

**Faculty Senate Policy Committee**  
**Meeting Agenda, Scholes Hall Room 141, March 2, 2016**

**Updates**

1. **D10 “Campus Security Authorities”**
2. **Faculty Handbook Website**
3. **A91 “Creation, Review, Reorganization, and Termination of UNM Research Centers and Institutes”** pg. 1
4. **Standard A91 #1 “Creation, Review, Reorganization, and Termination of Non-HSC Research Centers and Institutes”** pg. 5
5. **A53 “Development and Approval of Faculty Policies”** pg. 10

**Action Items**

**Consent Agenda Topic: None**

**Agenda Topics**

**1. E90 “Human Beings as Subjects in Research”** IRB Director, Linda Petree will present information on the UNM Main Campus IRB process. **pg. 15**

Key pre-meeting preparation: Review the proposed revisions to this policy, IRB materials, and refer to the UNM IRB Office website. Review E90 comments/concerns that were circulated via email.

Desired outcome: Information sharing on IRB process and separate Committee discussion on proposed E90 revisions.

**2.** Faculty observers at FS Policy Committee Meetings: There has been a recent request by a faculty member to attend our meeting. As this has never been done, there is no current precedent set for a request of this nature.

Key pre-meeting preparation: Consider this request and be prepared to discuss non-committee member attendance in general.

Desired outcome: Discussion

**3. Standard C190 #1 “Lecturer Annual and Promotion Reviews: Main and Branch Campus Implementation Standard”** Senior Associate Provost Carol Parker requested that another standard be developed by the Policy Committee for Lecturer reviews. Carol Parker developed a memo of the procedures she wanted included. Carol Stephens placed those procedures in the standard format. **pg. 50**

Key pre-meeting preparation: Review attached draft.

Desired outcome: Discussion and Approval.

**4. C05 “Rights and Responsibilities at the University of New Mexico”** The Committee reviewed this policy and determined that C05 appears to be incomplete. Leslie Oaks and Marsha Bum took the lead on looking into the statement of origin and will both report on what they have discovered in conducting their analysis. **pg. 53**

Key pre-meeting preparation: Review the attached policy draft.

Desired outcome: Discussion and possible revisions.

**5. C20 “Employment of UNM Graduates”** There was discussion in January 2014 surrounding whether this policy should be deleted? At the time Christine Sierra researched this and discovered that this Policy is not followed. Based on her research, the Policy Committee proposed the Policy be deleted.

Operations disagreed, and stated they wanted to keep the Policy, but it's not clear why. Carol Parker has expressed concerns as well. **pg. 62**

Key pre-meeting preparation: Review current policy.

Desired outcome: Discussion and possible revisions.

# A91: Creation, Review, Reorganization, and Termination of UNM Research Centers and Institutes



Approved By: Faculty Senate

Effective Date: 4/28/15 **DRAFT 2/15/16**

Responsible Faculty Committee: Research Policy Committee

Office Responsible for Administration: Vice President for Research and HSC Vice Chancellor  
for  
Research

Revisions to the Policy Rationale, Policy Statement, and Applicability sections of this document must be approved by the full Faculty Senate.

## POLICY RATIONALE

Research centers and institutes play an inevitable, integral, and increasing role in modern research universities. These roles stem from two facts. First, cutting edge research in most academic disciplines is increasingly multidisciplinary, interdisciplinary, and trans-disciplinary in nature. Second, research centers and institutes encourage thematically focused but synergistic collaborations that go beyond those that occur in traditional academic departments. This enhances both the intellectual impact of the activities as well as extramural funding opportunities. From time to time it is necessary for the University of New Mexico (UNM) to consider proposals for the creation of new research centers and institutes, or for major restructuring or termination of existing research centers and institutes. This Policy document provides policies and procedures for consideration of such actions regarding research centers and institutes.

## POLICY STATEMENT

The creation of a new research center or institute located on or off the UNM Albuquerque campus, or major changes to an existing research center or institute require approval of the Faculty Senate and the Provost or HSC Chancellor. Approval of the proposed action must be obtained prior to initiating operation of a new research center or institute, or making permanent major changes to an existing research center or institute. In no case is this to be construed as prohibiting an existing research center or institute from experimenting with temporary major changes prior to seeking approval of these on a continuing basis. However, it is expected that even in the case of experimental changes, stakeholders, such as affected faculty, staff, and students will be informed in advance and their input considered by the appropriate dean, director, or other administrator proposing the changes, prior to initiation. Policy A91 "Creation, Review, Reorganization, and Termination of Research Centers and Institutes" DRAFT 2/4/15 Page 2 of 4 All proposals to create, re-organize, or terminate a research center or institute shall follow the policies and procedures described herein, and any applicable standards or guidelines established by the Faculty Senate Research Policy Committee in consultation with representatives of the Provost or the HSC Chancellor and relevant research center or institute heads.

## APPLICABILITY

All UNM academic faculty and administrators, including the Health Sciences Center and Branch Campuses.

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Research Policy Committee, Policy Committee, and Operations Committee.

## DEFINITIONS

**Major actions.** A merger of two or more research centers or institutes, a division or dissolution of a research center or institute, or a change in the basic mission of a research center or institute.

## WHO SHOULD READ THIS POLICY

- Directors of research centers and institutes.
- Academic deans or other executives, department chairs, directors, and managers responsible for research centers and institutes.
- Administrative staff responsible for research centers and institutes.
- Faculty interested in creating a new center or institute

## RELATED DOCUMENTS

### *Faculty Handbook:*

Policy A61.16 “Research Policy Committee”

Policy A88 “Creation, Review, Reorganization, and Termination of UNM Academic Units”

Policy E60 “Sponsored Research”

Standard A91#1 “Creation, Review, Reorganization, and Termination of Non-HSC Research Centers and Institutes”

### *UNM Board of Regents’ Policy Manual:*

Policy 5.9 “Sponsored Research”

### *University Administrative Policies and Procedures Manual:*

Policy 2425 “Recovery of Facilities and Administration Costs”

## CONTACTS

Direct any questions about this policy to Office of the Vice President for Research, the HSC Office of the Vice Chancellor for Research, or the Faculty Senate Research Policy Committee.

## PROCEDURES

Research centers and institutes have three conceptual phases in their life cycle: the proposal phase, the operational phase, and the termination/reinvention phase.

**Proposal Phase.** The life cycle of a research center or institute begins with the proposal phase, during which faculty, staff, and administrators must work together to build a strong case for UNM to invest in a research center or institute. UNM administration should be provided evidence of the intellectual value of the research center or institute beyond that which can be achieved within the departmental or college structure. The proposal shall clearly identify the scope of the research center or institute; in particular which academic units will be contributing resources, including faculty time, staff, facilities and funds. The proposal should have funding plans for the short (e.g., one to five years) and the long (e.g., decades) terms.

**Operational Phase.** Once established, all resources for a research center or institute shall be defined, including building space, equipment, staff, faculty appointments, and effort shares. The director is appointed by the administrator appropriate to the research center or institute, and the conditions of the appointment and the term of service, including options for renewal, shall be clearly stated in the appointment letter. Directors shall be evaluated annually by a representative group of individuals. Guidance for the review is drawn from the proposal for the research center or institute and must include criteria for evaluation of the research center or institute vitality, achievement of goals, resource allocations, and budgets.

**Termination/Reinvention Phase.** The annual review processes from the Operational Phase shall reveal when a research center or institute is experiencing difficulty in managing resources or achieving its expressed goals. Although the director and other applicable administrators shall be

expected to take action to support and revive the research center or institute, they are also responsible for terminating or “sunsetting” the research center or institute, as well as redirecting the resources to other areas of UNM when necessary. The reinvention and redirection of research center or institute activities shall be completed via a process similar to that for creating a new research center or institute.

The website maintained by the Office of the Vice President for Research (OVPR) or the Office of the HSC Vice Chancellor for Research shall contain an annually updated list of all research centers and institutes governed by the Provost and HSC Chancellor and a summary of the most recent review for each research center or institute.

**Division Specific Standards.** Standards for the organization and review of research centers and institutes may vary within major components at UNM. To accommodate these differences each component should develop a standards document specific to the component. ~~This~~ These standards documents will provide standards and guidelines to ensure compliance with this Policy. Standard A91#1 Policy A91 ”Creation, Review, Reorganization, and Termination of Research Centers and Institutes” ~~DRAFT 2/4/15 Page 4 of 4~~ provides standards and guidelines applicable to non-HSC research centers and institutes. A standards document will be developed to provide standards and guidelines applicable to HSC research centers and institutes. In the event that a research center or institute has substantial involvement in both the HSC and non-HSC divisions of UNM, the director will work with the Provost and HSC Chancellor to determine which standard is applicable or if another standard needs to be developed.

## HISTORY

April 28, 2015 – Approved by the Faculty Senate.

**Standard  
A91 #1****Creation, Review, Reorganization, and  
Termination of Non-HSC Research Centers  
and Institutes**

Approved By: Faculty Senate Research Policy Committee

Effective Date: April 29, 2015

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Research Policy Committee. Collaboration on revisions with relevant administration and other interested parties is expected.

This document provides standards and guidelines applicable to non-HSC research centers and institutes to ensure compliance with Policy A91 “Review, Reorganization, and Termination of Research Centers and Institutes.”

