Standards and Guidelines
for the Accreditation of Educational Programs in
Clinical Research

Standards initially adopted in 2017; revised in 2019, 20xx; and effective xx/xxxx.

Developed by
Committee on Accreditation of Academic Programs in Clinical Research

Endorsed by
Consortium of Academic Programs in Clinical Research

and

Approved by the
Commission on Accreditation of Allied Health Education Programs

The Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredits programs upon the recommendation of the Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR).

These accreditation **Standards** are the minimum standards of quality used in accrediting programs that prepare individuals to enter the Clinical Research profession. Standards are the minimum requirements to which an accredited program is held accountable. Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required but can assist with interpretation of the Standards.

Standards are printed in regular typeface in outline form. *Guidelines are printed in italic typeface*.

Preamble

The Commission on Accreditation of Allied Health Education Programs (CAAHEP), Committee on Accreditation of Academic Programs in Clinical Research, and the Consortium of Academic Programs in Clinical Research cooperate to establish, maintain and promote appropriate standards of quality for educational programs in clinical research and to provide recognition for educational programs that meet or exceed the minimum standards outlined in these accreditation **Standards and Guidelines for the Accreditation of Educational Programs**. CAAHEP encourages innovation and quality education programs throughout the CAAHEP accreditation process, consistent with the CAAHEP policy on institutional autonomy. These **Standards and Guidelines** are designed to ensure the integrity of the CAAHEP accreditation process. Directories of accredited programs are published for the information of students, employers, educational institutions and organizations, credentialing bodies and the public.

These **Standards and Guidelines** are to be used for the development, evaluation, and self-analysis of clinical research programs. Site visit teams assist in the evaluation of a program's relative compliance with the accreditation standards.

Description of the Profession

The role of the clinical research professional (CRP) includes the evaluation of medical products, medical devices, medical procedures and social or behaviorial interventions to determine their efficacy and safety in humans. This evaluation is usually in the form of a human subject study or a clinical trial.

Clinical research professionals may be employed at research sites, such as hospitals, research institutes, or academic medical centers; or they may be employed by research sponsors, such as pharmaceutical companies, medical device companies, contract research organizations, a government agency such as The National Institutes of Health or the Food and Drug Administration, or an institutional review board (IRB) or institutional ethics committee (IEC). Clinical research professionals who contribute to the conduct of a research study may have job titles, such as clinical research coordinator (CRC), clinical research associate (CRA), clinical research monitor (CRM), IRB or IEC coordinator or analyst, research physician, project manager, research nurse, regulatory affairs coordinator or data management professional called a data management associate or data manager.

I. Sponsorship

A. Program Sponsor

A sponsoring institution must be at least one of the following

1. A post-secondary academic institution accredited by an institutional accrediting agency that is recognized by the U.S. Department of Education and must be authorized under applicable law or other acceptable authority to provide a post-secondary program, which awards a minimum of a diploma/certificate at the completion of the program.

2. A post-secondary academic institution outside of the United States and its territories that is authorized under applicable law or other acceptable authority to punctuation,provide a post-secondary program, which awards a minimum of a diploma/certificate or equivalent at the completion of the program.

3. A consortium, which is a group made up of two or more education providers, that operate an educational program through a written agreement that outlines the expectations and responsibilities of each of the partners. At least one of the consortium partners must meet the requirements of a program sponsor set forth in I.A.1.

Consortium does not refer to clinical affiliation agreements with the program sponsor.

B. Responsibilities of Program Sponsor

The program sponsor must

1. Ensure that the program meets the Standards;

2. Award academic credit for the program or have an articulation agreement with an accredited post-secondary institution; and

3. Have a preparedness plan in place that assures continuity of education services in the event of an unanticipated interruption;

Examples of unanticipated interruptions may include unexpected departure of key personnel, natural disaster, public health crisis, fire, flood, power failure, failure of information technology services, or other events that may lead to inaccessibility of educational services.

4. Ensure that all graduates have earned a minimum of an associate degree, or its international degree equivalent, before or concurrent with the completion of the program.

II. Program Goals

A. Program Goals and Minimum Expectations

The program must have the following minimum expectations statement: "To prepare clinical research professionals who are competent in the cognitive (knowledge), psychomotor (skills), and affective (behavior) learning domains to enter the profession."

Programs that adopt educational goals beyond the minimum expectations statement must provide evidence that all students have achieved those goals prior to entry into the field.

