



# **Academy of Clinical Research Professionals**

## **2015 Job Analysis Study**

*An Executive Summary for the Academy of Clinical Research  
Professionals Examinations*

**Certified Clinical Research Associate (CCRA®)  
Certified Clinical Research Coordinator (CCRC®)  
Certified Principal Investigator (CPI®)**

*January 2016*

The mission of the Academy of Clinical Research Professionals (ACRP) is to promote and maintain high standards and best practices of clinical research by recognizing those professionals who demonstrate a well-defined competency through valid and reliable credentialing programs.

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Above all, we thank the many dedicated professionals who generously contributed their time and expertise. Over 2,200 individuals participated in different phases of the job analysis including Task Force members, survey pilot test participants, survey respondents, and Test Specification Committee members.

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## Introduction

The mission of the Academy of Clinical Research Professionals (the Academy) is to “promote and maintain high standards and best practices of clinical research by recognizing those professionals who demonstrate a well-defined competency through valid and reliable credentialing programs.”

ACRP collaborated with Prometric, the Academy’s exam development and delivery service provider, to conduct the Job Analysis Study. The study was conducted for the Academy’s three certification programs- Certified Clinical Research Associate (CCRA®), Certified Clinical Research Coordinator (CCRC®), and Certified Principal Investigator (CPI®).



The CCRA, CCRC, and CPI are the only clinical research certification programs accredited by the National Commission for Certifying Agencies (NCCA). ACRP holds its certification programs to the highest standards, as established by NCCA, meaning they meet the highest standards for development, administration, and governance of certification and testing programs. NCCA accreditation assures the validity and credibility of the certification process.

Accredited certification programs are evaluated based on the process and products, rather than the content. Program content validity is demonstrated with a comprehensive job analysis conducted and analyzed by experts, with data gathered from stakeholders in the occupation or industry. To support content validity, NCCA Standards<sup>2</sup> state that a job analysis survey must lead to clearly delineated domains and tasks that characterize proficient performance and must be conducted frequently enough to ensure that the content specifications accurately reflect practice.

The NCCA standards are consistent with The Standards for Educational and Psychological Testing (AERA, APA, & NCME, 1999) and are applicable to all professions and industries. The Standards for Educational and Psychological Testing (1999) (The Standards)<sup>1</sup> is a comprehensive technical guide that provides criteria for the evaluation of tests, testing practices, and the effects of test use. The guidelines presented in The Standards have come to define the necessary components of quality testing. As a consequence, a testing program that adheres to The Standards is more likely to be judged to be valid and defensible than one that does not.

A job analysis study refers to procedures designed to obtain descriptive information about the tasks performed on a job and the knowledge, skills, or abilities requisite to the performance of those tasks. The specific type of information collected during a job analysis study is determined by the purpose for which the information will be used.

This summary describes the Job Analysis Study conducted for the Academy, including the:

- purpose for conducting the job analysis study;
- methods used to define tasks and knowledge;
- types of data analyses conducted; and
- test specifications summary



## Purpose of the Job Analysis Study

The 2015 Job Analysis was implemented to provide the necessary information to ensure the Academy certification programs and examinations reflect current practice and the changing roles of clinical research professionals. The results will also provide a roadmap for additional areas for potential consideration for credentialing beyond 2016.

The purpose of the ACRP Job Analysis Study was to

- validate important tasks, knowledge, skills, or abilities deemed currently important by CCRA, CCRC, and CPI professionals.
- define the test specifications for the CCRA, CCRC, and CPI Examinations, the extent to which examination content is representative of the important tasks and knowledge identified.

Through multiple levels of analysis, content validity of the certification examinations is demonstrated.

## Methodology

### *Study Design*

A well-designed job analysis study should include the participation of a representative group of subject matter experts who reflect the diversity within the profession. Diversity refers to regional or job context factors and to factors such as experience, gender, and race/ethnicity. Demonstration of content validity is accomplished through the judgments of subject matter experts. The process is enhanced by the inclusion of large numbers of experts who represent the diversity of the relevant areas of expertise. Survey research representative of the clinical research associate, clinical research coordinator, and principal investigator roles is an effective way to identify the tasks and knowledge that are important for CCRA, CCRC, and CPI professionals.

