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Best practices in social and behavioral research: report from the Enhancing Clinical Research Professional's Training and Qualifications project

Susan L. Murphy^{1,2*}, Christine Byks-Jazayeri¹, Nancy Calvin-Naylor³, Vic Divecha¹, Elizabeth Anderson¹, Brenda Eakin¹, Alecia Fair⁴ and Laura Denton⁵

¹ Michigan Institute of Clinical and Health Research, University of Michigan, Ann Arbor, MI, USA

² Department of Physical Medicine and Rehabilitation, University of Michigan, Ann Arbor, MI, USA

³ Institute for Research on Innovation and Science (IRIS), University of Michigan, Ann Arbor, MI, USA

⁴ Research Support Services, Vanderbilt University Medical Center, Nashville, TN, USA

⁵ Office of Faculty Development, University of Michigan, Ann Arbor, MI, USA

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Introduction. This article discusses the process of defining competencies and development of a best practices training course for investigators and clinical research coordinators who conduct social and behavioral research.

Methods. The first project phase established recommendations for training in Good Clinical Practice (GCP) and was done in conjunction with representatives from 62 Clinical and Translational Science Award (CTSA) hubs. Diversity in behavioral clinical trials and differences in regulation of behavioral trials compared with clinical trials involving drugs, devices, or biologics necessitated a separate Social and Behavioral Work Group. This group worked with CTSA representatives to tailor competencies and fundamental GCP principles into best practices for social and behavioral research.

Results. Although concepts underlying GCP were deemed similar across all clinical trials, not all areas were equally applicable and the ways in which GCP would be enacted differ for behavioral trials. It was determined that suitable training in best practices for social and behavioral research was lacking.

Discussion. Based on the training need, an e-learning course for best practices is available to all CTSA sites. Each institution is able to track outcomes for its employees to help achieve standardized competency-based best practices for social and behavioral investigators and staff.

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Introduction

Clinical trials yield the vast majority of discoveries that are translated into practice. The importance of the rigor of the research and scientific integrity of data collected necessitate regulatory processes and a highly trained workforce to conduct research in accordance with these processes. Although these processes are clearly laid out for drug, device, and biologic

clinical trials, the same is not always true for behavioral intervention studies. Behavioral intervention studies have not typically been held to the same intensity of regulation as drug, device, or biologic trials and thus the processes to conduct high-quality behavioral research have not been well specified. This may be because behavioral intervention studies tend to involve low risk to participants. In addition, any deliverables that result from these behavioral studies, such as specific behavioral intervention protocols, usually do not require regulation by the Food and Drug Administration (FDA), which is required for drugs and certain devices.

Recently, the National Institutes of Health (NIH) revised their definition of clinical trials to include behavioral research. Clinical trials are defined as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes” [1]. This new

* Address for correspondence: S. L. Murphy, Sc.D., O.T.R., Associate Professor, Department of Physical Medicine and Rehabilitation, University of Michigan, 24 Frank Lloyd Wright Drive, Lobby M, Suite 3100, Ann Arbor, MI 48105, USA.
(Email: sumurphy@med.umich.edu)

definition in which behavioral intervention studies are being called “clinical trials” is a paradigm shift in social and behavioral research. This shift demands competence in new professional domains for research teams. Thus, the need for competency-based training for investigators and clinical research coordinators (hereafter referred to as coordinators) of behavioral clinical trials is urgent. When engaging in drug, device, or biologic clinical trials, investigators and coordinators require training in Good Clinical Practice (GCP). This type of training is based on an international standard to ensure participant safety and data integrity, as well as to ensure consistency in reporting and regulation. Investigators and coordinators of behavioral clinical trials have not typically been required to undergo this training, as evidenced by a recent review from the GCP Training Project by the Clinical Trials Transformation Initiative [2]. Because GCP training was designed for drug, device, and biologic trials, a need was identified to examine how GCP training relates to social and behavioral research and particularly in the conduct of behavioral trials.

Other papers in this issue have discussed the background of the Enhancing Clinical Research Professionals’ Training and Qualifications (ECRPTQ) project, recommendations for training, and the process for defining competencies for study investigators and coordinators. This paper will present the process the Social and Behavioral Work Group undertook to determine how GCP relates to the conduct of behavioral clinical trials. This was done for the purposes of developing an e-learning course for best practices training in social and behavioral interventional research.

