

**Point by Point Supplemental Policy Statements in response to
ORI review of FHB Policy E40 dated December 2, 2014**

This document addresses areas of the current *FHB Policy E40*, by section, that ORI identified as either partially addressed, not properly addressed, not addressed or needing clarification in order to meet the current PHS regulations at 42 CFR Part 93. UNM HSC's Supplement to UNM Faculty Handbook Policy E40: Research Misconduct, dated February 9, 2015, is derived from these statements and has been implemented to ensure UNM HSC compliance with the current PHS regulations.

APPLICABILITY

Comment 1:

FHB Policy E40 notes certain requirements for reporting to ORI when U.S. Public Health Service (PHS) funding is involved but does not reference the citation (42 CFR Part 93). (§93.302(a))

Comment 2:

The introduction section of *FHB Policy E40* notes that the policy applies to most, if not all, members of the University's academic community, but there are only general references to PHS funding, as required. (§93.214 and §93.102)

Comment 3:

FHB Policy E40 does not include or incorporate by reference the limitation to research misconduct occurring within six years of the date that HHS or the institution receives an allegation of research misconduct. (§93.105)

HSC E40 Supplement Policy Statement:

1. INTRODUCTION AND SCOPE

- Change title of section 1. From "INTRODUCTION AND SCOPE" to "INTRODUCTION"
- Eliminate last paragraph of section 1. INTRODUCTION AND SCOPE
- Address "scope" in new section titled APPLICABILITY (see below)

2. APPLICABILITY (new section)

FHB Policy E40, along with this supplement, are intended to carry out UNM HSC's responsibilities under the PHS regulations on Research Misconduct, 42 CFR Part 93. *FHB Policy E40* and this supplement apply to allegations of research misconduct (as defined in *FHB Policy E40*), or in reporting research results involving:

- any individual who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with this institution; including, but not limited to, faculty, graduate/undergraduate students, staff, employees, contractors, visiting scholars, and any other member of the University's academic community and
- one or more of the following:
 - (1) PHS supported or non-PHS supported biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research

information, (2) applications or proposals for PHS support or non-PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal resulted in a grant, contract, cooperative agreement, or other form of support.

These policies and procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct that occurred within six (6) years of the date the institution or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

GENERAL PRINCIPLES

Comment 4:

Responding to each allegation of research misconduct in a thorough, competent, objective, and fair manner. (§93.300(b)) The E40 policy “generally meets” these criteria, but it is inferred rather than stated.

HSC E40 Supplement Policy Statement:

3. GENERAL PRINCIPLES

- Add the following language:

3.8. The institution will respond to each research misconduct allegation in a thorough, competent, objective and fair manner.

Comment 5:

FHB Policy E40 does not currently include information on how the institution informs its faculty and staff, beyond publication of the *FHB Policy E40*, of the policies and procedures related to allegations of research misconduct and the importance of compliance with those procedures. (§93.302(a)(2)(i))

HSC E40 Supplement Policy Statement:

3. GENERAL PRINCIPLES

- Add the following language:

3.9. UNM HSC will ensure its deans, directors, chairs, and graduate advisors are reminded annually of the institution’s policies and procedures on Research Misconduct including *FHB Policy E40* and the UNM HSC Supplement to *FHB Policy E40*. The HSC will also inform all faculty, students, and staff of (1) the need and importance of research integrity and (2) the importance of compliance with these policies and procedures.

Comment 6:

Section 3.3 states that “allegations must be made in writing, and signed and dated by the complainant”. The PHS regulation requires institutions initiate an inquiry into allegations of research misconduct if the allegations are “sufficiently credible and specific” without qualification. Anonymous and/or oral allegations that are credible and specific must be addressed. (§93.201)

HSC E40 Supplement Policy Statement:

3. GENERAL PRINCIPLES

- Replace section 3.3 with the following revised language:

3.3 All faculty and staff will report observed, suspected, or apparent research misconduct in accordance with section 4.1 of this policy. Allegations may be made in writing, orally or anonymously and in all cases, must be sufficiently credible and specific. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the Vice Chancellor for Research or HSC Research Integrity Officer (RIO) to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. A copy of this policy shall be made available to the complainant.

PRELIMINARY ASSESSMENT OF ALLEGATIONS

Comment 7:

The PHS regulations require that the policy provides for assessment of the allegation to determine if an inquiry is warranted because the allegation: (1) is within the definition of research misconduct in §93.103; (2) is an allegation to which the research misconduct regulation applies under §93.102; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified (§93.307(a))

HSC E40 Supplement Policy Statement:

4. PRELIMINARY ASSESSMENT OF ALLEGATIONS

- Replace section 4.3 with the following revised language:

4.3 Upon receiving an allegation of research misconduct, the Vice Chancellor for Research, or designee, shall conduct a preliminary assessment within seven (7) working days. The purpose of the preliminary assessment is to determine whether the allegation (1) is sufficiently credible and specific so that potential evidence of research misconduct may be identified, (2) whether the allegation falls within the definition of research misconduct and (3) whether it is within the jurisdictional criteria of this policy. An inquiry must be conducted if these criteria are met.

