



## **Association of Clinical Research Professionals Code of Ethics and Professional Conduct**

The Association of Clinical Research Professionals (“ACRP”) is a US registered nonprofit, tax-exempt corporation that functions as a global association of clinical research professionals. ACRP’s vision is that clinical research is performed ethically, responsibly, and professionally everywhere in the world. ACRP’s mission is to promote integrity and excellence in clinical research. The Academy of Clinical Research Professionals (the “Academy”) similarly is a nonprofit, tax-exempt organization that advances and promotes the professional interests of clinical research professionals and provides certification for such professionals.

[This Code of Ethics and Professional Conduct](#) (the “Code”) serves as a code of professional conduct for ACRP members and/or Academy Certificants. ACRP members and Academy Certificants are expected to adhere to this Code in all professional activities and relationships with each other, organizations with which they work, research participants and society in general. The core values of Integrity, Courage, Excellence, Dedication and Collaboration are manifest in the ACRP Code. The Code also applies to individuals who seek membership in and/or certification by ACRP and the Academy.

This Code is a summary of what ACRP and the Academy define as essential ethical behavior for clinical research professionals. Compliance with the Code is a requirement for initial and continued ACRP membership and/or certification through the Academy. ACRP members and Academy Certificants affirm their endorsement of the Code and acknowledge their commitment to uphold its principles by joining and subsequently renewing their membership in ACRP and/or by applying for and maintaining certification from the Academy. Violations of the Code may result in sanctions imposed under the [Discipline and Complaints Policy](#) (the “Policy”) adopted by ACRP and the Academy. This Policy was adopted to provide clarity of expected behavior and description of due process accorded to ACRP members and Academy Certificants necessary to protect the integrity, and ensure the efficacy, of the Code.

This Code is intended to be used by current and prospective ACRP members and Academy Certificants in conjunction with applicable national and international frameworks that govern the practice of clinical research, such as professional license requirements, ethical principles, guidelines, and laws and regulations applicable to clinical research, including, but not limited to, principles of the Declaration of Helsinki, Belmont Report, ICH GCP, US Codes of Federal Regulations, WHO “Ethical Standards and Procedures for Research with Human Beings,” and UK Research Governance Framework.

The term “Clinical Research Professional” as used herein encompasses many job titles, disciplines, and duties within the profession of clinical research. For the purpose of this Code, the term shall include anyone involved in the design, conduct, reporting, review and oversight

of clinical research who is an ACRP member or Academy Certificant or applicant for membership or certification, and those who represent ACRP in any elected or volunteer capacity (e.g. Chapter President, Treasurer, etc. or volunteers to serve on a local or national committee, speakers at a conference or event).

Clinical Research Professionals who are current or prospective members of ACRP and/or Academy Certificants (referred to herein as “Members” and “Certificants”) shall abide by and conform to the following ethical standards:

## **I. Beneficence and Nonmaleficence**

Members and Certificants shall:

1. Respect and safeguard the rights and welfare of all individuals with whom they interact professionally, including but not limited to research participants.
2. Always consider and act in furtherance of the best interests of research participants and society. Where societal and research participants’ interest conflict, best interests of the participants take precedence.
3. Ensure that the aims of all clinical research projects are to advance knowledge and promote the health and well-being of research participants.
4. When designing, reviewing, or conducting research, ensure that potential risks of the research are reasonable in relation to the anticipated benefits to the participants and the importance of the knowledge to be gained.
5. Ensure that potential risks to research participants are minimized to the greatest extent possible and take all necessary steps to protect the participants at all times.

Steps taken to uphold this ethical principle include, but are not limited to:

1. Design and conduct studies where a state of clinical equipoise exists, that is, to test hypotheses that have not yet been adequately tested through current or previous reported research results, to avoid unnecessary risks or inconveniences to participants of redundant research and to maximize often scarce research resources.
2. Design and conduct research studies with scientific value.
3. Ensure clinical research is conducted in accordance with currently accepted ethical guidelines and standards.
4. Never use coercion or undue influence when recruiting research participants. Seek autonomous informed and appropriately documented consent from participants or, where applicable, their legally authorized representatives prior to the instigation of any research procedure.
5. Never coerce, or attempt to coerce or induce individuals, such as staff members, vendors, contractors, investigators, or regulators, to act in an unethical manner in any respect.
6. Avoid using substances, such as alcohol or drugs, while performing professional duties that may impair professional judgment or performance.
7. Perform only those duties for which one is appropriately qualified and trained to perform.

8. Where an individual is a member of a professional organization with its own licensing requirements and/or code of ethical or professional conduct, operate within the scope of practice and professional standards outlined within those professional guidelines, codes or licenses.
9. Report any acts that appear to be unethical or illegal to appropriate organizational, institutional or legal authorities, so long as supported by reasonable evidence.