Materials and Methods

Formation of Social and Behavioral Work Group

The initial ECRPTQ meeting was held in Chicago to bring representatives of all 62 Clinical Translational Science Award (CTSA) hubs and key stakeholders in the human subject clinical research area together to adopt a standardized approach to GCP training for clinical trials. The attendees determined that an equivalent training for GCP in behavioral clinical trials was vital. The Social and Behavioral Work Group was formed with the primary purpose of ensuring that a core set of competencies and training in GCP would be relevant to behavioral trials. The work group was composed of 25 members including an administrative and faculty lead (online Supplementary Material). The members represented many CTSA-funded hubs nationwide and included both study investigators and coordinators who had experience in behavioral trials. The primary mode of interaction of this work group was through biweekly conference calls. A central web storage site was

used to share materials. The group co-leads reported, advised, and determined strategic direction from the ECRPTQ leadership through direct participation on the project steering committee.

Preliminary Discussions and Consensus Building

After the Social and Behavioral Work Group was formed, it was first necessary to orient the group to the NIH’s revised definition of clinical trials and to discuss how the definition related to behavioral interventions. Some group members had not conceptualized their intervention studies as clinical trials, and there was a need to operationalize what was considered a “behavioral” intervention. The group members and leads provided examples from their own work as well as relevant materials from the literature which were uploaded onto a central web storage site. Consequently, the group discussed various types of interventions that could be defined as behavioral in nature and tested through clinical trials. This discussion was important for the group to begin thinking about key differences between design and conduct of behavioral clinical trials compared with drug, device, or biologic trials. Examples of behavioral trials discussed are provided in Table 1. Differences between behavioral trials compared with drug and device trials included variety of research settings (such as clinics, schools, home), the tendency of these trials to be of lower risk to participants, and the increased complexity of these trials through the use of people who provide interventions (referred to as interventionists) and the fidelity tracking necessary to ensure integrity of the delivery and receipt of the intervention.

Once the group came to consensus regarding what was considered a behavioral clinical trial, they were oriented to the concept of GCP. The term GCP was not familiar to many members in the work group as most social and behavioral researchers do not undergo this training unless they are involved in a drug or device clinical trial. Relevant materials about GCP, its origins, and rationale for training were uploaded to the central web storage site for members to read and discuss on initial conference calls. The group reviewed the Minimum Criteria for GCP training of investigators and site personnel from TransCelerate BioPharma (based upon the document from the International Committee on Harmonization [ICH]) [3] and its criteria for relevancy to behavioral trials are listed in Table 2. This was done by sending an electronic survey to group members and asking them if they felt that each criterion was relevant, maybe relevant, or not relevant to behavioral clinical trials. The survey responses were tabulated and discussed in the group.

Building on these foundational activities, the group was asked to review existing training for GCP and to identify gaps specific to behavioral

Table 1. Examples of behavioral clinical trials

Trial example	Setting	Factors that may impact risk level	Use of interventionists	Fidelity tracking
Intervention to prevent childhood behavior problems	School based	Urban, high poverty sample	Trained teachers	Tracking of teacher delivery of intervention
Parenting intervention to reduce childhood obesity	Clinic setting	High-risk mothers who have experienced trauma	Social worker supervised by a psychologist	Sessions are videotaped
Brief intervention due to elevated alcohol consumption at their annual physical	Interactive voice response (phone) intervention	People followed by physician	No	No
Incentive programs to promote cigarette-smoking cessation (or cessation of other substance use) and reduce relapse rates		Smokers and/or substance abusers Assessments typically include urine samples that are analyzed as measures of recent smoking	No	No
Physical therapy for sepsis patients	Hospital, inpatient	Medically unstable patients, intervention may be risky for them to participate	Trained physical therapists	Yes
Rehabilitation for the reduction of tremors in multiple sclerosis (MS)	Clinic setting	Use of a mobile app to measure the degree of tremor before and after test	Trained occupational therapists	Yes

Table 2. TransCelerate criteria: results of survey and group discussion regarding behavioral trial differences

