SOCRA Exam

Prep Tips and Q&A

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SOCRA Exam Overview

- Qualifications
- Content
- Resources
- Tips
- Q&A

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SOCRA CCRP Eligibility

- You may qualify if you meet the following requirements:
  - 2 years full-time clinical research experience,
  - 1 year full-time experience + a degree in clinical research, or
  - 1 year full-time experience with a certificate in clinical research + a degree in health, science or related field.
- See the SOCRA Candidate Eligibility for more information on qualifications and required documentation.

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Major Content Areas	Description	% of Exam
Research Study Start-up	**Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study start up**	40
Research Study Implementation	**Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to conduct of the study**	45
Research Study Closure	**Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study close out and record maintenance**	15

https://www.socra.org/certification/ccrp-certification-exam/preparation-resources/

Test format

- Multiple Choice
- 130 questions (100 are scored)
- Must answer 72 of the 100 correctly
- No penalty for wrong answers

In person or Online?

- In person – paper
  - Fill in the bubbles
  - OHSU must have a minimum of 15 people register or we will be cancelled and won't be able to schedule for 2 years.
- Online
  - Testing Center (need to show room, computer requirements, show behind ears, etc., to show you don't have electronic or other reference materials, must keep camera on at all times)

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History and Ethics

- Ethical Codes and Research Standards:
  - The Nuremberg Code
  - The Belmont Report
  - The Declaration of Helsinki

Research Study Start-up (40%)

- **Regulatory Requirements of IRB/IEC**
  - **IRB regulations**
    - 21 CFR 56, IRB composition and review https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50
    - **Common Rule https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html**
- **Sponsors and investigators responsibilities for study start up**
- **Coordinate the development of initial research study protocol**
  - Study phases, study designs (randomization, cross-over, blinding)

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Study Start-up Cont.

- Create or obtain research study documents
  - Informed consent
    - elements of informed consent (45 CRF 46) https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116.
    - FDA consent regulations - (21 CFR 50.20 and 50.25) https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116
  - Case report forms,
  - Financial disclosure statements
- GCP essential documents https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf
- FDA forms and regulations

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Research Study Implementation

- **Regulatory Requirements of IRB/IEC**
- **sponsors and investigators related duties/task related to conduct of the study**
- **21 CFR 312 Subpart D https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4**
- **21 CFR 812 Subpart E https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-E**

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Study Implementation Cont.

- **Study records**
  - Device 21 CFR 812 140 https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf
  - Drug 21 CFR 312.57 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.57

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Research Study Closeout

- **Regulatory Requirements of IRB/IEC**
- **Sponsor's and Investigator's related duties/task related to study close out**
- **Record maintenance**
  - 21 CFR 812 140
    https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf

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Audits

- Inspection of records 312.68, 812.145
  - Forms 482, 483
- Inspection outcomes
  - NAI, VAI, OAI (AKA warning letters), NIDPOE letters

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Other Areas that may be covered

- 21 CRF Part 11 – Electronic Records, Signatures

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

- 42 CFR Part 11 (ClinicalTrials.gov)

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-11

Know the definition of a clinical trial and responsible party

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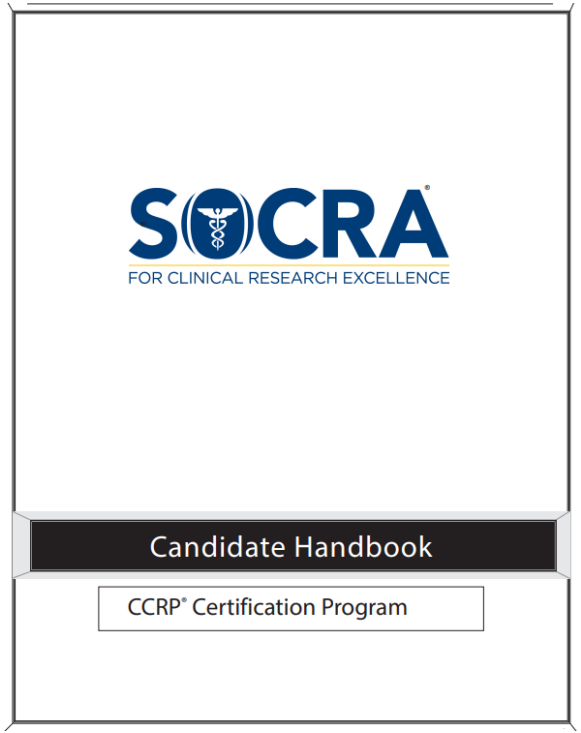
Study Prep –

SOCRA resources:

- https://www.socra.org/certification/ccrp-certification-exam/preparation-resources/
- SOCRA Candidate Handbook



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Study Prep –

- CITI Program - https://o2.ohsu.edu/citi/
  - Review all modules
  - Prepare PowerPoint presentation
  - Use the quizzes as a guide for content recognition
  - Create you own flashcards for key terms and specific regulation identification
    - https://quizlet.com/15347048/socra-certification-exam-flash-cards/

Day of the Test!

- Get a good night's sleep, eat a high protein breakfast, and drink plenty of water
- Don't study right before. Stay calm and focused on the material you have already studied
- Get to the test a little early
- Make the decision to ignore the people who finish early. Research shows those that leave early don't do as well as those who take more time

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Taking the test

- Read the directions and questions carefully
- Read the sentence stem, think of the answer, **and then** find it in the choices
- Read all the options before choosing
- Don’t dwell on the questions you don’t know, mark the question, and then move on to the questions you know. Later, go back to the one(s) you marked and try again

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Maintaining Your Certification

- Must renew your certification every 3 years
- 45 hours of continuing education is required
  - 22 must be clinical research related
  - Acceptable Credits can be found on the SOCRA Webpage
  - Must maintain a CEU tracking log

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Questions???

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Best of Luck!!!

—OCTRI

Thank You