AACP Research Misconduct Policy

INTRODUCTION

This policy covers research misconduct and allegations of research misconduct against AACP staff members, employees, volunteers, contractors or other individuals engaging in internal AACP research, i.e., research projects supported by internal AACP funds or resources or by external research sponsors through awards made to AACP. This policy does not apply to allegations of research misconduct and allegations of research misconduct made against AACP members regarding research not sponsored or supported by AACP.

All AACP staff members who engage in research projects must undergo training in the responsible conduct of research and refresh their training at least every three years. The minimum requirement for this training is completion of the CITI Program "Responsible Conduct of Research" basic or refresher course, as appropriate.

All AACP staff members, employees, volunteers, contractors or other individuals involved in AACP research projects must receive of copy of this research misconduct policy and information on AACP procedures for reporting and responding to allegations of research misconduct.

If a conflict between the terms of this policy and any other AACP policy arise, this AACP Research Misconduct Policy shall govern in all cases involving research projects supported by internal AACP funds or resources or by external research sponsors through awards made to AACP.

APPLICATION

This Policy applies to AACP employees, volunteers, contractors or other individuals engaging in internal AACP research, i.e., research projects supported by internal AACP funds or funds awarded to AACP by external sponsors for the purpose of performing research.

DEFINITION OF RESEARCH MISCONDUCT

For this policy "Research misconduct" is the fabrication, falsification, and plagiarism in proposing, performing, or reviewing research or in reporting research results, as defined by the Office of Research Integrity (ORI), U.S. Department of Health and Human Services. AACP considers research misconduct to be a type of scientific misconduct (see draft AACP Code of Conduct.)

Notes on definition (From Title 42 CFR Part 93, PHS Policies on Research Misconduct):

a. Fabrication is making up data or results and recording or reporting them.
b. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
c. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
d. Research misconduct does not include honest error or differences of opinion.

A finding of research misconduct under this policy will require that:

a. There be a significant departure from accepted practices of the relevant research community; and
b. The misconduct be committed intentionally, knowingly, or recklessly; and
c. The allegation be proven by a preponderance of the evidence.

Disclosure of the identity of complainants and respondents in AACP research misconduct proceedings is limited, to the extent possible, to those who need to know consistent with a thorough, fair, competent and objective

investigation. *When navigating investigations and proceedings related to research misconduct, AACP will seek to maintain confidentiality to the extent possible.*

REPORTING A RESEARCH MISCONDUCT CONCERN

Concerns about research misconduct should be raised by sending an email to Sibu Ramamurthy, AACP Vice President of Finance/Chief Financial Officer and AACP's Authorized Signing Official for federal grants, at sramamurthy@aacp.org.

A complaint should include the following information, to the extent possible:

- name of the individual involved in the alleged research misconduct and contact information;
- name and contact information of the person raising the concern and how the person became aware of the alleged research misconduct;
- names of any witnesses or others with pertinent information, and contact information, if known;
- description of the alleged research misconduct, with the date, approximate time, location/setting/activity, and all known relevant facts and circumstances;
- a clear statement of any facts that may indicate any ongoing concern of imminent threat to safety of any person(s) or safety or condition of property, and the sources of such facts, with contact information if known;
- any relevant documents available to the person filing the complaint;
- any other information that would help AACP understand the full nature of the alleged research misconduct; who was involved and who and what may be affected; who may have pertinent information and related context.

Confidentiality

When an expression of concern regarding research misconduct has been received, disclosure of the identity of respondents and complainants is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. All AACP members and staff are required to respect confidentiality of the identities of each individual involved in a research misconduct proceeding while it is being reviewed and resolved. Failure to do so is a serious violation of the draft AACP Code of Conduct. *This Policy also prohibits retaliation against those who raise concerns regarding research misconduct.*

Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

However, for research misconduct allegations involving research supported by the Public Health Service (PHS) AACP must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings.

