Dear Colleague:

Cell-based therapies, especially immune cells, have the potential to revolutionize human healthcare in various different contexts, including cancer and personalized medicine. For example, CAR (Chimeric antigen receptor) T-cell therapy for cancer requires modification, \textit{in vitro} culture and expansion of human T-cells. Manufacturing of therapeutic cells as the end product presents major engineering challenges. New therapies and cell-based products depend critically on the development of robust, reliable and reproducible biomanufacturing technologies.

Large-scale manufacturing of therapeutic cells has the potential to benefit millions of people with new life saving opportunities. Advanced biomanufacturing is a field that builds upon ground breaking discoveries in engineering and biology for producing the next generation of therapeutics. Cellular biomanufacturing is a very promising area of advanced biomanufacturing, and includes technological advances in large scale cell processing, cell preservation and distribution, and process monitoring and quality control.

The National Science Foundation's (NSF) Directorate for Engineering (ENG) has placed a high priority on advanced biomanufacturing. The Chemical, Bioengineering, Environmental and Transport Systems (CBET) Division at NSF seeks EArly-Concept Grants for Exploratory Research (EAGER) proposals that address key challenges in cellular biomanufacturing science and engineering, with the intended use of the final cell product in cellular therapies. Proposals that propose production of molecules as end products are discouraged.

This Dear Colleague Letter (DCL) is aimed at identifying opportunities for leveraging and synthesizing conceptual scientific and technological innovation integrating disciplines such as immunology, cell biology and engineering, and to enhance developments in cellular biomanufacturing for the purposes of accelerating solutions to critical challenges in the field.

Topics may include, but are not limited to:

- Culture configurations and bioreactor approaches for reproducible cell expansion for potential therapeutic applications.
- Optimal expansion of T cells specific for sub-dominant tumor-associated antigens and promoted expansion of T cells with central memory T-cell phenotype.
- Scalable and cost-effective cell separation and purification methods and strategies for the final biomanufactured cell product.
- Innovative platforms that reduce or eliminate cell product variability in developing robust biomanufacturing processes.
- Methods for rapid, non-destructive characterization of cellular property and potency.
Mathematical methods and computational models that enable characterizing variability of cell properties including cell subtypes during biomanufacture, and which could be used for process tracking and/or validation.

The proposed high-risk, high-impact projects must transcend approaches typically supported by the core research programs at NSF. Projects should have strong engineering and biological elements, integrating and advancing both disciplines. Academic-Industry collaborations are encouraged. While proposed studies should be potentially transformative and may be considered "high-risk, high-payoff," they should also be compatible with the time and budget limits of the EAGER funding mechanism. Specifically, total budget requests for each project may be up to $300K for up to two years duration. For more information on EAGERs, please consult the NSF Grant Proposal Guide (GPG).

EAGER SUBMISSION PROCESS

EAGER proposals will be accepted from a Principal Investigator (PI) or a consortium of Investigators led by a PI at an eligible U.S. institution.

Full EAGER proposals must be submitted to the Biomedical Engineering program, PD 15-5345, by June 1, 2016, 5:00 PM submitters local time, via Fastlane or Grants.gov, following the NSF Grant Proposal Guide instructions, and should clearly indicate the reason that the proposed work would be appropriate for EAGER support. Please be sure that the title of your proposal starts with "EAGER: Biomanufacturing:" It is anticipated that all EAGER awards will be made in FY 2016.

For more information or questions, please contact the CBET Division's Program Director for Biomedical Engineering, Carol Lucas, at carlucas@nsf.gov or (703) 292-2161.

Sincerely,

JoAnn Slama Lighty
Division Director
Division of Chemical, Bioengineering, Environmental, and Transport Systems
Directorate for Engineering