



Advancing People Advancing Health™

Association of Clinical Research Professionals Professional Ethics Committee Policy 8.1

Discipline and Complaints Policy

Purpose

Maintain and enforce standards of professional conduct and ethics within the membership of the Association of Clinical Research Professionals (ACRP) and individuals certified by or seeking certification from the Association and/or Academy of Clinical Research Professionals (Academy).

Scope

The Professional Ethics Committee (PEC) has the responsibility to maintain and enforce standards of professional conduct and ethics within ACRP and the Academy (see *ACRP Code of Ethics and Professional Conduct*). The Committee will review and respond to cases of possible or actual misconduct by members or certificants; past members or certificants who were members or certificants at the time of the alleged misconduct; and those seeking membership or certification. A complaint may be lodged by anyone who becomes aware of a perceived violation of the Code of Ethics.

The PEC will investigate complaints to ACRP which allege violations of the *Code of Ethics and Professional Conduct*. Complaints regarding alleged violations should be reported to ACRP via the online submission form for this purpose and should include a detailed description of factual allegations supporting the charges, the portion of the Code of Ethics alleged to have been violated, and any relevant supporting documentation. Complaints lacking sufficient detail may be dismissed by the PEC or ACRP staff.

The PEC will make every effort to follow the timeline requirements established in this policy. However, failure to do so will not prevent the resolution of any hearing or action, and disciplinary action may be decided and reported to the subject of the complaint, complainant, and the Board of Trustees at the conclusion of the process even if the timelines set forth herein are not met. Complainants and individuals who are the subject of the complaint are required to comply with established timeline requirements. Time extensions or postponements may be granted for good cause by the PEC.

Information exchanged during the complaint process and all hearings will be considered confidential and will be addressed in a discreet and professional manner by the members of the PEC, ACRP staff, and any consultants. However, absolute confidentiality cannot be guaranteed as circumstances may dictate that some level of disclosure is necessary, as determined in the reasonable discretion of ACRP staff and/or the PEC or applicable law.

Further, while individuals may request anonymity when submitting a complaint and while ACRP and the PEC will make their best efforts to honor such a request, there may be situations when an individual respondent may discern the identity of the complainant through the submissions. As such, ACRP cannot guarantee anonymity.

Process

Each complaint (made via the online submission form) should contain the following minimum information:

- 1) The name, address, and contact information of the complainant, if the complainant does not request anonymity;
- 2) The name of the individual against whom the complaint is being made, and his or her contact information, if known;
- 3) The provision(s) of the Code allegedly being violated;
- 4) The nature of the complaint, including the factual background and time-period involved;
- 5) The name of other individuals or organizations who may have information regarding the particulars set forth in the complaint; and
- 6) Any documentary information supporting the complaint.

Initial Complaint Review: Staff

Complaints will be received and reviewed by ACRP staff to determine if the complaint should be forwarded to the PEC. Each complaint will be evaluated based on the following three criteria:

- 1) Whether the subject of the complaint is or was an ACRP member, applicant for membership, certificant, or an applicant for certification at the time of occurrence
- 2) Do the facts alleged in the complaint, if accepted, constitute a violation of the ACRP Code of Ethics and Professional Conduct
- 3) Has sufficient information concerning the allegation been provided which would warrant the complaint to be forwarded to the PEC. NOTE: If uncertain, ACRP staff should consult the PEC Chair or Vice Chair in the Chair's absence.

Ethics complaints concerning individuals who are not ACRP members or certificants, and who were not members or certificants at the time of the alleged misconduct, are not reviewed by ACRP's Ethics Committee and may be referred to ACRP or its Boards of Trustees.

Initial Complaint Review: PEC

If the staff believes the complaint meets the criteria, all available information in its original form will be provided to the PEC to determine whether to accept the complaint. The PEC Chair, or Vice Chair in the Chair's absence, will schedule a committee meeting at the earliest possible time to discuss whether the complaint appears to constitute a violation of ACRP's Code of

Ethics, what provision of the code may have been violated, and if the source of the complaint is verified and/or trustworthy. Such meeting may be conducted face-to-face, by video, or teleconference.