**Guiding Principles**

The following principles should be followed regarding UNM research centers and institutes:

1. There should be demonstrable value added by the creation and continuation of all research centers and institutes. It is incumbent upon those wishing to create or continue a research center or institute to demonstrate that its stipulated objectives cannot be effectively accomplished within existing UNM structures, and these objectives should clearly be in concert with UNM’s fundamental mission of education, research, and service.
2. Research centers and institutes should be eligible for all available sources of funding, including I&G (instruction and general), extramural grants and contracts, F&A (facilities and administrative), gifts, donations, and endowments.
3. UNM should encourage and provide incentives for the formation of collaborative, multidisciplinary, interdisciplinary, and transdisciplinary research centers and institutes through its budgeting, hiring priorities, and strategic planning, including capital projects.

**Research Center and Institute Organization**

Depending upon the scope and range of the research centers and institutes involved, there should be different levels or categories of research centers and institutes. To facilitate the integration of research centers and institutes into the mission of the most relevant academic units, they should be managed at the most local administrative level practicable. Regardless of category, there should be consistency across research centers and institutes in terms of the rules, operating procedures, and reporting and evaluation mechanisms that govern research centers and institutes. This acknowledges that research centers and institutes will vary with

respect to focus, objectives, and outcomes, but the rules and procedures that govern their creation, operation, and continuation should be consistent.

With the goal of research centers and institutes to facilitate faculty activities beyond that which can be achieved in departments alone, it is critical that research centers and institutes be formed at the level within the institutional hierarchy that best supports this aim. The organizational structure that describes this goal is outlined below.

**Category I.** Category I research centers and institutes exist within departments, with directors reporting to the relevant department chair. These research centers and institutes are appropriate in cases where the majority of affiliated faculty and the scope of activities both generally lie within the confines of a traditional academic department, yet the creation of a Category I research center or institute would expand and enhance opportunities beyond those possible by relying on the traditional existing department infrastructure alone.

**Category II.** Category II research centers and institutes exist within colleges, but outside of the traditional department framework, with directors reporting to the dean. These research centers and institutes are appropriate in cases where the majority of affiliated faculty and the scope of activities span more than one department, but mostly remain within the confines of a single college or school. Category II research centers and institutes should expand and enhance opportunities beyond those possible by relying on Category I research centers and institutes or the traditional department and college/school infrastructure.

**Category III.** Category III research centers and institutes exist alongside colleges or schools, with directors reporting to a higher-level administrator, such as the Provost or Vice President for Research. These research centers and institutes are appropriate in cases where the majority of the affiliated faculty and the scope of activities span more than one college or school. Category III research centers and institutes should expand and enhance opportunities beyond those possible by relying on Category I or II research centers and institutes, or the traditional department and college/school infrastructure.

**Contract-focused Research Centers and Institutes.** There are several research centers and institutes existing across campus that, while critical to supporting UNM's core mission of teaching, research, and service, operate outside the realm of what is considered "typical" of a university research center or institute. These research centers and institutes (such as the Institute for Applied Research Services or the Earth Data Analysis Center) make critical contributions to UNM's core mission, but receive a majority of their funding in the form of contracts rather than grants, and a majority of their activities are sponsored by non-federal agencies (such as state agencies, private companies, and foundations). While this standard applies to all of UNM's non-HSC research centers and institutes, it is recognized that representatives from these organizations should work with the Provost or the Vice President for Research (OVPR) to develop procedures and guidelines specific to the operation of contract-focused research centers and institutes.

**Proposal Phase.** The life cycle of a research center or institute begins with the proposal phase, during which faculty, staff, and administrators must work together to build a strong case for UNM to invest in a research center or institute. UNM administration should be provided



evidence of the intellectual value of the research center or institute beyond that which can be achieved within the departmental or college structure. The proposal should highlight opportunities for attracting sustainable outside funding, for collaboration among faculty from disparate units, for advancing knowledge or technology, and for support of graduate student education.

The proposal shall clearly identify the scope of the research center or institute; in particular which academic units will be contributing resources, including faculty time, staff, facilities, and funds. Proposals to fund research centers or institutes should acknowledge, and reflect, the sources contributing resources. Commitments from each source should be delineated over time, for finite or recurring terms. The proposal should have funding plans for the short (e.g., one to five years) and the long (e.g., decades) terms. These plans should include funding sources (i.e. research grants, F&A return, and I&G funds), as well as plans for expenditures. It is expected that initial or start-up funds will come from the administrative levels at or above the level at which the research center or institute is created. Proposals should identify the administrative structure, particularly the roles of faculty and the director, who will be a faculty member at UNM.

Proposals to establish a research center or institute may be initiated by faculty or administrators, but shall be reviewed by a committee of faculty members; the recommendations provided by this committee shall then be reviewed at the appropriate administrative level, dependent on the category of the research center or institute. The final decision to create a center will be made by administration at the appropriate level but the expectation is that the recommendations of the faculty committee will be followed in all but exceptional cases.

- Proposals to establish Category I research centers and institutes will be reviewed by a committee made up of department faculty. Recommendations will be sent to the Chair for a decision.
- Proposals to establish Category II research centers and institutes will be reviewed by a committee of faculty from across the college or school. Recommendations will be sent to the Dean for a decision.
- Proposals to establish Category III research centers and institutes will be reviewed by a committee with faculty from across UNM. Recommendations will be sent to the administrator to whom the center director would report for a decision. This could be either the Provost or the Vice President for Research, depending on the scope of the center.

The recommendations of these committees shall be used by the Faculty Senate Research Policy Committee who will make the final recommendation to appropriate UNM administrators.

**Operational Phase.** Once established, all resources for a research center or institute shall be defined, including building space, equipment, staff, faculty appointments, and effort shares. Research centers and institutes shall have an advisory committee formed by faculty or staff deemed appropriate to the mission of the research center or institute. Advisory committees shall review the operations of the research center or institute, including the annual budget, the annual report, and selection of the director. Members of the advisory committee shall be

outside faculty or staff members who do not have a personal stake in the operation of the research center or institute.

Initially the director will usually be the principal investigator (PI) of the research grant establishing the research center or institute; however the director could also be chosen from a group of potential candidates. The director is appointed by the administrator appropriate to the research center's or institute's category, and the conditions of the appointment and the term of service, including options for renewal, shall be clearly stated in the appointment letter. Initial terms will normally coincide with the logical term of the establishing grant, or four years in the absence of such a condition.

As a broad guideline, being the director of a research center or institute shall be seen as part of a faculty member's workload. Only if the faculty member's research center or institute load increases beyond that considered standard or normal in the home department shall the faculty member's teaching and service load be reduced. However, within college and department guidelines, the faculty member may use grant money to partially release teaching responsibilities.

Directors shall be evaluated regularly by a representative group of individuals. Evaluations shall be "360-degree" processes involving research center or institute faculty, staff and students, as well as any constituencies of the research center or institute, particularly if the research center or institute is involved in teaching or providing services beyond the UNM community. Those familiar with the nature and level of activities being conducted shall evaluate the activities of a research center or institute. The review shall occur on a regular basis, and at least once every five years. Guidance for the review is drawn from the proposal for the research center or institute and must include criteria for evaluation of the research center or institute vitality, achievement of goals, resource allocations, and budgets.

**Termination/Reinvention Phase.** The regular review processes shall reveal when a research center or institute is experiencing difficulty in managing resources or achieving its expressed goals. Although the director, advisory committee, and other unit administrators shall be expected to take action to support and revive the research center or institute, they are also responsible for terminating or "sunsetting" the research center or institute, as well as redirecting the resources to other areas of UNM when necessary. The reinvention and redirection of research center or institute activities shall be completed via a process similar to that for creating a new research center or institute.

Proposals to terminate a research center or institute may be initiated by faculty or administrators, but shall be reviewed by a committee of faculty members; the recommendations provided by this committee shall then be reviewed at the appropriate administrative level, dependent on the category of the research center or institute. The final decision to terminate a center will be made by administration at the appropriate level but the expectation is that the recommendations of the faculty committee will be followed in all but exceptional cases.

- Proposals for termination/reinvention of Category I research centers or institutes shall be reviewed by a committee of department faculty. Recommendations will be sent to the Chair for a decision.
- Proposals for termination/reinvention of Category II research centers or institutes shall be reviewed by a committee of faculty from across the college. Recommendations will be sent to the Dean for a decision.
- Proposals for termination/reinvention of Category III research centers or institutes shall have proposals reviewed by the Faculty Senate Research Policy Committee. Recommendations will be sent to the administrator to whom the center director normally reports for a decision. This could be either the Provost or the Vice President for Research as determined when the center was established.

The current procedures shall be made accessible on the website maintained by the Office of the Vice President for Research (OVPR). The posted procedures shall also clearly reference and provide access to any other documents relevant to the formation, maintenance, or termination of a research center or institute. Finally, this website shall also contain an annually updated list of all research centers and institutes governed by the Provost and a summary of the most recent review for each research center or institute.

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## HISTORY

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April 28, 2015—Policy A91 “Creation, Review, Reorganization, and Termination of UNM Research Centers and Institutes” Approved by the Faculty Senate.

November 19, 2014—This standard A91#1 “Creation, Review, Reorganization, and Termination of Non-HSC Research Centers and Institutes” Approved by the Faculty Senate Research Committee.