DEFINITIONS & REQUIREMENTS

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b. The misconduct be committed intentionally, knowingly, or recklessly; and
c. The allegation be proven by a preponderance of the evidence.

Disclosure of the identity of complainants and respondents in AACP research misconduct proceedings is limited, to the extent possible, to those who need to know consistent with a thorough, fair, competent and objective investigation. *When navigating investigations and proceedings related to research misconduct, AACP will seek to maintain confidentiality to the extent possible.*

An *allegation* means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an AACP official or a research sponsor.

A *complainant* means a person who in good faith makes an allegation of research misconduct.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Inquiry means preliminary information-gathering and preliminary fact-finding

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this policy, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to an AACP official or representative of a research sponsor by a respondent in the course of the research misconduct proceeding.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by AACP or an AACP staff member in response to -

a. A good faith allegation of research misconduct; or
b. Good faith cooperation with a research misconduct proceeding.

This policy has been written to comply with PHS regulation Title 42 CFR Part 93, PHS Policies on Research Misconduct. Definitions given above have been adapted from the PHS regulation.

RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

Process: Review and Investigation:

1. **General process to address research misconduct concerns:**
   - **a.** Reviewing all conduct concerns. AACP will review all research misconduct concerns, raised through any of the means provided within this Research Misconduct Policy, regardless of the relative power positions of the individuals involved.
   - **b.** Responding when feasible. AACP will respond in some way when research misconduct concerns within the reach of the AACP Research Misconduct Policy are raised. However, the exception is when AACP's initial review determines there is a lack of any credible question regarding concerning conduct, or available information is inadequate to make that assessment or to pursue a resolution.
   - **c.** Engaging to address concerns when feasible. Even where a credible question is lacking or can't be determined, or the available information is limited, AACP may still engage in problem solving with those willing individuals most directly involved in a raised concern, e.g., by requiring additional training in responsible conduct of research or a specific aspect of research.
   - **d.** Regarding who investigates**.** Notwithstanding the other provisions of this Investigation Policy, in order to provide the factual basis for resolving a conduct concern, AACP may, in its discretion:
     - conduct its own investigation of a research misconduct concern, meaning an investigation conducted by employees or volunteers of (or contractors retained for that purpose by) AACP;
     - rely on facts determined in an investigation of the conduct concern by a third party (e.g., the home employing or educating institution of a member) in lieu of a Fact-finder, if a summary of facts found with supporting evidence is provided to AACP, and AACP determines in its discretion that the fact-finding is sufficient; or
     - rely on its own *and* a third party's investigations to determine the facts.

     If AACP relies in whole or in part on facts determined in a third party's investigation, AACP nevertheless will reach its independent conclusion as to whether a violation of the AACP Research Misconduct Policy has occurred and whether/what consequences are warranted. Also, in such event, AACP will provide an opportunity to the accused and any identified target—for 14-days after giving notice to them—to present to the Decision-maker pertinent facts and their respective perspectives in writing (or via other means determined by the Decision-maker) before the Decision-maker reaches a final conclusion.

2. How to Initiate a Research Misconduct Proceeding:

Submission of a research misconduct concern as provided in the "Reporting" section above is generally required to initiate a research misconduct proceeding. However, AACP will initiate a review, inquiry or investigation on its own initiative when it has reason to believe there is a research misconduct concern. That may occur, for example, if sufficient factual information is available to AACP regarding a widely known or credibly rumored concern, but no one has come forward to raise the concern through channels provided by AACP under this Investigation Policy.

3. Investigation and Resolution of Research Misconduct Concerns:

AACP will satisfy any applicable special requirements related to federal or other funder rules regarding handling research misconduct, which will govern when (and to the extent) there is a conflict or potential conflict with the following provisions. Also, "Regarding Who Investigates" above provides AACP with an option to rely on facts determined in an investigation by a third party, in lieu of or in addition to relying on an AACP "Fact-finder" to determine the factual basis for resolving a research misconduct concern.