If the PEC concurs by majority vote that the complaint is deemed actionable, the complaint will be considered accepted and will proceed to the *Complaints Accepted Process* outlined below. The Committee will discuss whether more information is needed, in addition to a response from the subject of the complaint, that should be gathered for sharing at a hearing. PEC Members will be asked to contact the Chair or staff to declare any potential conflicts of interest with the matter.

Complaints Not Accepted

If ACRP staff or the PEC finds that the complaint does not meet the three minimum criteria, staff will notify the individual who filed the complaint within 30 calendar days of the decision and provide the reason(s) for the determination in writing. If appropriate, staff may provide an opportunity for the complainant to provide additional details. If provided, the PEC may reconsider acceptance of the complaint.

NOTE: Willfully filing a frivolous or malicious complaint is considered a form of professional misconduct. Individuals who do so are subject to disciplinary action under this policy.

Complaints Accepted

If the PEC decides to accept a complaint, the following procedure will be followed:

- 1) A written notice will be issued to the subject of the complaint within 14 calendar days from the date the Committee determined a hearing is warranted, via any traceable method. The notice will include:
 - a. The substance of the complaint, its alleged factual basis, and the provision(s) of the Code alleged to have been violated,
 - b. A copy of the Discipline and Complaints policy,
 - c. A request to submit a response to the PEC,
 - d. Notification of the composition of the PEC,
 - e. Request for declaration of perceived conflict(s) of interest of the PEC members,
 - f. A deadline for the response to be received, which shall be no more than 21 calendar days from receipt of the notice, and
 - g. Notification that all communications from and to the subject of the complaint will be routed via ACRP's head office via the ethics liaison

- 2) A written notice will be issued to the complainant within 14 calendar days from the date the Committee determined an investigation was warranted, via any traceable method. The notice will include:
 - a. Notification that the PEC will pursue an investigation,

- b. A copy of the Discipline and Complaints Policy,
- c. Notification that the subject of the complaint will be notified, and that the complainant will be identified to the subject of the complaint (Note: if the complainant initially requested anonymity, the request will be honored to the extent possible),
- d. Notification of the composition of the PEC,
- e. Request for declaration of perceived conflict(s) of interest of the PEC members within 14 calendar days of receipt,
- f. Notification that ethics investigations are confidential, and the complainant is expected to maintain confidentiality at all times and should not be engaging in discussion with the subject of the complaint throughout the process,
- g. Notification that the PEC may seek additional information during the investigation process and the complainant is expected to comply with the requests in a timely manner, and
- h. Notification that the only communication channels are to be with the PEC email box, by mail to the ACRP office, and/or by contact with the PEC staff liaison. Notification also that attempted communications directly with any PEC member is deemed highly inappropriate and will not be accepted.

3) A Conflict-of-Interest Review will be held if needed.

If a PEC member, the complainant, or subject of the complaint declare a potential conflict of interest* held by any of the committee members, a Conflict-of-Interest Review will be held. After discussion, if the declared conflict is deemed by the PEC or ACRP counsel to affect the judgment of the PEC member in question to impartially adjudicate the complaint, that member will be recused from further involvement with the ethics case. Committee members with perceived conflicts may provide their perspective and discussion may be held about potential mitigation for the concerns described. After review, if concerns persist about the potential conflict affecting a member's ability to render an impartial decision related to the subject matter, a vote may be held. The Committee member in question will temporarily exit the discussion, and the remaining members shall decide by vote. If three (3) or more PEC members vote to affirm a conflict of interest, then the member in question will be recused.

The PEC members with no conflicts of interest or those with declared but manageable conflicts will participate in the hearing of the ethics case.