### *Survey Development*

Survey research functions as a “check and balance” on the judgments of the experts and reduces the likelihood that unimportant areas will be considered in the development of the test specifications. The use of a survey is also an efficient and cost-effective method of obtaining input from large numbers of experts and makes it possible for analysis of ratings by appropriate subgroups of respondents.

### *Conduct of the Job Analysis Study*

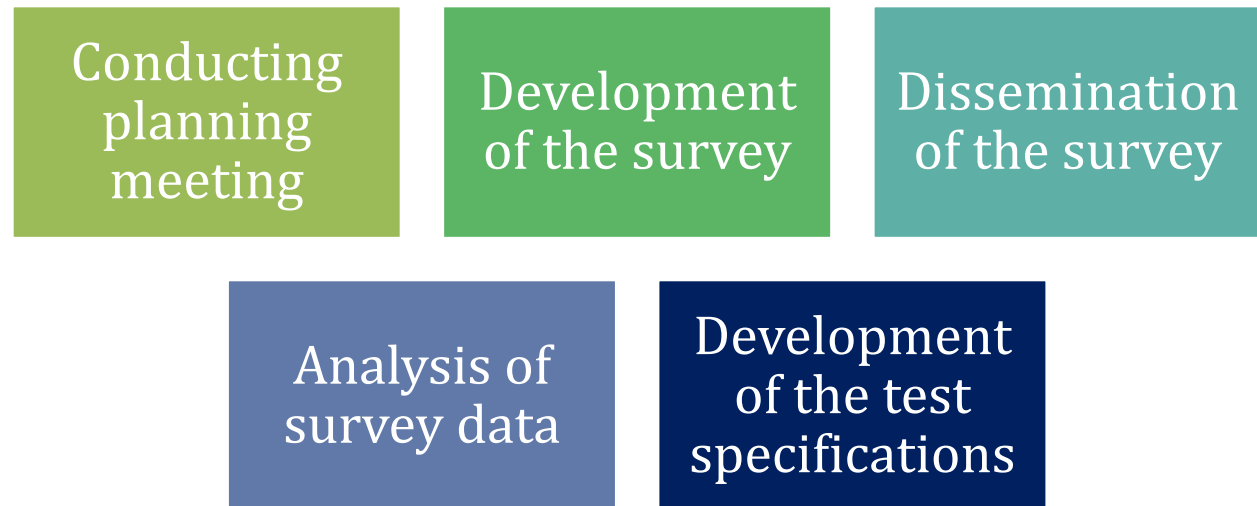
The job analysis study consisted of several activities: background research, collaboration with subject matter experts to ensure representativeness of the tasks and knowledge statements; survey development; survey dissemination; compilation of survey results; and test specifications



development. The successful outcome of the job analysis study depended on the excellent information provided by participating clinical research professionals.

## Conducting the Job Analysis Study

The job analysis study for CCRA, CCRC, and CPI exams involved a multi-method approach that included meetings with subject-matter experts and a survey. There were five major components within the conduct of the job analysis study.



### *Conducting the Planning Meeting*

In December 2014, a planning meeting was conducted to identify the subject matter experts who would comprise the three diverse groups or “Job Analysis Task Force Committees” and “Test Specifications Committees”, meeting dates, study timeline, and survey delivery.

### *Development of the Survey*

The Job Analysis Task Force Committee met to conduct several important activities for the purpose of identifying the tasks and knowledge necessary for the competent performance of CCRA, CCRC, and CPI professionals. This included reviewing and, as needed, revising the major domains and the associated task and knowledge statements within each domain. The draft list presented to the Task Force was developed using the results of the 2010 Job Analysis and The Joint Task Force (JTF) for Clinical Trial Competency Framework<sup>3</sup>. The mission of the JTF was to align and harmonize the many focused statements relating to core competency for clinical research professionals into a single, high level set of standards, which could be adopted globally and serve as a framework for defining professional competency throughout the clinical research enterprise.



