Characterization of Individuals and Institutions using *CIRTification* Online Human Research Protections Training for Community Researchers

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ABSTRACT:

Accessible, high-quality human research protections (HRP) training is essential to the ethical conduct of research. Here we describe the development and implementation of CIRTification Online, a comprehensive, freely available, and now completely online HRP training program designed specifically for community researchers. We characterize the over 5,800 individuals and 58 institutions that have used CIRTification Online during its first five years of availability. CIRTification users are diverse in terms of institutional affiliations, age, race and ethnicity, and research experience and roles. Formal adoption by academic research institutions has supported consistent increases in usage. Individuals affiliated with community-based organizations as well as large and small non-partner academic research institutions around the country (and some abroad) also use CIRTification. The steadily increasing rise in uptake by individuals as well as formal adoption by institutions suggests that CIRTification meets the HRP training needs of many community researchers.

KEYWORDS: Community health partnerships, Human research protections, Process, Research ethics, Online training

Introduction

To comply with federal regulations and the requirements of funding agencies,[1] research institutions require that all study personnel complete some form of human research protections (HRP) training prior to engaging in research. This includes principal investigators (PIs) as well as other individuals responsible for design and data analysis and those who interact with participants for recruitment, informed consent, and data collection purposes. Federal funding agencies such as the National Institutes of Health (NIH) or the National Science Foundation (NSF) do not endorse any specific courses to fulfill this training requirement; neither do government agencies who oversee HRP or research integrity, the Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP) and Office of Research Integrity (ORI), respectively. As a result, some institutions develop specific training programs for their researchers, while others use commercially available products.

Community-based participatory research (CBPR) and other forms of community-engaged research (CEnR) that include lay community members as researchers have become increasingly common. Yet, many studies report barriers to completing academic institutions' standard HRP training requirements.[2-4] First, while standard training programs are directed primarily towards individuals with graduate level research methods training, new community researchers may have limited familiarity with research methods and terminology.[5]

Second, community researchers' study roles often involve direct participant contact through recruitment, obtaining informed consent, and collecting data.[6-8] Standard HRP training is targeted to researchers who *design* the research, e.g., PIs and co-investigators, and as such spends less time on the ethics of interpersonal interactions that take place in the field compared with protocol and document preparation.[9] For example, how do you respectfully tell someone

that they do not qualify for a study that they perceive potentially beneficial? What do you do if you think a person is lying to gain access to a study?

Third, standard HRP training programs do not address unique ethical considerations that arise in research that takes place in community settings such as schools, parks, or local health care clinics or when individuals conduct research in their own communities. For example, what steps best maintain privacy and confidentiality and promote voluntary informed consent when participants know each other? What conflicts arise when individuals inviting potential participants to research also provide health or social services? What do you say if you run into a participant in the community?[10-13]

Fourth, standard HRP training programs are text heavy and may not adhere to adult learning best practices.[14] When developing educational programs for adult learners, Knowles' principles of andragogy should be considered.[15] Briefly, adult learners are intrinsically motivated, self-directed, want the experience they bring to learning to be respected, and prefer hands-on practical exercises. They want to understand why they are learning what they are learning and how it ties directly to their work and therefore desire content that directly applies to their current roles and helps them meet their professional goals. Standard HRP training can be especially challenging for individuals without college degrees or who have not participated in formal education in many years (or decades). Lastly, commercially available HRP training programs are expensive, limiting their accessibility for researchers from community-based organizations (CBOs) that want to conduct their own research.

HRP training is not just a practical issue; it is essential to the ethical conduct of research. Additionally, academic researchers owe it to our partner community researchers to provide worthwhile professional development opportunities. IRBs prospectively review research

protocols and materials to ensure studies are designed to minimize risk, balance risks with benefits, and promote justice, and ensure that consent forms and processes adequately inform prospective participants. However, IRBs are not there to monitor what happens in the field. Therefore, HRP training should not only prepare research personnel to design good studies and emphasize the importance of adhering to IRB-approved protocols, it should also support research personnel to make good ethical decisions in the field, especially because things may not go as planned. Inaccessible or irrelevant training that does not align with a learner's day-to-day job responsibilities may result in gaps in knowledge. It may also send a message that ethics and HRP training is just another box to check. HRP training sets the tone for how research personnel think about participant safety and well-being and research integrity in relation to other important "goods" – such as recruiting enough participants. It is therefore critical that HRP training be relevant, digestible, useful, and interesting.

