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## IRB-Approved Community-Engaged Research at VCU: Analysis of Baseline Data and Overview of New Data System

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# IRB-Approved Community-Engaged Research at VCU: Analysis of Baseline Data and Overview of New Data System

## **Abstract**

Within the academy and across VCU there is growing recognition that community-engaged research (CEnR) is a valuable framework that enables researchers to conduct research and produce results that can be directly translated into improvements in human health, education, sustainability, and economic development. One example of VCU's institutional commitment to community engagement is that a description of CEnR has been added to the revised university promotion and tenure guidelines. Additionally, it is included as a key strategy in advancing the discovery of new knowledge, creative expression, and innovation by increasing and diversifying sponsored research and promoting translational research and scholarship that contributes to human health and addresses the most complex global challenges (ULI 3).

VCU has not collected information on CEnR systematically. This creates challenges in establishing a baseline of activity against which to measure progress in increasing high quality, high impact CEnR. To address this gap, a team representing the Division of Community Engagement, Office of Research, Center for Clinical and Translational Research, and several academic units pursued a two-prong strategy. First, a survey of principal investigators at VCU was used to identify and collect information about CEnR studies approved by the IRB during 2011-2012. Concurrently, the team identified a brief series of questions that now have been added to the IRB application to track future CEnR studies. Institutionalizing the process for collecting these data, as well as the results of the inventory, will aid in future tracking of CEnR as well as support efforts to advance CEnR across the university.

This report highlights findings from the analysis of baseline data and provides an overview of the data collection system now being used as part of the IRB approval process.

## **Keywords**

IRB, institutional review board, community-engaged research, CEnR, data system, data

## **Disciplines**

Higher Education

# Virginia Commonwealth University

## IRB-Approved Community-Engaged Research at VCU

Analysis of Baseline Data and Overview of New Data System

November 14, 2013

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# VCU

VIRGINIA COMMONWEALTH UNIVERSITY

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## Executive Summary

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Within the academy and across VCU there is growing recognition that community-engaged research (CEnR) is a valuable framework that enables researchers to conduct research and produce results that can be directly translated into improvements in human health, education, sustainability, and economic development. One example of VCU's institutional commitment to community engagement is that a description of CEnR has been added to the revised university promotion and tenure guidelines. Additionally, it is included as a key strategy in advancing the discovery of new knowledge, creative expression, and innovation by increasing and diversifying sponsored research and promoting translational research and scholarship that contributes to human health and addresses the most complex global challenges (ULI 3).

VCU has not collected information on CEnR systematically. This creates challenges in establishing a baseline of activity against which to measure progress in increasing high quality, high impact CEnR. To address this gap, a team representing the Division of Community Engagement, Office of Research, Center for Clinical and Translational Research, and several academic units pursued a two-prong strategy. First, a survey of principal investigators at VCU was used to identify and collect information about CEnR studies approved by the IRB during 2011-2012. Concurrently, the team identified a brief series of questions that now have been added to the IRB application to track future CEnR studies. Institutionalizing the process for collecting these data, as well as the results of the inventory, will aid in future tracking of CEnR as well as support efforts to advance CEnR across the university.

This report highlights findings from the analysis of baseline data and provides an overview of the data collection system now being used as part of the IRB approval process.

### Key Findings

VCU researchers provided information on 755 studies approved by the IRB in 2011-2012. Principal investigators reported that:

- A total of 34.9% (263) of these studies involved community-engaged research (CEnR).
- 14.2% of sampled studies involved the most intensive level of community partner involvement.
- Identified CEnR studies attracted \$164,801,433 in funding; \$64,101,608 of that was associated with the most intensive level of community partner involvement.
- Nearly three-quarters (70.8%) of the identified CEnR studies involved social and behavioral research.
- Approximately 10% (n=27) of the identified CEnR studies were clinical trials.

### Next Steps

The IRB is now systematically identifying and collecting data on CEnR during initial protocol submission. This will allow VCU to track prospectively community-partner involvement for all IRB-approved studies. The next steps in implementing this new data collection system include:

- Evaluating the effectiveness of this system to identify CEnR studies.
- Determining the guidelines for accessing and reporting CEnR data collected by the IRB (e.g. how the information is accessed, how often reports will be generated, who can access the data).
- Identifying measures of progress on the overall goal of advancing high quality, high impact CEnR.
- Determining how these data can most effectively be used in strategic decision making to encourage high quality, high impact CEnR that advances VCU's mission and goals.

