RESEARCH CERTIFICATION EXAM REVIEW GROUP

Kelly Unsworth, MS, CIP, CCRC Director, Research Education & Training Office for Human Subject Protection SCORE Mtg – 12NOV2019

GENERAL CONSIDERATIONS

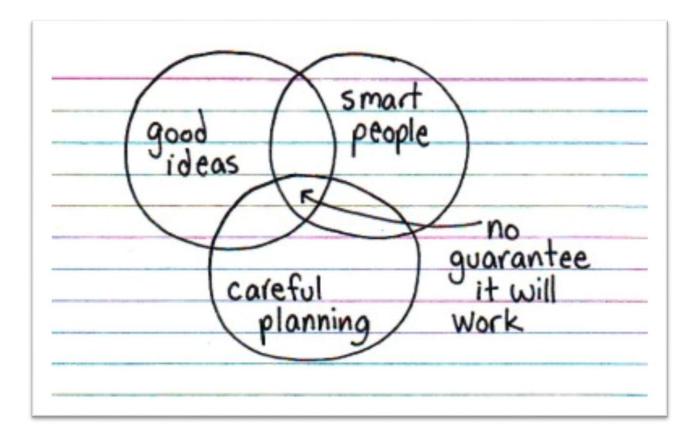
- <u>Thoroughly review</u> ACRP/SoCRA exam info
- Assess your own experience/skill
 Strengths? Weaknesses?
- Assess your other time commitments & comfort level
- Start early & plan ahead
 Schedule your study time
- Choose study methods that are right for you

GOALS & EXPECTATIONS

- Study Group Goal = <u>Exam prep</u>... but this is just a starting point
- General philosophy = self-directed learning
- Expectations:
 - Limit participation to those who are currently eligible to sit for exam or will be within the next 10 months



DISCLAIMER



FORMAT & SCHEDULE

- Weekly Sessions, January 6 February 24
 Mondays, 4-6pm, SRB 1404 (Or Zoom)
- Format (Most Sessions):
 - > Assigned materials to review <u>prior</u> to each session
 - Content area reading assignments and slide sets
 - Facilitated session review:
 - Review assigned slide sets to answer questions, clarify content, emphasize important content
 - Review practice questions
 - Independent group study for remainder of session
 - Additional resources provided: glossaries/abbreviation lists, guidelines & regulations, textbooks, online training options/resources, sources for practice questions

SCHEDULE

- Weekly Sessions, January 6 February 24
 - Mondays, 4-6pm, SRB 1404 (Or Zoom)

SESSION	CONTENT
1	Introduction & RCERP Overview
2	Historical Perspectives; Study Design Basics & Drug/Device Development; Federal Regulations & ICH GCP Overview; FDA-Regulated Research
3	The Study Protocol; Study Feasibility; Institutional Review Boards; Roles & Responsibilities; Recruitment & Retention; Informed Consent
4	Study Activities; Essential Documentation & GDPs; Adverse Events & Unanticipated Problems; Data & Safety Monitoring Plans
5	Guest Attendees
6	Monitoring, Audits & Inspections; Investigational Product Management; Data Management; Genetic Research; International Trials
7	Practice Questions & Wrap-Up

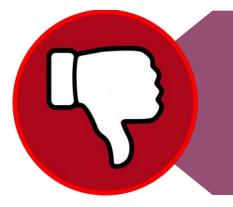
REVIEW MATERIALS

All you need is THEINTERNET (and donats)



Interested?

Sign-up sheet on side table (or email Kelly)



No Thanks!

Independent review materials are available