



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

Standards initially adopted in 2017; revised in 2019

Adopted by the
Consortium of Academic Programs in Clinical Research
Committee on Accreditation of Academic Programs in Clinical Research
and
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 and Guidelines** 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 in narrative form.

Preamble

The Commission on Accreditation of Allied Health Education Programs (CAAHEP) 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**. Lists of accredited programs are published for the information of students, employers, educational institutions and agencies, and the public.

These **Standards and Guidelines** are to be used for the development, evaluation, and self-analysis of Clinical Research programs. On-site review 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) involves the evaluation of medical products, medical devices and medical procedures to determine their efficacy and safety in humans; or it may involve evaluation of human social interaction or behavior. 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, assistant or associate, or data management professional called a data management associate or data manager.

I. Sponsorship

A. Sponsoring Institution

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 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 foreign post-secondary academic institution acceptable to CAAHEP, which is authorized under applicable law or other acceptable authority to provide a post-secondary program, which awards a minimum of a diploma/certificate or its equivalent at the completion of the program.

B. Consortium Sponsor

1. A consortium sponsor is an entity consisting of two or more members that exists for the purpose of operating an educational program. In such instances, at least one of the members of the consortium must meet the requirements of a sponsoring institution as described in I.A.
2. The responsibilities of each member of the consortium must be clearly documented in a formal affiliation agreement or memorandum of understanding, which includes governance and lines of authority.

C. Responsibilities of Sponsor

1. The Sponsor must ensure that the provisions of these **Standards and Guidelines** are met.
2. The Sponsor must ensure that all graduates have obtained or will obtain a minimum of an Associate's degree or equivalent upon completion of the program.

II. Program Goals

A. Program Goals and Outcomes

There must be a written statement of the program's goals and learning domains consistent with and responsive to the demonstrated needs and expectations of the various communities of interest served by the educational program. The communities of interest that are served by the program must include, but are not limited to, students, graduates, faculty, sponsor administration, employers, clinical research professionals, and the public.

Clinical research professionals may include physicians or other principal investigators.

Program-specific statements of goals and learning domains provide the basis for program planning, implementation, and evaluation. Such goals and learning domains must be compatible with the mission of the sponsoring institution(s), the expectations of the communities of interest, and nationally accepted standards of roles and functions. Goals and learning domains are based upon the substantiated needs of health care providers and employers, and the educational needs of the students served by the educational program.

B. Appropriateness of Goals and Learning Domains

The program must regularly assess its goals and learning domains. Program personnel must identify and respond to changes in the needs and/or expectations of its communities of interest.

An advisory committee, which is representative of at least each of the communities of interest named in these **Standards**, must be designated and charged with the responsibility of meeting at least annually, to assist program and sponsor personnel in formulating and periodically revising appropriate goals and learning domains, monitoring needs and expectations, and ensuring program responsiveness to change.

Advisory committee meetings may include participation by synchronous electronic means.

C. Minimum Expectations

The program must have the following goal defining minimum expectations: “To prepare competent entry-level Clinical Research Professionals in the cognitive (knowledge), psychomotor (skills), and affective (behavior) learning domains.”

Programs adopting educational goals beyond entry-level competence must clearly delineate this intent and provide evidence that all students have achieved the basic competencies prior to entry into the field.

Nothing in this Standard restricts programs from formulating goals beyond entry-level competence.

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: faculty; clerical and support staff; curriculum; finances; offices; classroom, laboratory, and, ancillary student facilities; clinical affiliates; equipment; supplies; computer resources; instructional reference materials; and faculty/staff continuing education.

Classroom and laboratory resources may be provided as virtual resources. Clinical research internship experience may be provided at face-to-face clinical affiliate sites, on-line, or as a hybrid of both.

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.

