List of Frequently Asked Questions about CEnR and VCU’s IRB:

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FAQ: Community-Engaged Research (CEnR) and VCU’s Institutional Review Board (IRB)

Conceptualizing Research as Community-Engaged

1. **What is Community-Engaged Research (CEnR)?**
   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 academic discipline and strengthening the well-being of the community. Community-engaged research (CEnR) identifies the assets of all stakeholders and incorporates them in the design and conduct of the different phases of the research process.” ([http://www.community.vcu.edu/files/2012/05/CER-Definitions-Updated-8-28-13.pdf](http://www.community.vcu.edu/files/2012/05/CER-Definitions-Updated-8-28-13.pdf))

2. **How do you define “community” in CEnR?**
   VCU defines community as “a group of people external to the campus who are affiliated by geographic proximity, special interest, similar situation or shared values. Communities may share characteristics such as age, ethnicity, gender, or sexual orientation.” ([http://www.community.vcu.edu/files/2012/05/CER-Definitions-Updated-8-28-13.pdf](http://www.community.vcu.edu/files/2012/05/CER-Definitions-Updated-8-28-13.pdf))

3. **When is an IRB review required in CEnR?**
   The Institutional Review Board (IRB) at VCU is charged with reviewing all research protocols involving human participants to ensure research is conducted ethically and in compliance with federal, state, and local regulations. Guidance and resources for researchers, research participants, and IRB members are provided on this site: ([http://www.research.vcu.edu/human_research/index.htm](http://www.research.vcu.edu/human_research/index.htm)). The IRB needs to review a protocol if the activity is “research” and will involve human participants. Research is defined as a “systematic investigation designed to develop or contribute to generalizable knowledge.” Involvement of human participants may include either an interaction/intervention with a living individual OR use of identifiable private information about living individuals. If an activity does not meet the definition of research, it does not need IRB approval even if human participants are involved. For example, some activities may be classified as quality improvement rather than research. However, you should err on the side of caution when it comes to generalizability. If there will be an intent at some point to contribute knowledge to a professional body of knowledge, it is likely that IRB review is needed. If you decide no review is needed, then you should put something in writing that explains why it is not human subjects research and that outlines what data is being collected, from whom, consent procedures, and intended plans for data usage (i.e. a memo between partners or a note in a research journal) about why you decided that you did not need an IRB review, but this does not have to be approved by the IRB office. If you are unsure, then you can ask for a consult from ORSP@vcu.edu and/or submit a proposal to our IRB, and if it is deemed as not human participant research, then it will come back to you marked accordingly.

4. **Why Community Engaged Research (CEnR)?**
   CEnR allows the research to more accurately target the development, implementation, and analyses of problems that impact the community as well as to develop more valid interventions that improve community level outcomes.a,b CEnR approaches can enhance research validity, as well as work to ensure that research findings foster social change at the local level.c Engagement of partners can help overcome common research challenges regarding local competence of research methods, tools, and processes, obtaining participants and improving the voluntariness of the sampling, identifying relevant disclosure aspects for the consent processes, and helping to translate research terminology to participants.d


5. **How does CEnR differ from traditional research?**

CEnR is committed to improving the overall research literacy of communities and establishes a role for the public in science and knowledge generation. Engaged researchers are embedded in communities and use partnership, cooperation, negotiation, and trust to address community priorities through research. CEnR is a framework or approach for conducting research, not a methodology in and of itself.\(^a\) To be quality CEnR, a project must have a research design that specifies empirical methods as connected to questions, with processes aligned for systematic inquiry that ensures the same rigor required for any other academic research. Where CEnR differs is that community is defined, and then representatives from this community are engaged through partnership to provide input and guidance into some or all of the phases of the research process.


