



Online Ethics Center
FOR ENGINEERING AND SCIENCE

Good Clinical Practice (GCP) Knowledge Test

Author(s)

Anonymous

Description

The Good Clinical Practice (GCP) Knowledge Test is a 32-item measure that assesses a clinical research coordinator's knowledge of good clinical practices in four competency domains: 1) clinical trial operations, 2) study site management, 3) ethical and participant safety considerations, and 4) data management and informatics.

Body

This validated assessment measure can be used to evaluate the effectiveness of Good Clinical Practice training programs and the knowledge of clinical research associates. It can also be used in research contexts where knowledge of GCP is a predictor or outcome.

Home Page: <https://bioethicsresearch.org/research-services/testing-services/#gcp>

Description: The Good Clinical Practice (GCP) Knowledge Test is a 32-item measure that assesses a clinical research coordinator's knowledge of good clinical practices in four competency domains: 1) clinical trial operations, 2) study site management, 3) ethical and participant safety considerations, and 4) data management and informatics. In a GCP validation study of 625 clinical research coordinators (CRCs), the sample had a mean score of 24.8 (SD = 3.8) and a median score of 25. The GCP

is positively related to CRC experience and formal certification and training, providing evidence for the validity of the measure. That is, the GCP accurately measures CRC knowledge. The GCP has adequate internal consistency ($\alpha = .69$), meaning that the test items reliably measure the knowledge of CRCs. The measure can be used to evaluate the effectiveness of GCP training programs and the knowledge of clinical research associates. It can also be used in research contexts where knowledge of GCP is a predictor or outcome.

What it Measures: The GCP assesses a clinical research coordinator's knowledge of good clinical practices in four competency domains: 1) clinical trial operations, 2) study site management, 3) ethical and participant safety considerations, and 4) data management and informatics.

Format: This assessment tool is usually delivered as a pre and post-test. It consists of a series a 32 item measure.

Disciplines:

- Health Sciences

Audience: Graduate, post-doc, faculty, research staff

Access/For More Information: Information about this assessment tool is available at the homepage of the [Bioethics Research Center](#) at Washington University in St. Louis School of Medicine. The Bioethics Research Center includes a form on their website that allows you to supply information about which test would like to administer, the context you which to use the measure, and options for how you would like to collaborate with the BRC, including receiving a copy of the test and user manual at no cost, or working with BRC staff to score the test and help analyze the result for a fee to cover staff time.

Associated References

1. DuBois, J. M., Mozersky, J. T., Antes, A. L., & Baldwin, K. A. (under review). Assessing Knowledge of Good Clinical Practice: An Evaluation of the State of the Art and a Test Validation Study.
2. Mozersky, J. T., Antes, A. L., Jenkerson, M. Baldwin, K. & DuBois, J. M. (under review). How do clinical research coordinators learn Good Clinical Practice? A

mixed-methods study of factors that predict uptake of knowledge.

Rights

Use of Materials on the OEC

Resource Type

Assessment Tools

Parent Collection

Evaluation Tools

Topics

Data Management

Human Subjects Research

Discipline(s)

Life and Environmental Sciences

Research Ethics