



Training in Research Ethics and Standards

A Self-study Guide for Promotores

Instructor's Guide





Training in Research Ethics and Standards:
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Preface

Instructor's Guide

Training of ethical practices specific to human subject protections is now an accepted part of academic research programs. Most existing educational programs were developed for principal investigators and others within the academic community who design and/or conduct research. Yet much research that focuses on health is community-based and utilizes a model that includes involvement of lay research staff. Lay research staff, who are often called *promotores* in the Latino community, have become an integral part of implementing community-based health interventions. In this role, they assist public health researchers by serving as liaisons between the academic environment and the communities involved in research.

In San Diego, because of the proximity to the Mexico border and the large Latino population, *promotores* are often involved in community-based research. However, existing English language, academically-oriented training materials on research ethics do not provide appropriate training for *promotores* serving as research staff members. The need for culturally relevant, performance appropriate, Spanish language training materials for *promotores* led to the development of Project TRES: *Training in Research Ethics and Standards*.

The Project TRES Self-study Guide introduces ethical principles and practices to *promotores* with a goal of enhancing awareness about the ethical conduct of research within the Latino community. Use of this curriculum is expected to result in improved awareness of ethical decision making and responsible research practices among lay research staff. This separate Instructor's Guide provides general information for principal investigators and project managers about Project TRES to enhance successful implementation of the Self-study Guide.

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Curriculum Needs Assessment

Kendra Brandstein, MPH, MSW	Scripps Mercy Hospital Chula Vista
Donna Castañeda, PhD	SDSU, Imperial Valley Campus
Nadia Campbell, MPH	SDSU Research Foundation
Jeanette Candelaria, MPH	
Janel Heinrich, MPH, MA	
Ana P. Martínez-Donate, PhD	
Mary M. Mulvihill, PhD	
Ofelia Sandoval, MPH	
Carol Sipan, MPH, RN	
Karen Senn, EdD, MPH	SDSU, Graduate School of Public Health
María Luisa Zúñiga, PhD	UCSD, Division of Community Pediatrics

Content Accuracy

Catherine Anson, MA, CRA, CIM	John Carroll University
Karen M. Hansen, BA	Fred Hutchinson Cancer Research Center
Charlotte H. Coley, MACT, CIT	Duke University Medical Center
Deborah L. Barnard, MS, CIP	Partners HealthCare, Inc.
Alma Britton, BA	National Institute of Environmental Health Sciences (NIEHS/ NIH)
Miriam F. Kelty, PhD	National Institute of Aging (NIA/NIH)

Culture and Language

Guillermina Fernández	Aventuras para Niños, SDSU/UCSD
Guadalupe García	
Araceli Molina	
Ofelia Molina	
Irma Rodríguez	
Rosa Vásquez	
Catalina Bernal	Por La Vida, SDSU/UCSD
Vilma Sofia Ceja	
Rosa Guillermina Coronado	
Irma D. Hernández	
Esthela Escobar	Project SOL, SDSU
María G. Martínez	
María Luisa Hernández	San Ysidro Health Center, Inc.
Martha Carrillo	Scripps Mercy Hospital Chula Vista
Carmen Richman	
Norma Toledo	
Maricruz Hernández	

Finally, the dedication of the Project TRES core staff is greatly appreciated. They brought expertise in program management, curricular development, and program evaluation to see that the end product reflected a value of research integrity and an uncompromised commitment to ethical and responsible research practices.

Project TRES Core Personnel

Karen Coleman, PhD	Program Evaluator
John Elder, PhD, MPH	Co-Investigator
Hector Guzman, MPH	Graduate Research Assistant
Michael Kalichman, PhD	Consulting Co-Investigator (UCSD)
Paulina Martínez, BS	Undergraduate Research Assistant
Lori McNicholas, PhD, RD	Curriculum Development Specialist
Izzybeth Rodriguez, BS	Undergraduate Research Assistant
Gayle Simon, MPH	Content Expert/Resource Specialist
Lolita Soto, BA	Administrative Assistant
Ana Talavera, MPH	Program Manager
Greg Talavera, MD, MPH	Co-Investigator
Jennifer Terpstra, MPH	Graduate Research Assistant
Carmen Violich, BS	Graduate Research Assistant

My sincere appreciation to all,



Camille Nebeker, Principal Investigator

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Curriculum Overview

T raining in Research Ethics and Standards: A Self-study Guide for Promotores is available in both Spanish and English and introduces *promotores* to ethical and responsible practices deemed appropriate when involved in the conduct of research. The training manual uses a self-study format and integrates writing exercises to facilitate the learning process with examples that reflect realistic situations that may be encountered in their work as a *promotor*. The Spanish acronym E.T.I.C.A. is used to link ethical practices with specific responsibilities associated with the *promotores*. The Three Principles associated with the ethical principles described in the Belmont Report are integrated across each session and anchored to key concepts.

