

PMC-EF2a

(20102)

**U.S. DEPARTMENT OF ENERGY  
EERE PROJECT MANAGEMENT CENTER  
NEPA DETERMINATION**

**RECIPIENT:**The Regents of the University of California; University of California Berkeley**STATE:** CA

**PROJECT TITLE :** Advanced Manufacturing Medical/Biosciences Pipeline for Economic Development (AM2PED) is a regional medical and biosciences manufacturing initiative targeting the I80/880 corridor in the SF East Bay.

<b>Funding Opportunity Announcement Number</b>	<b>Procurement Instrument Number</b>	<b>NEPA Control Number</b>	<b>CID Number</b>
JIAC2102AM	DE-EE0006026	GFO-0006026-001	GO6026

Based on my review of the information concerning the proposed action, as NEPA Compliance Officer (authorized under DOE Order 451.1A), I have made the following determination:

**CX, EA, EIS APPENDIX AND NUMBER:**

## Description:

**A9 Information gathering, analysis, and dissemination**

Information gathering (including, but not limited to, literature surveys, inventories, site visits, and audits), data analysis (including, but not limited to, computer modeling), document preparation (including, but not limited to, conceptual design, feasibility studies, and analytical energy supply and demand studies), and information dissemination (including, but not limited to, document publication and distribution, and classroom training and informational programs), but not including site characterization or environmental monitoring. (See also B3.1 of appendix B to this subpart.)

**B3.6 Small-scale research and development, laboratory operations, and pilot projects**

Siting, construction, modification, operation, and decommissioning of facilities for smallscale research and development projects; conventional laboratory operations (such as preparation of chemical standards and sample analysis); and small-scale pilot projects (generally less than 2 years) frequently conducted to verify a concept before demonstration actions, provided that construction or modification would be within or contiguous to a previously disturbed or developed area (where active utilities and currently used roads are readily accessible). Not included in this category are demonstration actions, meaning actions that are undertaken at a scale to show whether a technology would be viable on a larger scale and suitable for commercial deployment.

**Rational for determination:**

The U.S. Department of Energy (DOE) is proposing to provide federal funding to the University of California Berkeley (UCB) to conduct a "Bio-Manufacturing to Market" pilot program (Program) that would create interdisciplinary consulting/research teams of undergraduate and graduate students. The student consulting/research teams would provide technical advice and perform information gathering, analysis, dissemination and small-scale laboratory research in collaboration with local and regional medical and bio-manufacturing companies and industry partners to address industry related technical and business problems. Funding would be used to identify and fund student positions on the consulting/research teams and fund facility oversight positions involved in the management of the Program over three Budget Periods.

This DOE award is part of a multi-agency Federal Funding Opportunity partnership titled the Advanced Manufacturing Jobs and Innovation Accelerator Challenge (Advanced Manufacturing Jobs Accelerator). This NEPA Determination is for the DOE award.

The student consulting/research teams would engage in, but would not be limited to the following types of consulting activities with their industry partners:

- De-risking projects, technologies;
- Refining raw technology, prototyping for scalability;
- Assessing the needs of device/technology users and clinicians;
- Supply side challenges - life cycle assessments, production efficiency, and capacity utilization;
- Optimizing quality control processes;
- Market Assessments - market definition, customer segmentation, and product/service alignment with target market;
- Commercialization and scale-up challenges;
- Policy research and proposal analysis, regulatory barrier assessment and policy strategy;
- Assisting start-up ventures in identifying and securing potential sources of funding/research and writing for federal grants.

This Program is associated with the UCB QB3 Institute's Bio-Molecular Nanotechnology Center (BNC). Any laboratory research related to the student consulting projects would occur with design and fabrication equipment in the BNC laboratories, located at 137 Stanley Hall, UCB, Berkeley, California 94720.

UCB has completed a R&D questionnaire addressing the protocols in place for laboratory safety, risk management, chemical handling and waste disposal for the BNC laboratory. UCB and the BNC comply with standard laboratory safety procedures and labs are inspected by staff and safety personnel. Every individual utilizing the BNC is required to attend a safety orientation and be trained and certified on each individual piece of equipment. All handling and disposal of gases, chemicals and hazardous waste are subject to UCB Chemical Hygiene and Environmental Health and Safety (EHS) protocol which comply with all appropriate regulations. BNC operates under all applicable permits to conduct research and GMOs would not be used in this project.

Based on review of the project information and the above analysis, DOE has determined the proposed technical advice, information gathering, analysis, dissemination and small-scale laboratory research activities associated with the bio-manufacturing industry would not have a significant individual or cumulative impact to human health and/or environment. DOE has determined the proposed activities are consistent with actions contained in DOE categorical exclusions A9 "information gathering, analysis and dissemination," A11 "technical advice and assistance to organizations," and B3.6 "small-scale research and development, laboratory operations and pilot projects," and are categorically excluded from further NEPA review.

#### NEPA PROVISION

DOE has made a final NEPA determination for this award

Insert the following language in the award:

If you intend to make changes to the scope or objective of your project you are required to contact the Project Officer identified in Block 11 of the Notice of Financial Assistance Award before proceeding. You must receive notification of approval from the DOE Contracting Officer prior to commencing with work beyond that currently approved.

Note to Specialist :

Obadiah Broughton 12/10/2012

DOE funding: \$450,000  
 Cost share: \$474,936  
 Total Project Cost: \$924,936

#### SIGNATURE OF THIS MEMORANDUM CONSTITUTES A RECORD OF THIS DECISION.

NEPA Compliance Officer Signature: \_\_\_\_\_

NEPA Compliance Officer

Date: \_\_\_\_\_

12/10/2012

#### FIELD OFFICE MANAGER DETERMINATION

Field Office Manager review required

#### NCO REQUESTS THE FIELD OFFICE MANAGER REVIEW FOR THE FOLLOWING REASON:

- Proposed action fits within a categorical exclusion but involves a high profile or controversial issue that warrants Field Office Manager's attention.
- Proposed action falls within an EA or EIS category and therefore requires Field Office Manager's review and determination.

#### BASED ON MY REVIEW I CONCUR WITH THE DETERMINATION OF THE NCO :

Field Office Manager's Signature: \_\_\_\_\_

Field Office Manager

Date: \_\_\_\_\_