



Training Resources for Clinical Research Coordinators

This document offers information about various training resources that may be of interest for clinical research coordinators (CRCs) working on clinical trials for spinal muscular atrophy (SMA). The list includes information about training checklists, background reading on clinical research, and information about online and in-person trainings available through a variety of different organizations. CRCs are encouraged to peruse this list and utilize resources that they find relevant and beneficial.

Cure SMA also maintains information external resources on SMA and other clinical research topics, available on the Cure SMA Trial Readiness Hub (www.curesma.org/clinical-trial-readiness).

Training Checklists

ACRP Competency Domains for Clinical Research Professionals and Core Competency Guide for CRCs (Free)

ACRP maintains a number of useful resources for clinical research professionals. Its Competency Domains for Clinical Research Professionals is a free online tool that delves into key areas in clinical research, discussing important knowledge to possess. <https://acrpnet.org/competency-domains-clinical-research-professionals/>

The Core Competency Guide is a mail-order resource published in 2017 intended to help CRCs with self-assessment and creation of personal development plans; help research sites with the hiring, assessment, and development of CRCs; and aid CROs and sponsors in evaluating competence when conducting site assessments. <https://www.acrpnet.org/core-competency-guidelines-clinical-research-coordinators-crcs/>

UCSF Clinical Researcher Training Checklist (Free)

UCSF has created a comprehensive checklist of training steps for clinical researchers, which breaks training activities apart into three categories: new hire and onboarding resources, core training, and supplemental or advanced training. The checklist includes links to relevant resources (although many of these are specific to researchers at UCSF). <https://hub.ucsf.edu/sites/g/files/tkssra261/f/CRTTrainingList.pdf>

UCD Coordinator Training Checklist (Free)

The University of California-Davis Medical Center has a publicly available list of trainings for CRCs. http://www.ucdmc.ucdavis.edu/clinicaltrials/documents/coordinator_training_checklist.pdf

Toolkits and Books on Best-Practices and Resources toward the Conduct of Clinical Research

SMA Clinical Trial Readiness Toolkit (Free)

This toolkit focuses on SMA as a disease and the landscape for disease management and treatment options, providing research teams with foundational knowledge and vocabulary to aid them in their work. It also discusses steps involved in trial preparation and conduct, issues that may arise in SMA trials, and things to consider in day-to-day work. <https://www.curesma.org/clinical-trial-readiness/>

Best Practices for Clinical Research Coordinators in SMA (Free)

This toolkit, tailored specifically to the role of the CRC, includes a brief overview of the responsibilities of a CRC when coordinating any clinical trial, as well as information on steps to take when preparing for an SMA trial. The majority of the toolkit focuses on key stages and aspects of SMA clinical trials, with discussion of strategies and tactics to support trial management, and specific challenges that CRCs may encounter in the context of SMA clinical trials. <https://www.curesma.org/clinical-trial-readiness/>

Best Practices for Physical Therapists & Clinical Evaluators in Spinal Muscular Atrophy (Free)

To support PTs/CEs involved in SMA trials, Cure SMA, in collaboration with two PTs with significant experience in SMA and SMA clinical trials, has developed recommendations to promote the most effective conduct in clinical trials. These best practices are intended to help PTs/CEs – especially those new to SMA clinical trials – understand challenges they may encounter and find productive ways to navigate these challenges, but they may be of interest to research team members beyond PTs/CEs. Also included in this document is a set of appendices with links to additional resources, including seminal papers in SMA, manuals, and articles that delve more deeply into SMA issues. <https://www.curesma.org/clinical-trial-readiness/>

Textbook: Responsible Research: A Guide for Coordinators (Requires purchase)

This book, edited by Carol Fedor, Philip Cola, and Christine Pierre and first published in 2006, is a thirteen-chapter guide to all aspects of the CRC position, with both practical and ethical emphasis. Topics discussed include ethics and human subject's protection, responsible conduct, the informed consent process, pediatric informed consent and assent, study implementation and start-up, recruitment and retention of research subjects, documentation, quality assurance in clinical trials, communication, education and training, and future trends in professionalization. The book can be purchased from online sellers or ordered from a local bookstore.

Textbook: CRC Guide to Coordinating Clinical Research (Requires purchase)

Written by Dr. Karen Woodin and first published in 2004, this book is a training tool and reference guide for novice and experienced coordinators. Topics covered include CRC roles and responsibilities, regulations and GCP, study preparation, work with study subjects, informed consent, case report forms and EDC, and study closure, among other topics. The book has been updated since its first publication, and can be purchased from online sellers or ordered from a local bookstore.

Online and In-Person Courses, Programs, Certifications, and Degrees

ACRP Resources (Cost varies; some resources are free)

The Association of Clinical Research Professionals (ACRP) has an array of training resources for entry level, intermediate, and senior clinical research professionals. For online resources, users of their website can sort resources based on role, knowledge level, contact hours (if continuing education credits are needed), type of resource, and competency area. Many trainings are free to members, although others require payment for both members and nonmembers. ACRP also offers periodic in-person meetings and training workshops. <https://acrpnet.org/training/>

SOCRA ONLINE Educational Offerings for Clinical Research Education (Cost varies)

The Society of Clinical Research Associates (SOCRA) offers in-person and online training resources. Information about in-person meetings and training workshops can be found on the SOCRA website. Online courses are "intended to provide access to training and continuing education that will promote quality clinical research, protect the welfare of research participants and improve global health." The courses – which are in the form of webinars – focus on essential concepts in clinical research. The cost of the meetings and online courses varies, and some are free to members. <https://www.socra.org/conferences-and-education/online-courses/>

UCSF Trainings for Clinical Research Coordinators (Free)

UCSF has made a series of slides on clinical research topics for Clinical Research Coordinators at UCSF publicly available on their website. <https://hub.ucsf.edu/research-coordinator>

Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review (Free; non-contact hours)

An essential course for all clinical research professionals involved in the design and/or feasibility assessment of clinical research protocols. This interactive eLearning course incorporates a high-level overview of concepts and real-world scenarios you are likely to encounter when developing a protocol. And when reviewing protocols to ensure feasibility and compliance and communicating the feasibility of a study.

<https://acrpnet.org/courses/understanding-clinical-trial-protocols-key-considerations-effective-development-feasibility-review/>

Cure SMA welcomes your feedback!

We would love to hear from you! Please let us know which, if any of the above resources, were helpful to you in supporting your ability to more effectively conduct / manage your trials in SMA. Please email trialreadiness@curesma.org.