COMMENTS TO: <a href="mailto:handbook@unm.edu">handbook@unm.edu</a>	<a href="#">FACULTY HANDBOOK HOME</a>	<a href="#">TABLE OF CONTENTS</a>	<a href="#">TABLE OF POLICIES</a>	<a href="#">UNM HOME</a>
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# A53: Development and Approval of Faculty Policies

Approved By: Faculty Senate

Effective Date: January 19, 2016

Responsible Faculty Committees: Policy and Operations

Office Responsible for Administration: Office of the University Secretary

Revisions to the Policy Rationale, Policy Statement, and Applicability sections of this document must be approved by the full Faculty Senate.

## Policy Rationale

The *Faculty Handbook* provides University of New Mexico (UNM) faculty with a written record of faculty policies and procedures. Policies in the *Faculty Handbook* are unifying documents that describe academic principles, the reasoning behind the principles, and institutional procedures necessary for implementation. *Faculty Handbook* policies contain governing principles and procedures that mandate or constrain actions and apply to UNM faculty; therefore, the development of policies requires input from faculty members who have extensive knowledge on the subject matter and review by faculty members from a variety of academic disciplines at UNM.

## Policy Statement

All UNM policies which pertain primarily to faculty and academic matters are placed in the *Faculty Handbook* and are subject to the review and approval requirements defined in this Policy Document, with the exception of Section B “Academic Freedom and Tenure” which follows a separate review and approval protocol. The scope of *Faculty Handbook* policies is established by the [Faculty Constitution](#) and the right to review and take action on these policies is granted to the faculty by UNM Board of [Regents Policy 5.1](#) “The Faculty’s Role in the University’s Academic Mission.” This policy describes the process used to develop or amend *Faculty Handbook* policies, solicit input, and obtain approval.

**1. Proposing a New Policy or Changes to Existing Policy.** Any faculty member or academic administrator wishing to propose a change to an existing *Faculty Handbook* policy or propose a new policy should send their request to the Office of the University Secretary, who will forward it to the Faculty Senate Policy Committee (FSPC) for consideration. This request should include a draft policy document which shows proposed changes to the existing policy with track changes, or in the case of a new policy the request will include a proposed policy draft addressing the concerns it is intended to address. This request should also include a statement of the reason(s) for the proposed policy change(s) or the new policy. Because faculty policy is a shared governance process, policy actions generally require one to two full semesters for appropriate review, approval, and implementation. The FSPC will review the request and work

with the appropriate Faculty Senate committee(s) to determine the most effective course of action. The Office of University Secretary will notify the requestor of the action taken by the FSPC.

**2. Approval.** Proposed new faculty policy statements, in their entirety, and changes to the Policy Rationale, Policy Statement, and Applicability sections of existing policies will be posted on the *Faculty Handbook* website for review by UNM faculty members. The Office of the University Secretary in consultation with the Chair of the FSPC will address any comments received from faculty and will forward the final proposed draft to the Faculty Senate for approval. Due to the nature of the policy or previous approval history, specific policies will also require approval by University faculty, the UNM Board of Regents, and/or the UNM President and/or Provost or the Chancellor for Health Sciences. Proposed changes to definition, procedural, and information portions of a policy document will be reviewed by the FSPC in consultation with the responsible Faculty Senate Committee(s) listed in the Policy Heading. After review and consultation, the proposed changes can be made with approval by both the FSPC and the Faculty Senate Operations Committee.

### **3. Distribution and Notification of New or Amended Policy.**

Upon approval, the new or amended policy will be placed on the *Faculty Handbook* website and announced to the campus. Deans and department chairs, or their designees, are responsible for:

- informing their faculty members of new policies or changes to existing policies; and
- updating all related departmental processes, procedures, and/or documents to reflect new or amended policies.

## **Applicability**

All UNM academic faculty and administrators, including the Health Sciences Center and Branch Campuses.

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Policy and Operations Committee in consultation with the responsible Faculty Senate Committee listed in Policy Heading.

## **Definitions**

Policy and Procedures are sections of each policy document. Changes to the Policy Section require approval of the approving bodies listed in the policy heading; at a minimum this includes the Faculty Senate. Changes to the procedures section requires approval of the Faculty Senate Policy and Operations Committees.

**Policy.** Provides the overall intention and direction of the policy and major mandated actions or constraints.

**Procedures.** Provide the information and/or steps necessary for policy compliance and outlines how the policy’s requirements will be met.

To assist with implementation of the policy, standards and guidelines may be ~~issued~~ proposed by the office responsible for administration of a specific policy, as identified in the heading of each policy. Standards and changes to standards must be approved by the Faculty Senate Policy Committee.

**Standards.** Required processes necessary for compliance with the policy document.

**Guidelines.** Recommended practices or processes designed to streamline particular processes according to a set routine or sound practice. Guidelines allow some discretion or leeway in interpretation, implementation, or use.

## Who Should Read This Policy

- Board of Regents
- Faculty
- Academic staff
- Academic deans and other executives, department chairs, directors, and managers

## Related Documents

UNM Regents' Policy Manual [Policy 5.1](#) “The Faculty’s Role in the University's Academic Mission”

*Faculty Handbook* [Policy A50](#) “The Faculty’s Role in the University's Academic Mission”

*Faculty Handbook* [Policy A51](#) “Faculty Constitution”

[University Administrative Policies](#)

[University Catalog](#)

[Pathfinder](#)

HSC Policy on Policies, which contains procedures specific to the HSC

## Contacts

Direct any questions about this Policy to the [Office of the University Secretary](#).

## Procedures

*Faculty Handbook* policies are designed to ensure that policy level portions can only be changed with approval of the Faculty Senate, but also allow for a streamlined approval process for definition, procedural and information oriented sections of the policy to allow for timely updating to reflect new practices and/or information.

**1.***Faculty Handbook* policies are composed of the following sections.

**1.1 Heading.** In addition to policy title and number, the heading of the policy identifies:

- The approving bodies (i.e. Faculty Senate, Provost/Chancellor for Health Sciences, President, Board of Regents, and/or University Faculty).
- Responsible Faculty Senate committee(s).
- Office responsible for administration of the Policy.

**1.2 Policy Rationale.** Describes the reason for the policy, its relationship to UNM’s academic values and/or mission, and any philosophical, stewardship, legal, regulatory, or other requirements the policy aims to meet.

**1.3 Policy Statement.** Includes the overall intention and direction of the policy and major mandated actions or constraints. It does not include procedures, which are placed in a separate section to allow for greater flexibility when updating is necessary.

**1.4 Applicability.** Identifies which individuals and/or University units are subject to the policy. Some policies may apply to the entire academic community, while others may apply only to Main Campus, the Health Sciences Center, and/or Branch Campuses.

**1.5 Definitions.** Defines terms that have specialized or particular meaning in the policy.

**1.6 Who Should Read This Policy.** Lists individuals who must understand the policy in order to make decisions and/or do their jobs.

**1.7 Related Documents.** Lists related UNM policy documents and other UNM and external documents that provide helpful, relevant information.

**1.8 Contacts.** Contains information to assist faculty members in complying with the policy.

**1.9 Procedures.** Includes procedures necessary for policy compliance and outlines how the policy’s requirements will be met.

**1.10 History.** Lists dates of amendments and summary information on changes approved.

**2. Approval process for Policy Level Portions of Faculty Policies.** Changes to policy level portions of the policy (sections 1.2 –1.4, herein) require approval by the approving bodies listed in the policy heading. At a minimum this includes the Faculty Senate and depending on the impact of the policy, approval may also require action by the President or Provost/Chancellor for Health Sciences, Board of Regents, and/or University faculty.

**3. Approval process for Definitions, Procedures, and Information Portions of Faculty Policies.** Changes to definition, procedural and information portions of the policy (sections 1.5 – 1.10, herein) can be made with approval by both the Faculty Senate Policy Committee (FSPC) and the Faculty Senate Operations Committee in consultation with the responsible Faculty Senate Committee(s) listed in the policy heading.

## **History**

February 4, 2014 – Amended procedures approved by Faculty Senate Operations Committee

January 29, 2014 – Amended procedures approved by Faculty Senate Policy Committee

August 27, 2013 – Approved by the Faculty Senate

January 20, 2015 – Amended procedures section to remove AF&T and Research Policy Committees from process.

January 19, 2015 – Amended definitions



## E90: Human Subjects in Research

Approved By: Faculty Senate

Last Updated: **Draft 1/27/16**

Responsible Faculty Committee: Research Policy Committee

Office Responsible for Administration: Vice President for Research and HSC Vice Chancellor for Research

Revisions to the Policy Rationale, Policy Statement, and Applicability sections of this document must be approved by the full Faculty Senate.

### POLICY RATIONALE

In the oversight of all Human Subjects Research, the University of New Mexico (UNM) as a whole, is committed to protecting the rights and welfare of participants in Human Subjects Research consistent with the ethical principles outlined in the April 18, 1979, report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

- Respect for Persons
- Beneficence
- Justice

### POLICY STATEMENT

UNM aims to promote a culture of compliance with the highest legal and ethical standards for the conduct of human research. UNM recognizes research as one of its chartered enterprises and shares ~~with its individual faculty members~~ responsibility for promoting and managing ~~defending~~ this activity with its individual researchers when conducted under its auspices.

To ensure comprehensive protection of the rights and welfare of subjects in human research across a diverse social-behavioral and biomedical research enterprise, UNM holds two distinct Federal Wide Assurances (FWAs) approved by the U.S. Department of Health and Human Services, one for the University Main Campus and a separate FWA for the Health Sciences Center (HSC). Under these agreements, UNM assures that all of its activities related to human subjects in research (“Human Subjects Research”) are conducted in accordance with all applicable federal regulations (e.g., 45 C.F.R. § 46, 21 C.F.R. § 50, 21 C.F.R. § 56, 21 C.F.R. § 312, 21 C.F.R. § 812).