To meet the unique needs of community researchers, a range of alternative training programs have been developed for different projects and populations.[3,16-21] We previously reported on the development of in-person training materials to support delivery of CIRTification: Community Involvement in Research, a comprehensive, freely available HRP training program for community researchers.[22] CIRTification was developed in response to requests from community and academic researchers in Chicago. Development and dissemination of CIRTification locally and nationally has been supported by NIH funding through the University of Illinois Chicago's (UIC) Center for Clinical and Translational Science (CCTS) (UL1TR002003) since 2010.

Briefly, after extensive literature review, original research,[6] and consultation with diverse stakeholders including community and academic researchers and human research protection

program (HRPP) personnel, the lead author developed a facilitator manual that includes presentation materials, a participant workbook, and an assessment (available in both English and Spanish).[23] The model for this original iteration of CIRTification was in-person delivery by a PI (or project director), HRP professional, or both, ideally integrated with protocol-specific training.

Uptake of CIRTification in-person materials has been steady since first becoming available in 2012. Since January 2020, English language materials have been downloaded 191 times, and Spanish language materials 35 times. We have identified over 30 publications citing use of in-person CIRTification materials to train community researchers for projects funded by multiple NIH institutes, the Patient Centered Outcomes Research Institute (PCORI), and private foundations such as the Bill and Melinda Gates Foundation. These publications report on health research projects implemented in the U.S. and abroad with different populations focused on topics such as HIV prevention and home testing, oral health, maternal health, mental health for breast cancer survivors, and diabetes medication adherence. Many are randomized trials examining outcomes of community-based behavioral interventions [24-26].

Despite apparent widespread use of CIRTification materials to support in-person training, due to resource limitations, small numbers of community researchers needing training, or the need to train an additional person after a project has started, we consistently received requests for an online, self-directed version of the CIRTification training. As more academic researchers collaborate with communities to improve the validity and relevance of research findings, more federal grant opportunities require such collaborations, and more CBOs initiate their own research, more appropriate, accessible options for HRP training are needed. Here we describe the development and implementation of the online version of CIRTification (CIRTification Online),[27] which has been freely available to anyone, anywhere in the world regardless of

institutional affiliation since January 2020. Additionally, we characterize the individuals and institutions that have used the program during its first five years (January 1, 2020 through December 31, 2024).

Development of CIRTification Online

Development of CIRTification Online involved several steps, starting with adaptation of key content in the original CIRTification facilitator manual, presentation slides, and interactive activities to an online learning environment. The program consists of 152 total pages with graphics and minimal text. There is professionally-recorded audio throughout. Full-text audio scripts are available for learners with hearing impairments or who prefer to read. Multiple videos were re-purposed from a longer training program on informed consent.[28] Several features promote interactivity. Different visual elements are incorporated; for example, a page early in the training introducing different types of research activities instructs learners to click on different boxes such as "obtain informed consent" or "share research findings" for a brief overview. There are examples of appropriate and inappropriate recruitment flyers, highlighting elements such as photos and language that overestimate potential benefits. On some pages the learner is required to "drag and drop" words to demonstrate understanding of material, for example the three Belmont principles that are foundational to ethical research with humans. CIRTification Online includes many interactive scenarios, in which learners hear characters describe a specific scenario such as a question from a potential research participant, and choose what they would do. They then receive feedback (written and audio) explaining the potential consequences of their choice – and whether there might be a better one.

CIRTification Online includes seven modules covering core HRP topics: Introduction to Research, Research History, Eligibility and Recruitment, Informed Consent, the Institutional Review Board, Collecting and Protecting Data, and Handling Issues in the Field (see Table 1). Each module includes an overview of essential material including vocabulary, guiding ethical principles, regulations, and good practices as well as interactive exercises as described above. After going through all seven core modules but before the final quiz, there is a comprehensive review with four scenarios, each with multiple questions requiring application of key concepts and providing feedback on responses (See Table 1). Following this review, learners then take a brief assessment of 20 multiple choice and true/false questions and upon obtaining a score of 75% (multiple attempts are allowed with feedback to reinforce learning), they can print and save a dated certificate of completion.

