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***CIRTification*: Training in Human Research Protections for Community-Engaged Research Partners**

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Abstract

Background—Human research ethics training should provide relevant, meaningful information and build skills. Compliance should not be the only goal; training should also enhance knowledge, skills, and capacity. However, most currently available human research ethics training programs are geared toward learners who already have some research experience and working knowledge of research methods (e.g., graduate students, junior researchers); many community partners, however, have little or no prior exposure to research. More important, standard training programs do not adequately address the unique context of community-engaged research (CEnR).

Objectives—This article describes the development process, final curricular materials, and suggestions for successful implementation of *CIRTification*, a human research ethics training program designed specifically for community research partners who will be working on the “frontlines” of research.

Methods—Development of *CIRTification* involved an extensive literature review, consultation with stakeholders including community partners, academic researchers, and human research protection program personnel.

Conclusions—The curriculum, as well as information and materials to help potential users promote acceptance of the curriculum by their local institutional review boards (IRBs), are freely available online at www.go.uic.edu/CIRT. Ideally, community research partners who complete *CIRTification* will not only learn about the importance of protecting research participants but also be empowered to substantially contribute to the ethical practices of their respective research collaborations.

Keywords

Community-based participatory research; human research protections; ethics; community-engaged research; training; community research partners

Federal policy requires completion of formal education in the protection of human research participants by key personnel involved in the design and conduct of research studies.¹ Community partners involved in CEnR who have responsibilities related to recruiting participants, obtaining informed consent, and collecting data are required to complete such training. Most currently available human research ethics training programs and materials are geared toward learners who have some research experience and working knowledge of

research methods, such as graduate students and junior research faculty. Many community partners are typically community clinic/hospital staff or representatives of a community organization or social service agency and have little or no prior exposure to research. Standard training programs do not adequately address the unique context of CEnR.² Thus, these programs may not be appropriate for training community partners, nor will they be well-received. Although involvement of community partners in recruitment, informed consent, and data collection is consistent with key principles of community engagement, such as enhancing knowledge, building capacity, and sharing power, a mismatch between training needs and program content can result in limited understanding of key concepts and rules. For example, how to balance the demand to recruit a certain number of participants with the somewhat more vague requirement to ensure voluntariness may be confusing. Inadequate training may also engender feelings of uncertainty, lack of enthusiasm, or superficial involvement in the research process.³

Human research ethics training curricula have been developed specifically for community research partners, but many of these are project, population (e.g., Native American), or institution specific and therefore not readily adaptable for use by other groups.² The author is unaware of any curriculum tailored to CEnR that is widely accepted by multiple IRBs as a substitute for standard human research ethics training. Based on local demand, the author aimed to develop an alternative training program that would be more suitable and palatable to community partners and the academic investigators with whom they work and acceptable to IRBs responsible for reviewing this research. This article provides an overview of *CIRTification: Community Involvement in Research*, a training program in human research ethics tailored for community partners who will be working on the “frontlines” of CEnR projects and that can be used for projects employing a range of research methods. The development process, final curricular materials, and suggestions for successful implementation are presented.

Development

Identification of local need

In addition to the general need for community partner human research ethics training as described, community partners in Chicago faced an additional challenge. There are many academic institutions in the Chicago area, and many community organizations partner with more than one university. Therefore, a short-term goal was to develop and implement a training program that could be used at and accepted by all four local academic institutions that receive funding through the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program⁴: University of Illinois at Chicago (UIC), Northwestern University, University of Chicago, and Rush University. Members of these institutions make up the Chicago CTSA Consortium for Community Engagement (C3), which aims to provide a coordinated, synergistic approach to the development of genuine CEnR in Chicago.⁵

CTSA-funded researchers in Chicago conduct a broad range of public health, health promotion, health behavior, prevention, clinical, and translational research. Researchers are primarily working in urban and to a lesser extent, suburban communities that include

African Americans, Latinos, and European Americans as well as various Asian American groups. Many academic researchers partner with community-based health care providers and other social service agencies and use a variety of survey and qualitative data collection methods.

Although an immediate need was recognized in Chicago, and the immediate goal was to develop a product to meet local need, the ultimate goal was to develop a training program that could be used at any institution in the United States and throughout the world and that could be used by CEnR research projects regardless of population, setting, and research method, approach, or focus.

