PART 1. OVERVIEW INFORMATION

1.A. Program Title

POINT-OF-CARE INFLUENZA TESTING FOR EMERGENCY-PANDEMIC-DISASTER CARE

1.B. Sponsoring Organization and Theme
UC Davis-LLNL Point-of-Care Technologies Center. The theme of this Center is critical-emergency-disaster care. See: http://www.ucdmc.ucdavis.edu/pathology/poctcenter/.

1.C. Executive Summary
The UC Davis-LLNL Point-of-Care (POC) Technologies Center invites applications for exploratory projects in the area of new POC technologies that address unmet clinical needs in emergency-pandemic-disaster care focusing on multiplex influenza detection for use in situations of rapid triaging, decision making, management, and treatment.

1.D. Announcement Type: New

Program Announcement No.: UCD-POCTC-09

1.E. Key Dates and Deadlines

Release/Posted/Open Date: Monday, November 23, 2009

Letters of Intent Receipt Deadline: Monday, December 14, 2009

Application Submission Deadline: Monday, January 18, 2010

Announcement of Award: Monday, March 8, 2010

Earliest Start Date: See 1.J., “Subcontracting Process” (below).

1.F. Letter of Intent
A brief Letter of Intent describing the goal of the proposal, specific aims, primary scientific and bioengineering methods, and the practical utility of the proposed viral detection test and POC prototype should be submitted on or before Monday, December 14, 2009.

Please include: a) the descriptive title of the exploratory project; b) the name, address, telephone number, and email address of the Principal Investigator (PI) or Project Director (PD); c) names, titles, and affiliations of other key personnel; d) participating institution or organization; and e) identification number (UCD-POCTC-09) and title of this funding opportunity. Submit the Letter of Intent by email as a portable document format (PDF) file to Dr. Richard Louie, Center Fellow, at poctcenter@ucdavis.edu. The subject title line of the email should read: “POCTC Letter of Intent, [last name of the applicant].” Please do not submit in paper format. Note that a Letter of Intent is not required, is non-binding, and does not enter into the review of a subsequent application. The information it contains will help the Center plan the review.
1.G. Submission
Completed applications should be submitted by email to Dr. Richard Louie at postcenter@ucdavis.edu no later than Monday, January 18, 2010. The email subject line should read: “POCTC Application, [last name of the applicant].” The required proposal format, content, and length are described in Part 3 (page 7).

Applications must be submitted electronically as a single PDF file (preferred) not exceeding 15 MB in size, and must also clearly identify the corresponding person, title, address, phone number, facsimile number, and email for confirmation of receipt.

The Center will not accept responsibility for technical problems associated with application submissions. Therefore, applicants are encouraged to email their proposals well before the deadline to facilitate efficient processing. Late applications will be considered non-responsive and will not be reviewed.

1.H. Mechanism of Support
The University of California, Davis, will subcontract the successful applicant using POC Technologies Center funding (U54EB007959) from the National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH, under the authority of the parent RFA-EB-06-002, Point-of-Care Technologies Research Network (POCTRN) U54 (http://grants.nih.gov/grants/guide/rfa-files/RFA-EB-06-002.html).

All NIH guidelines, terms, and conditions of award stated in this parent RFA apply to subcontractors, the recipient institution or organization, and this funding opportunity. NIH regulations prohibit consultants and secondary subcontracts under this funding program. For NIH terms of agreement, please review: http://grants.nih.gov/grants/policy/nihgps%5F2003. For NIH policies regarding publications, please review http://publicaccess.nih.gov/policy.htm.

1.I. Funds Available
The total direct amount awarded will be approximately $300,000. The subcontract is limited to no more than two years in duration and a maximum of $300,000 in total direct costs with a limit of no more than $150,000 in the first year (12 months). There will be one award.

1.J. Subcontracting Process
UC Davis will enter into a formal written agreement that addresses the negotiated arrangements for meeting scientific, administrative, financial, and reporting requirements, including those necessary to ensure compliance with all applicable federal regulations and policies. The UC Davis Office of Sponsored Programs will determine the payment schedule.

Periodic expense and milestone reports will be required for continuation of payments. The Center reserves the right to discontinue funding if milestones are not attained satisfactorily. See also 4.D., Mid-Project Evaluation.