Survey rating scales and background and general information questions were presented, discussed, and revised as needed. Upon the completion of the Job Analysis Task Force Meeting, the draft survey was constructed. The survey covered the following task and knowledge domains (areas):

#### **Task Domain Areas:**

1. Scientific Concepts and Research Design
2. Ethical and Participant Safety Considerations
3. Product Development and Regulation
4. Clinical Trial Operations (GCPs)
5. Study and Site Management
6. Data Management and Informatics

#### **Knowledge Domain Areas:**

1. Scientific Concepts and Research Design
2. Ethical and Participant Safety Considerations
3. Product Development and Regulation
4. Clinical Trial Operations (GCPs)
5. Study and Site Management
6. Data Management and Informatics

These domain areas served as the foundation for the content-specific questions included on the Job Analysis Survey.

Each Task Force member reviewed their work and recommended any revisions. A pilot survey was developed from the work of the Job Analysis Task Force Committee.

### ***Dissemination of the Survey***

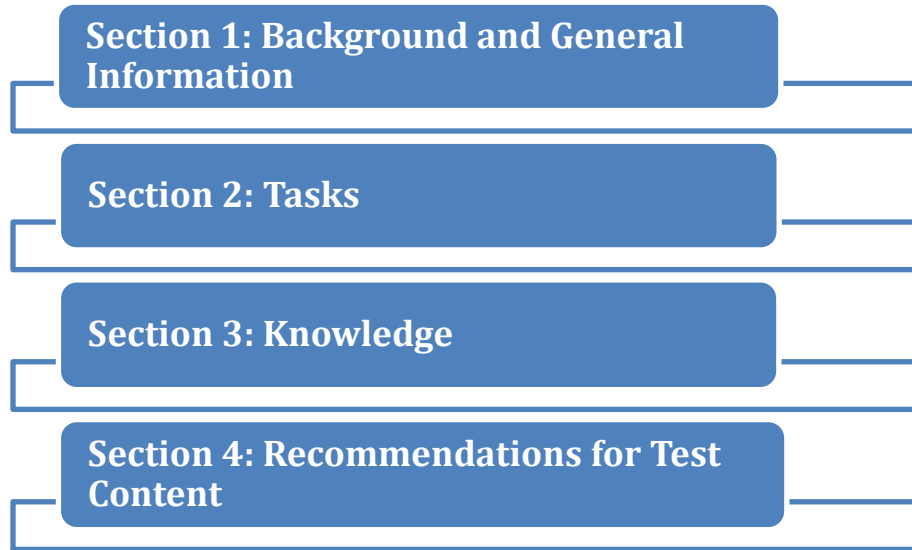
A small-scale pilot test was launched to allow professionals in the field who had no previous involvement in the development of the survey to review and offer suggestions to improve the survey. Pilot participants reviewed the survey for clarity of wording, ease of use, and comprehensiveness of content coverage. The Job Analysis Task Force revised and finalized the survey based on the review of the pilot test comments.

The final version of the survey, disseminated in June of 2015, consisted of five sections, listed below. ACRP distributed the survey to CCRA, CCRC, and CPI professionals as well as non-certified clinical research professionals.





## Survey Sections



The purpose of the survey was presented to the participants as follows:

**“To validate the tasks and knowledge which are important to the work performed by clinical research professionals. The results of the practice analysis will be used to update the test specifications of the Academy examinations to make sure they reflect current practice.”**

For each of the tasks and knowledge questions, participants were asked to provide ratings for:

- the task statements by importance for CCRA, CCRC, and CPI professionals;
- how frequently they perform the tasks during an average week of work;
- the knowledge statements by importance for CCRA, CCRC, and CPI professionals; and
- the cognitive level required, specifically, to what level the knowledge should be attained at the time the clinical research professional earns the credential.

## Analysis of Survey Data

### *Survey Responses*

A total of 4,547 clinical research professionals submitted completed surveys. Based on the analysis of survey responses, a representative group of 2,167 professionals completed the survey in sufficient numbers to meet the requirements for statistical analysis of the results. This is evidenced by review of the responses for each of the background and general information questions as well as confirmation by the Test Specifications Committee.