Integrating Stakeholder Input

Development of the *CIRTification* curriculum occurred over approximately 18 months. An extensive literature review was conducted by the author to identify key ethical issues in CEnR,² best practices in research ethics education and adult learning, and resources on key human research ethics topics. Federal guidance on human research ethics training is silent on appropriate content; no specific materials are endorsed or recommended, and there is no identified “gold standard.” However, because the Collaborative Institutional Training Initiative at the University of Miami (CITI) online training⁶ is used by all CTSA-funded Chicago institutions (and many more nationwide), an inventory of topics covered by CITI human research ethics modules was completed at the start of the project to guide basic content. Throughout the process, input was solicited formally and informally from three key stakeholder groups: community research partners, academic researchers, and IRB/human research protection program personnel.

Early in the process, focus groups were conducted to explore the views of academic and community partners regarding challenges to the protection of research participants and research integrity in CEnR. IRB approval was obtained from the UIC; results on the substantive issues identified are reported elsewhere.⁷ Briefly, both community and academic partners reported dissatisfaction with existing human research ethics training programs primarily because they are delivered online, offer limited interactivity, and do not provide examples from CEnR. Although online programs certainly have advantages, community partners wanted training to be delivered in person and to be engaging and immediately relevant to their day-to-day, research-related roles and responsibilities. Based on this information, the author determined that the best option would be a core curriculum with detailed background material for facilitators and audience-friendly activities and presentation materials. Local facilitators could then deliver training in-person to CEnR partners and select appropriate activities to meet their needs. Materials could be made available freely online so that they could be used by anyone. The curricular materials would be designed so that an individual with experience in CEnR (i.e., a principal investigator) or research ethics (i.e., an IRB education director) could deliver the program without any additional training.

During development, the author regularly consulted with the Ethics Subcommittee of the UIC Center for Clinical and Translational Science Community Engagement and Research Core, a group of academic professionals (including an IRB education director and a

compliance specialist) with interest and expertise in ethical issues in CEnR. (See the Acknowledgements for a list of committee members.) This group provided input regarding the content for facilitator background reading material, presentation and activity materials, and glossary of terms included in the participant workbook.

At several key points in the development process, the author also consulted with the Community Engagement Advisory Board (CEAB) of the UIC Center for Clinical and Translational Science, an ethnically diverse group that provides consultation to faculty members and students on all types of research studies. Active since 2002, CEAB membership fluctuates between 25 and 30 and includes representatives from various health care and social service agencies, churches, other community organizations, and voluntary associations; working and retired health care professionals; and researchers with extensive community engagement experience. Most commonly, consultation is provided regarding locations, strategies, and materials for recruiting specific populations or review of informed consent materials and questionnaires for culturally appropriate wording. Before conducting the focus groups, the author got input from the CEAB regarding focus group materials. After compiling a first draft of the curriculum, the author visited the CEAB again to present focus group findings and, in light of these, get feedback on a general outline of topics and balance of didactic material versus interactive activities. Once materials had been drafted, two CEAB members participated in an extensive review session during which they made suggestions for simplifying wording in presentation and activity materials. Finalized *CIRTification* materials were provided to the CEAB at a third visit to inform members that the project was completed and encourage them to recommend the training program to investigators seeking consultations as appropriate.

Field testing

Before finalizing the curriculum, the author field tested a 4-hour version of *CIRTification* with assistance from an experienced human research ethics education professional (Sandi Burbridge, Northwestern University, now deceased). Ten individuals hired to work on the National Children's Study and for whom approval had been granted to complete *CIRTification* in fulfillment of their human research ethics training requirement attended. Although a formal evaluation was not conducted, this field testing informed the ordering of activities and presentations, the time needed for individual presentations and activities, and the formatting of the facilitator manual and participant workbook.

Acceptance by IRBs

Once a complete draft of the final product was available, the author presented *CIRTification* to human research protection program personnel at each of the CTSA-funded Chicagoarea academic institutions. At all four institutions, the decision maker(s) responsible for making policy regarding human research ethics education agreed to accept *CIRTification* as an alternative to required training for community partners working on CEnR studies.

A cross-reference of *CIRTification* topics with CITI topics was completed to provide assurance that standard, appropriate content areas are covered (Appendix A available on line^{*}). The only issues that are de-emphasized in *CIRTification* are the IRB submission

process and the differences between exempt, expedited, and full board review. Otherwise, the primary difference is that the material is contextualized to CEnR and interactions with research participants. Therefore, the content of the curriculum was well-accepted by human research protection program personnel at all institutions. However, at some institutions there was concern regarding who would deliver the training. At UIC, project principal investigators (or their designees) are encouraged to deliver *CIRTification* to their own team members. However, at other institutions, the program is delivered only by certain designated individuals; principal investigators who feel that the generally required training is not suitable for their community partners must request *CIRTification* training from the IRB, which will then be delivered by one of these individuals.