Draft versions of initial modules were reviewed by 24 experts including community researchers with previous HSP training and experience collaborating on research studies, academic researchers with experience conducting community-engaged research, research ethics education experts, and HRPP professionals. Each group contributed unique perspectives critical to ensuring relevance, acceptability, and comprehensiveness. Their wholistic comments reinforced that we had included standard research ethics content and that the program was engaging, user-friendly, and simple to navigate. Before national dissemination, we invited six lay community members who were affiliated with CBOs but had no previous HRP training to complete the program and complete structured surveys on ease of navigation and satisfaction with the learning experience. This feedback, which was quite positive, assured us that we could make the program publicly available without technical difficulties. Anyone not affiliated with

UIC who provided input during development was paid as a consultant (unless a federal employee) and is acknowledged in the CIRTification Online credits.

CIRTification Online is hosted on the UIC CCTS Training Center learning management system, which provides a centralized home for professional development programs, tool instruction, and research education. In 2021, after the English version was finalized, the entire program was professionally translated into Spanish, and new audio was recorded. Through a partnership with University of Miami Clinical and Translational Science Institute, a Haitian Creole version became available in late 2022.

Reflections on Online vs. In-Person Learning

Despite the broad accessibility of CIRTification Online, we believe there is also value in continuing to disseminate the original materials developed to support in-person HRP training. As mentioned above, these materials (facilitator manual, workbook, presentation slides, and handouts) continue to be downloaded, although tracking their use is challenging. Some institutions and individual academic investigators have the resources and/or the preference to deliver in-person training. And, there are certainly different benefits of in-person and online training. In-person training allows learners to ask and receive answers to questions in real-time. In-person training can be tailored to institution- and project-specific protocols, informed consent templates, and data collection forms. Learning with colleagues and leadership reinforces the importance of protecting research participants and promotes buy-in and ethical culture. However, with so many research projects operating with limited budgets and tight timelines, the commitment to CEnR of small institutions, and CBOs that want to conduct their own research, the convenience of a free online program that delivers standardized material that can be

completed by an individual with a wi-fi connection and a laptop, tablet, or mobile device is attractive. Compared with 10 years ago, an internet connection is more accessible, and people of all ages frequently interact with screens for entertainment and education. With careful attention to the user experience, online learning programs can be high quality.

Characterization of Individuals Completing CIRTification Online

To enroll in CIRTification Online, all learners are asked to voluntarily submit information regarding their institutional affiliation, title, role(s) in research, and years involved in research, and demographics (race, ethnicity, age). This information is collected for all training programs that use the learning management system and cannot be altered; thus we are limited in what we currently know about those who enroll in CIRTification Online. The learning management system also tracks when the enrollee starts and completes the program; the total percent (%) of pages completed; number of sessions to complete the training; and language (English, Spanish, or Haitian Creole). Five years (60 months of data, January 1, 2020 through December 31, 2024) were downloaded into Excel and analyzed to present descriptive summary statistics on learner characteristics, learner research roles and experience, and user experience. Data collection activities were determined to be exempt by UIC's Institutional Review Board.

Between January 1, 2020, and December 31, 2024, 7605 individuals registered for CIRTification Online. Of these, 5806 (76.34%) completed the training program. 5478 (94.35%) have completed CIRTification Online in English and 328 (5.65%) in Spanish. The average length of time from enrollment to completion is nine days. 3165 (54.52%) learners who completed the program reported no previous research experience (see Table 2); the most common role in research noted was data collection and/or recording data (49.47%), and 1937

(33.36 %) noted that they would have a role in obtaining informed consent from research participants (see Table 3). CIRTification Online users are also diverse in terms of age, race, and ethnicity (see Table 4). They are affiliated with academic institutions in at least 30 different states, as well as the District of Columbia, Puerto Rico, and Guam. Learners are also affiliated with state, county and municipal health departments, local school districts and fire departments, health clinics, hospitals, independent (non-academic) research centers, community colleges, faith-based institutions, community-based social service organizations, national non-governmental organizations, and other non-profit agencies.

Both enrollment and completion have risen over time. During the first 12 months of availability (January through December 2020), an average of eight individuals per month completed CIRTification Online; during January 1, 2024 through December 31, 2024, the most recent 12 months of data, an average of 189 individuals per month completed the training. See Figure 1 for overall use by month (January 1, 2020 through December 31, 2024).