The following policy is not intended to relieve the individual scientist of his/her ultimate responsibility for moral and ethical conduct nor to deny her/him the right to reasonable freedom of inquiry. The policy does make explicit the criteria, by which the propriety of an action should be judged. The procedure is designed to protect human subjects who participate in research and UNM (including faculty, students and the administration) against alleged violation of these criteria.

1. In considering the participation of humans as research subjects, the guiding principle is that no one should be exposed to risk to health or well being without being given all reasonable protection and without being adequately informed. The rights and welfare of the study subjects are of paramount importance.
2. In general, informed consent must be obtained from all human subjects prior to their participation in research. The investigator must be satisfied that the explanation of participation has been understood, and consent must be obtained without duress, coercion, or undue influence.
3. It is the responsibility of the individual investigator to have adequate knowledge of the possible consequences of his/her research, or of research done under his/her direction.
4. Whenever possible, any hazards to health or well being of each procedure must first be investigated with animals.
5. Whenever medication or physical intervention is used, or whenever the subject is exposed to unusual environmental conditions, proper protection and supervision must be provided.
6. The subject's personal privacy and the confidentiality of information received from him/her must be protected.
7. The subject's time should not be invaded to the extent that the participation creates conflict with other obligations.
8. Remuneration may be offered for the time involved in a study, provided the remuneration is not so large as to constitute an improper inducement to participate.
9. Any individual may request termination of his/her participation at any time and this request will be honored promptly and without prejudice.
10. The review procedures as described below are intended to help maintain a positive attitude toward scientific research. All UNM faculty members are presumed to behave responsibly and in accordance to applicable local, state, and federal regulations, laws, and statutes.

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## APPLICABILITY

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All academic and research UNM units, including the Health Sciences Center and Branch Campuses.

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Research Policy Committee, Policy Committee, and Operations Committee.
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## DEFINITIONS

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[IRB NOTE](#) [May want to add a definition or explanation of acronym](#)

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## WHO SHOULD READ THIS POLICY

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- [Faculty and staff conducting sponsored research](#)
- [Members of the Faculty Senate and the Research Policy Committee](#)
- [Academic deans or other executives, department chairs, directors, and managers](#)
- [Administrative staff responsible for sponsored research management.](#)

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## RELATED DOCUMENTS

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*UNM Regents' Policy Manual*

[Policy 5.14](#) "Human Beings as Subjects in Research"

[Policy 5.13](#) "Research Fraud"

*Faculty Handbook*, [Policy E40](#) "Research Misconduct"

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## CONTACTS

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Direct any questions about this policy to Office of the Vice President for Research or the HSC Office of the Vice Chancellor for Research.

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## PROCEDURES

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[All Principal Investigators and involved researchers engaged in Human Subjects Research are required to:](#)

- [1. Follow the procedures established by the Main Campus Office of the IRB \(OIRB\), the Main Campus IRB, the HSC Human Research Protections Office and the HSC's Human Research Review Committees \(HRRC\), depending on the Principal Investigator's primary appointment. Procedures are posted on the respective websites and are regularly and continually updated to comply with federal regulations and accreditation standards.](#)
- [2. Obtain approval by IRB procedures. Approval by IRB procedures is required for all researchers engaged in human research.](#)
- [3. Monitor ongoing research and teaching activities under their supervision to ensure that they continue to be conducted in accordance with approved protocols.](#)
- [4. Ensure that all personnel involved in Human Subjects Research under their supervision are appropriately trained on the applicable laws, rules, and regulations regarding Human Subjects Research as well as the Main Campus IRB's or HRRC's policies and procedures, as the case may be, with respect to Human Subjects Research.](#)
- [5. Comply with and ensure compliance with all determinations and additional requirements of the IRB and/or HRRC, as the case may be, with jurisdiction over the research.](#)

~~The policy described above shall be implemented as follows.~~

1. All Institutional Review Boards (IRBs) shall be established in accordance with relevant federal regulations (45 CFR 46.107, 21 CFR 56.107). In addition:

(a) The dean of each school or college, or the chair of each department involved in human research, is responsible for establishing procedures to evaluate the scientific merit of proposals which may come from her/his faculty or professional staff.

(b) The number of persons to serve on an IRB, the term of membership, and the type of faculty representation and expertise on such a committee would be consistent with the policies and procedures developed by the respective IRB office. However, each IRB must include in its membership one or more non-scientists and at least one person unaffiliated with the college, school, or agency it specifically serves. FDA-regulated projects must be reviewed by a committee that includes at least one licensed physician.

2. The IRBs shall evaluate proposals against this Policy and the specific standards of the federal regulations and/or IRB policies, as well as such additional standards as may be appropriate to the research area. All federally funded research shall be reviewed according to relevant federal regulations (45 CFR 46.111, 21 CFR 56.111). In so doing, the IRB can call upon specialists including, where appropriate, consultants not on the UNM faculty, and may interview the investigator and his/her staff.

3. Each IRB shall maintain formal records of its decisions for at least three years. It shall conduct continuing review of federally funded non-exempt research at least annually and according to IRB policies, although the IRB may require more frequent reporting on some research and may make inspections or take other such actions as found necessary to ensure compliance with the policies and procedures herein stated.

4. The investigator shall be responsible for obtaining approval from an IRB prior to conducting any research involving human subjects. Application for approval is submitted according to the IRB's policies and procedures. Any changes in risk or any unexpected problems adversely affecting the subjects or others will be reported promptly to the IRB.

5. The investigator shall obtain continuing IRB approval for all non-exempt studies.

6. A faculty member must retain adequate records concerning the procedures described above. Research records, including those documenting informed consent, should be held for at least three (3) years after the study is closed with the IRB. Sponsors and federal agencies may have other retention requirements beyond three (3) years that must be adhered to.

7. Whenever a study has been disapproved by the IRB, the investigator may appeal the decision to the IRB, as appropriate. The IRB has the final decision regarding disapproval and this cannot be appealed to or overturned by any UNM official.

8. All faculty members share the responsibility for compliance with the policy as herein stated, but first-line responsibility resides with the individual faculty member for all work done under his/her direction (including student research) and second-line responsibility resides with the department chair who should remain cognizant of the research activities within his/her department.

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## HISTORY

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### Effective:

Revised November 15, 1966

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## DRAFT HISTORY

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September 6, 2015—Proposed revised draft placed in new policy format for review by the  
Faculty Senate Policy Committee  
July 1, 2015 Revised draft prepared by HSC

<a href="mailto:handbook@unm.edu">COMMENTS TO: handbook@unm.edu</a>	<a href="#">FACULTY HANDBOOK HOME</a>	<a href="#">TABLE OF CONTENTS</a>	<a href="#">TABLE OF POLICIES</a>	<a href="#">UNM HOME</a>
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# Regents' Policy Manual - Section 5.14: Human Beings as Subjects in Research

Adopted Date: 09-12-1996

Revised Draft 1/27/16

## Applicability

This policy applies to all research related to the University whether conducted on or off campus, whether done by faculty or students, and whether or not supported by extramural funds.

## Policy

Research involving human beings as subjects is authorized at the University, subject to specific limitations and procedures. A human subject is any individual who may be at risk as a consequence of participation as a subject in research, development, demonstration or other activities.

1. In considering the participation of humans as subjects, the guiding principle is that no one should be exposed to risk to health or well being without being given all reasonable protection and without being adequately informed.
2. In general, the purpose of the study, the procedures to be followed, and the possible risks involved must be explained to the subject. The investigator must be satisfied that the explanation has been understood, and consent must be obtained without duress or deception. Such an explanation may be postponed or even omitted where there are no risks to the subject, and a full account of the purposes and procedure in advance might bias the results.
3. It is the responsibility of the individual investigator to have adequate knowledge of the possible consequences of his research, or of research done under his direction.
4. Whenever possible, any hazards to health or well being of each procedure must first be investigated with animals.
5. Whenever medication or physical intervention is used, or whenever the subject is exposed to unusual environmental conditions, proper protection and supervision must be provided.
6. The individual's personal privacy and the confidentiality of information received from her/him must be protected.
7. An individual's time should not be invaded to the extent that the participation creates conflict with other obligations.
8. Remuneration may be offered for the time involved in a study, provided the remuneration is not so large as to constitute an improper inducement to participate.
9. Any individual may request termination of his/her participation at any time and this request will be honored promptly and without prejudice.
10. Unless there are reliable indications to the contrary, all University of New Mexico faculty members are presumed to behave responsibly, and all experimental subjects should be willing to contribute to the advancement of knowledge, provided their personal rights are respected.

## Implementation

The Board, in adopting the original Regents' Policy Manual in 1981, incorporated detailed policies and procedures which had previously been approved in 1966. The full text is printed in the [Faculty Handbook](#).

Research involving human beings as subjects is also subject to applicable federal laws and regulations.

## **Reference**

[Faculty Handbook](#), [1990 ed.], pages D-1 through D-4.

# MEMORANDUM

**TO:** Faculty Senate Policy Committee

**FROM:** Richard Larson, M.D., Ph.D., Executive Vice Chancellor and Vice Chancellor for Research, and Professor, Department of Pathology, UNM School of Medicine

**DATE:** January 28, 2016

**RE:** Revisions to Faculty Handbook Policy E-90

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## Current Policy E-90

The Faculty adopted the current Faculty Handbook Policy E-90 in 1966. The Faculty has not updated that Policy since that time. That policy was, as is clear from a reading of it, thoughtfully considered and appropriately detailed in its substance. At that time, there was very little federal government oversight to protect those individuals who elected to participate in human subjects research. It was, therefore, appropriate for the Faculty to spell out in some detail the procedures under which the Faculty could and should perform human subjects research.