6. **Are there scientifically grounded models to guide CEnR processes?**

Yes. At least since the 1990’s, academics have been working diligently to document process and outcomes related to the scholarship of engagement.\(^a\) Many models have emerged and the language around each is often unique to the discipline the model emerges from. Examples include Action Research (AR), Participatory Action Research (PAR), and community partnership models,\(^b\) prominent in disciplines such as Education and Social Work; Community-based Participatory Research (CBPR) prominent in public health disciplines; and Public Anthropology, Public Sociology, Critical Race Theory, Public Dialogues, Crisis Disciplines, and Social Entrepreneurship which are all used across the social and behavioral sciences.\(^c\)


7. **What if I am only supporting community partners to do their own research?**

You need to decide if you are engaged or not engaged in the actual research study. You are engaged in the research if you are involved in conducting interactions or interventions with human participants (e.g., informed consent, interviewing, etc.) or will have access to identifiable private information about research participants. If you are just doing education on how to conduct research, not conducting the actual research, then you are not engaged in their study. If you are collecting data, or even viewing personally identifiable data, then you are engaged and need to be covered by VCU’s IRB. The Commonwealth of Virginia statute requires all institutions engaged in conducting research to obtain IRB approval. However, if VCU is not engaged then VCU has no authority to require or grant approvals. See the Office of Human Research Protections guidance on engagement for more specific examples of when you may or may not be engaged in the conduct of research: [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html).
Engagement of Partners in CEnR

8. How do you define “partnership” in CEnR?
VCU defines partnership as a “sustained collaboration between institutions of higher education and communities for the mutually beneficial exchange, exploration, and application of knowledge, information, and resources. Examples are research, capacity building, or economic development.”
(http://www.community.vcu.edu/files/2012/05/CER-Definitions-Updated-8-28-13.pdf)

9. What types of CEnR partnerships exist between academic and community partners?
Three main typologies for CEnR partnerships exist that includes research or creative expression 1) with private business, industry, or commodity group partners; 2) with public nonprofit, foundation, or government partners; and 3) with other groups that may not be formalized as organizations. CEnR projects should specify the type of partnership and establish how partnering with the specified groups connect to the research questions. Different types of CEnR questions will require researchers to partner with different groups and also to produce dissemination products relevant to both academic peers and the community of engagement.


10. How are community partners engaged in research?
At the core of CEnR is the understanding that a representative group of community partners will be involved in a meaningful way in as many stages of the research design as is feasible. The reality is that partnerships for research can occur in many different ways and the model for engagement should be relevant to the community context, capacity, readiness, and the specified research design. A commitment to co-learning, asset development, and shared ownership guides the authentic engagement of partners and seeks to generate knowledge in a democratic way. Community partners and academics exchange local expertise and lived experience for scientific expertise and resources for knowledge development. Community partners can help generate and refine research questions, help design locally relevant methods, recruit participants, collect data, and/or assist in data management, analysis, and reporting, and in general, work to improve community attitudes towards research. Dissemination is often very important to community partners, who can serve to help translate research findings into real world change more readily than traditional academic dissemination channels alone.


11. What makes a community partnership effective for research?
Partnerships for research can occur in many different ways and should be structured in a way that is relevant to the academic and community contexts, and promotes equity among partners and sustainability of the innovations they co-create. Effective partnerships for research will have clear agreements about membership composition, data ownership, data use and dissemination, accountability for the research process, and mutual beneficence to all partners. These agreements can be informal, but will often need to be formalized for
participation in research. Examples include formalized Memorandums of Agreement,\textsuperscript{b,c} data sharing and authorship arrangements,\textsuperscript{d,e} and clear job descriptions.\textsuperscript{f}


12. Are there scientifically grounded models for assessing the effectiveness of CEnR partnerships?
Yes. Several tools are available for utilization including a partnership self-assessment tool,\textsuperscript{a} an institutional self-assessment tool,\textsuperscript{b} a community impact measurement tool,\textsuperscript{c} and an evaluation guide for university outreach to community partners.\textsuperscript{d} Compendiums of tools are also available online to support CEnR including CES4Health (CES4Health.info), CORUS (\url{https://ctsacorus.org/home}), and the Community Toolbox (\url{http://ctb.ku.edu/en/who-we-are#UI74z9LismE}).


13. Are community research partners ‘researchers’, ‘subjects’, or ‘participants’?
A recent VCU IRB language shift from "human subjects' research" to "human participants' research" signifies a larger shift in the academy that respects all humans involved in research as participating in some way; it is simply a matter of degree. The lines between community research partners and research participants can get blurry in a CEnR project, as the goal of engagement is to strike a more equal balance of power between the observer and the observed.\textsuperscript{a} In CEnR, community partners can be both researchers and participants. Some models have partners asking the questions in one part of the study (e.g., conducting interviews or focus groups) and participating in research activities in another part (e.g., as a respondent). Community partners may also be involved as researchers in helping to design a study and formulating study conduct methodology.
Therefore, it is important to identify what data will be collected for which research question and from which human participants.


