UNM HEALTH SCIENCES CENTER

HSC Supplement to UNM Faculty Handbook Policy E40: Research Misconduct

Title: HSC Supplement to UNM Faculty Handbook Policy E40: Research Misconduct		
Doc Type: Policy	**Policy #:** R.01.003.P	**Effective Date:** 8/12/2015
Owner(s) (Name and Title): Richard S. Larson, MD, PhD. Executive Vice Chancellor Vice Chancellor for Research	**Revision Date:** 10/1/2015	**Applies To:** See applicability

PURPOSE

The University of New Mexico's current *Faculty Handbook Policy E40: Research Misconduct (FHB Policy E40)*, revised in 2002 and approved by the UNM Board of Regents on April 13, 2004, predates the issuance of the current Public Health Service (PHS) regulation (42CFR Part 93) dated June 16, 2005. *FHB Policy E40 (*Section 8.7) provides that any amendment to the Federal requirements in addressing research misconduct shall supersede the relevant portions of the UNM policy. UNM is committed to taking the appropriate steps to address the necessary updates to the *FHB Policy E40* to meet the requirements of the current PHS regulations. However, given the time involved in addressing updates and obtaining approval of a Faculty Handbook policy, UNM HSC has implemented this supplement to the *FHB Policy E40* to ensure UNM HSC compliance with the current PHS regulations. Although the UNM HSC remains governed by the University's policies, it has the authority to implement additional or more restrictive policies to meet the needs of its operations and all federal laws and regulations.

APPLICABILITY

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).

POLICY STATEMENT

This UNM HSC supplemental policy addresses omissions or areas that require additional clarification in *FHB Policy E40* in order to meet the current PHS regulations at 42 CFR Part 93. Section numbers refer to sections of *FHB Policy E40.* *Only sections requiring modifications or additions are listed.*

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 Policies on Research Misconduct, 42 CFR Part 93. *FHB Policy E40* and this supplement apply to allegations of research misconduct (as defined below), 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 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).

3. GENERAL PRINCIPLES

- *Replace section 3.3 with the following revised language:*

  3.3 All applicable persons 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.

- *Add the following provision to section 3:*

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

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 this 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.

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.

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. Immediately upon ensuring that the research records are secure, the respondent shall be notified that an inquiry is being initiated and an inventory of the secured records shall be provided him/her. As soon as practicable, a copy of each sequestered record will be provided to the respondent, or to the individual from whom the record is taken if not the respondent, if requested. The

respondent shall be notified of the charges and the procedures to be followed.

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.

- *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.

- *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.

- *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 by ORI, 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.

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.

- *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.

- *Change sub-heading of section 8.3 from "Interim Administrative Action" to "Administrative Actions"*

- *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.

DEFINITIONS

See UNM Faculty Handbook Policy E40

REFERENCES

UNM Faculty Handbook Policy E40
PHS regulations at 42 CFR Part 93

RESPONSIBLITY

This supplemental policy applies to 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 the University of New Mexico Health Sciences Center (UNM HSC); including, but not limited to, faculty, graduate/undergraduate students, staff, employees, contractors, visiting scholars, and any other member of the UNM HSC.

UNM HEALTH SCIENCES CENTER

RESOURCES AND TRAINING

Resource/Department	Contact Information
Vice Chancellor for Research	Richard S. Larson, MD, PhD rlarson@salud.unm.edu 505-272-6950
Research Integrity Officer	Catherine Penick cpenick@salud.unm.edu 505-272-6950
Compliance Hotline and Online Reporting	HSC Compliance Hotline 1-888-899-6092. Anonymous online reporting EthicsPoint
Deans and Department Chairs	Consult UNM Directory

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
Owner	Richard S. Larson, MD, PhD, Vice Chancellor for Research		
Consultant(s)	[Name, Title]		
Recommender(s)		August 12, 2015	N/A
Committee(s)	Research Strategic Planning Committee		Yes
HSC Legal Office	Ariadna Vazquez, Esq. Associate University Counsel	July 9, 2015	Yes
Official Approver	Paul B. Roth, MD, MS Chancellor for Health Sciences CEO, UNM Health System Dean, School of Medicine		Yes
Official Approver Signature		Date: August 12, 2015	
2nd Approver			
2nd Approver Signature (Optional)		Date:	
Policy Origination Date: 7/9/2015			

ATTACHMENTS

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