Association of Clinical Research Professionals
ETH-06-02.01 Ethics and Accountability
ACRP Code of Ethics and Professional Conduct

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The Association of Clinical Research Professionals ("ACRP") is a nonprofit, tax-exempt 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") 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.

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 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, 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.

Clinical Research Professionals who are 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 respect and safeguard the welfare and rights of all individuals with whom they interact professionally, including but not limited to research participants. Members and Certificants shall act in the best interest of research participants and society. When designing, reviewing or conducting research, Members and Certificants shall ensure that potential risks to research participants prior to and throughout the research are minimized, and that those risks are outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained.

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

- 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.
- Design and conduct research studies with scientific value.
- Ensure clinical research is conducted in accordance with currently accepted ethical guidelines and standards.
- Never use coercion or undue influence when recruiting research participants. Seek autonomous informed and appropriately documented consent from participants or, where applicable, their legally acceptable representatives prior to the instigation of any research procedure.
- 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.

- Avoid using substances, such as alcohol or drugs, while performing professional duties that may impair professional judgment or performance.
- Perform only those duties for which one is appropriately qualified and trained to perform.
- 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.
- 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 educate themselves, and where applicable, their students and their colleagues, about responsible research practices. Members and Certificants shall apply sound ethical values, scientific principles and judgment in the design, conduct and analysis of clinical studies, and in interpretation of their results. Members and Certificants shall report research findings accurately and shall not misrepresent, fabricate or falsify results. Members and Certificants shall conduct research in accordance with an approved research protocol/plan. Members and Certificants shall make all research data available to authorized persons for verification in accordance with established standards of the clinical research profession. Within their scope of authority, Members and Certificants shall ensure the dissemination of scientifically sound information from clinical trials and other investigations, and shall 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. Conflict 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 misconduct. It is essential that Members and Certificants recognize when they may have a conflict of interest, and disclose such conflict as soon as the potential conflict is recognized. If participation in any research-related activity that poses a potential conflict of interest situation is unavoidable, Members and Certificants must 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. Members and Certificants shall not, under any circumstance, unduly exploit any professional relationship to further personal, political or business interest at the expense of others. Where Members and Certificants are part of an organization with a Conflict of Interest Policy, they are expected to respect and adhere to that Policy.

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

- Publicly disclose relationships and potential conflicts of interest in publications, speaking engagements, Advisory Boards and any other venue or activity in which the Member or Certificant is perceived as providing subject matter expertise.
- Retain documentation and use factual quantitative measures to conduct one's own professional duties and procurement of vendor services.
- Avoid dual relationships that could impair professional judgment or increase the risk of harm to others.
- Avoid performing services for direct competitors without the express knowledge and documented agreement of each party.

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 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.

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

- Store written and/or electronic records in secure locations with access provided only to authorized individuals.

- Collect and transmit only the minimum essential information required to accomplish the task at hand.
- Apply standards of confidentiality to retrospective, current and prospective data collection and protected personal information.
- 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. ACRP Members and Certificants shall uphold the profession's responsibility to society by promoting ethical and professional practice standards, and be willing to be held professionally accountable for upholding those standards. Members and Certificants shall not participate in criminal, fraudulent, or other illegal activities. If a Member or Certificant is faced with a conflict between abiding by a law or regulation and following an ethical principle, except in extraordinary circumstances such as an emergency, Members and Certificants shall consult with experienced, respected professional colleagues and seek their guidance. Members and Certificants shall 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 be personally committed, 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. Members and Certificants shall uphold standards of equality and nondiscrimination in all professional interactions, and shall cooperate with other professionals as appropriate and ethical. Members and Certificants have a duty to 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. Members and Certificants shall, in addition to adhering to this Code of Ethics and Professional Conduct, abide by their respective discipline's laws and ethical standards of conduct. Additionally, Members and Certificants who are also involved in the clinical care of patients shall take steps to avoid contributing to therapeutic misconception of

research participants, and to ensure that the roles and responsibilities of physicians and other health care professionals acting as investigators and care providers remain clear. Members and Certificants shall also 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.

VII. 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:

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

VIII. Complaints

To file a complaint against a Member or Certificant, or applicant Member or Certificant, please email 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

DATE MODIFIED BY COMMITTEE
December 14, 2015
November 3, 2017

DATE APPROVED BY COMMITTEE
December 14, 2015
November 3, 2017

DATE REVIEWED BY BOARD
December 17, 2015
December 13, 2017

DATE MODIFIED BY BOARD

DATE APPROVED BY BOARD
October 7, 2007
September 2012
December 17, 2015
December 13, 2017