### Submitting Your Study to the IRB

14. **How do you best present an emergent design to the IRB? (i.e. such as in an interview process)**

Think broadly but type concisely. Reviewers should accept a general concept for having a question bank and then allow for a process of refinement and finalization in the field. The purpose of the review is to see if questions are particularly sensitive and/or raise the risk around a potential disclosure of information once data is collected. If you need to work from a question bank or use an emergent design, you should justify why this method is best for the research question and include examples of what basis you will use for determining adaptations in the field. You do need to submit as close to the actual measures you will use specific enough so reviewers can determine the nature of the questions people will be asked, as well as how long it will take for them to complete the questions. You should be clear, concise, and specific while also allowing yourself enough room to respond to conditions of the field.

15. **Can a researcher expect that VCU’s IRB reviewers are trained in CEnR?**

To some degree, yes. VCU’s IRB is developing its capacity to review CEnR projects, and it is likely that someone on your review panel will be familiar with CEnR. However reviewers vary and you should take the space in your IRB submission to clearly present why CEnR is the best approach for the given research design. Many of our reviewers say that part of what they enjoy about serving as an IRB reviewer is the opportunity to learn about new methods and approaches, so you can to some degree look at this as a teachable moment in presenting your CEnR approach. You may be asked to provide more in depth information about a particularly new approach or method, but VCU’s IRB should be prepared to provide fair reviews of CEnR submissions. If a reviewer requests information or requires changes that will be especially prohibitory to your research design, it may be appropriate to have a conversation with the reviewer to more fully explain what you hope to accomplish. Good communication should enable a compromise to be reached.

16. **How much does the IRB need to know about non-research funded activities? (i.e. community planning meetings, social media marketing, etc.)**

The IRB is responsible for reviewing and approving the research components of community partner activity. We understand that community partnerships extend beyond a specific research project and that many activities may be going on at once. While these sorts of activities are likely very helpful to spell out for obtaining and reporting on funded contracts, unless the activity is directly related to human participant research, and/or produces personally identifiable data intended to be used for generalizations, then they do not need to be included in the IRB submission. You should provide just enough information about the overall project to explain why you are doing the research in the first place using a CEnR method, to present the community context the research may be occurring in, to describe how participants will be recruited, consented for research, and what specifically they will be asked to do for research purposes.

17. **What if I am collecting video journals/interviews with community members to share online?**

Unless the video recordings will somehow be used as part of a systematic research study that intends to use the data collected to make generalizations, then this is not human participant research and would not need an IRB approval. However, it is good practice to have participants sign a media release or similar document that outlines up front how their video footage will be used and disseminated.
18. What if the intent to publish and/or generalize changes after the data is collected?
If your intent changes because something great emerged from your data, then yes, you are able to submit to the IRB for an approval to use data that was collected for non-research purposes after the fact. If you created a document as discussed in FAQ#5 above, then you can include this in an IRB request for permission to publish on the data. You should discuss why the intent has now changed and that your community partners support this new intent.

19. What information do community partners need to provide for the IRB application process?
All IRB applications at VCU must be submitted through the RAMSIRB site (https://irb.research.vcu.edu/). The following questions are included in the process to identify and characterize community partner engagement in research involving human participants that is conducted by VCU investigators:

A. Is there at least one community partner* involved in the proposed study? Yes or No
B. If yes, provide the following details about each community partner (if there are more than 5 community partners, please provide the 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
C. Which of the three statements below best describes the role of the community partner in the study?
   i. Community partners only provide access to study participants or project sites. They are not involved with study design, participant recruitment, data collection, or data analysis.
   ii. Community partners do not make decisions about the study design or conduct, but provide guidance to the researcher about the study design, participant recruitment, data collection, or data analysis.
   iii. Community partners make decisions with the researcher(s) about the study's research activities and/or help conduct those activities (i.e. study design, participant recruitment, data collection, and/or data analysis).

