the criteria listed in the table on the following page. Each proposal will be read and evaluated by multiple reviewers and all reviewers on the panel will discuss each proposal prior to ranking for funding decisions. BioMADE Program Managers will use the proposal ranking to guide funding of projects, but they have the flexibility to recommend projects based on innovation area to maintain a suitable balance of projects in each of BioMADE's program areas.

Confidentiality in Proposal Review

To protect confidential, proprietary, and strategic information of our member organizations, we will have an internal review process for submitted project proposals. All reviewers will be BioMADE staff or government personnel who will protect the confidentiality of proposal content. Proposal information will be restricted to those individuals with a need to know during the review; however, proprietary information should be clearly marked and be limited to the minimum amount necessary to convey the highlights of the technical approach.

Documents submitted in response to this Project Call shall be labeled as "BioMADE and U.S. Government Only; Not for Public or General Member Distribution". This label is already in the provided template. Prior to the proposal decision and announcement to sub-awardees, the identity of the submitters and the content of the proposals will be limited to BioMADE staff and proposal reviewers within the U.S. Government. See more in the Proposal Evaluation section below.

Scoring Criteria

The following scoring criteria will be used to evaluate full proposals. Relative weights of scoring sections are noted in the table below.

Scoring Criteria	
Section (weight)	Scoring Criteria
Fit to BioMADE Mission and Priority Focus Areas (20)	<ul style="list-style-type: none"> Proposal addresses an important problem in bioindustrial manufacturing Proposed solution addresses Technical Innovation area(s) and need identified in the Priority Focus Areas (above) Has Department of Defense relevance Project is clearly and demonstrably in BioMRL 4-7
Personnel, Facilities, Infrastructure and Teamwork (15)	<ul style="list-style-type: none"> Team includes a diverse and relevant set of subject matter expertise with at least one industry partner. Project will clearly synergize to achieve goals that no single member could on their own. Personnel expertise and physical infrastructure selected are appropriate to accomplish project goals. Effective strategy to ensure productive teamwork and collaboration across partnering organizations is provided.
Project Approach (15)	<ul style="list-style-type: none"> Project approach is sound and likely to yield highly applicable and informative results. Project approach incorporates the appropriate tools, technologies, and methods. For manufacturing projects, a process block flow chart is included in the proposal.
Project Schedule and Milestones (15)	<ul style="list-style-type: none"> Schedule and milestones are appropriately scoped to the available time and funds. Periodic milestones are included that demonstrate progress toward project objectives and deliverables. Milestones, objectives and deliverables are SMART (Specific, Measurable, Achievable, Relevant, Timely) such that progress on project can be objectively measured. Timeline demonstrates how integrated programmatic components build on one another.
Impact, Deliverables, and Ecosystem benefit (15)	<ul style="list-style-type: none"> Clear articulation of what the final outcomes will be upon successful completion of the project Clear relevance to DoD Technical approach is sound and likely to yield interpretable results

	<ul style="list-style-type: none"> • Results will be of high impact to the entire field, regardless of what they are (i.e., even negative results would be impactful because of the design of the projects) • Clear articulation of Intellectual Property (IP) that will be generated and made available from completion of the project. Note: While IP sharing is not a formal requirement of this funding opportunity, projects that elect to share IP or articulate a compelling benefit to the biomanufacturing community that will result from their work will be scored favorably.
Safe, Secure, Sustainable, and Socially Responsible (4S) Integration (10)	<ul style="list-style-type: none"> • Proposal clearly articulates an understanding of the 4S aspects of the proposed work and offers insight and funding to 4S program area • Proposal offers mitigation of any 4S concerns
Budget and Cost share (10)	<ul style="list-style-type: none"> • Budget is appropriate and aligned with tasks and deliverables • Value and quality of cost share

6. Reporting and Invoicing Requirements After Award

Project leads are expected to have regularly scheduled calls with their BioMADE Program Manager, as well as submit written monthly reports using provided templates. Due dates for monthly reporting will be established prior to award of funds, and continued project funding is contingent on meeting reporting requirements.

Invoices for cost-reimbursable awards will be due on the 20th of the following month. Invoices must include detailed expenditures broken into budget categories for both the federally funded and cost shared portions of expenses for that month. If cost share detail is not included, invoice payment may be delayed.

Suggested Project Deliverable: Project teams, in collaboration with their BioMADE Program Manager, will provide a description and timeline of how/when project products, deliverables, and learnings will be made available and communicated to BioMADE. Modification of Statements of Work after onset of project funding require review and written approval from the Program Manager.