4. Resolution Roles and Responsibilities

The AACP Vice President of Finance/Chief Financial Officer, in their role as Authorized Signing Official for AACP, will appoint "Fact-finders" and "Decision-makers" to address research misconduct concerns raised. These AACP staff members will engage with persons reporting research misconduct concerns, individuals alleged to have engaged in research misconduct and other individuals who may have information about alleged research misconduct. They will conduct the initial inquiry, review and/or any investigation and processes that may be needed for resolution.

Fact-finders and Decision-makers assigned to address a particular research misconduct concern are required to be free of conflicts that would interfere with their performance of their responsibilities. When possible, Fact-finders for an allegation of research misconduct should not be part of the same AACP unit as the respondent.

a. **"Fact-finders"** are authorized by the AACP Executive Committee or its designee and shall receive, initially review, and take any other necessary short-term action to respond to a report of a research misconduct concern, including securing the research record. They are also authorized to and shall conduct an initial inquiry into the facts relating to a reported research misconduct concern. Fact-finders will make recommendations to the Decision-makers regarding the suitability (or not) of an informal resolution (in the case where an inquiry indicates no research misconduct) or the need for an investigation into the research misconduct concern. They are also authorized to conduct the investigation into the research misconduct concern or to advise on retention of outside contractors to conduct the investigation, if warranted.

Fact-finders may be employees or volunteers of the Society or outside contractors retained by the Society to perform this role. AACP may use the services of a consortium (i.e., a group of institutions, professional organizations, or mixed groups which will conduct research misconduct proceedings for other institutions) or person that AACP reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings.

The Fact-finders for a research misconduct proceeding should include at least two of the following:

- AACP Senior Vice President/Chief Academic Officer, Kelly Ragucci, PharmD, kragguci@aacp.org, 703-479-3841
- AACP Senior Director of Academic Programs and Professional Development, Sarah Shrader, PharmD, sshrader@aacp.org, 703-479-3820
- AACP Senior Director for Science Policy/Chief Science Officer, Dorothy Farrell, PhD, dfarrell@aacp.org, 703-479-3830
- AACP Vice President of Diversity and Strategy, Terri Moore, PhD, tmoore@aacp.org, 703-479-3818

b. "**Decision-makers**" are different individuals than the Fact-finders. Decision-makers may be employees or volunteers of the Society or outside contractors retained by the Society to perform this role.

The Decision-makers for a research misconduct proceeding are:

- AACP Executive Vice President, Lee Vermeulen, MS, lvermeulen@aacp.org, 703-479-3816
- AACP Senior Vice President/Chief Engagement Officer, Lynette Bradley-Baker, PhD, lbbaker@aacp.org, 703-479-3799

Decision-makers have the authority and responsibility to:

- determine whether to rely on a third-party investigation for fact-finding;
- require additional fact-finding by the Fact-finder(s) to supplement the initial Fact-finder's investigation and/or a third-party investigation;
- engage with complainant and respondent (at least providing an opportunity for input) and possibly engage other individuals most directly involved, to determine a resolution following the inquiry stage of a research misconduct proceeding, if a decision is made not to move forward with an investigation;
- apply the criteria specified in this Policy to determine the sufficiency or insufficiency of an informal resolution following an inquiry that doesn't lead to an investigation;

- provide written notice to the Department of Health and Human Service Office of Research Integrity (ORI) of any decision to open an investigation on or before the date on which the investigation begins, in cases where the research in question was funded by the Public Health Service (PHS.)
- make a determination in a formal resolution process of whether a violation of the AACP Research Misconduct Policy has occurred;
- make a determination of what consequences to impose in a formal resolution if a violation is determined, separate from any consequences imposed by ORI;
- request and accept, modify or reject recommendations from the Fact-finder.