## **Federal Government Oversight of Human Subjects Research**

Since the adoption of Faculty Handbook Policy E-90 in 1966, a number of mid-twentieth century research efforts in involving human subjects raised the specter of questionable ethics underlying that research and the potentially harmful effects of that research on the participants. As such, thereafter, in the late 1970s the *Belmont Report* was published, which outlined the three fundamentals upon which a human subjects research program and research protocols should be based:

- *Respect for persons*: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent;
- *Beneficence*: The philosophy of “Do no harm” while maximizing benefits for the research project and minimizing risks to the research subjects; and
- *Justice*: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly and equally.

Out of the *Belmont Report* arose two federal regulatory oversight schemes in 1991: the Office of Human Research Protections (“OHRP”) and the Food & Drug Administration (“FDA”) both housed in the U.S. Department of Health & Human Services. Both the OHRP regulations and published guidances and the FDA regulations and published guidances are complementary but not identical. These regulations endeavor to effectuate the *Belmont Report* as follows:

1. Ensure the research study is approved by an IRB;



2. Get informed consent from the patient/study participant;
3. Ensure that the patient/study participant understands the full extent of the experiment, and if not, will contact the study coordinator;
4. Ensure the patient/study participant wasn't coerced into doing the experiment by means of threatening or bullying;
5. Be careful of other effects of the clinical trial or research study that was not mentioned , and report it to the proper study coordinator;
6. Support the privacy of the patients/study participants identity, their motivation to join or refuse the experiment;
7. Ensure that all patients at least get the minimal care needed for their condition.<sup>1</sup>

To be compliant with this and so as to be able to conduct research involving human subjects, the University submitted two separate Federal Wide Assurances ("FWA"s), one for the Health Sciences Center and one for the Main Campus. These FWAs set forth the University's commitment to these principles and set forth the University's commitment to compliance with the OHRP's and FDA's regulatory requirements. The OHRP and the U.S. Department of Health and Human Services ("HHS") approved each of these FWAs. These FWAs are not identical in the method and manner by which the HSC, on the one hand, and the Main Campus, on the other, will effectuate their human research protections programs. Under both, however, consistent with federal regulatory scheme requirements, both the IRB on Main Campus and the Human Research Review Committees have adopted their own "Standard Operating Procedures" or "SOPs." Each of these SOP's are audited by the OHRP and, in the case of the HSC, the FDA. Additionally, the human research protections program at the HSC is accredited by AAHRPP, while the program at the Main Campus is not. The AAHRPP accreditation standards drive different policies, procedures, and documentation requirements than are required for a non-accredited program.

### **The Need to Modify Faculty Handbook Policy E-90**

A review of the current Faculty Handbook Policy E-90 indicates significant areas of dissonance with the federal regulatory scheme under which the University must operate to be able to continue to receive federal funding for human subjects research. There are also areas of dissonance with AAHRPP accreditation requirements. We want to thank the Main Campus IRB office for bringing this dissonance to the forefront and opening this dialogue. Because of operational differences between the human research protections program on Main Campus and the program at the HSC, we began our analysis of this situation by recognizing that any University-wide policy must be cognizant of these differences and should attempt to have that policy work in harmony and alignment with those separate programmatic requirements.

As a result, the HSC undertook to do several thing to inform this dialogue:

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<sup>1</sup> See Simms, Jennifer (July-August 2010), "A Brief Review of the "Belmont Report," *Dimensions of Critical Care Nursing* 29(4): 173-74.

- Contacted a respected, national consultant that advises several leading academic institutions and the HSC on IRB compliance with the federal regulatory scheme to obtain that firm’s best recommendation as to the form that Faculty Handbook Policy E-90 should take;
- Reviewed a number of peer institutions to determine what human subject research protections policies they have adopted;
- Asked the Office of University Counsel to seek legal input on the suggested approach; and
- Based upon that “research,” developed a draft revised Faculty Handbook Policy E-90 as our recommendation to the Faculty Senate Research Policy Subcommittee.

### **Findings**

#### **(1) *Outside Consultant Opinion***

As stated previously, the HSC contacted Karen Christianson, RN, BSN, CCRP, with HRP Consulting Group, Inc. in Clifton Park, New York, and asked for her advice relating to the form that a revised Faculty Handbook Policy E-90 should take. Ms. Christianson opined that in reviewing a variety of faculty handbook policies and other institution-wide policies:

The content tends to vary from brief statements about the obligation for faculty to perform research in accordance with ethical standards, regulations, and policies with a cross-reference to separate research policies, to a few pages that go into greater detail (background, core values, excerpts and citations) but still refer to the university or college research policies.

We are also of the collective opinion that it is best practice to keep the faculty handbook policy statement brief with cross-references to free-standing research policies, because this approach helps avoid contradictory language and minimizes the need to manage concurrent updates. Further, it is of utmost importance to clearly establish the authority and independence of the IRB in the fulfillment of their research review and oversight functions. This is best managed through the promulgation of an overarching policy or statement from the highest levels of leadership establishing the authority, independence, and responsibilities of the IRB(s) accompanied by detailed policies and procedures for the operation of the human research protection program and the IRB(s) that are developed and managed by those individuals within the organization with specific experience and expertise in the complex and extensive regulations, guidelines, and accreditation standards that govern the functions of the IRB and the conduct of research. Finally, it is also important that updates to the detailed policies and procedures of the human research protection program and IRB(s) are able to be managed somewhat nimbly as new regulations, guidelines, and standards are issued. It is our experience that the processes for development and approval of faculty policies are too cumbersome to manage the need for real-time updates.

(2) *Review of Peer Institutions*

As a part of this process, the policies adopted at peer institutions in our region of the United States were reviewed. These institutions were the University of Colorado, the University of Arizona, and the University of Utah. Specifically, the University of Colorado in Chapter IV of its Faculty Handbook states:

**F. Research Involving Human Subjects or Animal Studies**

Each campus of the University of Colorado has a policy or guidelines for situations dealing with human research subjects and animal studies. These campus policies or guidelines conform to federal regulations.

A review of each University of Colorado campus's policies indicates that the policies to which they refer are the institutional administrative policies and federally required SOPs.

At the University of Arizona, the University of Arizona's policy on "Research Involving Human Subjects" is set forth in Section 2.13.02 of their Human Resources Policies and provides as follows:

The University is required to safeguard the rights and welfare of human subjects involved in research. Any project originated at The University of Arizona, University Medical Center, University Physicians, or the affiliated Veterans Administration Hospital which uses human subjects must be submitted for review and approval by the University's Human Subjects Protection Program (HSPP) and the Institutional Review Board (IRB).

In compliance with federal regulations, the review shall ensure: (1) that the rights and welfare of the subjects involved are adequately protected; (2) that the risks to an individual (whether physical, psychological, or social) in any activity which goes beyond the application of accepted procedures are outweighed by potential benefits; (3) that subject selection is fair; and (4) that legal, informed consent of participants is obtained by methods that are appropriate and adequate. Approval of the IRB or HSPP must be obtained before the project is initiated.

Forms and instructions for securing approval for research involving human subjects and information about the Human Subjects Protection Program are available online as follows:

- Human Subjects Protection Program  
<http://ocr.arizona.edu/hssp>

Lastly, the University of Utah policy in this regard is set forth in Policy 6-316, entitled "Code of Faculty Rights and Responsibilities" and more specifically in Section 4C.1 of that Policy:

1. Faculty members are responsible for insuring that approval has been obtained from the appropriate review committees prior to initiating or becoming involved in research that involves human subjects, vertebrate animals, radiation or radioactive compounds, biohazards, toxic substances, or any other material or activity covered by university, state or federal regulation. Faculty members are also responsible for monitoring ongoing research and teaching activities under their supervision to ensure that they continue to be conducted in accord with approved protocols. In addition, faculty must ensure that all personnel involved in such activities under their supervision are fully trained in accordance with relevant regulations.

As is evident from this review, these leading institutions have adopted a policy pertaining to human subjects research that embraces the broad principles of the *Belmont Report* and conformance to the federal regulatory scheme under which those universities, just like this University, must operate to continue to receive federal funding for research involving human subjects. At the same time, these leading institutions have rejected the urge to add the actual procedural steps for faculty members to comply with these principles and, instead, have referred faculty to the human research protection programs and their SOPs that are in place at those institutions.

(3) *Office of University Counsel*

The HSC Office of Research consulted with representatives of the Office of University Counsel concerning this matter. The OUC advised that the current Faculty Handbook Policy E-90 is in need, from a legal standpoint, of revision. The OUC's view is that it is advisable to adopt a policy pertaining to human subjects research that embraces the broad principles of the *Belmont Report* and conformance to the federal regulatory scheme under which this University must operate to continue to receive federal funding for research involving human subjects, without diving down into procedural details. This is because, in their view, including the procedural details in the Faculty Handbook Policy E-90 could increase the risk to the University and research faculty of future inconsistency and misalignment of those procedural details to the federal requirements and to institution's SOP's that implement and operationalize compliance with the federal requirements.