Characterization of Institutions Using CIRTification Online

Anecdotally, we know that alternatives to standard HRP trainings for community researchers are accepted by some, although not all, academic IRBs. Since the 2020 launch of CIRTification Online, we have promoted formal adoption by institutional human research protections programs (HRPPs), the entities in which IRBs are housed. Formal institutional adoption of CIRTification as an acceptable option for community researchers who require HRP training can minimize burden on community researchers as well as on academic PIs and HRPPs. Formal adoption also increases overall awareness of CIRTification Online, encouraging HRPPs to provide information

on their internal websites and/or change their training policies to reflect the acceptability of CIRTification Online and/or other similar programs.

We have implemented a simple process for institutional HRPPs to formally adopt CIRTification Online by enrolling as partners. This simply involves providing contact information to the CIRTification team at UIC for at least one administrator who will have access to names and dated certificates of completion for all learners affiliated with their institution. We add the name of the institution to a drop-down list from which learners can select. We then work with HRPP leaders to disseminate information about CIRTification to their research communities and, if requested, develop policies on use that make sense.

As of December 31, 2024, 58 institutions have enrolled as CIRTification partners. Thirty-six of these are affiliated with NIH Clinical and Translational Science Award-funded hubs.. A list of partner organizations is available on our website.[29] Of the 5806 individuals who completed CIRTification during our reported timeframe, 3016 (51.95%) are affiliated with one of the 58 CIRTification partner institutions. This suggests that formal adoption promotes use at institutions with a critical mass of investigators engaged in community-based and community-engaged research.

Discussion

Understanding the basic characteristics of individuals and institutions using CIRTification Online can inform the development, improvement, dissemination, and evaluation of programs to meet the training needs of community researchers, research teams, and HRPPs. At the time of publication, CIRTification Online has been completed by over 5,800 individuals and almost 60 institutions are enrolled as CIRTification partners, endorsing use of the training for community

researchers when appropriate. Data on geographic location and institution demonstrate that a wide range of different types of institutions, academic as well as community-based, are taking advantage of CIRTification Online. Despite our data on individual learners being limited to basic demographics and research roles/experiences collected by the online learning platform, what we have learned about our users will inform more robust data collection efforts.

CIRTification Online users are diverse in terms of institutional affiliations, age, race and ethnicity, and research experience and roles. Based on increase over time and analysis of institutional affiliation, formal adoption by academic research institutions has supported consistent and exponential increases in usage, while individuals affiliated with community organizations as well as large and small non-partner academic research institutions around the country (and some abroad) also use CIRTification Online. The steadily increasing rise in uptake by individuals as well as formal adoption by institutions suggests that CIRTification meets the HRP needs of many community researchers, although further study is needed.

While community researchers have roles across the spectrum of research, we developed both the in-person CIRTification training materials and CIRTification Online to focus heavily on interactions with research participants and their data. Consistent with this approach, we found that CIRTification Online learners were much more likely to be involved in data collection, recruitment, and informed consent than they were protocol development (see Table 3). However, these findings do raise questions about how we in the academic research community can better engage community partners in protocol development and data analysis, and how we might support them to meaningfully contribute to these research activities.

We have found that adoption of CIRTification Online or other alternative training for community researchers may require both a PI who needs it urgently *and* an HRPP open in

principle to alternatives to standard training. It can also be helpful if someone from a central community engagement office (e.g., institutions funded through NIH CTSA grants have community engagement "cores" to facilitate CEnR) advocates for the suitability and quality of CIRTification as meeting the unique needs of community researchers. Anecdotally, we have heard from a very few academic investigators about pushback or even denial from their HRPP when requesting alternative training for community researchers. To assist investigators in such cases, we have materials on our website to help them advocate for their community partners.

Here we report user and institutional characteristics for CIRTification Online. In addition to challenges in obtaining complete data from our users (since we only require a name and email address, and individuals are free to leave all other fields blank or type in whatever they want), there are multiple challenges to assessing the efficacy and long-term impact of CIRTification Online. We have not yet been able to assess the impact of the training on knowledge of HRP or on behavior in the field. Importantly, we have not been able to compare the impact of CIRTification Online on HRP knowledge and behavior to that of other standard HRP training programs. Although measures of knowledge do exist,[30] a randomized controlled trial would be logistically challenging and resource intensive. However, our next steps include evaluating impact and obtaining formative feedback to inform future updates of CIRTification Online through surveys and interviews with both community researchers who have completed CIRTification Online and principal investigators who have used the training for their research teams.