Any one Decision-maker alone may take all authorized actions, ***or*** *multiple Decision-makers may take such actions as a committee by consensus* ***or*** *by majority vote of those serving* respecting a particular conduct concern or multiple conduct concerns relating to the same incident(s) or person(s).

c. Successors in Resolution Roles. Fact-finders and Decision-makers are "Resolution Roles" assigned to individuals only while they serve in particular employee or volunteer positions within AACP (or in particular employee roles at a contractor retained by AACP). If an individual no longer holds the employee or volunteer position that accompanied a Resolution Role when that Role was assigned, the successor holding the relevant employee or volunteer position is authorized and responsible to temporarily also fulfill the Resolution Role. That authorization and responsibility will continue until AACP posts notice of what employee or volunteer position and individual will fulfill the Resolution Role going forward. (The contract between AACP and a retained contractor will govern how the contractor's employees serving in a Resolution Role may change. AACP will also post notice of any such change.)

5. Informal Resolution

An "informal resolution" is one that focuses on community building and elevating understanding of why a research misconduct concern arose, enhancing understanding of responsible conduct of research standards, repairing relationships, and seeking to satisfy the individuals involved and the Decision-maker that recurrence of the concern is unlikely.

Criteria. An informal resolution is sufficient to resolve research misconduct concerns where the Decision-maker determines, following an inquiry and recommendations from the Fact-finders, that although research misconduct did not occur, concerns about adherence to good research practices remain, e.g., there was a departure from accepted practices of the relevant research community, but it was not committed intentionally, knowingly, or recklessly.

6. Investigation and Formal Resolution

If an inquiry into a research misconduct allegation determines that:

a. there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under the AACP Research Misconduct Policy; and
b. preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance,

an investigation into the research misconduct allegation is warranted. Additionally, If the Decision-maker determines that an informal resolution is not sufficient to resolve the conduct concern, even after it has begun, a "formal resolution" process is pursued. However, an investigation or formal resolution is not initiated or continued if the Decision-maker determines that there is an inadequate basis to pursue any resolution (e.g., no credible question of a violation or unavailability of needed individuals or information). (*See* Section 5. above for ***Criteria*** for determining the sufficiency of an informal resolution.)

a. ***Stages:*** Formal resolution involves 10 required stages:

(i) *The Fact-finder(s) finds the relevant facts and documents them*, gathering any documents and notes of any communications supporting the facts.

(ii) *Before finalizing the documentation of facts, the Fact-finder engages with any complainant and respondent* in some manner (with flexibility of means) to inform them of the nature of the research misconduct concern, to confirm that it is within the reach of the AACP Research Misconduct Policy, and to understand the facts from their perspectives.

- The Fact-finder may confer separately with complainant and respondent, or may confer with these parties together.
- However, if the Fact-finder confers in writing or separately with these parties, the Fact-finder [a] will provide an opportunity to each of the parties to access the factual record separately (including submissions by them to, and answers to questions asked of them by, the Fact-finder); and [b] then will provide an opportunity for each of these parties to raise questions for the Fact-finder to ask of the other party; and [c] the Fact-finder will ask those requested questions that the Fact-finder determines are likely to elicit relevant facts for resolution of the conduct concern or to surface issues of credibility (but need not ask duplicative or immaterial questions, as determined in the Fact-finder).

(iii) *The Fact-finder provides to the Decision-maker the documented facts*, together with any supporting documents and notes (including but not limited to the questions posed under (ii) and the responses received).

(iv) *The Decision-maker reviews the documented facts and supporting materials*; and, if needed in the Decision-maker's view, requires any supplementary fact-finding to be undertaken by the Fact-finder; and the Fact-finder follows through and submits any supplementary information to the Decision-maker.

(v) *The Decision-maker preliminarily determines whether or not a violation of the AACP Research Misconduct Policy has occurred* and identifies the facts found by the Fact-finder on which that determination is made.