Survey results provide information to guide the development of test specifications and content-valid examinations. What matters most is that a certification examination covers the important knowledge needed to perform job activities. A summary of the overall Job Analysis Survey is provided in the next section, “Develop the Test Specifications.” Analysis was conducted using survey data related to the respective job roles for the three programs separately.

## **Development of the Test Specifications**

In October 2015, the CCRA, CCRC, and CPI Test Specifications Committees convened to review the results of the Job Analysis Survey and to create the test specifications. The test specifications are used in the continuous creation of the CCRA, CCRC, and CPI examination forms. New forms are regularly constructed from the test specifications as all forms are periodically removed from circulation to best ensure the security of the exam content.

The steps involved in the development of test specifications included the following:

- presentation of the job analysis project and results to the Test Specifications Committees;
- identification of the task and knowledge statements to be included on the CCRA, CCRC, and CPI test specifications;
- development of the test content weights for the exam; and,
- linkage of the task and knowledge statements.

### ***Presentation of the Job Analysis Results***

The Test Specifications Committee reviewed the task and knowledge results to make final recommendations about the areas which should be included on the respective exam.

The survey results served as the primary source of information used by the Test Specifications Committee members to make test content decisions. Recommendations were based on the following criteria, by job role identified by survey respondents:

- the mean task and knowledge ratings for all respondents;
- the frequency distribution of ratings for all respondents; and,
- the appropriateness of the content for the examination.

### ***Identification of Tasks and Knowledge Statements/ Recommended for Inclusion***

Each Test Specifications Committee (CCRA, CCRC, and CPI) focused on the task and knowledge recommendations from their professional job role (Monitor/CRA (for CCRAs), Study Coordinator (for CCRCs), and Investigator (CPIs).

Each task and knowledge statement was analyzed for importance to the work of CCRA, CCRC, and CPI professionals using an Index of Agreement (IOA). The IOA is a measure of the extent to which subgroups of respondents agree on the importance of each task and knowledge. The IOA is derived



from the respondent ratings of importance from the survey responses. As expected, the IOA analysis showed a significant difference in the responses between the three roles. For this reason, each committee considered the means and standard deviations from the *respondents* in their roles, as well as the *overall* means and standard deviations. Using the mean IOA, the Test Specifications Committees were able to consider and make recommendations for all statements based on a mean importance rating, particularly those represented as “moderately important”. Additionally, respondents were given the opportunity to write in additional task and knowledge statements for the committee’s consideration. The committee evaluated all statements for final exclusion or inclusion in the CCRA, CCRC, and CPI Exam Test Specifications.

In addition to providing ratings for the task and knowledge statements, respondents rated how well the statements within each of the task and knowledge content areas (domains) covered important aspects of the area. The mean rating for the task content coverage and the knowledge content coverage show the areas were well covered in the survey for all three programs.

Write –in comments were also considered. Many survey respondents provided responses to the open-ended questions , for example, questions about expected changes in their job role over the next few years and professional development/continuing education needs. The Test Specifications Committee reviewed the comments to determine whether there were important statements not covered on the survey that should be included in the finalized test specifications.

### ***Development of Test Content Weights***

Survey participants were asked to assign a percentage weight to each knowledge domain to specify the appropriate emphasis of content by content area which should be represented on each exam. The sum of percentage weights was required to equal 100. This information guided the Test Specifications Committees in discussing and making decisions about how much emphasis the domains should receive on the test content outline.

In addition to providing weights for each exam, the Test Specifications Committees participated in an exercise to delineate the distribution of cognitive levels by each domain. The exams use three cognitive levels for questions: recall, application, and analysis. Each committee used the results of the knowledge cognitive level ratings from the survey to guide the discussion.