After the announcement of the award, UC Davis will subcontract during March, 2010. The typical time to complete a subcontract is 1 to 2 months. Project funds will be made available when the subcontract is completed and signed by the recipient institution/organization and by UC Davis. Subcontracts involving foreign institutions must be reviewed and approved by NIH and therefore, will require more time for processing and completion of documents.
1.K. Number of Applications and Number of Principal Investigators/ Directors
Applicants may submit only one application with one designated PI or PD.

1.L. Eligible Institutions and Organizations
You may submit an application if your organization has any of the following characteristics: non-profit or for-profit organization; public or private institution, such as universities, colleges, hospitals, and laboratories; unit of State government; unit of local government; eligible agency of the Federal government; domestic institution; or faith-based or community-based organization.

1.M. Foreign Applicants
Foreign institutions and organizations are welcome to apply and will be subject to foreign clearance approval by the NIH. Foreign applications deemed to have met all program requirements must be reviewed and approved by the NIH in addition to the UC Davis-LLNL POC Technologies Center and the UC Davis Office of Sponsored Programs.

1.N. Eligible Principal Investigators/ Directors (PI/PD)
Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work within their institution or organization to develop an application for support. Individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities are encouraged to apply. Applicants previously awarded a UC Davis-LLNL Center Exploratory Project grant and currently receiving funding are excluded from applying.

PART 2. FUNDING OPPORTUNITY DESCRIPTION

2.A. Definitions
Point-of-care testing (POCT) is defined as medical diagnostic testing at or near the site of patient care. POCT was codified by a multidisciplinary group representing critical care, laboratory medicine, industry, and other professionals (see Kost GJ et al. Chest 1999;115:1140-54). Handheld, bedside, transportable, near-patient, alternate-site, on-site, and more recently, point-of-service, point-of-contact, point-of-patient, and point-of-need testing represent common forms of POCT. In this document “novel H1N1” refers to the 2009 Pandemic Influenza A (H1N1) virus, as clarified in Morbidity and Mortality Weekly Report, October 2, 2009;58(38):1071-1074.

2.B. Background
Emergency Status. On June 11, 2009, the World Health Organization (WHO) declared a novel H1N1 (“swine flu”) pandemic. As of October 4, 2009, the WHO reported over 480,000 confirmed cases with over 6,000 deaths (http://www.who.int/csr/en/). The novel H1N1 strain achieved sustained human-to-human transmission in multiple global regions prompting additional measures to be taken to facilitate rapid detection and isolation of infected patients. Antiviral resistant H1N1 strains (e.g., H275Y mutation) have been identified. H1N1 vaccines are now available and the President of the United States now has declared this outbreak a national emergency. However, the nation was not prepared—no POC instrument, device, or test kit was available to detect novel H1N1 with high sensitivity and specificity. This example establishes the need for flexible and adaptable POC technologies that can detect not just novel H1N1, but also provide suitable detection platforms for future pandemic threats.

CDC Recommendations. The CDC recommends diagnostic testing for hospitalized patients with suspected influenza and to help aid in clinical decision-making for critical care, infection
control, and management of close contact [http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm]. Rapid detection facilitates early intervention, allows initiation of protective measures for high-risk groups exposed to infected individuals, and improves triaging and utilization of resources, thereby decreasing hospital bed shortages and improving treatment decisions. A POC novel H1N1 influenza test will allow organizations to map outbreaks and allocate appropriate prevention, control, and treatment resources.

Current rapid POC influenza immunoassays offer qualitative testing for Influenza A and/or B, but generally are not capable of subtyping strains. Immunoassays are capable only of nonspecifically detecting novel H1N1 virus in 10 to 70% of clinical samples, thus limiting their capacity for reliable diagnosis. The recommended method for confirming novel H1N1 is nucleic acid testing using real-time reverse transcriptase polymerase chain reaction (rRT-PCR) and viral culture. rRT-PCR tests have gained Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), but generally require expensive laboratory equipment and highly trained personnel.

This pandemic illustrates the need for POC devices capable of responding to emerging threats. For example, effective quarantine strategies require highly sensitive and highly specific diagnostic tests to quickly identify index cases. Availability of these tests will help optimize vaccine and antiviral drug distribution in low-resource countries.