(vi) *The Decision-maker provides a copy of the preliminary determination and supporting facts to the complainant and respondent* ("preliminary determination notice").

(vii) *The respondent has an opportunity during a 30-day period that begins when the preliminary determination notice is given to them, to again access the factual record and respond in writing*, providing the Decision-maker with any relevant facts or circumstances that the responder believes should inform the final determination and any consequences.

(viii) *The Decision-maker reviews any submission received*.

(ix) *Upon expiration of that 30-day period, whether or not response(s) are submitted, the Decision-maker makes a final determination and, if a violation is found, imposes consequences*.

(x) *The Decision-maker notifies (in writing or electronically) the complainant, the respondent, and any other individual who reported the concern of the Decision-maker's final determination and any consequences*. The notice of a final determination to the respondent and complainant will include notice of potential appeal rights and the conditions that must be met to pursue an appeal.

- Appeal information may be provided, either by linking to this Policy posted on the AACP website, or by pasting the relevant information into the notice. (*See* Part I, below).
- Any such notification will include a reminder of the obligation to maintain confidentiality until an appeal is decided or the appeal period expires without an appeal being filed.

b. ***Timing.*** The goal for timing to complete a formal process is 120 days from the submission of the research misconduct concern to the final determination (prior to any appeal). However, the Decision-maker may extend the period for good cause, such as due to limited availability of individuals most directly involved, difficulty of obtaining needed information, complexity of issues, exceedingly voluminous information, or resource capacity. The Decision-maker will inform the complainant and respondent of any extension. For allegations involving PHS-funded research, time limits for completion from CFR Title 42 will be adhered to.

c. ***Standard of Proof***. The Decision-maker will make a determination of whether there is a violation of the AACP Research Misconduct Policy using a preponderance of the evidence standard (i.e., more likely than not.)

7. Additional Responsibilities

a. ***General Responsibilities***

Fact-finders and Decision-makers will be responsible for the following:

- Ensuring AACP maintains adequate records for a research misconduct proceeding, consistent with the requirements of federal regulation when research misconduct concerns touch on federally funded research. This includes:
    1. Either before or when AACP notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. When the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;
    2. Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;
    3. Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding. When the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments; and
    4. Maintain the research records and evidence as required by law. when applicable (*i.e.*, seven years from completion of investigation for allegations involving PHS-funded research) and in compliance with AACP records retention policy.
- ***Confidentiality obligations of AACP.*** To the extent feasible and not at odds with legal, insurance or other binding requirements, maintain confidentiality about any research misconduct concern raised and the individuals most directly involved, while carrying out the research misconduct proceeding, to enable a fair review and meaningful resolution of the concern.
- ***Confidentiality instructions to AACP members and others.*** To the extent not at odds with legal, insurance or other binding requirements, instruct those with whom they need to communicate in the course of reviewing, investigating and resolving a research misconduct concern to maintain confidentiality, and that a failure to do so is a violation of the draft AACP Code of Conduct and Investigation Policy.
- ***Record of review/investigations***. Document a record of steps taken, sources and substance of information and documents obtained, and communications with individuals as part of research misconduct proceeding. Include in the record names, relevant affiliations and titles, dates and times.
- ***Internal Reporting***. Report to the AACP Executive Committee on the research misconduct concerns raised and how they were resolved on at least an annual basis.
- ***Reporting-out*****.** Provide data to the appropriate AACP officials for purposes of reporting-out to AACP members at least annually about the options for raising and resolving research misconduct

concerns; the types and frequency of research misconduct concerns raised; and the status and manner of resolution, without revealing the identities of individuals most directly involved.

b. Short-term Actions

Short-term actions that a Fact-finder and Decision-maker may or must (as indicated) take when receiving a research misconduct concern include the following:

(i) ***Confidentiality***.

a. Confidentiality of the name of the complainant. AACP will not name any complainant in communications about a research misconduct concern having been raised, a review or investigation having been initiated or concluded, or a violation having been determined, unless:

