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DISCIPLINE AND COMPLAINTS POLICY

Approved by the ACRP Board of Trustees on 12 December 2011

Purpose:

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

Scope:

The Ethics Committee has the responsibility to maintain and enforce standards of professional conduct and ethics within ACRP and draft position statements on behalf of the Association (see "Ethics Committee" policy in the ACRP Policy Manual). The committee will review and respond to cases of possible or actual misconduct by members or certificants and those seeking membership or certification.

The Ethics Committee will investigate violations of the *Uniform 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.

The 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.

Information submitted during the complaint investigation and any hearing process is considered confidential, and will be addressed in a discreet and professional manner by the ACRP staff and volunteers. At the conclusion of the proceedings, submittals will not be returned.

Procedure:

Initial Complaint Review

Each complaint must contain the following information:

- a. The name, address and contact information of the complainant;
- 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



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e. Any documentary information supporting the complaint.
Complaints will be received and reviewed by ACRP to determine if the complaint will be forwarded to the Ethics Committee for investigation. Each complaint will be evaluated based on the following:

- 1) Whether the subject of the complaint is an ACRP member, applicant for membership, certificant or an applicant for certification.
- 2) Whether the alleged misconduct, if proven, would be a violation of the *Uniform Code of Ethics and Professional Conduct*.
- 3) Whether relevant information concerning the charge is available.
- 4) Whether the charge appears to be justified considering the proof available.

If it is determined that a complaint should not receive further investigation, the individual submitting the complaint and the individual who is the subject of the complaint will be notified by letter within 30 days of the rejection decision, and provided the reason(s) for the determination in writing.

This decision may be appealed to the Ethics Committee. The written request for an appeal must be submitted within 30 days of the mailing of the rejection letter and must state the reason the rejection decision was incorrect and specific information in support of the acceptance of the charges. The Ethics Committee will consider and decide any appeal at the next scheduled Committee meeting. The decision of the Ethics Committee cannot be appealed.

Review by Ethics Committee

Once a complaint, or appeal of a denial, is accepted:

- 1) A written notice will be issued to the individual who is the subject of the complaint. The notice will include:
 - 1) the factual basis of the complaint,
 - 2) a copy of the Discipline and Complaints and Appeal policy,
 - 3) a request to submit a response to the Ethics, and
 - 4) a deadline for the response to be received.
- 2) The Ethics Committee will investigate the complaint.

Investigation Procedure

The Ethics Committee will review the complaint, any response received by the subject of the complaint, and any additional relevant information. The subject of the complaint may be present at the hearing to discuss the allegations directly with the sub-committee/committee or may be present by telephone.

A hearing date will be scheduled in consultation with all involved parties. The hearing, and any meetings of the sub-committee/committee, may be conducted in person or by teleconference, or any



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other manner in which all participants can hear each other. Hearing proceedings are not open to the public; however, testimony shall be recorded, either electronically or via transcription. If practical, the hearing will be held within 60 days of the acceptance of the complaint. If any parties involved in the complaint wish to have an attorney or witnesses present at the hearing they must notify ACRP at least 10 days in advance of the meeting date.

Following the hearing, the Ethics Committee will make a decision regarding the complaint. The decision will be based upon a review of the applicable evidence, the rules and regulations of ACRP, any applicable statutes or regulations promulgated by any state or federal entity or administrative body, the governing documents and policies of ACRP, and the best interests of ACRP.

The complainant and the individual who is the subject of the complaint will be notified of the decision and the appeals process in writing within 30 days following the hearing.

Disciplinary Actions

Disciplinary actions imposed by the Ethics Committee may include any 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) Decision to issue a public or private reprimand.
- 4) Suspension of membership and/or certification for a period determined by the committee.
- 5) Revocation of certification and/or membership.

A final decision which imposes discipline shall be published in *The Monitor* magazine and on the website of ACRP. This will include a Publication of Decision for Public Reprimands, Suspension and Revocation.

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

Appeals

Within four (4) weeks from the receipt of notice of a sanction, the affected member/certificant/applicant may appeal, in writing, any such revocation or decision via certified, return receipt mail or via other traceable carrier to the ACRP Board of Trustees. In the appeal, the Member/certificant/applicant shall clearly state the reasons of the appeal. The following are appropriate grounds for appeal of the decision of the Ethics Committee:

- 1) There were 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.



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Within thirty (30) days of receipt of the appeal, the ACRP Board shall constitute an Appeal Committee to review the complete record. Within six (6) weeks of its initial constitution, the Appeal Committee will seek to review the appeal, and issue a recommendation and a report to the ACRP Board regarding the appeal. Within four (4) weeks of receipt of the Appeal Committee's recommendation and report, the ACRP 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 Board, shall be sent via certified, return receipt mail or other traceable carrier.

The Appeal Committee may only review whether the determination of a violation of the *Uniform Code of Ethics and Professional Conduct*, was inappropriate because of the stated reasons in #1 and #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 decision of the Appeal Committee shall either affirm or overrule the determination of the Ethics Committee, but shall not address a sanction imposed by the Ethics Committee. The Appeal Committee can comment on irregularities in the process (i.e. facts not considered or policies not followed) but they cannot change the sanction determined by the Ethics Committee.

The decision of the Appeal Committee 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 decide to take one or more of the following actions:

- 1) Upholding the process and decision carried out by the original Ethics Committee;
- 2) Overturn the decision of the Ethics Committee and initiating a process to re-investigate the violation;
- 3) Establishing a new Ethics Committee or discharging certain members.

If the Appeal Committee determines that errors were made in the process that could have significantly changed the outcome, it may require the investigative procedures to be re-opened and order the process to be modified to focus on the aspect that was performed incorrectly or incompletely. A new Committee may be established or Committee members may be discharged depending on the approved recommendations of the Appeal Committee.

Admission of Guilt

At any point in the investigative or hearing process or appeals period, investigative procedures shall be stopped and the Ethics Committee shall recommend a sanction to the ACRP Board for approval and notification, if a member/certificant/appellant who is the subject of a disciplinary investigation admits



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to having violated the *Uniform Code of Ethics and Professional Conduct*. 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 subject of the individual who is the subject of the complaint voluntarily resigns his or her membership, certification, or application for membership or certification, the Ethics Committee may choose to continue until it completes the discipline and complaints process. A voluntary resignation will also be reported publicly, with a statement of the complaint made, and may be reported 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.