Program goals must be compatible with the mission of the sponsoring institution(s), the expectations of the communities of interest, and accepted standards of roles and functions of a clinical research professional. Goals are based upon the substantiated needs of health care providers and employers, and the educational needs of the students served by the educational program. Program goals must be written referencing one or more learning domains.

The program must assess its goals at least annually and respond to changes in the needs and expectations of its communities of interest.

B. Program Advisory Committee

The program advisory committee must include at least one representative of each community of interest and must meet annually. Communities of interest served by the program include, but are not limited to, students, graduates, faculty members, sponsor administrators, employers, clinical research professionals, and the public.

Clinical research professionals may include physicians or other principal investigators.

The program advisory committee advises the program regarding revisions to curriculum and program goals based on changing needs and expectations of its communities of interest, and an assessment of program effectiveness, including the outcomes specified in these Standards.

Program advisory committee meetings may be conducted using synchronous electronic means.

III. Resources

A. Type and Amount

Program resources must be sufficient to ensure the achievement of the program's goals and outcomes. Resources must include, but are not limited to

1. Faculty;

2. Administrative and support staff;

3. Curriculum;
4. Finances;
5. Faculty and staff workspace;
6. Space for confidential interactions;
7. Classroom and laboratory (physical or virtual);
8. Ancillary student facilities;
9. Supervised practice experiences;
10. Equipment;
11. Supplies;
12. Information technology;
13. Instructional materials; and
14. Support for faculty professional development.

B. Personnel

The sponsor must appoint sufficient faculty and staff with the necessary qualifications to perform the functions identified in documented job descriptions and to achieve the program's stated goals and outcomes.

At a minimum, the following positions are required.

1. Program Director

a. Responsibilities

The program director must be responsible for all aspects of the program, including but not limited to

1) Administration, organization, and supervision of the program;
2) Continuous quality review and improvement of the program;
3) Academic oversight, including curriculum planning and development; and
4) Establishing criteria for supervised practice experiences for programs that offer mentored practice experiences.

b. Qualifications

The program director must

1) Possess a minimum of an academic degree equivalent to that for which the graduates are being prepared;
2) Have documented education or experience in instructional methodology.

2. Faculty/Instructional Staff

a. Responsibilities

For all didactic, laboratory, and supervised practice instruction to which a student is assigned, there must be a qualified individual(s) clearly designated by the program to provide instruction, supervision, and timely assessments of the students' progress in meeting program requirements.

b. Qualifications

Faculty/instructional staff must be effective in teaching and knowledgeable in subject matter as documented by appropriate professional credential(s)/certification(s), education, and experience in the designated content area.

C. Curriculum

The curriculum content must ensure that the program goals are achievable. Instruction must be based on clearly written course syllabi that include course description, course objectives, methods of evaluation, topic outline, and competencies required for graduation. Instruction must be delivered in an appropriate sequence of classroom, laboratory, and clinical activities.

The program must demonstrate that the curriculum meets or exceeds the competencies listed in Appendix B of these **Standards**.

CAAHEP supports and encourages innovation in the development and delivery of the curriculum.

D. Resource Assessment

The program must, at least annually, assess the appropriateness and effectiveness of the resources described in these **Standards**. The results of the resource assessment must be the basis for ongoing program planning and change. An action plan must be developed when needed improvements are identified in the program resources. Implementation of the action plan must be documented, and results measured by ongoing resource assessment.

IV. Student and Graduate Evaluation/Assessment

A. Student Evaluation

1. Frequency and purpose

Evaluation of students must be conducted on a recurrent basis and with sufficient frequency to provide both the students and program faculty with valid and timely indications of the students' progress toward and achievement of the competencies in the required learning domains.

Validity means that the evaluation methods chosen are consistent with the learning and performance objectives being tested.

2. Documentation

Student evaluations must be maintained in sufficient detail to document learning progress and achievements.

B. Outcomes

The program must meet the established outcomes thresholds.

1. Assessment

The program must periodically assess its effectiveness in achieving established outcomes. The results of this assessment must be reflected in the review and timely revision of the program.

Outcomes assessments must include but are not limited to programmatic retention, graduate satisfaction, employer satisfaction, and placement in full or part-time employment in the profession or in a related profession.

A related profession is one in which the individual is using cognitive, psychomotor, and affective competencies acquired in the educational program.

Graduates pursuing academic education related to progressing in health professions or serving in the military are counted as placed.

2. Reporting

At least annually, the program must submit to the CAAPCR, the program goal(s), outcomes assessment results, and an analysis of the results.