## Background

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As a premier, urban research institution committed to community engagement, VCU has prioritized enhancing, supporting and providing professional development for the continued growth of community-engaged research, scholarship and creative expression as a key strategy in advancing the *Quest for Distinction* (University Level Initiative [ULI] 3). VCU is already among a small number of institutions to be designated as very high research activity and community-engaged by the Carnegie Foundation. In 2010, VCU received a NIH Center for Translational and Sciences Award partially due to its strong commitment to CEnR. The Division of Community Engagement (DCE) and the Center for Clinical and Translational Research (CCTR) have worked across the university to engage key stakeholders and enhance infrastructure that will further promote and support high quality, high impact CEnR.

In 2012, the DCE and CCTR partnered to develop a strategy to systematically identify CEnR across VCU. This process involved two parallel activities: 1) collecting CEnR information from faculty who had studies approved by the IRB during the prior two years; and 2) the formulation and addition of questions to the IRB application to track future CEnR. The institutionalization of this data collection process, as well as the results of the inventory, will aid in future tracking of CEnR as well as support efforts to advance CEnR across the university.

VCU defines CEnR as:

*a collaborative process between the researcher and community partner that creates and disseminates knowledge and creative expression with the goal of contributing to the discipline and strengthening the well-being of the community. CEnR identifies the assets of all stakeholders and incorporates them in the design and conduct of the different phases of the research process.*

### Retrospective Inventory of CEnR 2011-2012

To establish a baseline for CEnR across the university, representatives of the DCE, Office of Research and CCTR collected retrospective data on CEnR studies approved by VCU's IRB between January 1, 2011 to January 26, 2013. Project principal investigators (PIs) were invited to complete an online survey about their approved studies. Using data provided by the Office of Research, the online survey asked PIs questions regarding each protocol they submitted during this period. The questions asked in the survey were similar to the questions subsequently added to the online IRB application (see Appendices A & B). The information from the online survey of PIs was combined with additional data regarding these studies already held by the IRB, including:

- Project type (Biomedical or Social-Behavioral)
- Whether the study was a trainee or student project
- Study title
- Review type (exempt, expedited, full)
- Type of submission (research, clinical trial, etc.)
- Date approved
- Funding source(s)

- Amount received per funding source

### Future Tracking of CEnR

An expanded team of stakeholders was involved in creating a mechanism for collecting data on CEnR across VCU. The aim was to gather systematic information on CEnR by adding a brief series of questions to VCU's online IRB application (launched in August 2013). Initially, a literature search was conducted to identify best practices used in tracking and monitoring CEnR at the university level. Using this information, the team agreed upon four questions that could identify specific partners and differentiate levels of partner involvement (see Appendix B). Priority was placed on limiting respondent burden and ensuring questions were appropriate for inclusion on the IRB application.

The following information will be gathered when an IRB proposal is submitted for review:

- Whether community partners have been involved in the study's design and/or will be involved in its implementation
- Name and zip code/country for each community partner
- The role of the community partner(s) in the research
- Source and amount of funding received

The team was comprised of:

- John Clore, *Director and Principal Investigator, CCTR*
- Deborah DiazGranados, *Program Evaluator, CCTR*
- Amber Haley, *Associate Director, Community Engagement Core, CCTR*
- Valerie Holton, *Project Team Leader and Director for Community-Engaged Research, Division of Community Engagement*
- Cathy Howard, *Vice Provost, Division of Community Engagement*
- Alex Krist, *Co-Director, Community Engagement Core, CCTR*
- Maghboeba Mosavel, *Associate Professor, Social and Behavioral Health*
- Ann Nichols-Casebolt, *Associate Vice President for Research Development, Office of Research*
- Kelli Parmley, *Executive Director for Bridging Richmond and Special Assistant to the Provost for Quest Implementation*
- Elizabeth Ripley, *Executive Director, Clinical Research Services, CCTR*
- Kurt Stemhagen, *Associate Professor, School of Education*
- Michelle Stickler, *Director of Office of Research Subjects Protections, Office of Research*
- Steven Woolf, *Co-Director, Community Engagement Core, CCTR*