7. Contact Information

Project Call, Proposal, Eligibility Inquiries: proposals@biomade.org

Membership Inquiries: membership@biomade.org

Indirect Cost Rate Proposal Inquiries: finrequest@biomade.org

Appendix A: Bioindustrial Manufacturing Readiness Levels

The BioMADE Technical Working Group recently published a [formal description of the Bioindustrial Manufacturing Readiness Levels \(BioMRLs\)](#). SLAM projects will focus on BioMRLs 4-7, which correlate with advancing a pilot-scale manufacturing process through at-scale, production-representative environments. Early Research and Development (R&D) efforts (BioMRLs 1-3) focused on metabolic pathway engineering and improvements are not likely to be mature enough to fit into BioMADE's scope. Exceptions may include strain engineering efforts that are specifically tailored to address known issues with Scale-up Production (SUP) or Downstream Processing (DSP).

As part of the proposal, an estimation is required of the project's current and ending BioMRL. A formal manufacturing readiness assessment is not required at this stage, but evidence to support the estimated BioMRL classification is an important part of successful proposals. We encourage proposers to allocate project funds or cost share to perform a rigorous BioMRL assessment of their process as part of the funded research effort. More information on how to perform these assessments can be found at biomrl.org. A description of the MRLs relevant to BioMADE projects follows:

BioMRL3: *Proof-of-concept.* Components of the biomanufacturing process have been proven in a laboratory environment. This includes genetic engineering efforts needed to create strains capable of producing the desired products in titers that support the transition to pilot-scale production (typically in excess of 1 g/L). Methods for the purification and analysis of the product of interest are also required but can rely on lab-scale equipment that is not suitable for larger scale DSP.

BioMRL4: *Independent validation and verification of proof-of-concept.* The proof-of-concept system has been demonstrated in a strain suitable for commercial-scale manufacturing and has been independently reproduced/validated/verified. Additionally, an initial assessment of the manufacturability is complete, including technoeconomic analysis (TEA) and life-cycle analysis (LCA). This assessment should include plans for the scale-up production (SUP) and downstream-processing (DSP) needed to produce sufficient quantities to allow testing and evaluation by downstream stakeholders. These plans incorporate production-relevant environments. Product quality risk and mitigation plans are documented.

BioMRL5: *Demonstration of prototype unit operations in a production relevant environment.* Identification of enabling/critical unit operations is complete. Prototype materials, tooling and test equipment, as well as personnel skills, have been demonstrated empirically for unit operations in a production relevant environment. Scale-up production and downstream processing has been performed at suitable scales to deliver sufficient quantities of end-product to downstream stakeholders for testing and evaluation. The TEA has been refined to assess projected manufacturing cost. A risk management plan to mitigate technical and economic risks is integrated with the manufacturing strategy.

BioMRL6: *Demonstration of a prototype system or subsystem in a production relevant environment.* Manufacturing processes have been selected for the end-to-end manufacturing

pipeline, even if engineering and/or design variables still need to be optimized. Prototype manufacturing processes and technologies, materials, tooling and test equipment, as well as personnel skills, have been demonstrated on systems and/or subsystems in a production relevant environment. The TEA is refined based on system performance and is expanded to include inventory control, production scheduling, plant maintenance and production quality attributes (PQAs). Long-lead and key supply chain elements have been identified and supply chain risk mitigation strategies exist.

BioMRL7: *Demonstration of systems or subsystems in a production representative environment.* Detailed system design is complete. Manufacturing processes and procedures have been demonstrated in a production representative environment. Sufficient quantities of product have been made to test packaging and distribution systems. Unit cost reduction strategies, such as statistical process controls (SPCs), are underway in a production representative environment. Quality assurance of supply chains is in place, and procurement schedules for long-lead elements are established. The manufacturing process is sufficient to support low-level commercial manufacturing.

Appendix B: Safety, Security, Sustainability, and Social Responsibility (4S)

A commitment to incorporating safety, security, sustainability and social responsibility (4S) is part of the fabric of BioMADE. Consequently, proposals for BioMADE projects must address how they will further this mission, by improving safety and security of biological engineering and/or by commitments to sustainability and societal issues in ways beyond revenue or capital growth. Each project proposal is expected to address integration of at least one component of 4S. A portion of the project budget is expected to be dedicated to addressing 4S.