Second, we do not know why learners are completing CIRTification Online. For some, it will be a requirement for working on a research study, either by an IRB to be included on a protocol or for membership on a community advisory board. For others, completion of the

training may be self-initiated for broader professional development purposes. The large number of learners under the age of 30 suggests that perhaps undergraduate and graduate students are completing CIRTification as part of a formal course or that some institutions may be allowing completion of CIRTification by different types of learners (e.g., university-based student research assistants). Interestingly, about a third of learners responded that they do not have or do not yet know their specific role in research, which suggests that some learners complete CIRTification Online not necessarily because they are required to, or that they do not know why they are being required to complete it.

Third, we do not have information from community researchers and research teams that are NOT using CIRTification Online; specifically, we do not know if the academic institutions they work with require a standard HRP training or if they are using other alternatives, or why some institutions and not others continue to use the in-person materials but not the online program. We would be pleased to know that other alternatives are available. However, if individuals or teams are not using CIRTification programs because some institutions do not in principle allow alternative options for community researchers, or because CIRTification is not meeting their needs, then we want to understand why and work to change this, even if it means developing new alternatives.

Lastly, we do not know reasons for non-completion of about 25% of individuals who enroll, although we hypothesize that many of these individuals are academic PIs or HRPP professionals exploring CIRTification Online to determine its acceptability for project or institutional use. However, there may also be other important reasons for discontinuation worthy of exploration, such as learner fatigue. We hope to be able to collect this information in the future.

Moving forward, we have identified the need for continuing training options for individuals whose HRP training has expired. In response, we are currently working on a "refresher" version, and have engaged diverse stakeholder experts to appear in videos and to review the final produce prior to dissemination. In the future, we also hope to develop tailored "mini-modules" for emerging topics such as research with human tissue as well as modules for research with specific populations (e.g., immigrants and refugees, children).

Table 1. CIRTification Online Modules, Topics Covered, and Examples of Interactive Activities

CIRTification Online Modules	Topics Covered	Example of Interactive Activity
Introduction to Research	What it means to participate in research How research has impacted the world The people, process, and tasks of research	Deciding to participate in research: Learn about different elements of research and what potential participants consider in their decisions
Research History	Past research abuses The Belmont Report and federal regulations for research	Apply what you've learned: "Drag and drop" different ethical principles and regulatory requirements to match their descriptions
Eligibility and Recruitment	Inclusion and exclusion criteria The recruitment process; materials and strategies	Apply the eligibility criteria: Review descriptions of potential participants and decide if they meet study inclusion/exclusion criteria
Informed Consent	Elements of informed consent and key information Tips for obtaining informed consent Participants' right to withdraw	This is not what I thought I signed up for: Respond to a participant who wants to leave a study
The Institutional Review Board	Purpose of the IRB IRB submission process IRB review process	What do you think: Play the role of an IRB member and decide if the consent form for a study being reviewed at today's meeting is clear and accurate
Collecting and Protecting Data	The importance of following the protocol Protecting privacy and confidentiality The HIPAA privacy rule	What could have been done: Review scenarios of data breaches to note what could have been done to prevent the breach from happening
Handling Issues in the Field	Maintaining boundaries with participants Protecting participant confidentiality Compensating research participants What to do if a team member is not following the protocol	Maintaining boundaries with participants: Respond to a participant who asks to receive their payment before completing study activities

Comprehensive review applying what you've learned to different scenarios -A friend has been invited to take part in a research study. What can you tell them about research? -Your study has been submitted to the IRB for review. What happens next? -You will be recruiting and obtaining informed consent for a research study taking place at a community health clinic. What do you need to know? -You will be administering surveys in your community. How will you protect participants and their data?
Quiz (20 questions) – obtain score of $\geq$75% and obtain certificate of completion

Table 2. Years Involved in Research for Learners who have Completed CIRTification Online, January 1, 2020-December 31, 2024

Years Involved in Research	Total* (%)
No Research Experience	3165 (54.52%)
Two or Fewer	1268 (21.84%)
Three to Five	625 (10.78%)
Five to Ten	360 (6.20%)
Eleven or More	375 (6.46%)
Not Reported	13 (0.22%)

*Data reported from 5806 individuals who completed CIRTification Online in English, Spanish, or Haitian Creole