## Findings

The online survey findings reported here are from PIs with IRB protocols *approved* between January 1, 2011 and January 26, 2013. During that period, 701 PIs received approval for 1,696 protocols. Of these, 453 (64.6%) responded to this survey; the respondents represented 755 (44.5%) of all approved protocols.<sup>1</sup> Our analyses are based upon only those protocols for which PIs provided data. These are referred to as “sampled protocols.” Those involving community partners are labeled as “identified CEnR studies.”

### Involvement of community partner

Respondents were asked to indicate if a protocol involved at least one community partner in its design or implementation. A community partner was defined as “an individual or organization that is not affiliated with VCU or VCU Health Systems (e.g. VA Health Systems, a nonprofit or NGO, a business) but who is engaged with VCU or VCU Health Systems in the study.” A total of 263 sampled protocols (34.9%) involved community partners.

### Level of Community Partner Involvement

Nearly one-half (42.3%) of identified CEnR studies indicated the most intensive level of partner involvement. In this form of collaboration, the community partner was instrumental in helping to determine the study design and/or helped to conduct critical study activities. These studies represent one-seventh of all IRB-approved research across the university captured in our sample.

% CEnR Protocols (n=263)	% Sampled Protocols (n=755)	Type of Involvement
34.4	11.5	<b>Access</b> - Community partners only <u>provided access</u> to study subjects or project sites. They were not involved with study design, subject recruitment, data collection, or data analysis.
23.3	7.8	<b>Guidance</b> - Community partners did not make decisions about the study design or conduct, but <u>provided guidance</u> to the researcher about the study design, subject recruitment, data collection, or data analysis.
42.3	14.2	<b>Conduct</b> - Community partners <u>made decisions</u> with the researcher(s) about the study’s research activities and/or <u>helped conduct</u> those activities (i.e. study design, subject recruitment, data collection, and/or data analysis).

Note: No response was given for ten of the protocols that indicated community partners were involved (3.8%).

<sup>1</sup> A research project may involve more than one study. A given project or study may have submitted more than one IRB protocol over the two year period. We were able to identify unique studies; however, we were unable to identify reliably when more than one protocol was associated with a single study or project. Therefore some projects or studies may be overrepresented in these findings. We are unable to know the impact of this possible overrepresentation (i.e., it may result in lower or higher estimates of CEnR activity).

