

Association of Clinical Research Professionals

ETH-06-02.05 Ethics and Accountability

Discipline and Complaints Policy

Purpose

Maintain and enforce standards of professional conduct and ethics within the Association of Clinical Research Professionals (ACRP) and the Academy of Physicians in Clinical Research (APCR) for ACRP or APCR members and individuals certified by or seeking certification from the Academy of Clinical Research Professionals (Academy).

Scope

The Professional Ethics Committee has the responsibility to maintain and enforce standards of professional conduct and ethics within ACRP. APCR's and the Academy's policies commit to following the ACRP policy (see "Professional Ethics Committee" policy in the respective Policy Manuals). The committee will review and respond to cases of possible or actual misconduct by members or certificants 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 and Professional Conduct.

The Professional Ethics Committee will investigate complaints provided to it which allege violations of the *Code of Ethics and Professional Conduct*. Complaints regarding alleged violations should be reported to ACRP in writing, and should include a detailed description of factual allegations supporting the charges, and any relevant supporting documentation. Complaints lacking sufficient detail may be dismissed by the Professional Ethics Committee or ACRP staff.

The Professional Ethics Committee will make every effort to follow the time requirements established in this policy. However, failure to do so will not prevent the resolution of any investigation or action, and discipline may be imposed 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 time requirements. Time extensions or postponements may be granted for good cause by ACRP upon recommendation of the Professional Ethics Committee.

Information exchanged during the complaint investigation and any hearing process generally will be considered confidential, and will be addressed in a discreet and professional manner by the members of the Professional Ethics Committee, ACRP staff and any consultants. Nonetheless, circumstances may dictate that some level of disclosure is necessary, as determined in the reasonable discretion of ACRP staff and/or the Professional Ethics Committee. Further, while individuals may request anonymity when submitting a complaint and ACRP and the Professional Ethics Committee 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.

At the conclusion of the proceedings, submittals will not be returned.

Procedure

Note: the timelines referenced throughout the policy are in calendar days.

Initial Complaint Review

Each complaint must contain the following information:

- a. The name, address and contact information of the complainant, if the complainant does not request anonymity;
- b. The name of the individual against whom the complaint is being made, and his or her contact information, if known;
- c. The nature of the complaint, including the factual background and time period involved;
- d. The name of other individuals or organizations who may have information regarding the facts set forth in the complaint; and
- e. Any documentary information supporting the complaint.

Complaints will be received and reviewed by ACRP staff to determine if the complaint will be forwarded to the Professional Ethics Committee. Each complaint will be evaluated based on the following:

- 1) Whether the subject of the complaint is or was an ACRP or APCR member, applicant for membership, certificant or an applicant for certification at the time of occurrence.
- 2) Whether sufficient information concerning the allegation is provided which would warrant the complaint to be forwarded to the Professional Ethics Committee.

If it is determined that a complaint meets these criteria, then a redacted complaint will be forwarded to the Professional Ethics Committee to determine whether the complaint merits investigation. If deemed actionable by the Professional Ethics Committee, the complaint will be considered accepted. If the complaint does not meet these minimum criteria, ACRP staff will notify the individual who filed the complaint (if known) that insufficient information is available. If the complainant does not provide the missing details, ACRP staff will notify him/her that no investigation is warranted and the reason.

Initial Review by Professional Ethics Committee

To determine whether to accept a complaint, the Professional Ethics Committee will meet, and such meeting may be conducted by teleconference, to discuss the merits of the complaint.

If the Professional Ethics Committee determines that it will not accept a complaint, ACRP will notify the individual complainant (if known) by letter within 30 days of the rejection decision, and provided the reason(s) for the determination in writing.

If the Professional Ethics Committee decides to accept a complaint, the following procedure will be followed:

- 1) All available information in its original form will be provided to the Professional Ethics Committee and members of the committee will be instructed to declare any conflicts of interest. Any member who has a conflict of interest will be recused. Note: if the individual submitting the complaint requested anonymity, this will be preserved as much as possible while respecting the rights of the respondent to be informed of the details made available to the Professional Ethics Committee by the complainant.
- 2) A written notice will be issued to the individual who is the subject of the complaint within 14 days from the date the committee determined an investigation was warranted, via any traceable method. The notice will include:
 - 1) the factual basis of the complaint,
 - 2) a copy of the Discipline and Complaints policy,
 - 3) a request to submit a response to the Professional Ethics Committee, and