## **II. Integrity**

Members and Certificants shall:

1. Educate themselves, and where applicable, their students and their colleagues, about responsible research practices.
2. Apply sound ethical values, scientific principles and judgment in the design, conduct and analysis of clinical studies, and in interpretation of their results.
3. Report research findings accurately and avoid misrepresenting, fabricating or falsifying results.
4. Conduct research in accordance with an approved research protocol/plan.
5. Make all research data available to authorized persons for verification in accordance with established standards of the clinical research profession.
6. Ensure the dissemination of scientifically sound information from clinical trials and other investigations, and
7. Not withhold information relevant to full evaluation of the safety, efficacy or utility of clinical interventions, agents or devices under investigation for the benefit of medicine, patients, science and society regardless of the research outcome.

## **III. Conflicts of Interest**

It is recognized that real, potential and apparent conflicts of interest naturally occur from time to time. Conflicts of interest arise when personal, professional, business, political and/or financial influences have the potential to significantly impair professional judgment, and hence lead to consequent acts of research or business misconduct. Additionally, conflicts of interest may occur in relation to other professional and volunteer obligations, whether with ACRP or the broader research community.

It is essential that Members and Certificants:

1. Recognize when they may have a conflict of interest, disclose such conflict as soon as the potential conflict is recognized and be transparent in how the conflict will be managed.
2. If participation in any research-related activity that poses a potential conflict of interest situation is unavoidable, ensure that steps are taken to appropriately manage any such conflicts to safeguard quality and credibility of their professional judgment from inappropriate influence so that research participants' rights and safety are fully protected.
3. Do not, under any circumstance, unduly exploit any professional or volunteer relationship to further personal, political, or business interest at the expense of other

individuals or ACRP. This includes both professional and volunteer activities and cases where volunteer activities, as a professional or other body might pose a potential conflict of interest.

4. Respect and adhere to the Conflict-of-Interest policies if they are a member of any professional or industry organization, or an employee of an organization that has internal Conflict of Interest policies.

Steps taken to uphold this ethical principle include but are not limited to:

1. Publicly disclose relationships and potential conflicts of interest in publications, speaking engagements, Advisory Boards and any other venue or activity, including any ACRP chapter or other meetings in which the Member or Certificant is perceived as providing subject matter expertise or other authority
2. Retain documentation and use factual quantitative measures to conduct one's own professional duties and procurement of vendor services.
3. Avoid dual relationships that could impair professional judgment or increase the risk of harm to others.
4. Avoid performing services for direct competitors without the express knowledge and documented consent of each party, either volunteer or professional. Direct competitors are individuals or organizations with whom an exchange of services would create a conflict of interest – a situation in which personal, professional, business, political and/or financial influences have the potential to significantly impair professional judgment, and hence lead to consequent acts of research or business misconduct.

#### **IV. Privacy and Confidentiality**

Privacy refers to the legal rights of individuals to limit public scrutiny; to limit access to their private acts and their personal information; and to limit disclosure of such personal information. Confidentiality refers to the obligation to protect private information about an individual or organization from unauthorized disclosure. Clinical research professionals have access to confidential information, whether it is intellectual property of a company or personal health information of research participants and have the responsibility to maintain this confidentiality.

Members and Certificants must:

1. Maintain the privacy and confidentiality of research participants and of any confidential information received in connection with the Members and Certificants' research to the extent required by applicable law(s) and/or signed contractual agreements.
2. Maintain the privacy and confidentiality of any non-public information, intellectual property of a company or personal health information of research participants, that they may have access to in their roles as clinical research professionals.

Steps taken to uphold this ethical principle include but are not limited to:

1. Store written and/or electronic records in secure locations with access provided only to authorized individuals.
2. Collect and transmit only the minimum essential information required to accomplish the task at hand.

3. Apply standards of confidentiality to retrospective, current and prospective data collection and protected personal information. Treat all confidential data as if it were your own.
4. Ensure an understanding of all elements that could be considered confidential information of any kind.
5. Ensure that all aspects of the privacy of research participants and their families is respected prior to, during, and following, any clinical research project.

## **V. Duties to Society and Compliance with the Law**

By the very nature of their work, Members and Certificants are engaged in professional endeavors that enhance knowledge, skill, judgment and intellectual development that strives to contribute to improving the human condition. As such, clinical research professionals must be both aware and conscious of their duty to society and the clinical research arena.

Members and Certificants shall:

1. Uphold the profession's responsibility to society by promoting ethical and professional practice standards, and
2. Be willing to be held professionally accountable for upholding those standards.
3. Not participate in criminal, fraudulent, or other illegal activities.
4. If faced with a conflict between abiding by two conflicting laws or regulations, or between abiding by a law/regulation and following an ethical principle, consult with experienced, respected professional colleagues and seek their guidance whenever possible.
5. Not advocate, sanction, participate in, or condone any act that is prohibited by this Code, unless failure to do so would be seriously detrimental to the rights and well-being of others.