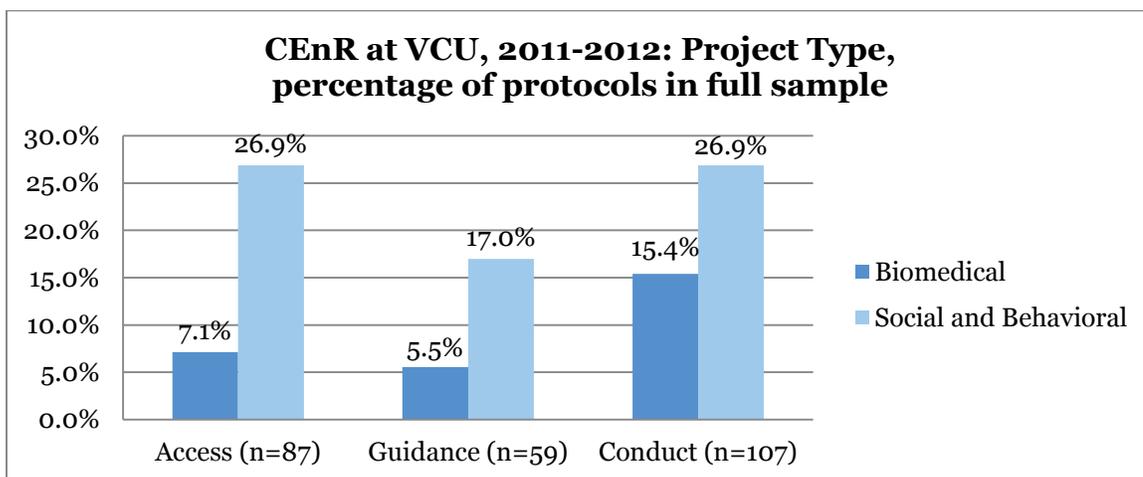
### Funding for CEnR

Identified CEnR studies during 2011-2012 attracted \$164,801,433 in funding (n=106). The funding by the level of involvement is indicated below. Three (3) protocols that were indicated as having community partner involvement did not indicate the level of involvement of the partner and accounted for \$1,812,280 of the research funding. The Office of Sponsored Programs reports that the total dollar value of awards received for those with human subjects protocols approved in 2011 was \$96,646,038 and in 2012 was \$74,985,932 (totaling \$171,631,970). See Appendix C for a list of the funding sources that supported one or more of the CEnR projects.

Level of Involvement	Amount
Access (n=27)	\$41,114,002
Guidance (n=26)	\$59,585,823
Conduct (n=50)	\$64,101,608
Unspecified (n=3)	\$1,812,280
Total (n=106)	\$164,801,433

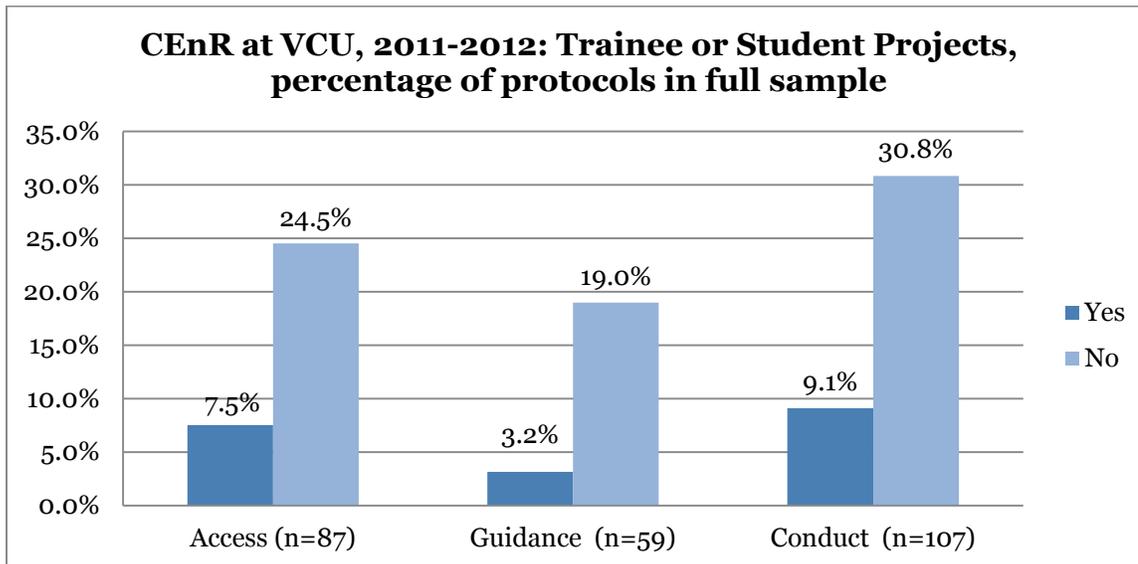
### Project Type

On the IRB application, PIs indicate one of two project types: 1) biomedical research (involving medical interventions and /or FDA-regulated products), and 2) social and behavioral research (social or behavioral research that does not involve medical interventions and/or FDA-regulated products). Across types of partner involvement, social and behavioral research was more prevalent. Overall, nearly three-quarters (70.8%) of the identified CEnR studies were denoted as social and behavioral research.