If established outcomes thresholds are not met, the program must participate in a dialogue with and submit an action plan to the CAAPCR that responds to the identified deficiency(ies). The action plan must include an analysis of any deficiencies, corrective steps, and timeline for implementation. The program must assess the effectiveness of the corrective steps.

V. Fair Practices

A. Publications and Disclosure

1. Announcements, catalogs, publications, advertising, and websites must accurately reflect the program offered.

2. At least the following must be made known to all applicants and students

- **a.** Sponsor's institutional and programmatic accreditation status;
- **b.** Name and web site address of CAAHEP;
- **c.** Admissions policies and practices;
- **d.** Technical standards;
- **e.** Occupational risks;
- **f.** Policies on advanced placement, transfer of credits, and credits for experiential learning;
- **g.** Number of credits required for completion of the program;
- **h.** Availability of articulation agreements for transfer of credits;
- **i.** Tuition/fees and other costs required to complete the program;
- **j.** Policies and processes for withdrawal and refunds of tuition/fees; and
- **k.** Policies and processes for assignment of supervised practice experiences.

3. At least the following must be made known to all students

- **a.** Academic calendar;
- **b.** Student grievance procedure;
- **c.** Appeals process;
- **d.** Criteria for successful completion of each segment of the curriculum and for graduation; and
- **e.** Policies by which students may perform supervised practice experiences while enrolled in the program.

4. The sponsor must maintain and make accessible to the public on its website a current and consistent summary of student/graduate achievement that includes one or more of these program outcomes programmatic retention and placement in full or part-time employment in the profession or a related profession as established by the CAAPCR .

B. Lawful and Non-discriminatory Practices

All activities associated with the program, including student and faculty recruitment, student admission, and faculty employment practices, must be non-discriminatory and in accord with federal and state

statutes, rules, and regulations. There must be a faculty grievance procedure made known to all paid faculty.

C. Safeguards

The health and safety of patients/clients, students, faculty, and other participants associated with the educational activities of the students must be adequately safeguarded. Clinical research students must be readily identifiable as students.

All activities required in the program must be educational and students must not be substituted for staff.

D. Student Records

Grades and credits for courses must be recorded on the student transcript and permanently maintained by the program sponsor in an accessible and secure location. Students and graduates must be given directions on how to access their records. Records must be maintained for student admission, advisement, and counseling while the student is enrolled in the program.

E. Substantive Change

The sponsor must report substantive change(s) as described in Appendix A to CAAPCR in a timely manner. Additional substantive changes to be reported to CAAPCR within the time limits prescribed include

1. Change in the educational institution's legal status or form of control;
2. Change in the educational institution's regional or national accreditation status; and
3. Change in the degree awarded.

F. Agreements

There must be a formal affiliation agreement or memorandum of understanding between the program sponsor and all other entities that participate in the education of the students describing the relationship, roles, and responsibilities of the program sponsor and that entity.

APPENDIX B

Curriculum Competencies for Educational Programs in Clinical Research

The competencies for clinical research professionals originate from the internationally adopted Joint Task Force Clinical Trial Competency Framework of the Joint Task Force for Clinical Trial Competency (JTF), located on the JTF website at the MultiRegional Cinical Trial Center (https://mrctcenter.org/clinical-trial-competency/framework/domains)

1. **Scientific Concepts and Research Design:** Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.

    a. **Apply** principles of biomedical science to investigational product discovery and development and health-related behavioral interventions. (Psychomotor)
    b. **Identify** scientific questions that are potentially testable clinical research hypotheses. (Psychomotor)
    c. **Explain** the elements and principles and processes of designing a clinical study. (Cognitive)
    d. **Maintain** awareness of new technologies, methodologies and techniques which enhance the conduct, safety, and validity of the clinical study. (Affective)
    e. **Critically analyze** study results. (Psychomotor)

2. **Ethical and Participant Safety Considerations**
    Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.

    a. **Differentiate** between standard of care and clinical study activities. (Psychomotor)
    b. **Define** the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical study. (Cognitive)
    c. **Apply** relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study. (Psychomotor)
    d. **Explain** the evolution of the requirements for informed consent from research participants and the principles and content of the key documents that ensure the protection of human participants in clinical research. (Cognitive)
    e. **Describe** the ethical issues involved when dealing with vulnerable populations and what additional safeguards should be in place for those populations. (Cognitive, Affective)
    f. **Evaluate and apply** an understanding of the relevant ethical issues and cultural variation as it applies to the commercial aspects of the clinical research and investigational product development process. (Psychomotor, Affective)
    g. **Explain** why inclusion, exclusion, and other criteria are included in a clinical protocol to assure human participant protection. (Cognitive, Affective)
    h. **Summarize** the principles and methods of distributing and balancing risk and benefit through selection and management of clinical study participants. (Cognitive)