In conducting the preliminary assessment, the complainant, respondent, or other witnesses need not be interviewed and data need not be gathered beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

INQUIRY

Comment 8:

On or before the respondent is notified of the research misconduct allegations, take all practical steps to sequester, inventory, and secure the research record and other relevant evidence (§93.305(a), §93.307(b), (§93.310(d)(2))), and after sequestration, allowing the respondent copies of , or reasonable, supervised access to the research records (§93.305(b))

HSC E40 Supplement Policy Statement:

5. INQUIRY

- Replace section 5.2 with the following revised language:

5.2 Securing Research Records:

Prompt securing of the research records is in the best interest of both the respondent and UNM HSC. After determining that an inquiry will occur, the Vice Chancellor for Research will direct a process 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, except that where 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. Sequestration of research records must occur on or before the date on which the respondent is notified of the allegation.

INVESTIGATION

Comment 9:

Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence or additional instances of possible research misconduct, and continue the investigation to completion (§93.310(h))

HSC E40 Supplement Policy Statement:

6. INVESTIGATION

- Replace first sentence of section 6.4 Investigation Process with the following:

The Investigation Committee will pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence or additional instances of possible research misconduct, and continue the investigation to completion.

Comment 10:

Section 6.5 provides the respondent an opportunity to review and comment on the draft report, but there is no specific provision to provide access to the relevant evidence on which the report was based. (§93.312(a))

HSC E40 Supplement Policy Statement:

6. INVESTIGATION

- Replace section 6.5 Investigation Report, paragraph 4 (beginning “The respondent will...”) with the following revised language:

The respondent shall be given a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed thirty (30) days from the date he/she received the draft report to submit comments. The respondent's comments must be included and considered in the final report. The complainant may be provided with those portions of the draft investigation report that address the complainant's role and opinions in the investigation, and the complainant will have thirty (30) days to submit any comments to the investigation committee. The report may be modified, as appropriate, based on the complainant's comments.

Comment 11:

The appeal process identified in FHB Policy E40, section 6.6 is limited to claims of procedural error, or a claim that the sanctions imposed as a result of a finding of research misconduct were inappropriate. If an institution's procedures provide for an appeal by the respondent that could result in the reversal of the findings of research misconduct in the investigation report, the institution must complete any such appeal within 120 days of the appeal's filing. Appeals from personnel or similar actions that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.

HSC E40 Supplement Policy Statement:

6. INVESTIGATION

- Replace 6.6 Institutional Review and Determination, paragraph 4 with the following revised language:

Respondents may appeal the final determination to the University President. An appeal is limited to: (1) a claim of procedural error; and/or (2) a claim that the sanction imposed as a result of a finding of research misconduct is inappropriate.

Comment 12:

At the completion of the investigation process, provide ORI with the investigation report (including the report, all attachments, and any appeal), the final institutional actions (that is, was there research misconduct, and if so, who was responsible), the institutional findings (the institution's acceptance of the investigation's findings) and any administrative actions against the respondent (§93.315) while ORI considers this provision “generally met” there are omissions of details outlined in the PHS regulations.

HSC E40 Supplement Policy Statement:

6. INVESTIGATION

- Replace 6.6 Institutional Review and Determination, paragraph 5 with the following revised language:

Except as to PHS funded research, the investigation shall be completed within 180 days of the first meeting of the Investigation Committee. However, for PHS sponsored research, unless an extension has been granted, the institution must submit the following to ORI within 120 days of the first meeting of the Investigation Committee: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

OTHER CONSIDERATIONS

Comment 13:

Notify ORI immediately if the health and safety of the public is at risk, if HHS resources or interests are threatened, if research activities should be suspended, if federal action is required to protect the research misconduct proceedings, if the alleged incident might be publically reported, or if the research community or public should be informed (§93.318). If a reasonable indication of possible criminal violations is found, ORI must be notified immediately (§93.318(d))

HSC E40 Supplement Policy Statement:

8. OTHER CONSIDERATIONS

- Replace section 8.1.5 with the following language:

ORI shall be notified immediately, at any time during a research misconduct proceeding, if there is any reason to believe that any of the following conditions exist:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
2. HHS resources or interests are threatened;
3. Research activities should be suspended;
4. There is a reasonable indication of possible violations of civil or criminal law;
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding;
6. The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
7. The research community or public should be informed

Comment 14:

Section 8.5 Record Retention, does not meet current PHS requirements for record retention) (§93.317(b) and §93.309(d))

Comment 15:

Provide for documentation in inquiries in sufficient detail to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation (§93.309(c))

HSC E40 Supplement Policy Statement:

8. OTHER CONSIDERATIONS

- Replace section 8.5 Record Retention with the following language:

8.5 Record Retention:

Records of the research misconduct proceeding will be maintained in a secure manner for 7 years after completion of any proceeding by the institution involving research misconduct allegation, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained. When it is determined that an investigation is not warranted, detailed documentation of the inquiry must be retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.

Comment:

Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; (§93.300(h))

HSC E40 Supplement Policy Statement:

8. OTHER CONSIDERATIONS

- Change sub-heading of section 8.3 from “Interim Administrative Action” to “Administrative Action”
- Add the following provision to section 8.3:

UNM HSC Officials shall ensure that administrative actions taken by the institution and ORI are enforced and shall take appropriate action to notify other involved parties such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.