**Recommendation**

Based on the external advice, the review of peer institutions, and the advice of the University's legal counsel, the HSC and Main Campus recommend that the Faculty adopt a revision to Faculty Handbook Policy E-90 in the form of Exhibit 2 to this Memorandum.



# Exhibit 1

## DRAFT Re-write

### Faculty Handbook Policy E90: Human Beings as Subjects in Research

The University of New Mexico aims to promote a culture of compliance with the highest legal and ethical standards for the conduct of human research. The University recognizes research as one of its chartered enterprises and shares responsibility for promoting and managing this activity with its individual researchers when conducted under its auspices.

To ensure comprehensive protection of the rights and welfare of subjects in human research across a diverse social-behavioral and biomedical research enterprise, the University of New Mexico holds two distinct Federal Wide Assurances (FWAs) approved by the U.S. Department of Health and Human Services, one for the University Main Campus and a separate FWA for the Health Sciences Center (HSC). Under these agreements, the University of New Mexico assures that all of its activities related to human subjects in research (“Human Subjects Research”) are conducted in accordance with all applicable federal regulations (*e.g.*, 45 C.F.R. § 46, 21 C.F.R. § 50, 21 C.F.R. § 56, 21 C.F.R. § 312, 21 C.F.R. § 812).

In the oversight of all Human Subjects Research, the University of New Mexico as a whole, is committed to protecting the rights and welfare of participants in Human Subjects Research consistent with the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

- Respect for Persons
- Beneficence
- Justice

All Principal Investigators and involved researchers engaged in Human Subjects Research are required to:

- Follow the procedures established by the Main Campus Office of the IRB (OIRB), the Main Campus IRB, the HSC Human Research Protections Office and the HSC’s Human Research Review Committees (HRRC), depending on the Principal Investigator’s primary appointment. Procedures are posted on the respective websites and are regularly and continually updated to comply with federal regulations and accreditation standards.
- Obtain approval by IRB procedures. Approval by IRB procedures is required for all researchers engaged in human research.

- Monitor ongoing research and teaching activities under their supervision to ensure that they continue to be conducted in accordance with approved protocols.
- Ensure that all personnel involved in Human Subjects Research under their supervision are appropriately trained on the applicable laws, rules, and regulations regarding Human Subjects Research as well as the Main Campus IRB's or HRRC's policies and procedures, as the case may be, with respect to Human Subjects Research.
- Comply with and ensure compliance with all determinations and additional requirements of the IRB and/or HRRC, as the case may be, with jurisdiction over the research.

## Candyce Torres

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**From:** Kimberly Gauderman  
**Sent:** Friday, February 05, 2016 6:42 AM  
**To:** Martha L Muller; Candyce Torres; Carol Stephens; Vivian Valencia  
**Cc:** Kimberly Gauderman  
**Subject:** Fw: Oral Histories and IRB

Hola Companeras,

As I mentioned in our meeting, my department is having discussions about the IRB and its jurisdiction over our research. Below is a part of our email exchange in the department, produced by a colleague.

We can discuss in our meeting-to-plan-the-meeting whether this is information that might also be helpful to our Committee in our discussion of E90.

Cheers,  
Kymm

Dr. Kimberly Gauderman  
Associate Professor  
Undergraduate Adviser

University of New Mexico  
Department of History  
MSC068760  
1 University of New Mexico  
Albuquerque, NM 87131-0001  
505-277-2451

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If you're interested in the nitty-gritty of it all, here is a detailed elaboration about the place of oral history and IRBs.

The so-called Common Rule (45 CFR 46.102(d)) is what gives the government the ability to require IRB review of all covered human subjects research. (This rule was invented in the aftermath of some pretty horrific cases of medical experimentation on humans with a lack of informed consent, and was designed with biomedical experimentation clearly in mind. There has been some "mission creep" over the years that has led to the current situation, where we are now talking about whether oral history is covered under this rule or not.)

The relevant bit of the Common Rule of concern here is that which defines covered research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Not all forms of human subject research "contribute to generalizable knowledge." According to the AHA, history does not produce such "generalizable knowledge" and hence is not subject to IRB review:



"It is primarily on the grounds that oral history interviews, in general, are not designed to contribute to 'generalizable knowledge' that they are not subject to the requirements of the HHS regulations at 45 CFR part. 46 and, therefore, can be excluded from IRB review. Although the HHS regulations do not define 'generalizable knowledge,' it is reasonable to assume that the term does not simply mean knowledge that lends itself to generalizations, which characterizes every form of scholarly inquiry and human communication. While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences they do not reach for generalizable principles of historical or social development, nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future."

<https://www.historians.org/jobs-and-professional-development/statements-and-standards-of-the-profession/statement-on-oral-history-and-institutional-review-boards>

The Department of Health and Human Services' Office of Human Research Protection (OHRP) has agreed with the AHA that oral history, in general, does not count as contributing to "generalizable knowledge":

"OHRP concurs with the proposed policy stating that oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB)."

<https://research.unl.edu/orr/docs/OHRPResponsetoOralHistories.pdf>

Indeed, according to the oral history activities of the OHRP itself, the ordinary practices of historians to interview, record, present, interpret, and even suggest implications from research are themselves not subject to review:

<http://www.institutionalreviewblog.com/2007/01/generalizable-revisited.html>

As this analysis makes clear, OHRP's own actions, in the course of carrying out its own oral history work, show that interviewing (structured or unstructured), the production of oral histories, and historical interpretations and conclusions made from these interviews and oral histories—and even further suggestions for policy—do not count as “contributing to generalizable knowledge” and are not subject to IRB review.

According to UNM's IRB (the documents recently circulated by Melissa), oral history is generally not subject to review. However, in the UNM IRB's “When do activities...” document, it suggests that oral history research does not require application "if interviews are not intended to draw conclusions, inform policy, generalize findings or be used for future research." This is infelicitously phrased. Research and findings are not the same thing as "generalizable knowledge" under the Common Rule. Paraphrasing this way unnecessarily extends the meaning of "generalizable research" into contradiction with the AHA's statement as well the OHRP's own policy and actual practice. Drawing conclusions from the study of a specific case, suggesting that this might inform policy, or expecting that one's research may be utilized by others in the future are ordinary practices of historians, do not count as contributions to “generalizable knowledge,” and are already not subject to review.

Because we are not producing "generalizable research" according to the very particular federal definition of those terms that authorizes IRB review, oral history research as practiced by historians, including for scholarship and publication, is not generally subject to IRB review.

So what, then, is an example of the kind of research based on oral histories that might actually require IRB review? This would be work that *does* involve the production of "generalizable knowledge." Columbia University has a very clear example outlined in their policy: collecting individual's stories about their experiences in the Vietnam War and doing all kinds of historical work with these stories is not subject to review. Analyzing these oral histories for experiences of PTSD and using this dataset to address a scientific hypothesis and predict the occurrence of PTSD, however, may require IRB review:

<http://www.columbia.edu/cu/irb/policies/documents/OralHistoryPolicy.FINAL.012308.pdf>

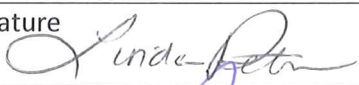
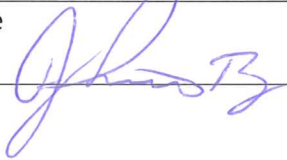
It seems that one easy way to remember this distinction might be to think of "history" vs. "science." History doesn't require IRB review; but science based on oral history interviews might. (This is what I meant in the footnote of my previous email, where I referred to the ways in which disciplinary boundaries lead to differing regulatory consequences.)

So with respect to Elena's email about the advice she received from the IRB office: "If you are performing oral history only for the sake of documenting a story, you do not need to go through the IRB process." This is true, whether for coursework or for scholarship and publication. You can do all the historical work you want to do with oral histories, without review.

Elena also wrote: "If, however, you are doing oral history as research and plan to use those histories as evidence (i.e. primary sources) to 'develop or contribute to generalizable knowledge' then you are required to complete the process." This is also true, but it is important to note that this is *not* the work that she or any of us are likely to be doing as historians. The only kind of work that would "develop or contribute to generalizable knowledge" is of the more scientific variety. Simply using oral histories as evidence in a historical argument, developing conclusions, or even suggesting policy, does not count as the production of generalizable research and so is not subject to review. Using those histories as evidence in a more "scientific" way, however, may lead to the production of generalizable research and may be required to undergo review.

Of course, all this is simply to clarify for us whether IRB review for oral history research is deemed necessary by virtue of employment/study at UNM. Cathleen raised an excellent point--there may be external institutional pressures that require IRB review, completely independently of federal or university policy. Access to archives or records under someone else's jurisdiction (hospitals, tribal offices) may involve any number of requirements, one of which may be a requirement for IRB approval by UNM's IRB. I am curious how our IRB will respond to such requests.



Standard Operating Procedures		
<b>SOP #406.0</b> <b>Revision 0</b>	<b>TITLE: Directed and Self-Audits</b>	Effective Date: 12/1/2015
Approved By: OIRB Director	Signature 	Date 12/2/2015
Approved By: IRB Chair	Signature 	Date 12/3/15

**PURPOSE**

The purpose of conducting audits is to ensure adequate protection of research participants. Audits are used for monitoring the implementation of approved protocols, identifying areas that need improvement, targeting education needs of researchers, and gathering information for continuing improvement of OIRB processes.

