



Information on NIIMBL Project Call 8.1 for Federal Stakeholders

Overview

NIIMBL released Project Call 8.1T/W/G in August of 2024 with member-driven and industry-led priority topic areas for technical (T), workforce development (W), (G) Global Health projects. As NIIMBL aims to lift the whole of the industry across the nation, the Federal expertise and perspective on needs should be represented, especially those of the regulators and standards developers. To capture that perspective, NIIMBL Project Calls are open to Federal proposers, as opportunities to suggest projects that NIIMBL should undertake as a community. The information below is a summary of the NIIMBL Project Call 8.1 process, intended to be of benefit to Federal scientists who may wish to submit a concept paper for consideration. Federal stakeholder participation in the process and any resulting projects must be compatible with agency missions and internal policies, and any constraints related to accepting resources from NIIMBL. Important constraints are included in the 'Opportunity for Federal Stakeholders' section below.

Please refer to the NIIMBL website (<https://www.niimbl.org/projects-programs/project-call-8-1/>) as the authoritative source of information on Project Call 8.1. However, the project call process as detailed in the RFP is targeted toward non-Federal proposers. This document is intended to convey the opportunity for Federal Stakeholders to participate in the NIIMBL Project Call. As a general practice, NIIMBL will strive to accommodate the unique constraints of Federal proposers in this process to reduce barriers to participation. Please contact NIIMBL's Federal Technical Program Manager, Kelley Rogers (kelley.rogers@nist.gov), with questions regarding Federal participation.

NIIMBL Project Call 8.1 Process Summary

NIIMBL will conduct a two-stage process.

Stage 1: The Concept Phase includes the submission of a 4-page Concept Paper and a short Concept Slide Deck. No teaming, detailed budget, or cost share information is required at this stage. A 1-minute video will be option this year and used during the virtual summit and SME reviewers. Concept Papers are due by 5:00 p.m. Eastern Time **September 30, 2024**.

Following submission of Concept Papers, invitations will be issued to participate in the Project Call Virtual Summit, where proposers will have opportunities to discuss their project. The Summit will be held virtually with a target date of the **Mid-October, 2024**. This Phase concludes with invitations issued to submit a full proposal in Stage 2 of the process.

Stage 2: Full Proposal Phase includes submission of a 14-page proposal with teaming, detailed budget, cost share, and other requirements listed in the RFPs for T/W/G. Full Proposals are due by 5:00 p.m. Eastern Time **January 31, 2025**.

This Phase concludes with a decision to fund or not fund the proposal by the NIIMBL Governing Committee.



Opportunities for Federal Stakeholders

Concept Papers and PC8.1 Virtual Summit

- Federal employees are encouraged to submit concept papers and/or partner within the NIIMBL membership to submit as a project partner.
- Federal proposers must obtain internal approval according to each agency's internal processes to participate in NIIMBL project calls or on NIIMBL project teams.
- Submitted concepts must be aligned with NIIMBL's RFP and must advance the development and deployment of precompetitive biopharmaceutical manufacturing enabling technology, focusing on Manufacturing Readiness Levels (BRL) 4-7, or workforce development.
- Concepts proposed by Federal stakeholders will be evaluated in the pool of concepts proposed by non-Federal stakeholders.
- Participation in the Project Call Summit may be adapted as needed to accommodate the unique needs of Federal partners.
- The short Concept Slide Deck may be used as an opportunity to identify a non-Federal champion to lead a project proposal team, with the initial Federal proposer acting as an advisor or direct partner, depending on needs and resources available.
 - *Example: A NIST Concept Proposer might suggest the development of a specific research-grade material as a community resource that will ultimately enable the design of a standard reference material in the future. The NIST proposer would submit a concept paper and short slide deck explaining the need, process for designing the material, the deliverables desired, and how the material could be used in an interlaboratory study or case study. If the concept paper presentation was ranked favorably by industry, NIIMBL members could self-identify as a proposal lead and assemble a team. If the proposal succeeded, the NIST proposer would act as an advisor or partner in design of the material and subsequent studies to characterize it.*
- Federal stakeholders are also encouraged to participate in other NIIMBL project teams as appropriate, and may request invitations to the Proposal Summit to determine if participation in specific NIIMBL projects would advance agency-specific objectives.

Proposal Evaluation

- NIIMBL also would welcome Federal scientists as reviewers for Project Call 8.1 evaluation panels for full proposals (Target: February 2025). If you would like to volunteer as a technical reviewer, please email Kelley Rogers (kelley.rogers@nist.gov). NIST Office of Advanced Manufacturing may sponsor travel for Federal reviewers if needed.



Key Considerations for Federal Participation in NIIMBL Projects

- Federal participation in project teams should be consistent with agency mission space and must have appropriate internal approval from management.
- Federal agencies cannot receive Federal dollars back from NIIMBL. However, for all agencies other than NIST, NIIMBL may provide non-Federal dollars as resources for projects as appropriate.
- Federal participants cannot contribute to project cost-share to meet a proposal team's obligation to match NIIMBL funds with non-Federal funds.
- Federal teams are not in general prohibited from leveraging NIIMBL resources provided by partners (materials, personnel, facilities, and equipment). However, participating agencies may have internal constraints on accepting these resources, so proposers must adhere to internal guidance. NIIMBL, as a non-profit, non-governmental entity, has reasonable flexibility in directing resources to support project costs, and encourages discussions with Federal stakeholders to understand how best to accommodate internal agency constraints where possible.
- Federal stakeholders are encouraged to consider partnering with NIST scientists (or other agency stakeholders) on proposal concepts as appropriate if necessary to avoid perceived conflicts of interest.

About NIIMBL

The mission of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce. NIIMBL is a non-profit, public-private partnership, where Federal funding from the National Institute of Standards and Technology (NIST) is matched at more than 1:1 by contributions from consortium members, to accelerate innovation in precompetitive enabling technologies for industry-wide benefit. More information about NIIMBL and its partners can be found at <https://www.niimbl.org/>.