**A Conflict of Interest occurs when pre-existing business, financial, volunteer, or personal relationships with the complainant or subject of the complaint exist in such a way that they could significantly affect a member's judgment and ability to render an impartial decision related to the subject matter. It is important to note that relationships or past contacts do not, by themselves, constitute a conflict of interest, but rather the nature and history of those contacts and the likelihood that they would affect*

judgment (for instance: meeting at a conference, participation on an ACRP committee together or working together on a research study would likely not affect judgment; whereas being close friends and/or business partners or being a direct competitor doing research on a competing drug could affect judgment).

Response Review

In the event that a response is received from the subject of the complaint, then within 60 calendar days of receipt of that response, at the discretion of the Chair or their designee, the PEC (except members recused due to conflicts of interest), will either hold a hearing (process outlined below) or, alternatively, convene a meeting of the PEC to review the response from the subject of the complaint and consider whether a violation of clinical research ethics has been presented that warrants holding a hearing. Options that could be considered at this meeting include the committee pursuing the complaint and holding a hearing, dismissing the case, and delaying the case to allow time for more information. Both the complainant and subject of the complaint should be notified of next steps decided at the review meeting.

If no response is received from the subject of the complaint, then the case will move directly to a hearing (process outlined below).

Hearing Overview

- 1) If the Committee decides to hold a hearing, to review the complaint together with all responses provided, it may be conducted by telephone or video conference. Follow-up hearings may be scheduled as necessary. The initial hearing should be held within 60 calendar days of the PEC's decision to move forward with a hearing (or if no response is received from the subject of the complaint, the deadline for the response).
- 2) The hearing may include: applicable witnesses, the subject of the complaint, members of the PEC, applicable staff, and/or an investigator, legal counsel, or consultant. The Committee may opt to appoint an investigator or consultant either within ACRP membership or staff, or an outside consultant with content expertise relevant to the complaint, to advise and inform the PEC but not vote on any action items before the Committee. All consultants must be approved, in advance, by the Executive Director. All consultants shall be bound by the confidentiality requirements in this policy.
- 3) The PEC may invite the subject of the complaint to be available to respond to questions during the hearing and any subsequent hearings as necessary. However, the subject of the complaint will not otherwise be entitled to participate. The subject of the complaint will be provided with the names of the PEC members as well as all consultants involved in the investigation. The subject of the complaint will have the right to notify ACRP of any potential conflict of interest he or she believes exists with any of the members of the PEC or consultants.
- 4) If, for valid and unavoidable reasons, the subject of the complaint is unable to attend the hearing as scheduled, or his/her representative(s) or material witness(es) are unable to

- attend, s/he may request a one-time rescheduling of the hearing to be held no later than 30 calendar days after the original hearing date.
- 5) If the subject of the complaint refuses to participate in a hearing or is otherwise unresponsive to inquiries from the PEC and/or ACRP, after at least two attempts to reach them, the hearing will continue in accordance with this policy. For a hearing to be conducted, the following individuals must participate:
 - A quorum of PEC members (i.e., 50% plus 1)
 - The Chair of the PEC or his/her designee
 - ACRP staff, including the Executive Director, as assigned (All staff will be non-voting and will participate only as requested)
 - 6) Hearings will not be open to the public. ACRP and the PEC will make every effort to ensure that hearings are fair, impartial, and follow a format consistent with this policy and a meeting procedure determined by the PEC Chair and provided to the subject of the complaint not less than one calendar day prior.
 - 7) Following the hearing, the PEC members present at the hearing will make a decision regarding the complaint. The decision will be based on the affirmative vote of the majority of members present and upon review of the applicable evidence, ACRP rules and regulations, any applicable statutes or regulations promulgated by any state or federal entity or administrative body, the governing documents and policies of ACRP and/or the Academy, and the best interests of ACRP and/or the Academy. The PEC members making such a decision shall apply a preponderance-of-the-evidence standard when evaluating whether one or more Code of Ethics violations occurred.

