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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 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. The Academy's policies commit to following the ACRP policy (see *ACRP Code of Ethics and Professional Conduct* 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 to ACRP 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, 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 Professional Ethics Committee or ACRP staff.

The Professional Ethics Committee 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 investigation or action, and disciplinary action may be recommended to the Board of Trustees 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 timeline requirements. Time extensions or postponements may be granted for good cause by ACRP upon recommendation of the PEC Professional Ethics Committee.

Information exchanged during the complaint investigation and any hearing process will be considered confidential, and will be addressed in a discreet and professional manner by the members of the PEC Professional Ethics Committee, ACRP staff and any consultants. However,



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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 [PEProfessional Ethics Committee](#) or applicable law. Further, while individuals may request anonymity when submitting a complaint and while ACRP and the [PEProfessional Ethics Committee \(PEC\)](#) 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.

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

Process:

~~Note: the timelines referenced throughout the policy are in business days.~~

Initial Complaint Review

Each complaint 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;
- 2)3) The provision(s) of the Code allegedly being violated
- 3)4) The nature of the complaint, including the factual background and time-period involved;
- 4)5) _____ The name of other individuals or organizations who may have information regarding the particulars set forth in the complaint; and
- 5)6) _____ Any documentary information supporting the complaint.

Complaints will be received and reviewed by ACRP staff to determine if the complaint should be forwarded to the [PEProfessional Ethics Committee](#). Each complaint will be evaluated based on the following:

- 1) ~~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.
- 1)2) Whether the facts alleged in the complaint, if accepted, would constitute a violation of the ACRP Code of Ethics and Professional Conduct
- 3)2) Whether sufficient information concerning the allegation is provided which would warrant the complaint to be forwarded to the [PEProfessional Ethics Committee](#). NOTE: If uncertain, ACRP staff should consult the PEC Chair or Vice Chair in the Chair's absence.



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If ~~the Staff believes that the complaint would appear to constitute a violation, it is sent to the PEC for acceptance. It is determined that a complaint meets these criteria, then the complaint with identifying information redacted, will be forwarded to the Professional Ethics Committee to determine whether the complaint merits investigation.~~ If ~~the PEC concurs that the complaint is~~ deemed actionable by ~~majority vote of the committee, the Professional Ethics Committee,~~ the complaint will be considered accepted ~~and will proceed to the Initial Review by the PEC.~~

~~If the complaint does not meet these minimum criteria, ACRP staff will notify the individual who filed the complaint. If the complainant does not provide additional detail, ACRP staff will notify him/her that it was determined based on the ACRP Discipline and Complaints Policy that no investigation is warranted.~~

~~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 to proceed. If the complainant does not provide additional detail, ACRP staff will notify him/her that no investigation is warranted and the reason.~~

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.

Initial Review by Professional Ethics Committee

To determine whether to accept a complaint, the Professional Ethics Committee will schedule a meeting at the earliest possible time to discuss the merits of the complaint. Such meeting may be conducted face-to-face, by video or teleconference.

If the ~~PEC~~ Professional Ethics Committee determines that it will not accept a complaint, ACRP will notify the individual complainant (if known) by letter within 30 ~~calendar~~ business days of the rejection decision, and provide 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 ~~PEC~~ Professional Ethics Committee. ~~Members of the committee will be instructed to declare any real or potential conflicts of interest. The Committee will determine the seriousness of the conflict and, if deemed manageable, determine how the conflict will be managed. Declaration of real or potential conflict of interest, its nature, assessment of manageability and method will be recorded in the minutes. Any member who has an unmanageable conflict of interest, or~~



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~~who so prefers even if the PEC determines the conflict is manageable, will be recused. The recused person may not participate in the discussion, deliberation or vote; however, if s/he may have information potentially relevant to the investigation, s/he may provide the information to the Committee. Note: if the complainant requests anonymity, this will be preserved as much as possible while respecting the due process rights of the respondent to be informed of the details provided to the Professional Ethics Committee by the complainant.~~

- 2) A written notice will be issued to the subject of the complaint (Individual or Respondent) within ~~145 calendar business~~ days from the date the committee determined an investigation was warranted, via any traceable method. The notice will include:
 - 1) The substance of the complaint, ~~and~~ its alleged factual basis, and the provision(s) of the Code alleged to have been violated
 - 2) A copy of the Discipline and Complaints policy,
 - 3) A request to submit a response to the ~~PE~~Professional Ethics Committee,
 - 4) A deadline for the response to be received, which shall be no more than ~~210 calendar business~~ days from receipt of the notice, and
 - 5) Notification to the Individual (Respondent) that all communications from and to the subject of the complaint will be routed via ACRP's head office via the ethics liaison.
- 3) A written notice will be issued to the complainant within ~~145 calendar business~~ days from the date the committee determined an investigation was warranted, via any traceable method. The notice will include:
 - 1) Notification that the ~~PE~~Professional Ethics Committee will pursue an investigation;
 - 2) A copy of the Discipline and 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, the ~~request is~~ request will be honored preserved to the extent possible;
 - 4) Notification of the composition of the ~~PE~~Professional Ethics Committee;
 - 5) Request for declaration of perceived conflict(s) of interest of the PEC members within ~~145 calendar business~~ 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 ~~PE~~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; and