- the complainant consents;
- the AACP Executive Committee (or senior designee) or Decision-maker determines there is a legal, regulatory, safety, insurance coverage or other contractual requirement to do so; or
- under the other exceptions below.

b. Confidentiality of the name of the respondent. Until a final determination is made, AACP will not name the respondent in any communication that may become necessary about the matter to the public or particular individuals, unless:

- the AACP Executive Committee (or senior designee) or Decision-maker determines there is a legal, regulatory, safety, or insurance coverage requirement to do so;
- it is part of notice to the respondent's home and certain other institutions where the respondent has an affiliation; or
- under the other exceptions below.

c. Other exceptions. The other exceptions that permit naming any identified target or the accused are when the AACP Executive Committee (or senior designee), Fact-finder or Decision-maker determines there is a need to do so:

- in confidential communications with those who are involved in or advising (a) the investigation or (b) determination of needed action or consequences or (c) implementation of temporary safety measures **and** (d) who are reminded of their confidentiality obligation or bound by a professional ethical standard to maintain confidentiality;
- to those who have a fiduciary or oversight function for AACP, including a fiduciary duty to maintain confidentiality; or
- notice to ORI or other research sponsor of the decision by AACP to open an investigation into a research misconduct allegation, as required by the funder's policies, e.g., under Title 42 Part 93 for research funded by PHS.

(ii) ***Other Short-term actions.*** The Decision-maker may take any other short-term actions, and may periodically adjust or end any short-term actions, when the Decision-maker determines such action(s) are in the best interests of AACP and its mission, pending a final decision resolving the research misconduct concern.

8. Consequences That May Be Imposed for Research Misconduct Violations

a. A violation of the AACP Research Misconduct Policy may result in the following consequences (including combinations):

- *private reprimand;*
- *public reprimand or statement;*
- *removal or suspension from a volunteer position;**
- *removal or suspension from a leadership position, following the provisions for removal of in the AACP Policy on Honors, Awards and Leadership Positions and associated procedures;*
- *administrative leave from any role for AACP;**

- *denial or revocation of honors or awards, consistent with the procedures associated with the AACP Policy on Honors, Awards and Leadership Positions;*
- *suspension or permanent prohibition from attending or making presentations at AACP meetings;**
- *temporary or fixed-term no-contact requirements for the accused and identified target;**
- *notification by the Decision-maker of the AACP's determination of a violation (the allegations, facts and conclusion) to the violator's home institution (employing) and other institutions where the violator has an affiliation;*
- *disciplinary action, up to and including suspension or termination of employment for AACP employees;*
- *restorative or community-building practice (which may be pursued to address conduct concerns even without a determination of a violation of the Policy.)*

**Suspension and administrative leave may be imposed by a Fact-finder or Decision-maker on an interim basis*

b. Considerations and Proportionality. Consequences imposed will be proportional to the severity of the violation, and the corresponding harm caused or threatened to individuals, AACP, academic pharmacy, or society-at-large. Considerations to determine severity of the harm include, but are not limited to:

- the nature of the violation;
- whether the violation is repetitive;
- the frequency of the violation;
- the other actual effects or threatened effects of the violation (harm or threatened harm to individuals, AACP and/or pharmacy education, including, *e.g.*, regarding reputation, operations, legal exposure, finances or other resources);
- whether the violations implicate safety interests;
- the stage of career and role of the accused; and
- whether the accused, in a first-time violation situation, has taken responsibility, demonstrated an appreciation of the severity of the violation, and taken or committed to action to remedy the adverse effects.