Hearing Procedure

At the hearing, the PEC will:

- Review the complaint
- Identify the proposed violation(s) of the Code of Ethics
- Review the membership and/or certification history of the subject of the complaint
- Review outreach to the subject of complaint and their response
- Hear from the subject of the complaint or other witnesses; or determine that they need to be heard from*
- Review the relevant facts
- Discuss if there are any questions that remain unknown that the PEC needs to know*
- Discuss the risks and/or harms related to the complaint
- Consider if there are precedent cases of complaint(s) to the PEC and/or relevant historical context that should inform the PEC's thinking
- Determine if the group is satisfied with the PEC making a decision on the ethics case based on the evidence in hand*

- Discuss possible disciplinary action options the PEC could take if warranted (as outlined in policy)
- Propose a motion for disciplinary action - or other resolution of complaint (any PEC member may make a motion); second the motion, and hold discussion
- Take a PEC vote on the motion; requires majority vote (as outlined in policy)
- Document the outcome of deliberation in the meeting minutes
- Distribute hearing meeting minutes to PEC members and vote on approval of the meeting minutes at the next PEC meeting

** If more information is needed, the PEC will consider holding one or more additional hearings before action, taking time in the interim to reach out to witnesses, gather more information, or consult legal counsel/other consultant.*

Disciplinary Actions

Disciplinary actions imposed by the PEC may include any one or combination of the following actions:

- 1) Decision that the member/certificant/applicant be ineligible for membership, certification, or recertification and/or that an application for membership and/or certification be denied.
- 2) Requirement that corrective actions be taken by the subject of the investigation.
- 3) Suspension of membership and/or certification for a period determined by the Committee.
- 4) Revocation of certification and/or membership.
- 5) Decision to recommend to the ACRP and/or Academy Board of Trustees that ACRP consider imposing a public or private reprimand*
- 6) Decision to recommend to the appropriate Board that ACRP consider taking legal action against the subject of the complaint or notify the appropriate government or professional bodies of any final disciplinary action taken.

** The PEC may recommend publishing the final decision of sanctions in Clinical Researcher and/or on the ACRP website, based on the violation's nature and severity. This should be titled Publication of Decision for a Public Reprimand, Suspension, or Revocation, and will not disclose complaint details, only the individual's name and geographical location. Publication would occur after the appeals process is complete.*

Hearing Conclusion

The complainant and the individual who is the subject of the complaint will be notified by the PEC Chair of the decision and the appeals process in writing via traceable method within 21 calendar days following the hearing.

The PEC operates independently of the ACRP and Academy Boards of Trustees to review, investigate, and make a decision about a complaint; once the subject of the complaint and the

complainant are notified and the appeals period has expired, the PEC then reports to the appropriate Board on the outcome of the hearing when the Board next meets. The Boards shall determine public or private reprimand or further legal action if warranted.

Disciplinary action will be carried out by the appropriate ACRP staff and/or Committee member only after the period of time for which an appeal can be sought has expired without an appeal being raised (30 calendar days after receipt of the notice of sanction).

Appeals

Within 30 calendar days from the receipt of notice of a sanction, the affected member/certificant/applicant may appeal, in writing, any such revocation or decision via traceable method to ACRP or the Academy, as applicable. In the appeal, the member/certificant/applicant shall clearly state the reason(s) for the appeal. The following are the sole appropriate grounds for appeal of the final decision:

- 1) There were substantial errors of fact or omission in the consideration process that would have significantly changed the outcome of the hearing;
- 2) The Committee failed to conform to published criteria, policies, or procedures which significantly changed the likely outcome of the investigation; or
- 3) Important new information becomes available that may have affected the deliberation and determination of the Committee.

Within 30 calendar days of receipt of the appeal, the ACRP or the Academy Board of Trustees, as appropriate, shall constitute an Appeal Committee constituted of individuals with familiarity with ethics processes to review the complete record. A similar conflict of interest review will be conducted for the appeals committee and Board members as discussed above. Within 45 calendar days of its initial constitution, the Appeal Committee will seek to review the appeal, and issue a recommendation and a report to the ACRP or the Academy Board regarding the appeal.

The Appeal Committee may, at its sole discretion, permit the appellant to make an oral or a written presentation. The appellant may be asked to appear in person before the Committee. The appellant or the Appeal Committee may consult with legal or other counsel at any time during the appeal process.