TransCelerate criteria	n	Report of “yes it applies” [% (n)]	Comments from group on how behavioral trials are different
1			
Investigator qualifications and agreements			
Investigator qualification (education, training, experience)	15	93 (14)	No IP
Demonstrate evidence of adequate training (provide up-to-date CV)		93 (14)	No requirement to comply to GCP
Awareness of and compliance with GCP and regulatory requirements		67 (10)	Different methods of monitoring, audit, and inspection (may be different within behavioral trials depending on risk level of trial)
IP familiarity		7 (1)	
Allow for monitoring/auditing/inspection to enable sponsor/regulatory oversight		40 (6)	Sponsor/regulatory oversight is different
Introduce definitions of monitoring (1.38), audit (1.6), and inspection (1.29)		47 (7)	
Use of qualified support staff		100 (15)	
Document delegation of duties to appropriately qualified persons		87 (13)	
2			
Adequate resources			
Potential to recruit suitable subjects	15	93 (14)	
Sufficient time to conduct trial		93 (14)	
Sufficient qualified staff and adequate facilities to conduct trial		93 (14)	
Staff are adequately informed about protocol, IP, and tasks related to the protocol		80 (12)	
3			
Medical care of trial subjects			
Qualified physician or dentist who is an investigator or sub-investigator should be responsible for all trial-related medical decisions	15	27 (4)	Trial dependent
		40 (6)	May not need a qualified physician, dentist, etc. for trial-related medical decisions
During and following the trial, the investigator/institution should ensure appropriate medical care for AEs and clinically significant lab deviations related to trial and inform subjects if medical care is needed for intercurrent illness		33 (5)	Ensuring appropriate care for AEs or lab deviations
			Ascertain reasons for a subject’s premature withdrawal from a trial
Physician to make a reasonable effort to ascertain the reasons for subject’s premature withdrawal from the trial			Good for tracking purposes in behavioral trial, but maybe not for “medical care” reasons
4			
Communication with IRB/IEC			
Definition of IRB (1.31) and IEC (1.27)	15	93 (14)	No investigational brochure required
Before trial begins, obtain written, dated approval/favorable opinion for protocol and all documents provided to subjects (eg, ICF, advertisements)		80 (12)	May be different level of communication depending on risk level of behavioral trial
		7 (1)	
Provide a copy of investigator’s brochure/updated IB		80 (12)	
Before and during the trial, provide all documents required by IRB/IEC for review and appropriate approval/favorable opinion			
5			
Compliance with protocol			
Conduct trial according to approved protocol, GCP, and applicable regulatory requirements, for example, sufficient documentation to support subject meeting inclusion/exclusion criteria	15	93 (14)	Do not conduct trial according to regular GCP
Document the acceptance to follow protocol in a protocol signature page or contract		60 (9)	Documenting acceptance to follow protocol in a protocol signature page (trial specific, depends on study sponsor)
Protocol deviation process—no deviations or changes before sponsor and IRB/IEC approval/favorable opinion		60 (9)	Protocol deviation may not need same level of reporting (ie, documented and rationale submitted to sponsor)
6			
IPs			
Responsibility for IP (refer to 1.33) accountability and delegation of activities and supervision of an appropriately qualified person	15	33 (5)	Not applicable
		20 (3)	
Documentation of delivery, inventory, dispensation, usage, disposal or return, and reconciliation of all IP and other study medication		20 (3)	
		20 (3)	
Stored per requirement			
Explanation of correct use of IP to subjects and periodic check for understanding/compliance			