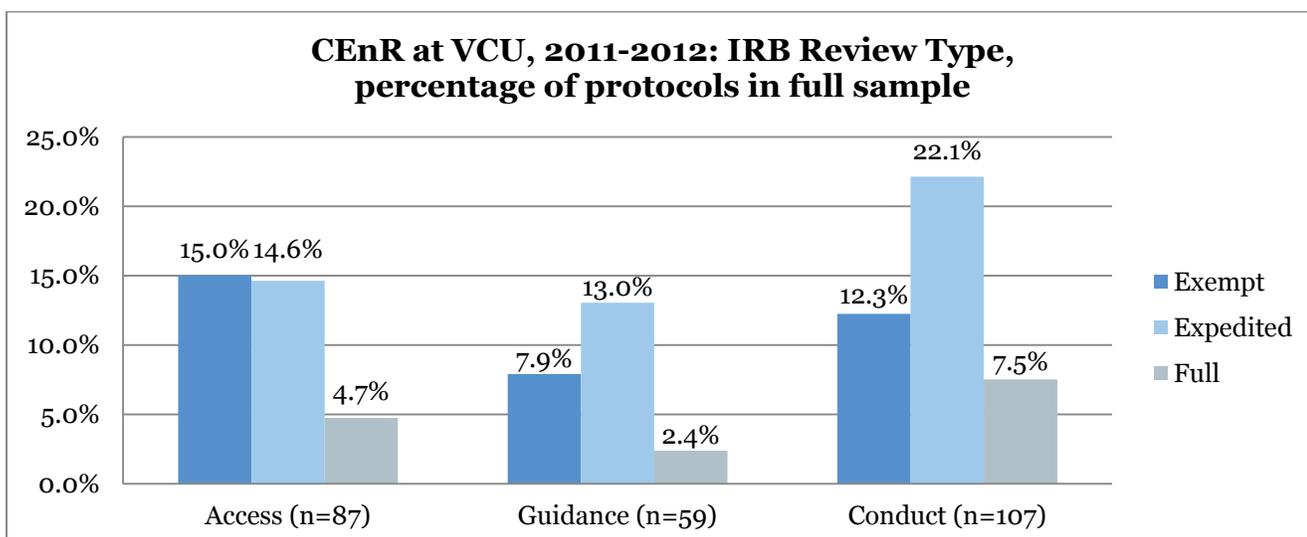
### Trainee or Student Project

On the IRB application, PIs indicate if the study is a trainee or student project. Less than a quarter (19.8%) the identified CEnR studies were reported to be trainee or student projects. The proportion of trainee or student-led projects did not vary greatly by type of partner involvement.



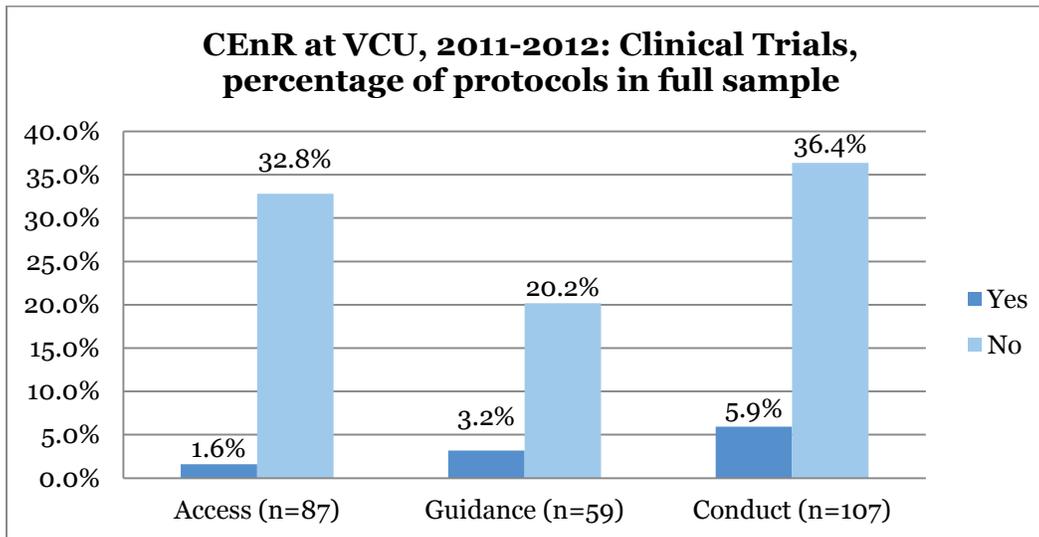
### IRB Review Type

Half of the identified CEnR studies were reviewed as expedited (49.8%), followed by exempt (35.2%) and full (14.6%).