Table 3. Research Roles of Learners who have Completed CIRTification Online, January 1, 2020 – December 31, 2024

| Research Role	Total* (%)
Protocol development	1167 (20.10%)
Recruitment of research participants	2178 (37.51%)
Obtaining informed consent	1937 (33.36%)
Collecting and/or recording data	2872 (49.47%)
Data analysis	1665 (28.68%)
None of the above/don't know	2119 (36.50%)

*Data reported from 5806 individuals who completed CIRTification Online in English, Spanish, or Haitian Creole; Respondents can choose more than one role, so percentages add up to more than 100%

Table 4. Demographics of Learners who have Completed CIRTification Online, January 1, 2020 – December 31, 2024

	Total* (%)
Age	
Under 21	384 (6.61%)
21-30	2337 (40.25%)
31-40	1148 (19.77%)
41-50	846 (14.50%)
51 or older	1078 (18.57%)
Not reported	13 (0.22%)
Race	
White	2924 (50.36%)
Black or African-American	1312 (22.60%)
Asian	600 (10.33%)
American Indian or Alaska Native	121 (2.08%)
Native Hawaiian or Pacific Islander	27 (0.46%)
Multi Racial (*marked more than 1 race)	390 (6.72%)
Other	237 (4.08%)
None of the above	182 (3.14%)
Not reported	13 (0.22%)
Ethnicity	
Hispanic/Latino	1218 (20.99%)
Non-Hispanic/Latino	4575 (78.81%)
Not reported	13 (0.22%)

*Data reported from 5806 individuals who completed CIRTification Online in English, Spanish, or Haitian Creole

Figure 1. Use of CIRTification by Month, January 1, 2020 – December 31, 2024

Total # Individuals Completing CIRTification Online by Month, January 2020 - December 2024
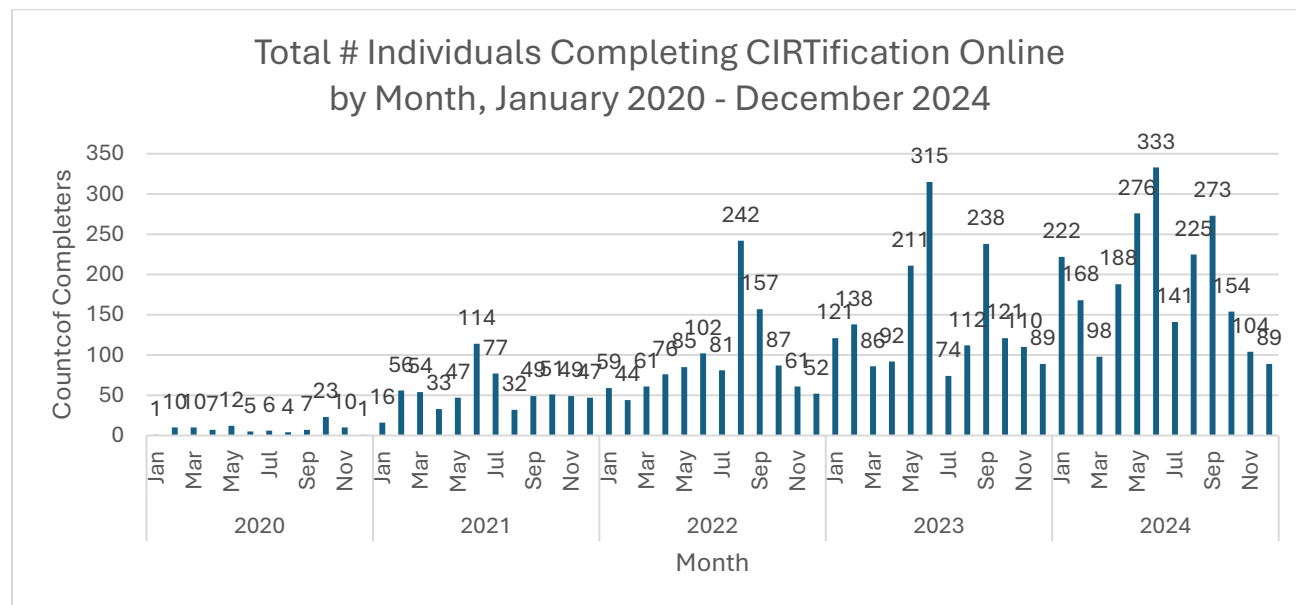
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