3. **Investigational Products Development and Regulation**
    Encompasses knowledge of how investigational products are developed and regulated.

    a. **Discuss** historical events that precipitated the development of governmental regulatory processes for investigational products. (Cognitive)
    b. **Describ**e the roles and responsibilities of the various institutions participating in the investigational

products development process. (Cognitive)

c. **Explain** the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products. (Cognitive)
d. **Summarize** the legislative and regulatory framework that supports the development and registration of investigational products and ensures their safety, efficacy, and quality. (Cognitive)
e. **Describe** the specific processes and phases that must be followed for the regulatory authority to approve the marketing authorization for a medical product. (Cognitive)
f. **Describe** the pre- and post- approval safety reporting requirements of regulatory agencies. (Cognitive)
g. **Appraise** the issues generated and the effects of global expansion on the approval and regulation of medical products. (Psychomotor)

4. **Clinical Study Operations (Good Clinical Practice)**

Encompasses study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product.

a. **Explain** how the design, purpose and conduct of individual clinical studies fit into the goal of developing a new intervention. (Cognitive)
b. **Describe** the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines. (Cognitive)
c. **Evaluate** the design, conduct and documentation of clinical studies as required for compliance with Good Clinical Practice Guidelines. (Psychomotor)
d. **Compare and contrast** the regulations and guidelines of global regulatory bodies related to the conduct of clinical studies. (Pyschomotor)
e. **Describe** appropriate control, storage and dispensing of investigational product. (Cognitive)
f. **Differentiate** the types of adverse events (AEs) that may occur during clinical studies and explain the identification process and reporting requirements to IRBs/IECs, sponsors and regulatory authorities. (Pyschomotor)
g. **Describe** how global regulations and guidelines assure human participant protection and privacy during the conduct of clinical studies. (Cognitive)
h. **Understand** the role and process of mentoring a clinical study. (Cognitive)
i. **Understand** the role and purpose of clinical study audits. (Cognitive)
j. **Describe** the various methods by which safety issues are identified and managed in clinical studies. (Cognitive)

5. **Study and Site Management**

Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs).

a. **Determine** whether to sponsor, supervise, or participate in a clinical study. (Pyschomotor)
b. **Develop and manage** the functional and operational efficiencies and personnel resources necessary to conduct a clinical study. (Pyschomotor)
c. **Describe** the management and training approaches to mitigate risk to improve clinical study conduct. (Cognitive)
d. **Develop and implement** strategies to manage participant recruitment, retention, compliance and track study activities. (Psychmotor)
e. **Identify** the legal responsibilities, liabilities, and accountabilities that are involved in the conduct of clinical studies. (Cognitive)
f. **Identify and explain** the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CROs and regulatory authorities that relate to the conduct of a clinical study.

(Cognitive)

g. **Identify, organize, analyze, and report** project performance for comprehensive management of a clinical study. (Psychomotor)

6. Data Management and Informatics

Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.

a. **Describe** the role and importance of statistics and informatics in clinical studies. (Cognitive)
b. **Describe** the origin, flow, and management of data through a clinical study. (Cognitive)
c. **Apply** best practices and resources for standardizing data collection, capture, management, analysis, and reporting. (Psychomotor)
d. **Develop and implement** processes for data quality assurance. (Psychomotor)

7. Leadership and Professionalism

Encompasses the principles and practice of leadership and professionalism in clinical research.

a. **Describe and apply** the principles and practices of leadership, management, and mentorship in clinical research. (Psychomotor)
b. **Identify and address** ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention and management. (Psychomotor)
c. **Adhere** to professional guidelines and codes of ethics that apply to the conduct of clinical research. (Affective)
d. **Appreciate** the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct. (Affective)

8. Communication and Teamwork

Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators.

a. **Demonstrate** strong teamwork skills necessary for conducting a clinical trial. (Psychomotor)
b. **Recognize** the importance of team science and methods necessary to work effectively with cross-functional, multidisciplinary and interprofessional research teams, which may include external partners. (Affective)
c. **Discuss** the relationship and appropriate communication between Sponsor, CRO, and clinical research site. (Psychomotor)
d. **Effectively communicate** the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientific community. (Psychomotor)
e. **Describe** the components of a traditional scientific publication. (Cognitive)