Table 2. Continued

TransCelerate criteria	n	Report of “yes it applies” [% (n)]	Comments from group on how behavioral trials are different
7			
Randomization procedures and unblinding			
Follow the trial’s randomization procedures	16	88 (14)	May not need to unblind in a behavioral trial
Blinded trials: promptly document and report to sponsor any premature unblinding		38 (6)	
8			
Informed consent of trial subjects			
Definition of informed consent (1.28)	16	82 (13)	Informed consent process not often feasible to be documented in medical record as these trials may occur outside a clinical setting
Explain the informed consent process and ICF		94 (15)	
IRB/IEC written approval in advance of use for written consent and other written information to be provided to subjects		94 (15)	
Subject to be fully informed of all pertinent aspects of the trial before participation		94 (15)	
The informed consent discussion and form needs to include all relevant explanations.		94 (15)	
Refer or link to ICH 4.8.10		94 (15)	
Language used in oral and written information (ICF) should be understandable to subject or legal representative and impartial witness (where applicable)		94 (15)	
Subject should have ample time to review the ICF and to ask any questions and receive answers before decision is made		94 (15)	
Subject should not be unduly influenced to participate		88 (14)	
ICF should be obtained/signed before a subject’s participation in a trial (before any study procedures are performed)			
Subject should be aware that withdrawal is possible at any time			
Subject should not be asked to waive legal rights or release investigator or sponsor from liability for negligence			
Written ICF must be updated/approved when new information is available that may be relevant to subject’s consent			
Informed consent of special population	16	88 (14)	
Refer to or add definition of vulnerable subjects (1.61)		94 (15)	
When a subject (eg, minor, incapacitated) can only be enrolled with the consent of the legal representative, the subject must be informed to the level of their understanding, provide assent (where this is feasible), and personally sign and date the consent form		75 (12)	
provide assent (where this is feasible), and personally sign and date the consent form		94 (15)	
In emergency situations, where the subject and legal representative are unable to consent, enrollment requires protective measures to be described in protocol or other IRB/IEC-approved documents. Subject or legal representative should be informed as soon as possible and consent to continue and other consent as appropriate		82 (13)	
In emergency situations, where the subject and legal representative are unable to consent, enrollment requires protective measures to be described in protocol or other IRB/IEC-approved documents. Subject or legal representative should be informed as soon as possible and consent to continue and other consent as appropriate		82 (13)	
If the subject/legal representative are unable to read, an impartial witness must be present during the consent discussion and sign and date the consent form		50 (8)	
Informed consent documentation			
The ICF should be signed and personally dated by the subject and/or the legal representative and by the person who conducted the consent			
A signed and dated copy of the ICF should be given to the subject or the legal representative (including any other written information provided to the subject)			
The informed consent process should be documented in the medical record/source file (as well as documentation regarding communication of new information)			

Table 2. *Continued*

	TransCelerate criteria	n	Report of "yes it applies" [% (n)]	Comments from group on how behavioral trials are different	
9	Records and reports				
	Definition of source documents: the actual documents (originals), GCP glossary 1.52 (brief)	16	69 (11)	Source documents and essential documents may have specific meaning for drug trials not applicable/known to behavioral trials	
	Refer to or add definition of source data (1.51)		56 (9)		
	Definition of essential documents (section 8)		69 (11)	Financial aspects in sponsor agreement appears to refer to drug trials only	
	The need to maintain essential documents. Refer/link to section 8		75 (12)		
	Retention of essential documents		81 (13)		
	CRFs and all required reports (written or electronic)		75 (12)		
	Corrections are dated and initialed, do not obscure original entry and explained if necessary (applies to written and electronic changes/updates). Retain records of changes and corrections		75 (12)		
	Financial aspects documented in an agreement between sponsor and investigator/institution		75 (12)		
	Direct access to all trial-related documents by the monitor, the auditor, the IRB/IEC, or regulatory authority				
10/13	Progress reporting/final reports				
	Investigator submits written summaries of progress to IRB/IEC at least annually or as required	16	88 (14)		Final report submitted to IRB/regulatory authorities may be trial specific
	Provide written reports to sponsor and IRB/IEC (and institution where required) of any significant changes affecting the study or increased risk to subjects		81 (13)		
	Upon completion of trial, provide sponsor with all required reports		81 (13)		
	Final report with a summary of trials and outcomes submitted to IRB/IEC and regulatory authorities as required		75 (12)		
11	Safety reporting				
	AE definition (1.2)		6 (1)	ADR is not applicable Reporting of SAEs is likely to be on different timeline than in drug trials	
	Refer to or add definition of ADR (1.1) and unexpected ADR (1.60)		56 (9)		
	AE reporting—all AEs and/or laboratory abnormalities should be reported to the sponsor within the time period defined in protocol		56 (9)		
	All SAEs should be reported immediately to the sponsor except for those SAEs that the protocol or other document (eg, investigator's brochure) identifies as not needing immediate reporting				
12	Premature termination or suspension of trial				
	Responsibility to promptly inform the trial subjects and ensure appropriate therapy and follow-up. Inform regulatory authorities when required	16	63 (10)	May be trial specific	
	Responsibility for communication of study termination or suspension of study to sponsor, IRB/IEC, and institution as applicable, including a detailed written explanation		75 (12)		

GCP, Good Clinical Practice; IP, investigational product; AE, adverse event; ICF, informed consent form; SAE, serious adverse event; ADR, adverse drug reaction.

research. Pairs of reviewers were assigned to submit a written review of each of the programs. Individually they accessed the training and completed the course. Reviewers were asked to evaluate the effectiveness of the content for best practices training for social and behavioral researchers. They also reviewed the courses for design features and were asked to describe what they liked and did not like about the experience of taking the course. During conference calls, reviews were discussed, compared, and synthesized. Pairs of group members were assigned different GCP training courses and their ratings were compared and discussed in conference calls.