### ***Linkage of Task and Knowledge Statements***

Task and knowledge linking verifies that each knowledge area included on an examination relates to the competent performance of important tasks. As such, linking supports the content validity of the task included in the test specifications. Linking does not require the production of an exhaustive listing; rather, task-knowledge links are developed to ensure that each knowledge statement is identified as being related to the performance of at least one, or in most cases, several important tasks. Linking also provides guidance for item (exam question) writing activities. When item writers develop questions for specific knowledge areas, they have a listing of tasks that relate to the knowledge they are testing. Linking provides context for developing examination questions, and



assists the item writers in question design. Further to that point, examination candidates will use this information to understand the breadth of knowledge for which they could be tested.

### ***Final Test Specifications***

The test specifications were constructed to outline the knowledge a professional is expected to have in order to perform tasks important to the specific job role. The knowledge and tasks are grouped into six (6) main content areas and will be used for future CCRA, CCRC, and CPI Examinations. These final content areas are aligned with six of the eight core competencies found on The Joint Task Force (JTF) for Clinical Trial Competency Framework, introduced in the “Development of the Survey” section. The Test specifications also include the number of questions, by cognitive level, which will be given within each main content area. This level of detail is provided strictly for item writing purposes.

The six (6) Content Areas are displayed in the chart below. The percent of questions dedicated to each content area, by program are also provided.

| <b>Content Areas</b>   | <b>Percentage of Questions on Exam</b> |             |             |
|--|--|-------------|-------------|
|  | <b>CCRA</b>                            | <b>CPI</b>  | <b>CCRC</b> |
| <b>I. Scientific Concepts and Research Design<br/>Ethical and Participant Safety</b> | 12%                                    | 17%         | 8%          |
| <b>II. Considerations</b>  | 20%                                    | 25%         | 22%         |
| <b>III. Product Development and Regulation</b>                                       | 10%                                    | 10%         | 14%         |
| <b>IV. Clinical Trial Operations (GCPs)</b>  | 25%                                    | 15%         | 22%         |
| <b>V. Study and Site Management</b>  | 23%                                    | 23%         | 22%         |
| <b>VI. Data Management and Informatics</b>   | 10%                                    | 10%         | 12%         |
| <b>Total</b>   | <b>100%</b>                            | <b>100%</b> | <b>100%</b> |

A complete Detailed Content Outline (DCO) for each program will be finalized in February 2016. Each DCO will provide the knowledge statements linked to the related tasks within each of the main content areas. This is a comprehensive outline of the knowledge which will be tested on examinations beginning in early 2017.



## Summary and Conclusions

In summary, this study used a multi-method approach to identify the tasks and knowledge that are important to the competent performance of CCRA, CCRC, and CPI professionals.

The task and knowledge statements were developed through an iterative process involving the combined efforts of ACRP, subject matter experts, and Prometric staff. These statements were entered into a survey format and subjected to verification/refutation through the dissemination of a survey to CCRA, CCRC, and CPI professionals. The survey participants were asked to rate the importance of task and knowledge statements.

The results of the study support the following:

- All of the task and knowledge statements that were verified as important through the survey provide the foundation of empirically derived information from which to develop test specifications for the CCRA, CCRC, and CPI Examinations.
- Evidence was provided in this study that the comprehensiveness of the content within the task and knowledge domains was adequately to very well covered.
- The process utilized and all of the information that resulted from the analysis supported the development of the test specifications.

The job analysis process allowed for input from a representative group of CRAs, CRCs, and PIs and was conducted within the guidelines of professionally sound practice. The results of the job analysis will be used by the ACRP to develop the CCRA, CCRC, and CPI Exam to be administered in 2017. The information derived from the Job Analysis Study will be used to align relevant content used for Maintenance of Certification. The results can also be used to align and develop content for ACRP professional development courses for CCRAs, CCRCs, and CPis.

## References

- <sup>1</sup> American Educational Research Association, American Psychological Association, National Council on Measurement in Education. (1999). *The Standards for Educational and Psychological Testing*. Washington, DC: American Psychological Association.
- <sup>2</sup> National Commission for Certifying Agencies (NCCA), Institute for Credentialing Excellence. (2004, Last revised 2014) *Standards for the Accreditation of Certification Programs*. Washington, DC.
- <sup>3</sup> The Clinical Researcher, Association of Clinical Research Professionals. (June 2014) *Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional*. Alexandria, VA.