- 4) a deadline for the response to be received, which shall be no more than 21 days from receipt of the notice.
 - 5) Notification to the Individual that all communications from and to the subject of the complaint will be routed via ACRP's head office.
- 3) A written notice will be issued to the complainant within 14 days from the date the committee determined an investigation was warranted, via any traceable method. The notice will include:
- 1) Notification that the Professional Ethics Committee will pursue an investigation;
 - 2) A copy of the Discipline & Complaints Policy;
 - 3) 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, this will be preserved to as much extent possible.
 - 4) Notification of the composition of the Professional Ethics Committee members
 - 5) Request for declaration of perceived conflict of interest within 14 days of receipt;
 - 6) 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 respondent throughout the process.
 - 7) Notification that the Professional Ethics Committee may seek additional information during the investigation process and the complainant is expected to comply with the requests in a timely manner;
 - 8) Notification that the only communication channels are to be with the Professional Ethics Committee email box, by mail to the ACRP head office and/or by contact with the Ethics Committee Staff Liaison.
- 4) The Professional Ethics Committee will investigate the complaint in accordance with the investigation procedure described below.

Investigation Procedure

- 1) The Professional Ethics Committee will meet (which may be by teleconference) to review the complaint, any response provided by the subject of the complaint and any additional information, within 21 days of receipt of a response. The Committee may, as necessary, appoint from outside the Professional Ethics Committee consultants with content expertise relevant to the complaint. Any such external reviewers shall be bound by the confidentiality requirements in this policy and may not vote on any action items before the Committee.
- 2) The Professional Ethics Committee may invite the subject of the complaint to be available telephonically in order to respond to questions during the review meeting and any subsequent review meetings as necessary. However, the subject of the complaint will not otherwise be entitled to participate.
- 3) Based upon the evidence obtained to date which indicates the allegation may ultimately be substantiated, the Professional Ethics Committee will schedule a hearing which includes all involved parties—applicable witnesses, the subject of the complaint, members of the Professional Ethics Committee, and applicable staff. The subject of the complaint will be provided with the names of the members of the Professional Ethics Committee as well as the names of any consultants involved in the investigation.
- 4) The subject of the complaint will have the right to notify ACRP of any potential conflict of interest they believe exists with any of the members of the Professional Ethics Committee or consultants. Based

- upon the information provided by the subject of the complaint, ACRP will determine if any individual should be recused from participating in further deliberations of the Committee.
- 5) The hearing may be conducted in person or by teleconference depending upon the recommendation of the Professional Ethics Committee as approved by ACRP. The subject of the complaint will be expected to participate in the hearing. The subject of the complaint shall be entitled to make a brief, no more than ten minute, statement providing any additional information relative to the complaint after which the subject of the complaint will respond to questions posed by members of the Professional Ethics Committee.
 - 6) If the subject of the complaint refuses to participate in a hearing or is otherwise unresponsive to inquiries from the Professional Ethics Committee and/or ACRP, the hearing will continue in accordance with this policy.
 - 7) If practical, the hearing will be held no more than 90 days of the acceptance of the complaint. If the subject of the complaint wishes to have an attorney or witness(s) participate in the hearing he/she must notify ACRP staff at least 10 days in advance of the hearing date. Any attorney representing the subject of the complaint may advise the subject of the complaint but is otherwise prohibited from participating in the deliberations of the committee.
 - 8) ACRP reserves the right to have its attorney present.
 - 9) In order for a hearing to be conducted, the following individuals must participate
 - a. The Chair of the Professional Ethics Committee or his/her designee
 - b. The Vice Chair of the Professional Ethics Committee or his/her designee
 - c. At least three other members of the Professional Ethics Committee
 - d. ACRP staff as assigned
 - 10) Hearing proceedings will not be open to the public.
 - 11) Testimony will be recorded either electronically or via transcription. The subject of the complaint will have the right to request a copy of the testimony.

Following the hearing, the Professional Ethics Committee members who were 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, the rules and regulations of ACRP/APCR and/or the Academy, any applicable statutes or regulations promulgated by any state or federal entity or administrative body, the governing documents and policies of ACRP/APCR and/or the Academy, and the best interests of ACRP/APCR and/or the Academy. The Professional Ethics Committee members making such decision shall apply a preponderance-of-the-evidence standard when evaluating whether one or more Code of Ethics violations occurred.