To provide further guidance to BioMADE members as they integrate these 4S components into their work, we have developed the following definitions:

Component	Definition	Application Examples
Safety	Practices, controls, and measures taken to protect people and the environment from harm from biomanufacturing development processes and/or physical products or byproducts. Includes safety of the workplace, consumers, and the general public.	Identify ways in which your project will help improve compliance with existing professional norms and regulations (e.g., including training in safety protocols) and/or will identify areas in need of additional or different guidance.
Security	Measures taken across biomanufacturing sectors including food and agriculture, materials, and energy, to manage potential threats and loss due to theft, misuse, diversion, unauthorized possession of property (including intellectual property) or intentional release of biological risk and/or technology.	Please describe how your proposed work: <ol style="list-style-type: none"> 1. Proactively addresses potential biological or economic security risk, and 2. Impacts the industry or national security in biotechnology.
Sustainability	Measures taken to maintain or improve the long-term sustainability of the environment and economy due to advancing biomanufacturing processes. These include consideration of the impacts of products and processes on the environment, supply chain, as well as local public / consumer acceptance and practices.	Please describe how your proposed work will meet or exceed emerging norms and standards for environmental protection, reduction of greenhouse gases, or development of business models that are adapted to long-term economic accessibility and stability for a wide range of users.
Social Responsibility	A principle that acknowledges the impacts of biomanufacturing on stakeholders with	Please describe your plans for social responsibility as it relates to the execution

	<p>respect to associated benefits, risks, and consequences throughout its value chain. This implies taking actions that optimize positive social outcomes through adherence to ethical standards, including seeking ways to make products and processes that improve societal welfare. Special attention to this commitment includes equitable distribution of benefits and risks and a responsiveness to society's needs and values.</p>	<p>of your project. Examples may include community engagement, whether as education or consultation; or for workforce development that addresses the need for diversity and inclusion; or for creative initiatives to bring open dialogue, perspectives and appreciation of biomanufacturing and economic possibilities to the general public.</p>
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Appendix C: Cost Share Guidelines

Cost share is an important part of BioMADE, which is funded through a Cooperative Agreement with the United States Department of Defense. **Project awardees receiving funds from BioMADE are sub-recipients under the Cooperative Agreement.** This Appendix offers guidance for cost share required by BioMADE funded project awards. Guidance for cost share required as part of BioMADE's annual membership dues may be found on the BioMADE website.

The minimum cost share for BioMADE Institute-funded projects is 1:1. The cost share ratio must be maintained throughout the life of each Institute-funded project, as well as the overall BioMADE program. For a project with a 1:1 cost share ratio, for example: a sub-awardee provided \$250,000 in Institute funded project funds would be required to contribute \$250,000 in cost share, for a total project amount of \$500,000. The 1:1 match can be divided between partnering entities at their discretion but must adhere to Federal guidelines.

Project cost share is a contribution made towards the sub-recipient's project that is beyond the amount funded by BioMADE. Allowable cost share items include costs, such as salaries and equipment, that directly benefit the project. Cost share is used for expenses eligible to be charged to the project but are instead charged to the sub-recipient. Costs that are not allowable to be charged to BioMADE are not allowable for cost sharing. As with costs directly charged to BioMADE, allowable cost share expenses must be reasonable, allocable, and consistent with the terms of the award. Examples of unallowable cost sharing can include items such as alcoholic beverages and facility construction costs.

Eligible cost share must meet all the following criteria: verifiable from sub-recipient records; not from federal funding sources or included as contribution to any other federally-assisted program(s); necessary and reasonable for proper and efficient accomplishment of the project or program objectives; allowable as a direct cost under applicable federal cost principles; and falls within defined cost principles as defined in [2 CFR 200.306](#), and provisions of Chapter I, Subchapter C of Title 32, CFR, "DoD Grant Agreement Regulations" Other than part 33.

A detailed budget of how the funds will be distributed across various cost categories should be provided to allow BioMADE to review/approve any associated costs being used as cost share. The sub-recipient is responsible for providing the total amount and/or source of cost share accepted by the sponsor. Should the actual value, source, or type of cost share change, you will need to contact BioMADE as soon as possible.

Cash and Cash Equivalent Cost Share

Any contribution of funds, services or materials for which the sub-recipient is required to pay cash and which would normally be authorized for reimbursement as a direct or indirect charge to the sub-award. Examples include paying labor (including benefits and direct overhead associated with that labor), acquiring materials and authorized travel. Equipment purchases over \$5,000 require approval by BioMADE. To the extent feasible, volunteer services shall be supported by the same methods used to support the allocability of regular personnel costs. Overhead and General and Administrative costs for project participants are also sources of cash cost share. Only the additional resources or monies spent that will be provided to carry out the current project can be counted. Independent Research and

Development (IR&D) funds may also be used as cost share when provided in direct support of BioMADE. Cash contributions cannot include profit or fee.