1. Program Director

a. Responsibilities

The Program Director must:

1. coordinate all aspects of the program, including the organization, administration, continuous review, planning, development and achievement of the program’s goals and outcomes; and
2. establish criteria for clinical sites for programs that offer experiential/capstone experiences.

b. Qualifications

The Program Director must:

1. possess an earned degree at least at the same academic level as that awarded by the program; and
2. be a full-time faculty member of the sponsoring institution.

The Program Director should have competency in the curriculum content described in Appendix B

2. Faculty and/or Instructional Staff

a. Responsibilities:

Faculty and other instructional staff must provide instruction and assess students’ skills, knowledge and attitudes surrounding competency-based courses as well as experiential education/capstone experiences if offered by the program

b. Qualifications:

Faculty and instructional staff must:

1. have competence in the subject matter taught; and
2. have a minimum of three (3) years of clinical research experience in the area in which they are providing instruction.

C. Curriculum

The curriculum must ensure the achievement of program goals and learning domains. Instruction must be an appropriate sequence of classroom, laboratory, and/or clinical activities. 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.

The program must demonstrate by comparison that the curriculum offered meets or exceeds the content outline listed in Appendix B of these Standard and Guidelines.

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 annual resource assessment must be the basis for ongoing program planning, and appropriate change. An action plan must be developed when deficiencies are identified in 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 and learning domains stated in the curriculum.

2. Documentation

Records of student evaluations must be maintained in sufficient detail to document learning progress and achievements.

B. Outcomes

1. Outcomes Assessment

The program must periodically assess its effectiveness in achieving its stated goals and learning domains. The results of this evaluation must be reflected in the written review and timely revision of the program.

Outcomes assessments must include, but are not limited to: programmatic retention/attrition, graduate satisfaction, employer satisfaction, job (positive) placement, national credentialing examinations and programmatic summative measures. The program must meet the outcomes assessment thresholds.

“Positive placement” means that the graduate is employed full or part-time in the profession, or in a related field; or continuing his/her education or serving in the military. A related field is one in which the individual is using cognitive, psychomotor, and affective competencies acquired in the educational program.

“National credentialing examinations” are those accredited by the National Commission for Certifying Agencies (NCCA) or American National Standards Institute (ANSI). Participation and pass rates on national credentialing examination(s) performance may be considered in determining whether or not a program meets the designated threshold, provided the credentialing examination(s), or alternative examination(s) offered by the same credentialing organization, is/are available to be administered prior to graduation from the program. Results from said alternative examination(s) may be accepted, if designated as equivalent by the same organization whose credentialing examination(s) is/are so accredited.

2. Outcomes Reporting

The program must periodically submit to the CAAPCR, the program goal(s), learning domains, evaluation systems (including type, cut score, and appropriateness), outcomes, its analysis of the outcomes, and an appropriate action plan for improvement, based on the analysis.

Programs not meeting the established thresholds must begin a dialogue with the CAAPCR to develop an appropriate plan of action to respond to the identified shortcomings.

V. Fair Practices

A. Publications and Disclosure

1. Announcements, catalogs, publications, and advertising must accurately reflect the program offered.
2. At least the following must be made known to all applicants and students: the sponsor's institutional and programmatic accreditation status as well as the name, mailing address, web site address, and phone number of the accrediting agencies; admissions policies and practices, including technical standards (when used); policies on advanced placement, transfer of credits, and credits for experiential learning; number of credits required for completion of the program; tuition/fees and other costs required to complete the program; policies and processes for withdrawal and refunds of tuition/fees.
3. At least the following must be made known to all students: academic calendar, student grievance procedure, criteria for successful completion of each segment of the curriculum and for graduation, and policies and processes by which students may perform clinical work, while enrolled in the program.
4. The sponsor must maintain, and make available to the public, current and consistent summary information about student/graduate achievement that includes the results of one or more of the outcomes assessments required in these **Standards**.

The sponsor should develop a suitable means of communicating to the communities of interest the achievement of students/graduates (e.g., through a website or electronic or printed documents).