Although the facilitator manual provides sufficient background materials for preparation, one of the institutions requested that the author provide formal facilitator training for individuals who would be designated to deliver *CIRTification*. This was then offered to the other institutions. An 8-hour facilitator training session was attended by 12 individuals with IRB or CEnR experience and/or job responsibilities from all four C3 institutions. The author took advantage of this opportunity to get feedback from the perspective of potential facilitators; attendees provided informal feedback on user friendliness of materials, as well as wording of presentation and activity materials before the curriculum was finalized and professionally formatted.

Overview of *CIRTification* curriculum materials

The *CIRTification* curriculum is approximately 150 pages long and includes a facilitator manual, PowerPoint slides and presentation notes, activity handouts, and a participant workbook. These components, as well as information and materials to help potential users to promote acceptance of the curriculum by their local IRB, are freely available online at www.go.uic.edu/CIRT.

The core curriculum consists of three parts, each containing unique content: 1) Human Research Rules and Regulations, 2) Asking People to Participate in Research: The Informed Consent Process, and 3) Being Careful with Research Information (Appendix B^{*}). The facilitator manual includes session learning objectives (Appendix C^{*}) and key messages that highlight primary take-away points; lay language glossaries and facilitator background reading that provide context and additional content related to presentations and activities; and lesson plans that include discussion cases and questions, presentations slides and notes, participant handouts, and facilitator guides for activities (Appendices D and E^{*}). The participant workbook includes an introduction to each section, glossary terms, and key messages.

* Appendices A–E available on line http://muse.jhu.edu/journals/progress_in_community_health_partnerships_research_education_and_action/v009/9.2.anderson_supp01.pdf; http://muse.jhu.edu/journals/progress_in_community_health_partnerships_research_education_and_action/v009/9.2.anderson_supp02.pdf; http://muse.jhu.edu/journals/progress_in_community_health_partnerships_research_education_and_action/v009/9.2.anderson_supp03.pdf; http://muse.jhu.edu/journals/progress_in_community_health_partnerships_research_education_and_action/v009/9.2.anderson_supp04.pdf; http://muse.jhu.edu/journals/progress_in_community_health_partnerships_research_education_and_action/v009/9.2.anderson_supp05.pdf

Educational Approach and philosophy

The *CIRTification* curriculum is unique because it focuses on core ethical issues that are most relevant to CEnR and from the perspective of a novice community research partner who will be responsible for recruiting participants, obtaining informed consent, and collecting data from research participants. For example, the informed consent module presents challenges to voluntariness and privacy/confidentiality that may arise if you are recruiting people you know to participate in research. Other topics include how to respectfully let ineligible individuals who want to participate in research—perhaps owing to perceived benefits of research or incentive payments—know that they cannot participate. In this way, community partners' day-to-day interactions with research participants are at the center of the curriculum. There is also discussion of group-level harms, as well as the idea that community engagement can provide additional protections through increased transparency and improved informed consent. All case studies present a community partner as the central decision maker in a dilemma encountered in a CEnR project.

CIRTification is interactive, addresses ethical issues in plain language, and uses real-world examples in activities that allow participants to practice newly acquired skills. Short presentations are included in each of the three sections, but the bulk of training time is to be spent on brainstorming activities, discussions of cases that present ethical dilemmas, and other interactive activities (Appendix D). For example, there is an informed consent role play that requires participants to play different characters, including research staff members and potential research participants, and act out situations they may encounter in the field, such as an individual who is suspicious of university researchers.

Because about one-half of American adults have limited literacy,⁸ it was critical that this training to be accessible widely. The language used in the PowerPoint slides and participant workbook is appropriate for English-speaking individuals with a high school education. Furthermore, the facilitator manual is written in plain language to the extent possible to help facilitators explain key concepts related to research, research ethics, and the responsible conduct of research to a lay audience. Participatory activities such as brainstorming, case-based discussions, and role playing provide learners with opportunities to see, hear, discuss, and apply.⁹

Although *CIRTification* accounts for community partners' limited research experience, the curriculum also aims to empower community partners by emphasizing the importance of protecting and respecting research participants—not simply “compliance”—and the important role that community partners play in ensure appropriate research protections and integrity. By providing opportunities for community partners to learn research skills, *CIRTification* aims to build community research capacity.