Other details about the specific involvement of the community partner should be provided in the research methodology section of the smart form, as well as in response to other smart form questions as appropriate. If applicable, attachments may be required to the IRB submission including letters of support from partners, memorandums of agreement, job descriptions, compensation plans, data sharing agreements, authorship agreements, dissemination planning, and/or innovation ownership agreements. Documentation should fit the project and work to clarify accountability and ownership among partners throughout the knowledge generation process.

20. What is a Federal Wide Assurance?
A Federal Wide Assurance (FWA) is an agreement with the Department of Health and Human Services indicating that an institution that takes federal funds for the conduct of research will abide by the federal regulations pertaining to the conduct of research involving human participants. When a study is supported by a direct federal award to VCU and involves a community partner organization, that organization may be required to obtain a FWA in order to enable VCU to perform IRB review on the partner’s behalf. When submitting your study to the IRB, be sure to complete the non-VCU site details section appropriately. During the review process, the IRB will advise you if a community partner needs to obtain a FWA. If a community partner already has an FWA and will conduct its own IRB review, this can be denoted in the non-VCU site details section of the RAMS-IRB smart form. You can look up entities to see if they have an FWA by going to this search site: http://www.hhs.gov/ohrp/assurances/status/index.html.

21. If partners are providing data and engaged in the research design, how do you present this to the IRB?
The role of community partners as either researchers or participants should be clearly articulated for each CEnR project. If you are simply collecting evaluation data about how community partners are engaged in a larger research project (i.e. documenting sign-in sheets, member agreements completed, training satisfaction surveys, etc.) then this activity can likely be integrated into a single IRB submission. If no identifiers are collected and there is no intent to generalize, this type of evaluation may not be considered human participant
research. However, it is common in CEnR partnerships to explore multiple research questions simultaneously. It is possible the community members involved may be research partners in one study where they conduct focus groups with their peers; and then research participants in another study where reflexive journals they have completed about their engagement in research will be analyzed for themes. If this is the case, individualized research designs may be more appropriate for each distinct set of research questions, as each presents a different level of risk and benefit for participants. As a rule, if there are completely separate recruitment, sampling, consent, and/or data management processes, it may be best to manage research protocols with separate IRB approvals.

22. What if the partners working as Research Personnel change after our IRB has been approved?

The Personnel section of the RAMS-IRB study (or Personnel Roster on a paper study) would need to be updated to include anyone who is collecting and/or has access to personally identifiable data from human participants. Once you submit the updated form, this is a simple process and you should hear back about approval of the change within 48 hours.

23. Should community research partners be trained in human participant protection?

If partners will be interacting with human participants for research, then yes, they should receive some form of training related to research ethics and human participant protections training. For advanced partners, the online CITI training may be appropriate (https://www.citiprogram.org/). The University of Illinois at Chicago makes an equivalent certification for CEnR partners available online meant to be provided in a face to face format with participatory discussion (http://www.uic.edu/depts/mcam/CCTS/CIRTification/download-curriculum1.shtml). If it is not feasible for partners to complete a federally recognized certification program, you should at minimum provide a basic overview of human research protections. If you feel it is more appropriate to have your community partners complete customized education, your plan for providing such training must be clearly explained in your IRB application and approved by the IRB. For example, if you want to use a PowerPoint presentation that focuses on issues of informed consent, privacy, and confidentiality, you should explain to the IRB why this is most appropriate, how it will be delivered, and provide the PowerPoint to the IRB. If your project employs young people under age 18 to be engaged as researchers collecting data from other human participants, then parental consent to do so may also be required separately from parental consent to participate as a research participant providing data. Your submission should discuss these issues and include how you will prepare young people for the task of collecting data while also protecting humans.