While all facts and circumstances are considered, a violation perpetuated by a respondent who is in a senior stage of career, or in a leadership role, is generally considered more severe than the same violation perpetuated by a respondent who is in a junior stage of career and is not in a leadership role. However, some violations, by nature, are severe in any event.

c. When Effective. Consequences imposed by the Decision-maker as its final decision will become effective upon expiration of the period in which an appeal may be filed, without an appeal being filed. If an appeal is timely filed by an "authorized appeal party" under this Policy, the Appeal Authority will decide the final consequences (and any consequences decided by the Decision-maker will not become effective unless ultimately affirmed by the Appeal Authority). The final consequences will become effective immediately upon the appeal authority giving notice to the authorized appeal parties of the final determination of the appeal.

d. Notice to Home Institution/Other Institutions. Upon the final decision becoming effective, the Decision-maker will notify the accused's home institution and any other institutions with which the accused has an affiliation of a determination that there was no violation of the AACP Code of Conduct found. However, such notice of the final decision will be given only if the Decision-maker notified these institutions of the allegation or if the accused requests that the notice be made

9. Appeals

An appeal of a final determination of a research misconduct concern may be available to the respondent, but only regarding the final determination made by the Decision-maker in a formal resolution process, and only if the following additional appeal standards and appeal conditions are met:

a. ***Standard.*** The appeal standard is: newly surfaced, consequential facts that were not previously available when the determination was made and consequences were imposed; consequences grossly disproportionate (in leniency or stringency) to the violation found, considering how similar situations were handled, if any, under current AACP policies (*i.e.*, not under prior policies); lack of facts to support the determination; a consequential conflict of interest by the Decision-maker; a failure to fulfill process requirements with consequential effects on the appealing person's ability to address important considerations.

b. ***Conditions for right to file.*** The appeal conditions are:
   - An appeal may be filed by a respondent only within 30 days after that party receives notice of the final determination and any consequences imposed by the Decision-maker ("appeal submission deadline").
   - A statement of appeal, explaining the appeal bases, and all supporting materials must be submitted, so that they are received by the appeal submission deadline at sramamurthy@aacp.org.
   - If the only applicable appeal basis is newly surfaced information, only documents reflecting the new information will be considered and should be submitted. Supporting information that was available when the final determination was made by the Decision-maker in the formal resolution process will not be considered and should not be submitted or referenced. However, previously submitted information may be referenced if the new information alters the meaning or import of the previously submitted information.

Decision-maker for an Appeal. An appeal will be decided by the "Appeal Authority," who are individual(s) appointed by the AACP Authorized Signing Official for this role, either for one particular appeal or for appeals generally. The Appeal Authority may be an individual (who may be a volunteer or employee of AACP or an external consultant retained by AACP) or an ad hoc or standing committee of such individuals. The Appeal Authority assigned to address a particular conduct concern are required to be free of conflicts that would interfere with their performance of their responsibilities.

Appeal Decision Process. The Appeal Authority will endeavor to decide an appeal within 60 days of receiving complete submissions from all authorized appeal parties who file before the appeal submission deadline, initiating the appeal. However, the Appeal Authority may extend the time on its own initiative for good cause, adhering to any legal requirements (*i.e.*, ORI requirement for PHS-funded research that reviews be completed within 120 days.) The Appeal Authority will notify the authorized appeal parties in writing of any extension. The Appeal Authority will decide the appeal based on the submissions, unless it notifies all authorized appeal parties of a need for amplifying information. Any requested amplifying information will be in written form. (An Appeal Authority may, for example, pose written questions and require written responses.) All authorized appeal parties will have access to the written appeal submissions (initial and any supplements required by the appeal authority) and the final decision, if requested. Upon deciding the appeal, the Appeal Authority shall notify the authorized appeal parties of the determination of the appeal. The determination of the appeal is final.

Short-term Safety Measures. During the period for filing an appeal and while an appeal is pending, any short-term safety measures previously imposed by the Decision-maker (including any interim suspension, administrative leave, or temporary no-contact) will continue in effect. However, during a pending appeal, the Appeal Authority may modify, supplement or replace any short-term safety measures that were previously imposed with amended, additional and/or different measures.

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