In-Kind Cost Share

In-kind cost share may include labor, authorized travel, materials, and equipment. In-Kind Cost Share is defined as the reasonable value of such cost items, loaned/provided equipment, materials or other property used in the performance of BioMADE and the resulting Institute-funded project statement of work. In-kind contributions are sometimes hard to value (such as space or use of equipment and intellectual property). The in-kind value of equipment (including software) cannot exceed its fair market value and must be prorated according to the share of its total use dedicated to carrying out the project. Outreach activities and tech transfer activities can be considered allowable cost share if they are necessary and reasonable for the proper and efficient accomplishment of project or program objectives (i.e., contained in a Statement of Work). The in-kind value of space (including land or buildings) cannot exceed its fair rental value and must be prorated according to the share of its total use dedicated to carrying out the project. Intellectual Property value should primarily be determined commensurate to its fair market value.

Cost Share Reporting and Documentation

Documentation for all cost share expenditures must be included on each monthly sub-recipient invoice and provided to BioMADE quarterly/annually and at the conclusion of the project to ensure that the commitment has been fulfilled. Supporting documentation of all cost and cost share incurred must be maintained by the sub-recipient and provided to BioMADE. Supporting documentation must be available for audit by Government or BioMADE. An audit of cost share may be initiated at any time by the BioMADE or the federal funding agency.

Quarterly Cost Share Reports

Reporting must be completed quarterly, on standard reporting templates to be provided by BioMADE. A link to current Federal Post-Award reporting form SF-425 is included in Exhibit I below.

Quarterly Financial Status Reports

Sub-recipients shall submit Financial Status Reports to BioMADE quarterly using standard reporting templates provided by BioMADE. In addition to the Quarterly Cost Share Reports, this may include Standard Form 425. Subrecipient must maintain such books, records, documents and other supporting data to verify the in-kind contributions from the sub-recipient for 3 years from the date of the final payment by the Institute to the subrecipient. Quarterly reports are due 60 days after the end of each calendar quarter (March 31, June 30, September 30, December 31). A fillable version of the Standard Form 425 is linked in Exhibit I below.

Compliance

Sub-recipients that do not comply with cost share requirements may be subject to payment garnishment commensurate with their cost share deficit. For instance, if a sub-recipient's cost share requirement is 1:1 and their current invoice reflects a cumulative total of \$10,000 federal funds incurred, their cumulative cost share contribution must meet or exceed \$10,000. Cost share contributions in excess of the ratio required by the member's sub-award are not grounds for additional payment using federal

funds. Members will only be reimbursed for actual costs incurred, provided the sub-award’s funded amount has not been exceeded and cost share requirements have been met.

Sub-Award Modifications

When a modification to a sub-award incorporates additional scope or provides additional Government funds, the status of cost share should be evaluated to ensure that the project cost share ratio contained in the sub-award remains appropriate. If the amount of Government funds deviates from the original total, either by adding or deobligating Government funds, the cost share dollar amount must be adjusted by sub-award modification to ensure the original cost share ratio is maintained.

Types of In-Kind Cost Share

Labor	Services furnished by professional and technical personnel, consultants or other skilled and unskilled labor that are not charged directly to a BioMADE project or other Government program. The service is an integral and necessary part of an approved project, or to BioMADE. Labor rates for services shall be consistent with those paid for similar work in the labor market in which the sub-recipient competes for the kinds of services involved. Paid fringe benefits that are reasonable, allowable and allocable may be included in the valuation.
Travel	Travel taken and donated in support of an approved BioMADE project, program, or meeting may be included as cost share, provided that all costs are reasonable, allowable, and allocable under the sub-recipient’s applicable cost guidelines and not charged directly to a BioMADE project or other Government program.
Materials	Donated supplies or materials may include laboratory supplies or workshop and classroom supplies, provided that all costs are reasonable, allowable, and allocable under the sub-recipient’s applicable cost guidelines and not charged directly to a BioMADE project or other Government program.
Equipment	For support activities that require the use of equipment, buildings or land, normally only depreciation or use charges for equipment and buildings may be made. However, the full value of equipment or other capital assets and fair rental charges for land may be allowed, provided that the charges are approved and an integral and necessary part of an approved project or the BioMADE program, provided that the equipment is not charged directly to a BioMADE project or other Government program. The value of donated equipment shall not exceed the fair market value of equipment of the same age and condition at the time of donation.
Indirect Costs	Unrecovered indirect costs may be included as cost share, provided that the costs are consistent with the sub-recipient’s approved negotiated indirect cost rate, or other allowable rate such as the de minimis rate (10%), and evidence of such is provided.