**REVISIONS FROM PREVIOUS VERSION**

None

**POLICY**

Audits of approved research protocols may be conducted either for cause or randomly at any time. Audit authority includes but is not limited to the following:

- Observation of the informed consent process;
- Observation of research procedures including interactions and/or interventions with study participants;
- Surveying participants enrolled in the study about the informed consent process and their experience as a participant;
- Review of all documents and materials pertaining to the permission for or conduct of research activities.

When research procedures or interactions with participants are observed as part of an audit, the authorized observer shall acquire prior permission from participants being observed. If the participant is a minor or an adult who did not directly provide informed consent to enroll in the research, audit permission shall be acquired from the parent, guardian, or legally authorized representative who previously provided permission for the minor or adult to enroll in the research.

**RESPONSIBILITIES**

Execution of SOP: Researchers, IRB, OIRB, Research Integrity Officer (RIO).

**PROCEDURE**

*Types of audits*

Audits for cause: If a concern or complaint about the conduct of a research study is discovered or reported to the OIRB staff, any member of the IRB, the university Research Integrity Officer (RIO), or

other administrative official, an audit for cause may be initiated. The determination of the need for an audit for cause shall be made by the IRB chair in consultation with the OIRB Director. Audits for cause may occur at any time. An audit may be study-oriented (focused on a specific study) or researcher-oriented (focused on all the studies of a particular researcher).

Random audits: Approximately 5% of all open, non-exempt research protocols shall be selected for random audit on an annual basis. Random audits may occur at any time. The OIRB will conduct routine audits of studies for the purposes of quality assurance oversight with a specific focus on the following study criteria:

- Recruitment of vulnerable populations;
- Federal funding;
- Involves large numbers of participants;
- PI has large number of active studies and pattern of noncompliance;
- More than minimal risk to participants.

#### *Conducting an Audit*

1. The OIRB has the principal responsibility for conducting audits of research studies involving human participants. At the discretion of the OIRB, assistance conducting an audit may be requested from the IRB chair, RIO, IT staff, or other experts.
2. In order to determine the facts surrounding the conduct of the study and if the study is in compliance with written procedures and regulations, the auditor may review the researcher's files, participant research records, signed consent/assent forms, and other documents that could serve to provide factual information.
3. The auditor may review all records on site and compare those records with information in the OIRB office records to ensure compliance.
4. The auditor may review any written SOPs or procedures and plans that should be followed by the research staff to ensure appropriate conduct of the research.
5. The auditor may conduct interviews with the PI, members of the study team, or research participants.
6. The auditor will record findings during the audit and, when feasible, review the summary of findings with the research staff at the close of each audit day to allow clarifications or additional information to be communicated as appropriate.
7. Alternatively, the OIRB may elect to conduct an audit of consent forms only or other limited scope audits to screen for potential quality issues. For a consent only audit, the researcher will be informed to submit all signed consent/assent signature pages for all participants enrolled during a specified period. These documents must be submitted at the time requested by the OIRB. The researcher will also be notified that failure to submit documents will result in an on-site audit of study documents.
8. External sponsors of human subject research may conduct research compliance audits, investigations, site visits, or evaluations as detailed in the sponsor contract. Audits initiated by research sponsors, internal or external to UNM, normally do not include audit of OIRB files, records, meetings, or interviews with IRB members except as required by a federal agency or with prior written agreement by the IRB chair. Such audits, investigations, site visits and evaluations may be random or for cause and must be coordinated in advance through the OIRB under the direction of the OIRB Director.



### *Confidentiality*

Knowledge of audit procedures and the content of any findings shall be kept appropriately confidential by all parties involved in the audit. A signed confidentiality agreement may be requested of participating parties at the discretion of the OIRB.

### *Notification of Investigators*

The principal investigator of a study randomly selected for audit shall be notified at least five (5) working days in advance of the audit. The principal investigator of a study that has been selected for audit for cause shall be notified at least one (1) working day in advance of the audit.

### *Response to findings*

If, based on the conduct of an audit, the OIRB has reasonable suspicion of non-compliance or of research misconduct as defined by UNM policy, a written Audit Report shall be submitted to the IRB chair. At the discretion of the IRB chair, the IRB members may be notified of some or all individual audit findings.

### *Review by the IRB*

The IRB Chair (and/or IRB) will be given the Audit Report and will make a determination regarding any restrictions or additional monitoring to ensure compliance:

- Study is in full compliance with the regulations and policies, no deficiencies noted;
- Study has objectionable practices or conditions noted, but no major departures from regulations and policies; or
- Study has objectionable practices or conditions representing major departures from regulations and policies.

The study may have additional stipulations or restrictions placed on it or the researcher may be required to attend additional training sessions or other reasonable remedial actions may be taken as agreed upon by a majority of IRB members at a convened meeting.

### *Reports*

A summary report of all audit findings including corrective action plans and preventive measures, but excluding personal identifiers, shall be made to the IO annually.

### **REFERENCES**

45 CFR 46.109(e)

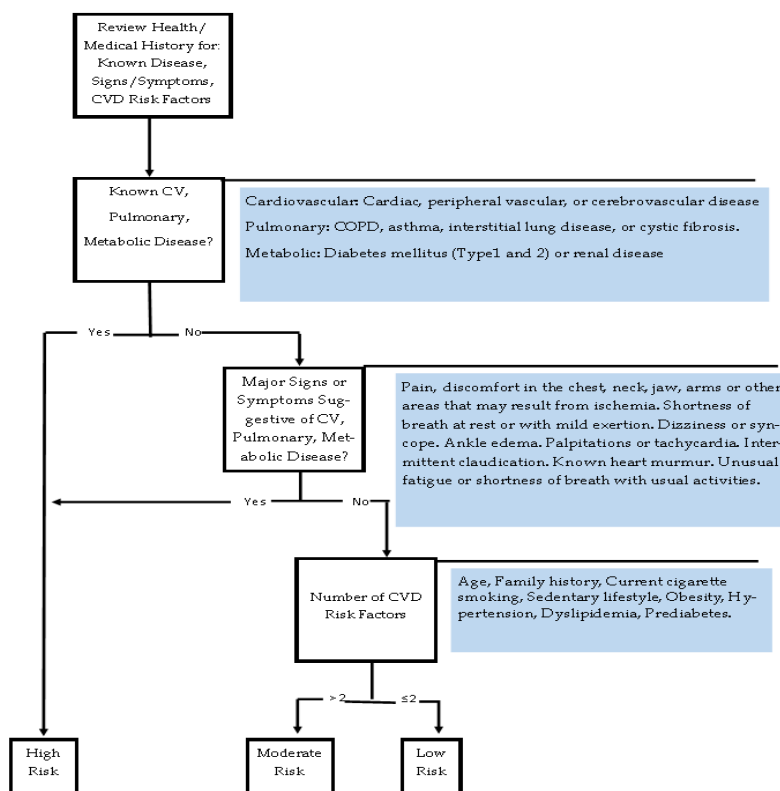
21 CFR 56.109(f)

### Guidance on Research involving VO<sub>2</sub> max Testing

In Exercise Physiology research, it is often disputed whether some physiological tests should be classified as “minimal risk” or “greater than minimal risk”. This guidance highlights the most controversial of these physiological tests – VO<sub>2</sub> max testing, and aims to present the predisposing factors that would determine the review level and information that should be included in the protocol to help aid in this decision.

OHRP (Office for Human Research Protections) defines minimal risk as “the probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life” (45 CFR 46.102(i)). In the case of VO<sub>2</sub> max testing, the potential for harm must be identified and estimated for the proposed participants because different populations may have different responses to the same test. For example, an older population with a history of cardiovascular disease may be at greater risk of harm during the test vs. young healthy trained athletes.

The American College of Sports Medicine has set guidelines for exercise testing and prescription to determine the risk level involved in testing particular individuals/populations (Pescatello, L.S. (2014) *ACSM’s guidelines for exercise testing and prescription*. Philadelphia, PA: Wolters Kluwer/Lippincott Williams & Wilkins Health). The diagram below demonstrates a hierarchy of circumstances that would predispose an individual to being at higher risk.



ACSM's Guidelines for Exercise Testing & Prescription. LWW, 2014 (p.26).

### *Participant Screening:*

1. The first information to review with the participant is their medical history for known disease, signs/symptoms, and cardiovascular (CV) risk factors. If the individual has known CV, pulmonary, or metabolic disease then he/she is considered high risk during  $VO_{2\max}$  testing.
2. If the individual does not have any known diseases then the next step is to review major signs and symptoms suggestive of CV, pulmonary or metabolic disease; these include pain in the chest, shortness of breath, dizziness, ankle edema, etc. If the participant shows signs of any of these then he/she is at high risk.
3. For participants who answer no to the previous two steps, the last step is to review cardiovascular disease (CVD) risk factors. CVD risk factors include: age, family history, current cigarette smoking, sedentary lifestyle, obesity, hypertension, dyslipidemia, and prediabetes.

Regardless of age, if the participant has more than two of these risk factors he/she is considered to be at moderate risk for  $VO_{2\max}$  testing; if they have  $\leq 2$  factors they are at low risk. Medical professionals should be present during testing of moderate to high risk populations and accessible for low risk populations.

### *Preparing the IRB Protocol:*

For studies using  $VO_{2\max}$  testing, the following items should be addressed in the protocol:

- the population being studied (age, gender, health status),
- screening procedures to determine health conditions and risk factors,
- a list of the known risks of  $VO_{2\max}$  testing,
- actions that will be taken if known risks of the study occur (ie. terminating the test), and
- procedures for medical oversight (who will be present/accessible) during testing.