Participation in Research Competency Adaptation for Social and Behavioral Trials

Representatives of the Social and Behavioral Work Group participated in the face-to-face meeting at the ECRPTQ conference in Dallas in February 2015 as described in the paper by Calvin-Naylor *et al.* [5]. These work group members helped to evaluate and refine research competencies that were part of a larger framework developed by the Joint Task Force for Clinical Trial Competency [4]. The work group offered recommendations which resulted in some adaptations to competencies shown in the appendix of that paper. The competencies served as a foundation for conceptualizing GCP training for social and behavioral researchers.

Results

Table 2 shows the results of the relevance of the GCP criteria to behavioral clinical trials. There were 15–16 responses for each criterion and the results were presented and discussed on a conference call with the group for clarity. The areas thought to be least relevant to behavioral trials included investigational products, medical care, safety reporting, and premature suspension of trials. Investigational products is an area clearly not relevant to behavioral trials, as having an investigational product would classify the trial as a drug, device, or biologic for regulation through the FDA. As behavioral trials typically pose minimal risks to participants and may not be conducted in a clinical setting, medical care of a qualified physician was considered to be only necessary in specific situations, such as behavioral trials with ill or medically unstable participants. This same line of reasoning applied to safety reporting as the reporting would be different for minimal risk trials. In addition, the group felt that unblinding or premature suspension of a trial would be a rare occurrence in behavioral trials.

Review of Existing GCP Training

Four commercial e-learning courses as well as one course through the NIH were reviewed. Across all courses reviewed, significant gaps in training were identified. The topics, with the exception of the focus on regulatory processes related to GCP, were felt to be largely relevant. However, the content was not specific to behavioral trials and lacked examples or scenarios that arise in social and behavioral research. In courses that were geared toward social and behavioral researchers, there was discussion about the breadth and depth of content presented. Most of the training was thought to be either too general or too specific for a best practices course. Some course content seemed redundant with basic training in human subject protections that investigators and coordinators need to take at their institutions when engaging in research. Other course content was deemed to be appropriate but highly specialized, such as modules about working with prisoners or international research studies. With regard to the user experience with each course, aspects that reviewers mentioned as promoting their engagement included high visual appeal, good narration, and interactive features. One course included job aids and reference links that were deemed especially useful. Although some reviewers felt that quizzes or knowledge checks throughout the

course were engaging, others liked the ability to test out of a course altogether by taking a quiz separate from the course itself.

Discussion

The activities of the Social and Behavioral Work Group identified a clear need for specifying the construct of GCP for social and behavioral researchers. The term GCP was largely unfamiliar to the content experts and required group discussion and consensus building to relate GCP to the design and conduct social and behavioral research. After thorough review, it was determined that existing GCP training was not applicable for researchers conducting behavioral trials. Therefore, the Social and Behavioral Work Group recommended to ECRPTQ leadership that a new training program be created, focusing on the specific needs and unique research processes of social and behavioral research teams.

Best Practices Training in Social and Behavioral Research

In order to develop appropriate training, it was necessary to better define the construct of GCP for social and behavioral researchers. Fig. 1 shows the conceptual model used. We felt that we should rename GCP to “best practices” as GCP in the traditional sense is not a term typically used in the context of social and behavioral research and has specific ties to regulation from FDA that is usually not applicable. Despite differences, there is an overlap in the competencies required for research personnel of FDA-regulated trials and behavioral trials. In order to create best practices training, it was necessary to address the overlap of what all research personnel need to know. Thus, the training requires an introduction to the context of GCP and definition of terms specific for behavioral research personnel. However, it is also important to de-emphasize areas not relevant to social and behavioral research. In addition, because behavioral trials often have additional complexity in design and implementation, specific content needed to be addressed, such as treatment fidelity. Content for best practices needed tailoring from GCP and needed to focus on specific job skills for both investigators and clinical research coordinators.