Needs Assessment Results. This solicitation for proposals is based on needs assessment surveys conducted in the United States and abroad that generated design specifications for POC viral and pathogen detection devices. Please see [http://www.youtube.com/watch?v=UaMod5MmSDo] for preliminary survey results, which showed that novel H1N1 influenza testing was deemed necessary for emergency and disaster settings, where handheld test cassette-based devices are preferred. Survey results rank design specifications in the following order of importance: high clinical sensitivity, rapid time to result, and high clinical specificity.

The most competitive proposals for exploratory projects under this funding program will meet the above needs-based challenges including, but not limited to, achieving high clinical sensitivity and specificity well in excess of 90%. For example, the strongest proposals will produce sensitivity in the order of 95 to 99.5%, which is necessary to effectively rule out novel H1N1 as well as high specificity of 95% or better. Innovative technologies will produce high value of information on site during emergencies, pandemics, and disasters, and also will meet challenging environmental conditions by providing a reliable and rugged POC test method.

2.C. Purpose and Focus
The goal of this solicitation is to address current and future influenza threats and to move emergency-pandemic-disaster care forward through the discovery, invention, innovation, and implementation of highly portable POC technologies using novel viral detection methods that can be used for rapid response in the United States and other countries.

2.D. Research Objectives
Proposals for exploratory projects must be production-oriented with the objective of developing robust POC testing prototypes for multiplex influenza detection using durable single unit-use disposable tests that medical teams can transport conveniently and use quickly during actual field rescue under adverse conditions lasting several days.
Prototypes must have high clinical impact, be designed for eventual FDA licensing, and have the potential for Clinical Laboratory Improvement Act (CLIA)-waived status. That is, the ideal new technology will demonstrate simple and accurate methods that will have insignificant risk of erroneous results.

The assay must be capable of multiplex testing, detecting clinically relevant strains of Influenza A (see below), and subtyping H1, H3, and H5. It must also differentiate seasonal H1N1 from novel H1N1 variants. The device must report unknown variants of Influenza A. The most competitive proposals will provide a means to report viral drug sensitivity. The Center reserves the right to fund only a component of a proposal or to request topical modifications.

Ultimately, the new POC technology and the experience derived from demonstrated use in this collaborative program will transform public health preparedness for pandemics and disasters by allowing physicians, nurses, and other first responders to practice rapid and mobile evidence-based diagnosis for efficient on-site decision making.

2.E. Specific Research Objectives
Specific research objectives include, but are not limited to, the following—

- To develop an assay which is capable of detecting clinically relevant strains of Influenza A and subtyping H1, H3, and H5, and is capable of differentiating seasonal H1N1 from novel H1N1 variants.
- To develop novel POC methods for influenza testing that can be implemented in highly portable formats intended for FDA licensing and potential CLIA-waived status as handheld devices.
- To support early technology development that will produce POCT devices that can be used to equip first responders in the United States and throughout the world.
- To focus on multiplex influenza detection (including antiviral treatment sensitivity testing) in order to facilitate rapid diagnosis of emerging infections, effective treatment, and efficient triaging of patients to appropriate backup care, as well as to improve patient workflow and assignment for emergency evacuation, alternative medical facilities, or hospital settings.
- To create a modular testing platform that can be adapted quickly to new and emerging viral strains.
- To generate one or more working POC prototypes within the two-year term.
- To identify how the clinical sensitivity and specificity of viral detection will be determined.
- To describe how the quality of the diagnostic testing will be assured, that is, the process for quality control.

2.F. Review Process and Criteria
Applications deemed responsive will be reviewed by experts not directly affiliated with the UC Davis-LLNL POC Technologies Center, the UCD Health System, or the UC Davis campus. The new NIH scoring system will be used. This system is based on five core review criteria: (a) significance, (b) investigator(s), (c) innovation, (d) approach, and (e) environment, each with a 9-point rating scale (1, exceptional; 9, poor).

Reviewers determine which applications are highly competitive. An individual proposal score will reflect evaluation of the overall impact that the project will have on emergency, pandemic, and disaster care. The overall impact score is determined by calculating the mean of all reviewer scores. This overall impact score will be reported on the summary statement. If the new scoring
system produces identical scores ("ties"), other important factors, such as program relevance and portfolio balance, will be considered in making the Center funding decision. Please see (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html) for details. Applications deemed to have the highest impact will be assigned a priority ranking, receive a written critique, and be assessed by Center staff and the Scientific Advisory Committee (SAC) for funding.

