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Competency Index for Clinical Research Professionals (CIRCP) - Assessment with Scoring Guide

Carlton Hornung
University of Louisville, cahornung@louisville.edu

Competency Index for Clinical Research Professionals-I (CICRP-I)

Please respond to the items below using the 0-10 scale.

Items	0 = Not at all confident, 10 = Completely confident
1. Describe the role and process for monitoring a study.	0 1 2 3 4 5 6 7 8 9 10
2. Describe the roles and responsibilities of the various institutions participating in the medicines development process.	0 1 2 3 4 5 6 7 8 9 10
3. Compare and contrast clinical care and clinical management of research participants.	0 1 2 3 4 5 6 7 8 9 10
4. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management.	0 1 2 3 4 5 6 7 8 9 10
5. Explain the elements (statistical, epidemiological and operational) of clinical and translational study design.	0 1 2 3 4 5 6 7 8 9 10
6. Identify the legal responsibilities, issues liabilities and accountability that are involved in the conduct of a clinical trial.	0 1 2 3 4 5 6 7 8 9 10
7. Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products.	0 1 2 3 4 5 6 7 8 9 10
8. Compare the requirements for human subject protection and privacy under different national and international regulations and ensures their implementation throughout all phases of a clinical study.	0 1 2 3 4 5 6 7 8 9 10
9. Describe the significance of data quality assurance systems and how SOPs are used to guide these processes.	0 1 2 3 4 5 6 7 8 9 10
10. Critically analyze study results with an understanding of therapeutic and comparative effectiveness.	0 1 2 3 4 5 6 7 8 9 10
11. Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biologicals and ensures their safety, efficacy and quality.	0 1 2 3 4 5 6 7 8 9 10
12. Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards.	0 1 2 3 4 5 6 7 8 9 10
13. Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials.	0 1 2 3 4 5 6 7 8 9 10
14. Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product.	0 1 2 3 4 5 6 7 8 9 10
15. Differentiate the types of adverse events which occur during clinical trials, understand the identification process for AEs and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities.	0 1 2 3 4 5 6 7 8 9 10
16. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct.	0 1 2 3 4 5 6 7 8 9 10
17. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research.	0 1 2 3 4 5 6 7 8 9 10

18. Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial.	0 1 2 3 4 5 6 7 8 9 10
19. Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study.	0 1 2 3 4 5 6 7 8 9 10
20. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research.	0 1 2 3 4 5 6 7 8 9 10

Subscale scoring for CICRP-I:

Subscale scores are computed by summing the responses to each of the items together.

General operation and management of clinical trials: 1, 3, 6, 9, 13, 16, 17, 18, 19, 20

Medicines development: 2, 7, 11, 14, 15

Ethics and participant safety: 1, 3, 8, 12, 15

Data collection and management: 4, 9, 16, 17, 20

Scientific concepts in clinical research: 3, 5, 10, 13, 16

Competency Index for Clinical Research Professionals-II (CICRP-II)

Please respond to the items below using the 0-10 scale.

Items	0 = Not at all confident, 10 = Completely confident
1. Describe the role and process for monitoring a study.	0 1 2 3 4 5 6 7 8 9 10
2. Describe the roles and responsibilities of the various institutions participating in the investigational product development process.	0 1 2 3 4 5 6 7 8 9 10
3. Differentiate between standard of care and clinical study activities.	0 1 2 3 4 5 6 7 8 9 10
4. Describe and assess best practices and the importance of informatics for standardizing data collection, capture, management, analysis, and reporting.	0 1 2 3 4 5 6 7 8 9 10
5. Explain the elements of clinical and translational study design.	0 1 2 3 4 5 6 7 8 9 10
6. Identify the legal and regulatory responsibilities, issues, liabilities and accountabilities that are involved in the conduct of clinical studies.	0 1 2 3 4 5 6 7 8 9 10
7. Explain the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products.	0 1 2 3 4 5 6 7 8 9 10
8. Apply relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study.	0 1 2 3 4 5 6 7 8 9 10
9. Describe and develop processes for data quality assurance.	0 1 2 3 4 5 6 7 8 9 10
10. Critically analyze clinical and translational study results.	0 1 2 3 4 5 6 7 8 9 10
11. Summarize the legislative and regulatory framework that supports the development and registration of investigational products and ensures their safety, efficacy and quality.	0 1 2 3 4 5 6 7 8 9 10
12. Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards.	0 1 2 3 4 5 6 7 8 9 10
13. Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical studies.	0 1 2 3 4 5 6 7 8 9 10
14. Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product.	0 1 2 3 4 5 6 7 8 9 10
15. Differentiate the types of adverse events (AEs) that may occur during clinical studies, explain the identification process for AEs, and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities.	0 1 2 3 4 5 6 7 8 9 10
16. Describe the reporting requirements of global regulatory bodies relating to clinical study conduct.	0 1 2 3 4 5 6 7 8 9 10
17. Describe the impact of diversity and demonstrate cultural competency in the design and conduct of clinical research.	0 1 2 3 4 5 6 7 8 9 10
18. Define the concepts of clinical equipoise and therapeutic misconception as they relate to the conduct of clinical studies.	0 1 2 3 4 5 6 7 8 9 10
19. Recognize the management and training approaches to mitigate risk to improve clinical study conduct.	0 1 2 3 4 5 6 7 8 9 10
20. Identify and apply the professional guidelines and codes of ethics related to the conduct of clinical research.	0 1 2 3 4 5 6 7 8 9 10

Subscale scoring for CICRP-II:

Two scoring methods are available for the CICRP-II. The first method sums a respondent's 0 to 10 self-rating of competence across the 10 core competencies defining Routine Competencies and the 0 to 10 self-rating of competence for the 10 items defining Advanced Competencies. The summed score for each factor has a potential range from 0 to 100 with higher scores indicating higher self-ratings. The second method utilizes dichotomous self-ratings with responses 0 to 5 collapsed to indicate "Not Competent" (scored 0) and responses of 6 to 10 collapsed to indicate "Competent" (scored 1). A count score is created by simply counting the number of items for each factor that a respondent claimed competence. The count scores are easy to calculate and each score has a potential range from 0 to 10.

Routine competencies: 3, 4, 8, 9, 10, 12, 15, 17, 19, 20

Advanced competencies: 1, 2, 5, 6, 7, 11, 13, 14, 16, 18