After receiving approval to move forward, a subset of volunteers from the Social and Behavioral Work Group were recruited to define content areas for a social and behavioral best practices training program. A mapping process was employed to identify potential topics and link them to competency domains defined by the ECRPTQ project. To do this, the work group team leads at the University of Michigan researched existing GCP and social and behavioral research training and provided information to the subgroup members. The Work Group leads reviewed several books on implementing GCP, examined educational materials on the principles of GCP from various sources, examined the results of the TransCelerate survey (shown in Table 2), and reviewed the current human subject training University of Michigan offers for social and behavioral research. Through a series of discussions via conference call, 8 topic areas were selected for inclusion as modules in a training program (see Table 3).

Content experts were identified for each training module topic. Working with an instructional designer, these experts defined

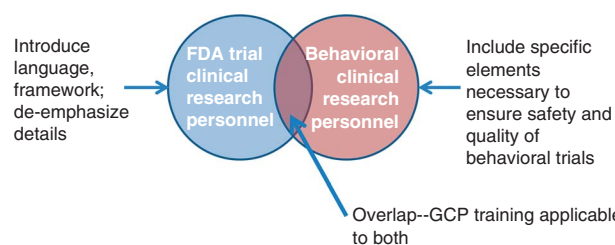


Fig. 1. Conceptual framework of how Good Clinical Practice (GCP) relates to behavioral clinical trials. FDA, Food and Drug Administration.

Table 3. Training modules for social and behavioral best practices course

Module topics	Learning objectives By the end of this module, the participant will:
Introduction	Be familiar with the role of ICH in providing guidelines for regulations Be able to define GCP and the goals of GCP Be able to articulate how GCP relates to regulations of clinical trials in social and behavioral research
Research protocol	Describe elements of a research protocol Articulate the importance of standard operating procedures Gain knowledge in aspects of treatment fidelity as they apply to behavioral trials Be familiar with protocol violations and how to handle them
Roles and responsibilities	Understand roles and responsibilities of the sponsor, IRB, research investigator, and clinical research coordinator
Informed consent	Identify key aspects of the consent process that ensure participants rights, safety, and well-being are prioritized Analyze an informed consent process between study team member and participants to determine areas needing improvement
Confidentiality/privacy	Differentiate concepts of confidentiality and privacy Select strategies to ensure confidentiality and privacy Identify instances when confidentiality or privacy are compromised and when to report to IRB
Recruitment/retention	Identify best practices for recruitment including appropriate wording on flyers and in advertisements and ensuring adequate representation from women and diverse populations Identify strategies to retain participants
Participant safety/adverse event reporting	Be familiar with aspects of seriousness and relatedness as they relate to an adverse event Choose appropriate strategies to detect adverse events Define the role of a data safety and monitoring board
Quality control/assurance	Articulate the importance of quality assurance in a clinical trial Select strategies that can help systematically track participant progress through a study Define sources of bias that can affect data quality in a behavioral trial Assess how different biases can affect data quality from a case-based example
Research misconduct	Define research misconduct and who this applies to Describe the process for reporting an instance of misconduct Name consequences of research misconduct

GCP, Good Clinical Practice.

learning objectives and outlined content for inclusion in the training modules. Learning objectives and content were thoroughly discussed by the entire work group and consensus was reached regarding the overall structure and learning objectives for a new social and behavioral training program. At this time, the course has been completed and available for download by interested institutions [6].

Conclusion

The goal of this project was to tailor competencies and the fundamental principles of GCP into what are deemed as best practices for social behavioral research and to translate those competencies into a framework for a series of e-learning modules. This project involved a high level of collaboration across CTSA hubs and codevelopment with benchmarking organizations such as The Clinical Trials Transformation Initiative that allowed for the opportunity to create a translational bridge between more traditional clinical trials and behavioral interventions. The training program is currently tailored to the specific needs and unique research processes of social and behavioral researchers and consequently will fill a critical training gap identified through the ECRPTQ process.

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Declaration of Interest

The authors have no conflicts of interest.

Supplementary Material

To view supplementary material for this article, please visit <https://doi.org/10.1017/cts.2016.3>

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