The SAC also will consider the following general criteria in making funding decisions: a) merit of the proposed project as determined by peer review, b) availability of funds, and c) relevance to program priorities. The membership of the Center SAC is shown in the organizational chart on the Center website.

Applications will be evaluated based on the Specific Research Objectives in 2.E., the following specific criteria, and how well individual criteria are integrated into the project as a whole—

• Scientific and technical merit
• Clearly defined and realistic milestones
• Significance and relevance to the UC Davis-LLNL POC Technologies Center mission
• Pre-analytical efficiency and rapid analytical speed of processing of complex biological specimens (e.g., blood, sputum, and saliva) of appropriate volume to produce accurate test results. Whole blood, nasopharyngeal swabs, tracheal/pharyngeal aspirates, brochoalveolar lavage (BAL), sputum, and saliva represent acceptable sample types for POC devices funded under this initiative.
• Suitable limit of detection, sensitivity, specificity, and dynamic range of viral detection
• Rapid turnaround time (i.e., total analytical processing time)
• Ability to compensate for confounding factors associated with complex matrices found in critically ill patients (e.g., abnormal hematocrit)
• Novelty of viral detection concepts and methods, including originality, invention, and adaptability to new and emerging influenza strains
• Analytical specificity adequate for the assay to differentiate Influenza A subtypes from other members of the Orthomyxoviridae family
• Multiplex testing for clinically relevant Influenza A viral subtypes (see 2.G. below)
• Antiviral sensitivity testing [e.g., oseltamivir (Tamiflu®), zanamivir (Relenza®), amantadine (Symmetrel®), rimantadine (Flumadine®), or others] and the justification provided for inclusion in the test cluster in terms of decision making in emergency, critical care, pandemic, and disaster settings
• Ability or potential to perform quantitative viral detection
• Ability to withstand heat, cold, high humidity, vibration, high altitude, and/or other environmental stresses encountered during urban and rural emergencies and disasters
• Appropriate quality assurance and quality control routines
• Safe sample collection method and biohazard containment
• Competence and experience of the investigative team
• Bioengineering and research environment in which the work will be performed
• Likelihood of success when used by first responder and rescue teams
• Practical suitability, mobility, and transportability for use in near-patient applications in emergencies, at the bedside, or directly on site in the field during disasters
• Incorporation of testing principles that can be reduced to practice in the production of one or more operating handheld prototypes within the two-year term
• Plan for effective clinical evaluation of the diagnostic method in appropriate settings and low resource environments
• Potential for connectivity of information obtained during testing via wireless or telemedicine systems for integrated disaster response
• Potential for FDA licensing and CLIA-waiver status

2.G. Device Display
The diagnostic test cluster would resemble this mock-up of the instrument result screen—

<table>
<thead>
<tr>
<th>TEST</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza A</td>
<td>Positive/Negative</td>
</tr>
<tr>
<td>Subtype</td>
<td></td>
</tr>
<tr>
<td>Novel H1N1</td>
<td>Positive/Negative</td>
</tr>
<tr>
<td>H3N2</td>
<td>Positive/Negative</td>
</tr>
<tr>
<td>H5N1</td>
<td>Positive/Negative</td>
</tr>
<tr>
<td>Unknown</td>
<td>Positive/Negative</td>
</tr>
</tbody>
</table>

The display screen reports a positive or negative result for general Influenza A with results subtyped and also displays drug sensitivity results (not shown) for antivirals of relevance for triage, management, isolation, and therapy of critically ill patients. Inclusion of Influenza B is optional and must be justified in the context of emergency-pandemic-disaster care.

2.H. Exclusions
Applicants previously awarded a UC Davis-LLNL Center Exploratory Project grant and currently funded are excluded. The intent of this initiative is to promote new POC methods for direct influenza testing and implementation of a highly portable handheld device. Therefore, proposals using other specimen types (e.g., cerebrospinal fluid), involving complex pre-analytical processing with time-consuming manual steps, requiring cumbersome physical separation of pre- and post-analytical steps to avoid contamination, possessing little or no practical chance for use in field settings, or intended for veterinary medicine will be considered non-responsive and will not be reviewed.