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, students, faculty, and other participants associated with the educational activities of the students must be adequately safeguarded.

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

D. Student Records

Satisfactory records must be maintained for student admission, advisement, counseling, and evaluation. Grades and credits for courses must be recorded on the student transcript and permanently maintained by the sponsor in a safe and accessible location.

E. Substantive Change

The sponsor must report substantive change(s) as described in Appendix A to CAAHEP/CAAPCR in a timely manner. Additional substantive changes to be reported to CAAPCR within the time limits 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 sponsor and all other entities that participate in the education of the students describing the relationship, roles, and responsibilities of the sponsor and that entity.

APPENDIX A

Application, Maintenance and Administration of Accreditation

A. Program and Sponsor Responsibilities

1. Applying for Initial Accreditation

- a. The chief executive officer or an officially designated representative of the sponsor completes a “Request for Accreditation Services” form and returns it electronically or by mail to:

The Committee on Accreditation of Academic Programs in Clinical Research
c/o CAAHEP
9355 – 113th Street N. #7709
Seminole, FL 33775

The “Request for Accreditation Services” form can be obtained from the CAAHEP website at <https://www.cognitofoms.com/CAAHEP2/RequestForAccreditationServices>.

Note: There is **no** CAAHEP fee when applying for accreditation services; however, individual committees on accreditation may have an application fee.

- b. The program undergoes a comprehensive review, which includes a written self-study report and an on-site review.

The self-study instructions and report form are available from the Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR). The on-site review will be scheduled in cooperation with the program and CAAPCR once the self-study report has been completed, submitted, and accepted by the CAAPCR.

2. Applying for Continuing Accreditation

- a. Upon written notice from the CAAPCR, the chief executive officer or an officially designated representative of the sponsor completes a “Request for Accreditation Services” form, and returns it electronically or by mail to:

The Committee on Accreditation of Academic Programs in Clinical Research
c/o CAAHEP
9355 – 113th Street N. #7709
Seminole, FL 33775

The “Request for Accreditation Services” form can be obtained from the CAAHEP website at <https://www.cognitofoms.com/CAAHEP2/RequestForAccreditationServices>.

- b. The program may undergo a comprehensive review in accordance with the policies and procedures of the CAAPCR.

If it is determined that there were significant concerns with the conduct of the on-site review, the sponsor may request a second site visit with a different team.

After the on-site review team submits a report of its findings, the sponsor is provided the opportunity to comment in writing and to correct factual errors prior to the CAAPCR forwarding a recommendation to CAAHEP.

3. Administrative Requirements for Maintaining Accreditation

- a. The program must inform the CAAPCR and CAAHEP within a reasonable period of time (as defined by the CAAPCR and CAAHEP policies) of changes in chief executive officer, dean of health professions or equivalent position, and required program personnel (Refer to Standard III.B.).
- b. The sponsor must inform CAAHEP and the CAAPCR of its intent to transfer program sponsorship. To begin the process for a Transfer of Sponsorship, the current sponsor must submit a letter (signed by the CEO or designated individual) to CAAHEP and the CAAPCR that it is relinquishing its sponsorship of the program. Additionally, the new sponsor must submit a "Request for Transfer of Sponsorship Services" form. The CAAPCR has the discretion of requesting a new self-study report with or without an on-site review. Applying for transfer of sponsorship does not guarantee the transfer will be granted.
- c. The sponsor must promptly inform CAAHEP and the CAAPCR of any adverse decision affecting its accreditation by recognized institutional accrediting agencies and/or state agencies (or their equivalent).
- d. Comprehensive reviews are scheduled by the CAAPCR in accordance with its policies and procedures. The time between comprehensive reviews is determined by the CAAPCR and based on the program's on-going compliance with the Standards, however, all programs must undergo a comprehensive review at least once every ten years.
- e. The program and the sponsor must pay CAAPCR and CAAHEP fees within a reasonable period of time, as determined by the CAAPCR and CAAHEP respectively.
- f. The sponsor must file all reports in a timely manner (self-study report, progress reports, probation reports, annual reports, etc.) in accordance with CAAPCR policy.
- g. The sponsor must agree to a reasonable on-site review date that provides sufficient time for CAAHEP to act on a CAAPCR accreditation recommendation prior to the "next comprehensive review" period, which was designated by CAAHEP at the time of its last accreditation action, or a reasonable date otherwise designated by the CAAPCR.