## Clinical Trials Involving CEnR

On the IRB application, PIs indicate if the study meets the definition of a clinical trial. Approximately 10% (n=27) of the identified CEnR studies were reported to be clinical trials. The largest number of these CEnR clinical trials PIs reported the most intensive form of community partner involvement.



## Summary and Next Steps

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This baseline assessment of CEnR activity during 2011-2012 reveals that many VCU researchers are actively collaborating with community partners in the conduct of research involving human subjects. The intensity of community partner involvement varies across these studies. In a significant proportion, partners help to design and/or conduct the research. Most identified CEnR studies are social-behavioral; few are student or trainee led or designed as clinical trials. Nevertheless, VCU is home to a substantial body of research activity linking VCU faculty and the community. The baseline information gathered through the inventory provides critical information to evaluating the university's efforts to encourage CEnR.

While this report shows that data on CEnR can be captured retroactively, key stakeholders from across the university recognized that it was necessary to create an institutionalized means of collecting this information prospectively. A brief series of questions was added to the IRB application that will systematically identify CEnR activity and the associated community partners.

The next steps in implementing this new data collection system include:

- Evaluating the effectiveness of this system to identify CEnR studies.
- Determining the guidelines for accessing and reporting CEnR data collected by the IRB (e.g. how the information is accessed, how often reports will be generated, who can access the data).
- Identifying measures of progress on the overall goal of advancing high quality, high impact CEnR.
- Determining how these data can most effectively be used in strategic decision making to encourage high quality, high impact CEnR that advances that advances VCU's mission and goals.

## Appendix A

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The following questions were used in the online survey.

You were listed as PI on the following protocols from January 1, 2011 to December 31, 2012. Please indicate which studies involved at least one community partner in its design or implementation. A community partner is an individual or organization that is not affiliated with VCU or VCU Health Systems (e.g. VA Health Systems, a non profit or NGO, a business) but who is engaged with VCU or VCU Health Systems in the study.

[list of the titles of protocols]

For the study entitled, [title of each protocol selected], which of the three statements below best describes the role of the community partner(s)?

- Community partners only provided access to study subjects or project sites. They were not involved with study design, subject recruitment, data collection, or data analysis.
- Community partners did not make decisions about the study design or conduct, but provided guidance to the researcher about the study design, subject recruitment, data collection, or data analysis.
- Community partners made decisions with the researcher(s) about the study's research activities and/or helped conduct those activities (i.e. study design, subject recruitment, data collection, and/or data analysis).

Finally, have you ever used services of the VCU CCTR Research Incubator, whether for the projects noted here or your other work?

- Yes
- No
- I am not familiar with the CCTR Research Incubator

*If "I am not familiar with the CCTR Research Incubator" is selected:*

Here is the link to the CCTR Research Incubator <http://www.cctr.vcu.edu/researchincubator/>

*If "Yes" Is Selected*

Which services did you use? (Check all that apply)

- Regulatory assistance such as help with IRB/IACUC submissions
- Help with budgets and contracts
- Assistance identifying/accessing research resources (e.g., equipment, personnel)
- Opportunities for researchers to network/develop collaborations
- Assistance identifying mentors
- Help developing strategies for patient recruitment
- Educational programs regarding study design/methodology
- Educational programs regarding grant writing/preparation
- Training programs for research personnel (e.g., research coordinators, regulatory personnel)
- Other \_\_\_\_\_

## Appendix B

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The following questions have been added to the online IRB application to identify and characterize community partner engagement in research involving human subjects that is conducted by VCU investigators. The project team selected questions regarding the role of the partner(s) that were adapted from:

Khodyakov, D., Stockdale, S., Jones, A., Mango, J., Jones, F., & Lizaola, E. (2012). On measuring community participation in research. *Health Education & Behavior*, 40(3), 346-354.

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Is there at least one community partner\* involved in the proposed study?

Yes

No

\*A community partner is an individual or organization that is not affiliated with VCU or VCU Health Systems (e.g. VA Health Systems, a non profit or NGO, a business) but who is engaged with VCU or VCU Health Systems in this proposed study.

If yes ...