24. What if I want community input on an existing research question and/or design?

VCU recently established a Community Review Board (CRB). A CRB is a structured forum for researchers interested in feedback from community members. It is composed of community members who serve as expert reviewers and provide feedback on various aspects of a proposed or ongoing research project, including the design, study implementation, instrument development, recruitment strategies, dissemination, and applying research findings to practice. Community reviewers can inform the researcher process by:

a) Providing a deeper understanding of a community and population’s unique circumstances
b) Increasing sensitivity to the community
c) Determining the feasibility and appropriateness of the project
d) Providing immediate feedback to the researchers

Currently, CRB reviewers are available from the Metro Richmond area only for any research topic. The VCU CRB is available to VCU faculty only. There is no cost to researchers for a one-time review session; however, should the researcher choose to maintain an ongoing partnership, the investigator will be responsible for any fiscal and administrative support necessary to maintaining the partnership (http://www.ccctr.vcu.edu/community/reviewboard.html).

For more information about community engaged research at VCU visit: www.community.vcu.edu
25. Can my community partner have their own study reviewed by VCU’s IRB?

VCU’s IRB has the authority to review studies where a VCU affiliated individual is engaged in the conduct of the research. Thus, a study that is submitted by a VCU principal investigator may request that the VCU IRB review the study on behalf of a community partner. The IRB review will take into account the roles and responsibilities of the community partner. A formal agreement specifically denoting this IRB reliance will be done only if the study is supported by a direct federal award to VCU. If a study is being conducted by a community partner and VCU is not engaged, the VCU IRB cannot provide the IRB review.

26. How can research Affiliate Status be obtained by my partners?

VCU’s Affiliate Status serves to formally recognize volunteer partnerships and connect partners to VCU resources, including a @vcu.edu email address, a VCUID card, and library access. Registering an Affiliate must be completed at the unit level through the Banner system, and units must specify the parameters of the Affiliate’s relationship with VCU (http://www.hr.vcu.edu/pdf_docs/AffiliateUserGuide.pdf).

27. How can a community partner gain access to the REDCap data management system?

Five total steps are needed to gain access (assuming the partner is currently NOT a VCU person):
1. The partner needs to get a VCU eID (VCU affiliate status) – can get that via your HR representative
2. The affiliate/partner then needs to be “sponsored” by a VCU faculty or staff member (link at go.vcu.edu/redcap)
3. The affiliate/partner then needs to login into REDCap (link at go.vcu.edu/redcap) SEE #4 if off campus.
4. NOTE: if logging in remotely (NOT on campus), the affiliate/partner must install and launch VPN (link at go.vcu.edu/redcap) on his/her computer
5. The affiliate/partner needs to be added as a user within a project and assigned the appropriate user rights to gain project-level access.

You may also email tranpl@vcu.edu (REDCap admin) if you want or need more REDCap related assistance.

28. How can I connect with community partners and/or other engaged scholars?

The best way to connect with partners is to be present. If you are new to the Richmond area, you should first connect with engaged scholars in your discipline area to identify which partnerships already exist between your academic unit and community partners. Many VCU units host events related to CEnR and you can seek out and attend those to connect with engaged scholars beyond your discipline area. A good way to keep up with what is going on at VCU is to subscribe to the CEnR listserv: http://www.vcu.edu/cgi-bin/listsub?cenr-interest-group-l. If you wish to build new partnerships with community groups, you should go to where they are at. An internet search can help you identify which partners may be relevant to your area of scholarship. You can reach out to the ones that you feel have a mission that aligns with your work. Building relationships for research can take time, and showing up consistently in service to community groups can help to demonstrate your commitment and facilitate research partnerships. Additionally, VIVO is a research-focused discovery tool that enables collaboration among researchers across disciplines. It is currently under development by VCU’s Center for Clinical and Translational Research (CCTR), but will include partnering organizations and will allow researchers to indicate their interest in engaging stakeholders in their research. (http://vivo.cctr.vcu.edu/vivo/).

29. What do you do if you have problems in the review process or get inconsistent feedback?

First, open channels of communication with the reviewer are most expeditious to resolving difficulties. You can also email your Panel Coordinator or someone else in the IRB office to discuss if you think that changes need to be made or if you get conflicting information. VCU’s IRB has established ORSP@vcu.edu as well to receive questions regarding reviews.

30. How do I stay up to date with the latest VCU supports for CEnR?

Opportunities for support for CEnR are increasing and the best way to keep up with opportunities for professional development, funding, or to increase your support networks is to subscribe to the CEnR listserv by clicking here: http://www.vcu.edu/cgi-bin/listsub?cenr-interest-group-l.