Failure to meet any of the aforementioned administrative requirements may lead to administrative probation and ultimately to the withdrawal of accreditation. CAAHEP will immediately rescind administrative probation once all administrative deficiencies have been rectified.

4. Voluntary Withdrawal of a CAAHEP- Accredited Program

Notification of voluntary withdrawal of accreditation from CAAHEP must be made by the Chief Executive Officer or an officially designated representative of the sponsor by writing to CAAHEP indicating: the desired effective date of the voluntary withdrawal, and the location where all records will be kept for students who have completed the program.

5. Requesting Inactive Status of a CAAHEP- Accredited Program

Inactive status for any accredited program may be requested from CAAHEP at any time by the Chief Executive Officer or an officially designated representative of the sponsor writing to CAAHEP indicating the desired date to become inactive. No students can be enrolled or matriculated in the program at any time during the time period in which the program is on inactive status. The maximum period for inactive status is two years. The sponsor must continue to pay all required fees to the CAAPCR and CAAHEP to maintain its accreditation status.

To reactivate the program the Chief Executive Officer or an officially designated representative of the sponsor must provide notice of its intent to do so in writing to both CAAHEP and the CAAPCR. The sponsor will be notified by the CAAPCR of additional requirements, if any, that must be met to restore active status.

If the sponsor has not notified CAAHEP of its intent to re-activate a program by the end of the two-year period, CAAHEP will consider this a “Voluntary Withdrawal of Accreditation.”

B. CAAHEP and Committee on Accreditation Responsibilities – Accreditation Recommendation Process

1. After a program has had the opportunity to comment in writing and to correct factual errors on the on-site review report, the CAAPCR forwards a status of public recognition recommendation to the CAAHEP Board of Directors. The recommendation may be for any of the following statuses: initial accreditation, continuing accreditation, transfer of sponsorship, probationary accreditation, withhold of accreditation, or withdrawal of accreditation.

The decision of the CAAHEP Board of Directors is provided in writing to the sponsor immediately following the CAAHEP meeting at which the program was reviewed and voted upon.

2. Before the CAAPCR forwards a recommendation to CAAHEP that a program be placed on probationary accreditation, the sponsor must have the opportunity to request reconsideration of that recommendation or to request voluntary withdrawal of accreditation. The CAAPCR’s reconsideration of a recommendation for probationary accreditation must be based on conditions existing both when the committee arrived at its recommendation as well as on subsequent documented evidence of corrected deficiencies provided by the sponsor.

The CAAHEP Board of Directors’ decision to confer probationary accreditation is not subject to appeal.

3. Before the CAAPCR forwards a recommendation to CAAHEP that a program’s accreditation be withdrawn or that accreditation be withheld, the sponsor must have the opportunity to request reconsideration of the recommendation, or to request voluntary withdrawal of accreditation or withdrawal of the accreditation application, whichever is applicable. The CAAPCR’s reconsideration of a recommendation of withdraw or withhold accreditation must be based on conditions existing both when the CAAPCR arrived at its recommendation as well as on subsequent documented evidence of corrected deficiencies provided by the sponsor.

The CAAHEP Board of Directors’ decision to withdraw or withhold accreditation may be appealed. A copy of the CAAHEP “Appeal of Adverse Accreditation Actions” is enclosed with the CAAHEP letter notifying the sponsor of either of these actions.