Please provide the following details about each community partner. If there are more than 5 community partners, please provide the following information on the 5 most significant community partners. If a community partner is a collaboration of multiple partners, please indicate the name of the larger collaboration and the zip code or country of the location where the majority of the research is taking place.

- Name of the organization
- Zip code or Country of the organization

Which of the three statements below best describes the role of the community partner in the study?

- Community partners only provide access to study subjects or project sites. They are not involved with study design, subject recruitment, data collection, or data analysis.
- Community partners do not make decisions about the study design or conduct, but provide guidance to the researcher about the study design, subject recruitment, data collection, or data analysis.
- Community partners make decisions with the researcher(s) about the study's research activities and/or help conduct those activities (i.e. study design, subject recruitment, data collection, and/or data analysis).

## Appendix C

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The following 229 funding sources supported one or more of the CEnR projects; 153 of the protocols did not list a funding source.

Funding Sources
Abbott Laboratories
AesRx, LLC
Agency for Healthcare Research and Quality/DHHS
Allegro Diagnostics, Inc.
Allina Health System
Allos Therapeutics, Inc.
American Cancer Society, VA
American College of Radiology Imaging Network
American Heart Association
Astellas Pharma US, Inc.
AtriCure, Inc.
Autism Speaks
Brain & Behavior Research Foundation
Brooks Health Foundation
Capital One
Centers for Disease Control and Prevention/DHHS
Centers for Medicare and Medicaid Services/DHHS
City of Richmond
Cochlear Americas
Commonwealth Health Research Board
Corporation for National and Community Service
Cystic Fibrosis Foundation
Department of Defense
Department of Education
Eastern Virginia Medical School
Elsa U. Pardee Foundation
EnteroMedics
Fetzer Institute
Food Allergy and Anaphylaxis Network
Genzyme Corporation
George Washington University
Health Resources and Services Administration/DHHS

Funding Sources
Henry M. Jackson Foundation
INO Therapeutics
Institute of Education Sciences/Department of Education
Jackson (Henry M.) Foundation
Jeffress
LUNGevity Foundation
McGuire Research Institutes
Medtronic
Merck & Co., Inc.
Montefiore Medical Center
Mount Sinai School of Medicine
National Art Education Association Foundation
National Athletic Trainers' Association Research and Education Foundation
National Cancer Institute/NIH/DHHS
National Disease Research Interchange
National Heart, Lung, and Blood Institute/NIH/DHHS
National Institute of Allergy and Infectious Diseases/NIH/DHHS
National Institute of Child Health and Human Development/NIH/DHHS
National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS
National Institute of Environmental Health Sciences/NIH/DHHS
National Institute of General Medical Sciences/NIH/DHHS
National Institute of Mental Health/NIH/DHHS
National Institute of Neurological Disorders and Stroke/NIH/DHHS
National Institute of Nursing Research/NIH/DHHS
National Institute on Alcohol Abuse and Alcoholism/NIH/DHHS
National Institute on Drug Abuse/NIH/DHHS
National Institute on Minority Health and Health Disparities
National Institutes of Health
National Lung Cancer Partnership
National Science Foundation
Nestle Nutrition
NXStage Medical, Inc.
Oasis Institute (The)
Office of Behavioral and Social Sciences Research/NIH/DHHS
Office of the Attorney General
Pacific Biometrics Research Foundation

Funding Sources
Patient Centered Outcomes Research Institute
Pew Charitable Trusts
Pfizer Inc., U.S. Pharmaceuticals Group
Qatar National Research Fund
Research Triangle Institute International
Reynolds (Donald W.) Foundation
Saucony Run for Good Foundation
Signal Processing Technologies
Social & Scientific Systems, Inc.
Sponsor To Be Created
Susan Komen Breast Cancer Foundation, Richmond Aff
SynCardia Systems, Inc.
Thoratec Corporation
University of Chicago
University of Florida
University of Michigan
Vertex Pharmaceuticals, Inc
Virginia Center on Aging
Virginia Dental Association
Virginia Department of Education
Virginia Department of Health
Virginia Department of Social Services
Virginia Foundation for Healthy Youth
Virginia Literacy Foundation
Virginia State University
Virginia Tobacco Indemnification and Community Revitalization Commission
Wayne State University
XeChem International, Inc.