PART 3. PROPOSAL FORMAT, CONTENT, AND LENGTH
Provide full contact information for the PI or PD. Applications must include appropriate identification of, and approval by, the applicant institution or organization, and sections a-c and e-i as described below. Sections a-e of the application should not exceed seven (7) NIH-style continuation pages (PHS 398/2590, Rev 11/07, continuation page). The page limit does not apply to sections f-i. For readability, use Arial font 11 point or larger with 1 inch margins. Appendices are not permitted. Identify the following sections by letter in the order listed—

a. Summary—In a paragraph of 300 words or less, provide a succinct summary of the goals of the research project and expected outcomes. This description should be comprehensible to a lay audience, identify uniqueness to POC testing, and conclude by explaining how the project relates to the Center mission and specific research objective of influenza detection.

b. Specific Aims—Include a practical list of up to four specific aims for the proposed project. Each specific aim should have a set of hypotheses or expected outcomes. List project milestones with each specific aim. Milestones must be quantifiable and logically justified. There must be at least two milestones identified in each year of the project. The milestones also must be identified by date of completion on the project timeline.
c. Background and Significance—Provide reviewers with sufficient information to understand the developmental research, design principles, proposed project, utility of the prototype device, and relevance to viral detection in emergency-pandemic-disaster. Explain how the device will be applied and used at the point of care by medical teams and rescue units.

d. Preliminary Observations (optional)—The proposal can include proof of concept, preliminary data, or evidence of clinical feasibility germane to the proposed project. This section is limited to 1 page in length and counts in the 7 page limit.

e. Experimental Procedures—Describe the research, development, and evaluation procedures in sufficient detail to assure reviewers that the exploratory project is feasible and will result in the production of a working POC prototype within the two-year term allowed. Provide a project timeline in the form of a compact figure or graph with explanation. Clearly identify the technical and developmental milestones for the prototype POCT device, their dates of completion, and the date on which a working prototype first will become available for demonstration of viral detection. Identify how the quality of the testing will be assured. Describe statistical methods of data analysis and statistical power. Applicants should consider the following practical design criteria: sample volume, lack of interference/inhibition, absence of contamination, reagent stability both in storage and under adverse field conditions, appropriate user interface, understandable operating and user instructions, integrated internal quality control, efficient power consumption, and portable battery, solar, or alternative energy source.

f. References, Key Words, and Experts (not included in the 7 page limit)—List references in the order cited by number in square brackets (e.g., “[…]”) in the text. Place the list of references formatted in Index Medicus style after the experimental procedures. When there are more than three authors, list the first three followed by “et al.” Include full titles. At the end of the reference list, place a list of at least 10 key words (not included in the project title) related to important project attributes. These key words will assist the Center in planning review processes. Next, nominate five experts who are capable of reviewing the application and are not associated with the applicant institution, organization, or research program.

g. Biographical Sketches (not included in the 7 page limit)—Provide NIH-style biographical sketches for all key personnel (PHS 398/2590, Rev 11/07—biographical sketch form, limited to 4 pages per individual). Identify the PI or PD and any Co-PIs/PDs. Include institutional affiliations and locations. List the total effort anticipated during each year of the project term. List current and pending research support. For each grant or award, list effort in months per year.

h. Budget (not included in 7 page limit)—A one-page detailed budget for the first year (PHS 398, Rev 11/07, form page 4: detailed budget for initial budget period), a similar outline for the second year, and a sound justification of the budget and the appropriateness of expenditures are required. Budgets should include appropriate time and effort commitment (in months per year) and salary/benefits allocations for all personnel, including the PI or PD. The Center may provide, subject to advance negotiation after the award is announced, limited evaluation of prototypes and reagents under predefined conditions of environmental thermal stress. See 4.E. (below). Funds for travel are not available. NIH regulations prohibit consultants and secondary subcontracts under this funding program.

i. Facilities, Unique Resources, and Experience with POC Testing (not included in the 7 page limit)—Include in this section a statement of the facilities to be used in the conduct of the
research and engineering of the device (see section 4.B. for special facility considerations). By submitting the application, your institution is committing these facilities for the conduct of the research. While experience with POCT, per se, is not a prerequisite to participating in this program, applicants should describe briefly (no more than 1 page) if such experience exists and how it, as well as unique resources and facilities, both bench and clinical, will contribute to success in developing the new POC technology for emergency-pandemic-disaster care.