At the completion of due process, when accreditation is withheld or withdrawn, the sponsor’s Chief Executive Officer is provided with a statement of each deficiency. Programs are eligible to re-apply for accreditation once the sponsor believes that the program is in compliance with the accreditation Standards.

Note: Any student who completes a program that was accredited by CAAHEP at any time during his/her matriculation is deemed by CAAHEP to be a graduate of a CAAHEP-accredited program.

APPENDIX B

Curriculum for Educational Programs in Clinical Research

Given the variety of roles and role specific competencies within the clinical research and medicine development enterprise, it is recognized that educational programs may focus on one or more specific roles, or may vary in the level of professional competence at which their learning outcomes are structured. Programs must provide appropriate learning outcomes within each of the eight required competency domains listed below.

1. Scientific Concepts and Research Design

- a. *Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development*
- b. *Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature*
- c. *Explain the elements (statistical, epidemiological and operational) of a clinical or translational study design*
- d. *Design a clinical trial*
- e. *Critically analyze study results with an understanding of therapeutic and comparative effectiveness*

2. Ethical and Participant Safety Considerations

- a. *Compare and contrast clinical care and clinical management of research participants*
- b. *Define the concepts of “clinical equipoise” and “therapeutic misconception” as they relate to the conduct of a clinical trial*
- c. *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*
- d. *Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents which ensure the protection of human participants in clinical research*
- e. *Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards*
- f. *Evaluate and apply an understanding of the past and current ethical issues, cultural variation and commercial aspects on the medicines development process*
- g. *Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection*
- h. *Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of the clinical trial subject*

3. Medicines Development and Regulation

- a. *Discuss the historical events which precipitated the development of governmental regulatory processes for drugs, devices and biologicals*
- b. *Describe the roles and responsibilities of the various institutions participating in the medicines development process*
- c. *Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products*
- d. *Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biological and ensures their safety, efficacy and quality*

- e. *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*
- f. *Describe the safety reporting requirements of regulatory agencies both pre and post approval*
- g. *Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products*

4. Clinical Trial Operations

- a. *Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan*
- b. *Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines*
- c. *Evaluate the design conduct and documentation of clinical trials as required for compliance with Good Clinical Practice Guidelines*
- d. *Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials*
- e. *Describe appropriate control, storage and dispensing of investigational product*
- f. *Differentiate the types of adverse events which occur during clinical trials, understand the identification process for adverse events and describe the reporting requirements to institutional review boards/institutional ethics committees, sponsors and regulatory authorities*
- h. *Describe how global regulations and guidelines assure human subjects protection and privacy during the conduct of clinical trials*
- i. *Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct*
- j. *Describe the role and process for monitoring of the study*
- k. *Describe the roles and purpose of clinical trial audits*
- l. *Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research*

5. Study and Site Management

- a. *Describe the methods utilized to determine whether or not to sponsor, supervise or participate in a clinical trial*
- b. *Develop and manage the financial, timeline and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study*
- c. *Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study*
- d. *Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures and track progress*
- e. *Identify the legal responsibilities, issues, liabilities and accountability that is involved in the conduct of a clinical trial*
- f. *Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, contract research organizations (CRO) and regulatory authorities which relate to the conduct of a clinical trial*

6. Data Management and Informatics

- a. *Describe the role that biostatistics and informatics serve in biomedical and public health research*
- b. *Describe the typical flow of data throughout a clinical trial*

- c. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management*
- d. Describe the International Conference on Harmonisation (ICH) Good Clinical Practice Guideline (GCP) requirements for data correction and queries*
- e. Describe the significance of data quality assurance systems and how standard operating procedures (SOPs) are used to guide these processes*

7. Leadership and Professionalism

- a. Describe the principles and practices of leadership, management and mentorship, and apply them within the working environment*
- b. Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research*
- c. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research*
- d. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research*

8. Communication and Teamwork

- a. Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site*
- b. Describe the component parts of a traditional scientific publication*
- c. Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community*
- d. Describe methods necessary to work effectively with multidisciplinary and inter-professional research teams*