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8) Notification that the only communication channels are to be with the PEC Professional Ethics Committee email box, by mail to the ACRP head office and/or by contact with the PEC Professional Ethics Committee staff liaison. Notification also that attempted communications directly with any PEC member is deemed highly inappropriate and will not be accepted.

3) 4)—The PEC Professional Ethics Committee members with no conflicts of interest or those with declared but manageable conflicts will make up the Investigation Team.

Conflict of Interest Review

- 1) Once responses are received from the complainant and the subject of the complaint, the PEC will first review all potential Conflicts of Interest. A Conflict of Interest for the PEC 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, being a direct competitor doing research on a competing drug or a past fight could affect judgment).
- 2) Committee Members will be instructed to declare any conflicts of interest. Any member who declares a conflict of interest will be recused if the declared conflict is deemed by the PEC and ACRP counsel to affect the judgement of the PEC member in question to impartially adjudicate the complaint. Any member who declares a conflict of interest will automatically be recused, unless the nature of the declared conflict is deemed by the PEC and ACRP counsel to affect the judgment of the PEC member in question to impartially adjudicate the complaint. Any member who declares their own conflict of interest will automatically be recused. In addition to pre-existing relationships, this includes any Committee Member who might act as a witness and/or in, or otherwise has significant knowledge of the actions alleged in the investigation. 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 PEC by the complainant.
- 4)3) All perceived Conflicts declared in the responses will be reviewed by the PEC. If the Committee Members do not agree that they have a Conflict, Committee Members with perceived conflicts will provide their perspective and potential mitigation for the concerns described in the responses. The PEC will ask questions of



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the Committee Members and have further discussion, as necessary. After discussions, if there is any concern about a potential conflict of interest, the committee member in question will temporarily leave the room 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 removed from the discussion of the subject matter. After discussions, if three (3) or more PEC Members think that the Committee Member has a conflict, then the member will be removed from the discussion of the subject matter. If necessary for quorum purposes, temporary PEC members will be appointed for purposes of that specific investigation.

Investigation Procedure

- 1) - ~~Once they have received~~ the response and any supporting documentation from the subject of the complaint (respondent) has been received, and ~~discussed~~ any Conflicts of Interest identified, ~~t~~ The PEC Professional Ethics Committee Investigation Team will meet to review the complaint, ~~together with any response provided by the subject of the complaint and any additional information,~~ within ~~30-20~~ calendar business days ~~days~~ of receipt of a response from the Respondent. The Committee may, as necessary, appoint an investigator or consultants ~~either within ACRP membership, ACRP staff or outside investigator or consultant with content expertise relevant to the complaint from outside the Professional Ethics Committee with content knowledge and expertise relevant to the complaint~~ to advise and inform the PEC but shall not vote on any action items before the Committee. Any consultants must be approved, in advance, by the Executive Director. Any such external consultants shall be bound by the confidentiality requirements in this policy.
- 2) The PEC Professional Ethics Committee may invite the subject of the complaint to be available by telephone 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~~ inculpatory evidence obtained to date ~~that appears to support the allegations of professional misconduct which indicates the allegation may ultimately be substantiated~~, the PEC Professional Ethics Committee will schedule a hearing which includes: applicable witnesses, the subject of the complaint, members of the PEC Professional Ethics Committee, and applicable staff. The subject of the complaint will be provided with the names of the members of the PEC 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 he or she believe exists with any of the members of the PEC Professional Ethics Committee or consultants. ~~Based on the information provided by the subject of the~~



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complaint, unless the complaint involves the Executive Director then they will determine if any individual should be recused from participating in further deliberations of the Committee. ~~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 tele/videoconference depending upon the recommendation of the [PEProfessional 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 statement, no more than ten minutes, providing any additional information relative to the complaint after which the subject of the complaint will respond to questions posed by members of the [PEProfessional Ethics Committee](#).
- 6) 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 [calendarbusiness](#) days after the original hearing date.
- 7) 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.
- 8) If practical, the hearing will be held no more than 60 [calendarbusiness](#) days from 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 [140 calendar](#) 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.
- 9) ACRP reserves the right to have its attorney present [and may participate to guide the discussion as necessary. ACRP's attorney may not provide an opinion or vote.](#)
- 10) In order for a hearing to be conducted, the following individuals must participate:
 - 1) The Chair of the [PEProfessional Ethics Committee](#) or his/her designee,
 - 2) The Vice Chair [of the Professional Ethics Committee](#) or his/her designee,
 - 3) At least [one but preferably three other members of the PECa sufficient number of other members of the Professional Ethics Committee](#) to achieve quorum (i.e., 50% plus 1)
 - 4) ACRP staff, [including the Executive Director](#), as assigned [\(All staff will be non-voting and will participate only as requested\)](#)
- 11) [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](#)



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and a meeting procedure determined by the PEC Chair and provided to the Subject of the Complaint not less than one calendar day prior. ~~Hearing proceedings will not be open to the public, and~~

12) 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.