The award is subject to NIH terms of agreement, regulations, assurances, and guidelines. The PI or PD must follow NIH human subjects guidelines, and if human subjects are directly or indirectly involved, upon request provide tracking data for minorities, gender, and other details. Incomplete applications will be considered not responsive and as a result, will not be reviewed.

PART 4. SPECIAL CONSIDERATIONS

4.A. Institutional Review Board (IRB) Approval

General Requirements. Exploratory projects must meet all requirements of the sponsoring institution or organization’s IRB. Documentation of IRB approval is required prior to funding. Funding will not start without written IRB approval by the institution sponsoring the research. PI or PD notification will follow NIH “Just In Time (JIT)” practice. Therefore, applicants will have limited time to obtain IRB approval after JIT notification.

Compliance. UC Davis requires IRB approval by the sponsoring institution even if biological specimens (i.e., whole blood) are purchased or obtained from sources other than the applicant’s primary sponsoring institution. The PI or PD must follow NIH human subjects guidelines, and if human subjects are directly or indirectly involved, upon request provide tracking data for minorities, gender, and other details. The NIBIB and NIH may further require documented proof of compliance with these guidelines and may adjudicate cases of noncompliance.

Human Subjects Protection. Federal regulations (45CFR46) require that proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Use of Animals in Research. Activities involving live vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals http://grants.nih.gov/grants/olaw/references/phspol.htm as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm). Conformance to local oversight committees such as an institutional Animal Care and Use Committee also is required.

4.B. Biosafety Facility Requirements and Assay Validation

Applicants must have access to sources of the target viruses and facilities to validate their assays. According to the fifth edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, specimen collection, processing, and testing of the novel H1N1 virus requires a Class II biosafety cabinet (BSC) in a biosafety level 2 (BSL-2) laboratory (http://www.cdc.gov/h1n1flu/guidelines_labworkers.htm). A BSC Class II should have laminar air flow with HEPA filtration for personal protection and environmental safety. The institution where the development and testing of the POC device will occur must have access to BSL-2 cabinets.
These interim recommendations for research performed using the novel H1N1 virus are subject to change as more information becomes available. Viral culture should not be attempted on specimens from patients with increased risk for Avian influenza (H5N1), unless conducted under BSL-3 conditions with enhancements (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109385.htm).

4.C. Technical Readiness Level (TRL) and Milestone Progress Reports
The funded laboratory must provide an assessment of the technical readiness level (TRL) prior to funding, at the end of the first year, and then, at the conclusion of the project. The TRL concept means that the PI or PD should define necessary technical resources available to allow the proposed POC technology to come to full fruition. The TRL projection should include a description of the steps required to demonstrate that the POC technology is ready and working and the resources developed to complete the work, thereby ensuring that the device will be ready for implementation and field use. The PI or PD must report progress upon achieving major milestones defined in section 3 above.

4.D. Mid-Project Evaluation
Project renewal and second year funding depend on satisfactory progress during the first year, as documented by a progress report and successful attainment of defined milestones. The progress report is due 30 days before the renewal date, that is, 11 months after the start of funding. Center staff reserve the right to visit the PI or PD and conduct a site inspection of the funded laboratory any time during the term of the project. Delay in providing expenses reports and progress reports, or unsatisfactory progress will result in termination of funding. A final progress report is due within 60 days of the end of funding. Progress reports and evaluations are reviewed by the Center and by NIBIB Science Officers.

4.E. Point-of-Care Technologies Research Network
The UC Davis-LLNL POC Technologies Center, one of four Centers funded by the NIBIB, is a member of the Point-of-Care Technologies Network (POCTRN). Goals include partnering to pipeline POCT concepts from clinical needs assessment to field-testing of working prototypes. The Network provides resources that broaden technology development communities. Subject to budgetary limitations and by advance negotiation, our Center will be available for consultative guidance and will provide an assigned consultant who will assist the funded laboratory in environmental testing of the POCT prototype and reagents and provide guidance on clinical evaluation. These activities bridge technical and clinical aspects of POCT within the Network community. For background information, please see Kost GJ et al. Point of Care 2008;7:41.