The complainant and the individual who is the subject of the complaint will be notified by the Professional Ethics Committee Chair of the decision and the appeals process in writing via traceable method within 30 days following the hearing. Then, the outcome of the investigation hearing by the Professional Ethics Committee will be forwarded to the applicable Board(s) of Trustees as per Appendix 1, within 10 days after the subject of the complaint has been notified.

Disciplinary Actions

Disciplinary actions imposed by the Professional Ethics Committee 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 that ACRP consider imposing a public or private reprimand.

Depending upon the nature, severity, and circumstances of the violation the Professional Ethics Committee may recommend to ACRP Executive Director for the final decision that sanctions imposed shall be published in *Clinical Researcher* magazine and on the website of ACRP/APCR. This will include a Publication of Decision for Public Reprimands, Suspension and Revocation and will not include details of the complaint or investigation. Only name and geographical location will be disclosed. Publication in *Clinical Researcher* and on the website will be made once the appeals process is completed, if the individual who is the subject of the complaint/proceeding elects to pursue an appeal; or after the time period in which the individual may pursue an appeal is exhausted without an appeal being submitted.

In addition to the foregoing, ACRP/APCR or the Academy may notify appropriate government or professional bodies of any final disciplinary action taken.

Appeals

Within 30 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 the ACRP, APCR or the Academy, as applicable. In the appeal, the member/certificant/applicant shall clearly state the reasons for the appeal. The following are the sole appropriate grounds for appeal of the final decision:

- 1) There were substantial errors of facts or omissions in the consideration process that would have significantly changed the outcome of the investigation;
- 2) The Committee failed to conform to published criteria, policies, or procedures which significantly changed the likely outcome of the investigation.

Within 30 days of receipt of the appeal, the ACRP, APCR or the Academy, as appropriate, shall constitute an Appeal Committee constituted of individuals with familiarity with ethics processes to review the complete record. Within 45 days of its initial constitution, the Appeal Committee will seek to review the appeal, and issue a recommendation and a report to the ACRP, APCR or the Academy regarding the appeal. Within 30 days of receipt of the Appeal Committee's recommendation and report, the ACRP, APCR or Academy Board shall render a decision, and notification to the appellant, the complainant, if there is one, and all other appropriate parties, as determined by the Appeal Committee of the ACRP, APCR or the Academy, shall be sent via traceable method.

The Appeal Committee may only review whether the determination of a violation of the *Code of Ethics and Professional Conduct*, was inappropriate because of the stated reasons in #1 or #2 above.

The appellant may consult with legal or other counsel at any time during the appeal process. The Appeal Committee may consult legal counsel at any time during the appeal process. 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 recommendation of the Appeal Committee shall either affirm or overrule the determination of the Ethics Committee. If the Appeal Committee recommends affirming the determination of the Professional Ethics

Committee and such recommendation is confirmed by the applicable Board, the disciplinary sanctions imposed by the Professional Ethics Committee shall remain intact.

The decision of the applicable Board with regard to an appeal is binding upon ACRP, APCR and the Academy, the member/certificant/applicant who is subject to the determination, and all other persons. The Appeal Committee may recommend to the applicable Board one or more of the following actions:

- 1) Upholding the decision of the Professional Ethics Committee;
- 2) Overturning the decision of the Professional Ethics Committee and re-opening the investigation, if the Appeal Committee determines and the applicable Board agrees that errors were made in the process that could have significantly changed the outcome. In this case, the applicable Board will appoint a new committee. The determination of this committee will be considered final and not subject to appeal.
- 3) Overturning the decision of the Professional Ethics Committee and closing the investigation.

Admission 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 Professional Ethics Committee shall determine a sanction and notify the ACRP, APCR or Academy Board, as appropriate. By admission of guilt, the member/certificant/appellant waives his or her right 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 Professional Ethics Committee may choose to cease or continue its consideration until it completes the discipline and complaints process. A voluntary resignation will be reported to ACRP, APCR 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, APCR, 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)

DATES MODIFIED BY COMMITTEE

September 29, 2015
October 2, 2015
November 13, 2015 (by Governance Committee)

DATES APPROVED BY COMMITTEE

September 29, 2015
October 2, 2015
November 13, 2015 (by Governance Committee)

DATES REVIEWED BY THE BOARD

December 12, 2011
February 5, 2015
December 17, 2015

DATES APPROVED BY THE BOARD

December 12, 2011
February 5, 2015
December 17, 2015

Appendix 1