Facilitator Role and Curriculum Implementation

CIRTification was developed with the intent that a local expert facilitator(s) would deliver training in person to small groups. The facilitator could be an individual currently responsible for delivering human research ethics training, who may have expertise in research ethics but not CEnR. The facilitator could also be a principal investigator of a

CEnR project, who may have experience with community engagement but not in teaching research ethics. The background reading included in the facilitator manual aims to fill gaps in facilitator knowledge, contextualize basic research ethics content for CEnR, and present key research ethics concepts using lay language and terminology. The facilitator manual includes sufficient preparatory information such that no additional training is needed. Facilitator preparation time, printing, and space, if needed, are therefore the only costs of the program. To maximize benefit it is recommended that the project principal investigator(s) facilitate or co-facilitate training with someone who has expertise in research ethics and/or a community partner with significant research experience.

Facilitators should deliver all the presentations and may select which activities will be most appropriate for their group given their expected research roles. For example, if individuals will be responsible for obtaining informed consent, then the informed consent role play activity should be used. At a minimum, the 3-hour lesson plan should be followed to ensure fidelity to the learning objectives. However, because the material will be quite new to most participants, and to facilitate productive conversations, a longer time period (at least 5–6 hours) is ideal. Assessing the existing knowledge, strengths, needs, and expectations of your audience can help to determine the optimal length of time and activities. The three-part format of *CIRTification* allows for flexibility; the training can be delivered over the course of several shorter sessions if needed. Integration of *CIRTification* with protocol-specific training (e.g., use project consent forms, modify case studies to reflect the population/ research setting) is highly recommended.

Although the primary intended end user is the “frontline” community partner who is new to research with responsibilities that include recruiting research participants, obtaining informed consent, or collecting data, *CIRTification* can be modified to train students, academic faculty, community advisory board members, or other groups. Ideally, training should be delivered to community–academic research teams at the start of a project, regardless of which individuals need to satisfy training requirements and whether they fall into the categories of “community” or “academic” partner.

Ultimately, use of *CIRTification* will need to be approved by the local IRB that is responsible for reviewing the research protocol on which community partners are named as key personnel. Individual facilitators will need to identify which curricular activities are best suited to the needs of their community partners and present these for approval. Initial experience with institutions in Chicago and a few others suggest that *CIRTification* is acceptable to IRBs as means of meeting federal training requirements.

Future Directions

CIRTification is a work in progress, with continuous improvements and addition of enhancements. Evaluation of the acceptability and effectiveness of *CIRTification* at the individual trainee, partnership/project, and institutional levels is ongoing. Evaluation of ethics education can be challenging.¹⁰ First, no other human research ethics education programs have been evaluated robustly, making comparisons of *CIRTification* with standard programs complex and resource intensive. Second, the target outcomes of ethics training are

long term and difficult to operationalize and measure (e.g., minimizing harm, enhancing respect for research participants, promoting research integrity). The primary focus of current evaluation efforts is on satisfaction and ease of implementation for facilitators and acceptability/adoption at the institutional level.

Recently, a companion training video on informed consent has been produced and is also freely available on the *CIRTification* website. The curricular materials have also been translated into Spanish.

Limitations

Although the curriculum itself is available freely, in-person training programs can be time and resource intensive, especially for smaller projects/institutions that may not be able to identify appropriate facilitators easily. Therefore, adaption for online/self-study is being considered. Although significant efforts were made throughout development to gather community input, given the nature and scope of the project, this input was limited and more consultative in nature. Although the curriculum may be “static,” its use is dynamic. Therefore, a primary aim is to promote use and facilitation at the community organization level by increasing the number of community research partners trained to be *CIRTification* facilitators. This will ideally lead to curricular improvements and enhancements, including development of materials that are written at even lower reading levels and therefore accessible to a wider range of community partners.

Conclusion

To foster authentic community engagement, human research ethics training should provide relevant, meaningful information and build skills. Compliance with a requirement should not be the only goal; training should also enhance knowledge, skills, and capacity. Ideally, community research partners who complete *CIRTification* will not only learn about the importance of protecting research participants but also be empowered to substantially contribute to the ethical practices of their respective research collaborations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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