The Appeal Committee may only make a recommendation as to whether the determination of a violation of the *Code of Ethics and Professional Conduct* and/or any recommended disciplinary action were inappropriate because of the stated reasons in #1, #2, or #3 above.

And the Appeal Committee may recommend to the applicable Board one or more of the following actions:

- 1) Upholding the decision of the PEC
- 2) Overturning the decision of the PEC and re-opening the investigation, if the Appeal Committee determines and the applicable Board agrees that errors were made in the process or new information is made available that could have significantly changed the outcome, then the applicable Board will refer the matter back to the PEC, providing input for re-evaluation and final decision
- 3) Overturning the decision of the PEC and closing the investigation

Within 30 calendar days of receipt of the Appeal Committee's recommendation and report, the ACRP or Academy Board shall render a decision, and notification to the appellant, the complainant, and all other appropriate parties, as determined by the Appeal Committee, shall be sent via traceable method.

If the applicable Board affirms the determination of the PEC, after hearing the appeals committee's recommendation, the disciplinary sanctions imposed by the PEC shall remain intact.

The decision of the applicable Board with regard to an appeal is binding upon ACRP and the Academy, the member/certificant/applicant who is subject to the determination, and all other persons.

Admission or Conviction of Guilt

At any point in the investigative or hearing process or appeals period, an individual who is the subject of a disciplinary proceeding may admit to having violated the Code of Ethics. At such point, investigative procedures shall be stopped, and the PEC shall determine a sanction and notify the ACRP or Academy Board, as appropriate. By admission of guilt, the member/certificant/applicant waives his or her right to a hearing or appeals process.

If an ACRP member or Academy certificant is found guilty in a court of law for a criminal or civil clinical research offense or activity that is in violation of ACRP's code of ethics, the matter shall be put before the PEC without a hearing for determination of disciplinary action. (This may be done by written or email ballot.) By conviction in a court of law, the member/certificant/ applicant's right is waived to a hearing or appeals process.

Voluntary Resignation

If at any point in the investigative or hearing process, the individual who is the subject of the complaint voluntarily resigns his or her membership, certification, or application for membership or certification, the PEC may choose to cease or continue its consideration until it completes the discipline and complaints process. A voluntary resignation will be reported to ACRP or the Academy as appropriate and may be reported publicly and/or to a

governmental agency as set forth herein. The individual surrendering his or her membership, certification, or application shall not be eligible for future membership or certification with ACRP or the Academy until after the matter is finally decided.

MONITORING AND REVIEW SCHEDULE

At least every three years by the Professional Ethics Committee.

DATES REVIEWED BY COMMITTEE

September 8, 2015 (by Governance Committee)
September 29, 2015
October 2, 2015
November 13, 2015 (by Governance Committee)
November 3, 2017 (by PEC)
February 7, 2017 (by PEC)
November 11, 2019 (by PEC)
February 2020 (by PEC)
October 10, 2023 (by PEC)
January, 2024 (by PEC Chair)

DATES MODIFIED BY COMMITTEE

September 29, 2015
October 2, 2015
November 13, 2015 (by Governance Committee)
November 3, 2017
November 11, 2019 (by PEC)
February 2020 (by PEC)
October 10, 2023 (by PEC)
January 2024 (by PEC Chair)

DATES APPROVED BY COMMITTEE

September 29, 2015
October 2, 2015
November 13, 2015 (by Governance Committee)
November 3, 2017
November 11, 2019 (by PEC)
February 2020 (by PEC)
October 10, 2023 (by PEC)
January, 2024 (by PEC Chair)

DATES REVIEWED BY THE BOARD

December 12, 2011

February 5, 2015

December 17, 2015

December 13, 2017

December 11, 2019

March 17, 2020

June 17, 2020

November 11, 2023

February 2, 2024

DATES APPROVED BY THE BOARD

December 12, 2011

February 5, 2015

December 17, 2015

December 13, 2017

June 17, 2020

November 11, 2023

February 2, 2024