SOCRA Exam
Prep Tips and Q&A

DATE: September 8th 2022 PRESENTED BY: NAME Brian Booty, Manager CTRC, Bridget Adams, Manager OCTRI RKS,
SOCRA Exam Overview

• Qualifications
• Content
• Resources
• Tips
• Q&A
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.
<table>
<thead>
<tr>
<th>Major Content Areas</th>
<th>Description</th>
<th>% of Exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Study Start-up</td>
<td>Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study start up</td>
<td>40</td>
</tr>
<tr>
<td>Research Study Implementation</td>
<td>Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to conduct of the study</td>
<td>45</td>
</tr>
<tr>
<td>Research Study Closure</td>
<td>Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study close out and record maintenance</td>
<td>15</td>
</tr>
</tbody>
</table>

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)
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
- Sponsors and investigators responsibilities for study start up
- Coordinate the development of initial research study protocol
  - Study phases, study designs (randomization, cross-over, blinding)
Study Start-up Cont.

• Create or obtain research study documents
  – Informed consent
    • elements of informed consent (45 CRF 46)
    • FDA consent regulations - (21 CFR 50.20 and 50.25)
  – Case report forms,
  – Financial disclosure statements
• FDA forms and regulations
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/CFRSear ch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4
Study Implementation Cont.

- **Study records**
  - Device 21 CFR 812 140  
  - Drug 21 CFR 312.57  
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
Audits

• Inspection of records 312.68, 812.145
  – Forms 482, 483

• Inspection outcomes
  – NAI, VAI, OAI (AKA warning letters), NIDPOE letters
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)
  Know the definition of a clinical trial and responsible party
Study Prep –

SOCRA resources:

• [https://www.socra.org/certification/ccrp-certification-exam/preparation-resources/](https://www.socra.org/certification/ccrp-certification-exam/preparation-resources/)

• SOCRA [Candidate Handbook](#)
Study Prep –

- CITI Program - [https://o2.ohsu.edu/citi/](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
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
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
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
Questions???
Best of Luck!!!

—OCTRI
Thank You