Achievement of session objectives is tested using examples at the end of each session where the *promotor* assesses a situation and is provided with additional feedback on what is considered an ideal response. An optional pre/post-test is also available to assess changes in knowledge and awareness of the training materials. The post test may also be used to verify satisfactory understanding of key concepts. The certificate provided can be awarded to the *promotores* who complete the training.

Project TRES training materials can be adapted to your training needs. Additional details on layout and content for the Self-study Guide follow:

Outline

Each of the three sessions contains the following sections:

- Summary page with session objectives
- Topic narrative
- Applying E.T.I.C.A. as a *Promotor*

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- Applying E.T.I.C.A. as a *Promotor* – Example (1)
- Applying the Three Principles
- Applying the Three Principles – Example (1)
- What You Learned – Examples (3)

Symbols

Symbols are used to visually organize the structure of each session and provide guidance for the *promotor* when progressing as an independent learner. This visual guidance may be especially useful when using the writing exercises to provide important practice opportunities for application of the concepts. In the Self-study Guide, symbols are initially introduced with the following description:



Key point

This symbol represents an important training concept of each section that directly relates to a learning objective.



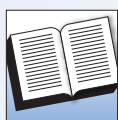
Example

This symbol represents an example related to the theme of the section. The example represents the work of a *promotor*. Each example is followed by a question or a series of questions.



Your answer

This symbol represents an opportunity for the *promotor* to provide a written answer to the questions from the example.



Answer in more detail

This symbol represents a more detailed explanation (the “correct” answer) to the questions from the example.



Situation

This symbol represents a situation relating to the session objective(s). It allows the *promotor* to “stop and think” about what has been learned.

Project TRES Sessions

The sessions of the Project TRES Self-study Guide build upon one another; however, they may be used independently. Repetition and reinforcement of concepts provide a sense of continuity and consistency within the topic areas for those who review the materials from beginning to end. A section titled “Terms to Remember” alphabetically lists words with definitions for easy reference by the *promotor*.

Session 1: Laying the foundation

The first session offers an introduction to research and provides a foundation for implementing ethical research practices. The learning objectives are:

- Define research and explain why it is important.
- Know the difference between research studies and service projects.
- Explain why government protections for research participants were established.
- Name the four groups involved in the protection of research participants.
- Define five key areas of responsibility for a *promotor* when conducting ethical research practices.
- Apply one of the three principles of the Belmont Report.

Session 2: Protecting the participant

The second session provides an overview of the risks and benefits to participating in research, as well as the importance of confidentiality. The learning objectives are:

- Explain how research may benefit the participant and community represented.
- Identify the four elements of risk associated with a research study.
- Define confidentiality.
- Explain why practices to protect confidentiality are important to ethical conduct of research.
- Describe two ways in which a *promotor* can protect confidentiality.
- Apply one of the three principles of the Belmont Report.

Session 3: Presenting the information

The third session provides a description of the components of the informed consent process. The learning objectives are:

- Define the purpose of the informed consent process.
- Name the three components of the informed consent process.
- Describe what information is presented to the potential participant during the consent discussion.
- Define voluntary participation.
- Describe what factors may influence the decision to participate.
- Apply one of the three principles of the Belmont Report.

Availability of Materials

Training in Research Ethics and Standards: A Self-study Guide for Promotores may be downloaded in PDF from the Project TRES website (<http://projecttres.sdsu.edu>). English and Spanish hard copies of the Self-study Guide and/or Instructor's Guide may also be ordered from San Diego State University for a nominal fee. Please contact:

Camille Nebeker, Director
Division of Research Affairs
Graduate and Research Affairs
Principal Investigator, Project TRES
San Diego State University
5500 Campanile Drive, MC 1643
San Diego, CA 92182-1643

619-594-5938
619-594-4109 (FAX)
nebeker@mail.sdsu.edu
<http://gra.sdsu.edu/research>
<http://projecttres.sdsu.edu>

Additional Resource

Additional regulatory information and guidance on human research protections may be found through the Office for Human Research Protections (OHRP). OHRP is a federal organization responsible for providing leadership and support to institutions involved in human research.
<http://www.hhs.gov/ohrp/>

How to Use this Curriculum

Self-study

T *raining in Research Ethics and Standards: A Self-study Guide for Promotores* was developed as a stand-alone training for the convenience of *promotores* working in remote locations. The self-study format involves narrative, key points and examples, as well as a writing process to reinforce learning of concepts. Results from pilot testing of the Self-study Guide indicate most *promotores* take about two hours to complete each session, using either the print or web-based format.

