

SOCRA CCRP Certification Exam Study Guide **2024 Update.**

Nuremberg Code - Correct answer the first set of principles outlining professional ethics for clinical research.

Nuremberg Code elements - Correct answer 1. Voluntary informed consent

2. Research benefits society
3. Should be based on prior animal work
4. Avoid suffering and injury
5. Research where death and disabling injury is expected shouldn't be conducted
6. Risks should be justified
7. Proper preparations and adequate facilities
8. Conducted by scientifically qualified
9. Subjects can withdraw
10. Research must end the study if there is probable because that continuing would lead to injury, disability, or death.

Timeline of Historical Events - Correct answer Nuremberg Code first (1947). Declaration of Helsinki second (1964). Belmont Report third (1979).

Belmont Report Principles and Application - Correct answer there are 3:

1. Respect for persons = informed consent
2. Beneficence = risk/benefit analysis
3. Justice = appropriate selection of patients

Language Level Recommended for Informed Consent - Correct answer 6th-8th grade

8 Basic Elements of informed Consent - Correct answer 1. Statement explaining the study involves research.

2. Description of risks or discomforts.
3. Description of benefits.
4. Alternative treatments/procedures.
5. Confidentiality.
6. Compensation for involvement and/or injury.
7. Who to contact.
8. Voluntary and can discontinue

Additional Elements of Informed Consent - Correct answer 1. Unforeseeable risks to subject.

2. Participation can be terminated by investigator.
3. Any additional costs.
4. Consequences of the subject's decision to withdraw
5. Significant new findings will be shared
6. approx. # of subjects in the study.

Differences between short and long informed consent form - Correct answer Long = the standard consent form.

Short = document states that the elements have been presented orally to and understood by the subject or LAR.

ICF Monitoring Considerations - Correct answer 1. Subject has signed most recent IRB approved version

2. Subject signature is present in addition to subject name

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L Darling-Hammond



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Table of Contents Ccrp Study Guide

1. Understanding the eBook Ccrp Study Guide
 - The Rise of Digital Reading Ccrp Study Guide
 - Advantages of eBooks Over Traditional Books
2. Identifying Ccrp Study Guide
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Ccrp Study Guide
 - User-Friendly Interface
4. Exploring eBook Recommendations from Ccrp Study Guide
 - Personalized Recommendations

- Ccrp Study Guide User Reviews and Ratings
- Ccrp Study Guide and Bestseller Lists
- 5. Accessing Ccrp Study Guide Free and Paid eBooks
 - Ccrp Study Guide Public Domain eBooks
 - Ccrp Study Guide eBook Subscription Services
 - Ccrp Study Guide Budget-Friendly Options
- 6. Navigating Ccrp Study Guide eBook Formats
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 - Ccrp Study Guide Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Ccrp Study Guide
 - Highlighting and Note-Taking Ccrp Study Guide
 - Interactive Elements Ccrp Study Guide
- 8. Staying Engaged with Ccrp Study Guide
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Ccrp Study Guide
- 9. Balancing eBooks and Physical Books Ccrp Study Guide
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Ccrp Study Guide
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Ccrp Study Guide
 - Setting Reading Goals Ccrp Study Guide
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Ccrp Study Guide
 - Fact-Checking eBook Content of Ccrp Study Guide

- Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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