~~13) The hearing will be conducted impartially, following due process.~~

Following the hearing, the ~~PE~~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 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 and/or the Academy, and the best interests of ACRP 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 ~~21 calendar~~30 business days following the hearing. Then, the outcome of the investigation hearing by the ~~PE~~Professional Ethics Committee will be forwarded to the applicable Board(s) (subset of the Academy Board assigned to review decisions/recommendations of the PEC) as per Appendix 1, within ~~14 calendar~~0 business days after the subject of the complaint has been notified.

Should the ~~PE~~Ethics Committee make a determination that action needs to be taken with respect to the Individual's (Respondent's) Academy certification, ACRP staff liaison will notify the Academy staff member in charge of Certification immediately.

The PEC decision and recommended disciplinary actions, if any, will be submitted to ACRP Executive Director and Trustees and are subject to return to the PEC for further consideration before decisions and disciplinary actions are made final. Once final, the Respondent is duly informed by ACRP staff of the decision and actions, if any. Once the period of appeals has expired, ACRP Staff will inform the Academy.

Disciplinary action unrelated to the Individual's certification will be carried out by the appropriate ACRP staff and/or Committee member only after the period of time for which an



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appeal can be sought has expired without an appeal being raised (30 calendar days after receipt of the notice of sanction).

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 PEProfessional Ethics Committee may recommend to the ACRP Executive Director that the final decision of sanctions imposed be published in *Clinical Researcher* and/or on the website of ACRP. 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 or the Academy may notify appropriate government or professional bodies of any final disciplinary action taken.

Appeals

Within 30 calendar~~business~~ 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 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) 2)~~ The Committee failed to conform to published criteria, policies, or procedures which significantly changed the likely outcome of the investigation.



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2)3) Important new information becomes available that may have affected the deliberation and determination of the committee

Within 30 ~~calendar~~^{business} days of receipt of the appeal, the ACRP 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 business 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 regarding the appeal. Within 30 business 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, if there is one, and all other appropriate parties, as determined by the Appeal Committee of the ACRP or the Academy, shall be sent via traceable method.

The Appeal Committee may only make recommendation as to review 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 ~~were as 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 ~~PE~~^{Professional Ethics Committee}. If the Appeal Committee recommends affirming the determination of the ~~PE~~^{Professional Ethics Committee} and such recommendation is confirmed by the applicable Board, the disciplinary sanctions imposed by the ~~PE~~^{Professional Ethics Committee} 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. The Appeal Committee may recommend to the applicable Board one or more of the following actions:

- 1) Upholding the decision of the ~~PE~~^{Professional Ethics Committee};
- 2) Overturning the decision of the PED 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 appoint a new committee. ~~Overturning the decision~~



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~~of the PE 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 PE 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 or Academy Board, as appropriate. By admission of guilt, the member/Certificant/apellant 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 PE 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 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.

DEFINITIONS

Applicant: An individual who has submitted an application for membership or certification

Certificant: An individual who holds a CCRA, CCRC, CP, CPI, or a newly added certification status through the Academy of Clinical Research Professionals

~~An individual who holds a CCRA, CCRC, CP or CPI certification status through the Academy of Clinical Research Professionals~~

Complainant: _____ The individual who reported the incident of non-compliance

~~Days: _____ Business Day. (If practical, timelines may be extended as needed)~~

Individual (Respondent): The subject of the complaint



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Investigation: The process of evaluating all relevant information related to the complaint received

Investigation Team: The team of individuals comprised of Ethics Committee members and any requested consultants to aid in evaluating the investigation

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 Ethics Committee)

DATES MODIFIED BY COMMITTEE

September 29, 2015

October 2, 2015

November 13, 2015 (by Governance Committee)

November 3, 2017

[November 11, 2019](#)

DATES APPROVED BY COMMITTEE

September 29, 2015

October 2, 2015

November 13, 2015 (by Governance Committee)

November 3, 2017

DATES REVIEWED BY THE BOARD

December 12, 2011

February 5, 2015

December 17, 2015

December 13, 2017

DATES APPROVED BY THE BOARD

December 12, 2011

February 5, 2015

December 17, 2015



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December 13, 2017