Print Version

Promotores are most familiar using print as a learning modality. Using the hard-copy version, *promotores* can review prior sections and write (or erase) responses as they are prompted throughout the applied aspects of the curriculum. There are no limits to the time spent reviewing the hard copy materials.

Web-based Version

The web-based version of the Self-study Guide was adapted from the print version and is available in both Spanish and English via the Project TRES website (<http://projecttres.sdsu.edu>). There are potential time restrictions for the on-line learner, either self-imposed or because of locality and access.

The web-based version is also intended for the self-study learner and adaptations were made to facilitate a web-training modality. While the Self-study Guide allows for a written response in the print version, the web format requires the learner to type responses to various prompts. Examples in the web version use videos to allow trainees access to applications of ethical practices in the field.

Special Features

The web platform offers special features. All or some of these features can be used by the trainee. Special features include:

- Definition of terms: Term definitions appear when the trainee clicks on the word that is highlighted.

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- **Feedback:** Feedback may be provided to Project TRES about the curriculum that can be used for programmatic improvements.
- **User log-in:** The log-in feature allows the trainee to complete the Self-study Guide over time. The system will keep track of progress and allows the trainee to resume review of the materials at a later time.
- **Certificate of Completion:** After the trainee has reviewed the Self-study Guide and completed the associated activities, a certificate may be printed, completed and signed by a supervisor (e.g., investigator or project director) indicating successful completion of the training. This documentation may be needed for verification of training as per NIH requirements.

System Requirements

In order to use the web-based version of the Self-study Guide, the user must have access to the following:

- A computer with one of the following browsers:
 - Internet Explorer, version 6 or higher
 - Mozilla, version 1.5 or higher
 - Mozilla Firefox, version 1.5 or higher
 - Opera, version 8 or higher
- A high-speed Internet connection is recommended.
- Adobe Flash Player version 9 or higher is required to view the video examples.
- Adobe Reader 7 or higher is required to review or download PDF files.

Group Presentation

While the Self-study Guide may be used by *promotores* to study independently, we strongly encourage presenting Project TRES training in conjunction with standard research training. Engaging the *promotor* trainee using a process that involves discussion, role-play, and reflective writing is most likely to produce an increased understanding and application of ethical research practices. If distance precludes group or individual meetings from occurring, telephone conference calls or on-line interactions may also be used to integrate Project TRES training with activities to complement a specific research project.

To optimize learning, it is recommended that each of the three sessions become a 1-2 hour training session. Group training will allow time for discussion and may incorporate role-play of scenarios which will increase internalization of concepts and will enhance thorough interaction between *promotores*. Ideally, integration of the three training sessions are best scheduled closely to allow *promotores* a better advantage of retaining the information and understanding the appropriate application.

A recommended outline for group training follows:

- Review Previous Session Bullets (for all sessions except Session 1)
 - Encourage trainees to ask questions that have come up since the last session.
 - Provide answers to these questions.

- Introduction of Current Session Topics
 - Introduce the current session (i.e., what general topics will be covered).
 - State the session objectives.
 - Pause during the presentation so that participants can share their answers to the discussion questions. Have one or two volunteers share their answers with the group.

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- Role Plays
 - Encourage trainees to role-play the examples from the Self-study Guide, either reading aloud the print copy or using the web-based video stream.
 - Discuss what ethical concerns/dilemmas were portrayed during the role-play/examples to include the pros and cons of the choices made. Complement those examples with what may be experienced specific to the project the *promotor* is being trained.
 - Discuss the “Answer in more detail” provided for each example in the Self-study Guide.
- Closing
 - Review key points from the session.





Certificate of Completion

Awarded to

For successfully completing

Training in Research Ethics and Standards: A Self-study Guide for Promotores

Project Title

Principal Investigator/Project Director verifying completion

Date