## **VI. Duties to Professional Discipline and Beneficiaries of Practice**

Members and Certificants shall:

1. Be personally committed to, and encourage others, to engage in safe, sound research practices consistent with the relevant ethical and scientific standards and the requirements of their professional discipline.
2. Uphold standards of equality and nondiscrimination in all professional interactions and cooperate with other professionals as appropriate and ethical.
3. Assist colleagues entering the profession by sharing knowledge and understanding of the ethics, responsibilities and needed competencies of their chosen area of research and practice. Where Members or Certificants seek to acquire or maintain a medical or other professional license, additional laws and ethical standards of conduct that are not pertinent to clinical research may apply.
4. In addition to adhering to this Code of Ethics and Professional Conduct, abide by their respective discipline's laws and ethical standards of conduct.
5. Take affirmative steps to make it clear to research participants and others that there is a distinction between research and standard therapy. Ensure that the roles and responsibilities of physicians and other health care professionals acting as both investigators and care providers remain clear to all concerned.

6. Ensure that all contributory information provided to research participants, their legal representatives and other health care providers not involved with the research is fair, balanced, accurate, understandable and sufficiently comprehensive to enable well-informed decisions about the use of pharmaceuticals, medical devices or other clinical services or interventions.
7. Ensure that when consent is waived, that reasons for waiver of informed consent are valid, that the waiver reasons and process comply with applicable regulations, e.g. regulations in 21 CFR 50 and 56, and that IRB approval for a waiver has been sought, as is generally applicable.
8. If a clinical investigation is conducted or supported by HHS and involves an FDA regulated product, the study is subject to both 45 CFR 46 and part 21 CFR 50 and 56. Where the regulations differ, the regulations that offer the greater protection to human subjects should be followed.

## **VII. Duties to ACRP and the Greater Research Community**

While there are many professional and personal benefits to volunteering for leadership positions in the community, members and certificants who volunteer for ACRP committee, officer or Board positions at the local chapter and/or international level, have a duty to act in a professional manner and be mindful that they are acting as a representative of ACRP when fulfilling the requirements of their positions, and as such have some greater duties.

In their leadership/volunteer capacities, Members and Certificants shall:

1. Ensure that they have the skills and experience to fulfill the requirements of the position they have volunteered for or actively seek training to gain those skills and/or ask for assistance from ACRP staff or other sources to perform necessary functions.
2. Commit to understanding, following and upholding the bylaws of the organization in which they are a leader, in addition to the ACRP Code of Ethics.
3. Avoid engaging in self-dealing, as well as actual conflicts of interest relating to business affairs. Additionally, they shall use their best efforts to avoid appearance of impropriety, self-dealing or conflict of interest.
4. Avoid representing multiple organizations simultaneously in a manner which could potentially be harmful to ACRP or the other organizations.
5. Refrain from publicly (including social media) disparaging ACRP, its staff or its membership and/or disseminating false information about ACRP or its affiliates.

## **VIII. Grounds for Disciplinary Action**

A Member or Certificant shall be subject to disciplinary action if the actions of such Member or Certificant are determined, in accordance with the Discipline and Complaints Policy, to constitute one or more of the following:

1. Gross negligence or willful misconduct in the performance of services, or other unethical or unprofessional conduct based upon demonstrable violations of this Code of Ethics and Professional Conduct.
2. Conviction of a Member or Certificant of a felony or other crime of moral turpitude under federal or state law, particularly in a matter related to the conduct of the profession.

3. Fraud or misrepresentation in the application or maintenance of ACRP membership, Academy certification, or other professional recognition or credential.

Individuals aspiring to become a Member or Certificant shall ensure awareness of and adherence to this Code as an element of eligibility criteria of Membership and/or Certification. Applicants who knowingly fail to adhere to the Code shall be ineligible for Membership and/or Certification.

## **IX. Complaints**

To file a complaint against a Member or Certificant, or applicant Member or Certificant, please email [ethics@acrpnet.org](mailto:ethics@acrpnet.org). Complaints will be addressed according to the Discipline and Complaints Policy, available [here](#), developed by the ACRP Professional Ethics Committee.

### **MONITORING AND REVIEW SCHEDULE**

Review every three years by the ACRP Professional Ethics Committee.

#### **DATE REVIEWED BY COMMITTEE**

December 14, 2015  
November 3, 2017  
February 7, 2017  
November 11, 2019  
February 2020

#### **DATE MODIFIED BY COMMITTEE**

December 14, 2015  
November 3, 2017  
November 11, 2019  
February 2020

#### **DATE APPROVED BY COMMITTEE**

December 14, 2015  
November 3, 2017  
November 11, 2019  
February 2020

#### **DATE REVIEWED BY BOARD**

December 17, 2015  
December 13, 2017  
December 11, 2019  
March 17, 2020  
June 17, 2020

#### **DATE MODIFIED BY BOARD**

December 11, 2019  
March 20, 2020

**DATE APPROVED BY BOARD**

October 7, 2007

September 2012

December 17, 2015

December 13, 2017

June 17, 2020