Keep in mind that UNM IRB reviews studies involving greater than minimal risk procedures at full board, while studies involving populations at low risk ( $\leq 2$  CVD risk factors) can be considered for expedited review.

## **VO<sub>2</sub> Submaximal Testing**

The use of a submaximal exercise test vs. a maximal test depends largely on the reasons for the test, risk level of the individual, and availability of appropriate equipment and personnel. It should be noted that submaximal measures are not as accurate as maximal testing measures as the test determines the heart rate response to one or more submaximal work rates and uses the results to predict  $VO_{2\max}$ . Additional measures to collect should include heart rate, blood pressure, workload and rating of perceived exertion and other subjective indices as valuable information regarding one's functional response to exercise. ASCM asks that medical professionals be present during the testing of high risk populations and accessible for moderate to low risk populations.

Similar to exercise protocols using  $VO_{2\max}$  testing, protocols performing submaximal tests should also include: the population being studied (age, gender, health status), screening procedures to determine health conditions and risk factors, a list of the known risks of  $VO_{2\max}$  testing, actions that will be taken if known risks of the study occur (ie. terminating the test), and the name of the medical oversight whom will be present/accessible during testing.



## Self-Assessment Tool

This form is for researchers to use to conduct self-assessments of their IRB approved studies to ensure those studies are being conducted in compliance with the approved procedures and IRB regulations and policies. The UNM IRB encourages researchers to conduct self-assessments at least annually. The IRB may also request that self-assessments be conducted and reported to the UNM IRB. Please keep copies of completed assessments with your IRB related records. If needed, use additional pages for notes.

1805 Sigma Chi NE

Tel: (505) 277-2644

Fax: (505) 277-2697

Email: [IRBMainCampus@unm.edu](mailto:IRBMainCampus@unm.edu)

### Project Identification

<i>Principal Investigator (PI)</i>		<i>Student Investigator (SI)</i>		<i>Assessment completed by:</i>	<input type="checkbox"/> PI	<input type="checkbox"/> SI	<i>Date Conducted:</i>	
<i>IRB reference number:</i>		<i>Project title:</i>						

### Records Review

<b>1. Approval and Record Keeping</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
Does the project have current IRB approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all IRB related records being retained in an accessible location? All records must be kept for at least 5 years after closure of the study. Examples: approval letters, signed applications, approved consent forms, correspondence, protocol, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all study team members current (completed in last 3 years) in their human subjects' protections training (CITI)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all study team member training certificates on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have all revisions to the project been reviewed and approved by the IRB prior to implementation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>2. Participant Recruitment and Screening</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
Were participants identified and recruited according to the procedures approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Were the advertising and/or recruitment materials used approved by the IRB prior to use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Were all inclusion and exclusion requirements followed as listed and approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If <b>no</b> , were the deviations reported to the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
For participants that did not meet eligibility requirements (failed screening), were IRB approved procedures followed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
How many participants have been enrolled to date?				
Is the number of participants enrolled no greater than the IRB approved participant enrollment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>3. Informed Consent Process and Documentation</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
Was the IRB approved stamped version of the consent(s)/assent(s) used to enroll participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If using an oral or online consent, was the IRB approved script/text used to enroll participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Were any expired consent forms used to consent participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Informed Consent Process and Documentation (cont.)</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
Did an IRB approved study team member obtain consent from all participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a signed and dated consent form on file for every participant enrolled in the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Did an IRB approved study team member sign and date each consent form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Do the participant and researcher consent dates match?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If changes were made to the consent form, were the changes submitted and approved by the IRB prior to use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Did every participant receive a copy of the consent form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>4. Research Protocol</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
Was the research conducted consistent with the description and procedures as approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Were the data collection tools (e.g. surveys, interview questions, etc.) used approved by the IRB, prior to use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
For each participant, was consent obtained prior to any study procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all participant compensation records being documented and stored appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If changes were made to the protocol, were the changes submitted and approved by the IRB prior to implementation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have all reportable events been addressed as required by the UNM IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>5. Privacy, Data Storage, and Confidentiality</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
Were privacy standards and procedures implemented as approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If you collected data anonymously, has anonymity been maintained in the physical/electronic records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are signed consent forms and coded study data stored separately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are signed consent forms secured as approved by the IRB? Provide location:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are study data secured as approved by the IRB? Provide location(s):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If electronic data are being stored on a desktop, is it secured as approved by the IRB? Provide computer location:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are electronic data secured (e.g. password protected, encrypted, etc.) as approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are you aware of the security on your computer and server?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is access to computer, electronic files, and physical files limited to appropriate study personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Was/are identifiers stored/disposed of as approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Was/is the research data (raw) stored/disposed of as approved by the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

6. Continuing Review	Yes	No	N/A	Notes
Are you aware of when the IRB approval for this project expires? Expiration date:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have you placed a reminder on your schedule to submit continuing review documents 30 days prior to expiration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have there been any lapses in IRB approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If <b>yes</b> , did you report any research activity that was done during the lapse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have there been any adverse events, unanticipated problems, or complaints while conducting this research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If <b>yes</b> , have all details been reported to the IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has the researcher become aware of new information that changes the risk benefit ratio of this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has the number enrolled on the continuing reviews included individuals who consented but did not complete the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Study Completion	Yes	No	N/A	Notes
Is data collection complete for this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have all identifiers been destroyed in accordance with IRB approved procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If <b>yes to both questions above</b> , submit a Closure Application (and supporting documentation) to the OIRB.				

Certification			
I certify that all information provided in this document is accurate and that the IRB has been informed of any necessary issues.			
Principal Investigator Signature		Student Investigator Signature	
Date		Date	

## Guidance on Research involving Alcohol Administration

The University of New Mexico conducts research on many types of disorders, including substance abuse and other addictive behaviors. Therefore, it is important to provide recommendations and establish guidelines for working with research participants who may become intoxicated as part of participation in a research study.

### Considerations

- Principal Investigators (PIs) are ultimately responsible for ensuring the safety of their research participants and staff. If it is anticipated that the study will involve intoxicated participants, it is recommended that research staff are appropriately trained and a study specific checklist or plan be developed using this guidance.
- Participants should be appropriately screened, depending on the nature of the research, including verification of legal drinking age.
- Consider whether proposed participants are drug or alcohol abusers, and whether their participation is likely to expose them to harm.
- If potential participants have completed the initial phase of treatment for addiction and progressed into rehabilitation or recovery, their involvement in research in which alcohol will be administered requires extremely strong scientific justification and risk/benefit assessment.
- It is considered inappropriate to administer alcohol to any recovering alcoholic who is abstinent and living a sober life in the community.
- Adequate provisions must be made to eliminate the risk of alcohol impairment before the participant leaves the research site.
- It is the PI's responsibility to procure all necessary equipment for their studies, including breathalyzer, pregnancy tests, specimen cups, and any other materials needed for testing (e.g. calibration supplies, latex gloves, food/drink, droppers/pipettes, etc.). Equipment used to assess blood alcohol level (BAL) must be routinely calibrated and a procedure for assessing accuracy and reliability of the equipment is required in the research protocol.

### Recommended Guidelines

#### *Screening participants for an alcohol challenge study:*

- Potential participants should be screened and excluded for alcohol dependence (recommend use of Alcohol Dependence Scale (Harvey A. Skinner and John L. Horn); score of 8 or higher is considered dependent). Consider providing these individuals with referrals for community addiction resources (e.g. UNM Alcohol Clinic).
- Exclude individuals who are in recovery for alcohol or drug addiction.
- Screen individuals for medications that are contraindicated for alcohol use including, but not limited to:
  - antidepressants,
  - anxiolytics,
  - daily insulin,
  - long term antibiotics or pain medication,
  - medications for ADD or ADHD (e.g. Ritalin, Adderall).
- Possibility of pregnancy in females should be assessed using urine testing prior to each

alcohol administration.

- Consider excluding individuals who are trying to reduce their alcohol consumption.

*Participants who become intoxicated from participation in a study:*

- In New Mexico, a person can be arrested for driving with a BAL (blood alcohol level) **>.000**. A person can be convicted of DWI even if the breath or blood test is below the legal limit (.080) if it is proven that their ability to drive was impaired to the slightest degree by drugs or alcohol. Therefore, it is recommended that you do not allow any participant (or potential participant) to drive themselves home with a BAL **>.000**. In order to release participants with a BAL **>.000**, you must have documented IRB approval to do so, as well as a clearly documented procedure for release of these participants.
- Participants who have a BAL **>.000** can be offered a variety of options for release:
  - Have a friend or family member pick them up.
  - Wait until their BAL = **.000** and then drive home.
  - Cab ride home.
  - (If medically indicated), walk the person to UNM Hospital Emergency Room or call 911. Do not leave the participant unsupervised until a resolution is reached (so that they do not leave and drive intoxicated).
- During detoxification, allow participants to wait and rest in a comfortable area with bathroom facilities nearby that do not require unnecessary effort to access. Provide water, non-alcoholic beverages, and snacks as needed.
- A detoxification checklist is provided (Appendix 1) that contains sample procedures to follow and document the detoxification process.
- If the participant has a BAL  $\geq .08$  (considered legally intoxicated) and insists on driving home and/or leaves without authorization, and/or is belligerent and you are worried about your safety and/or the safety of others, notify police with jurisdiction over the geographical areas of the performance site (e.g. APD or UNM police).

See NIAAA guidelines: <http://niaaa.nih.gov/Resources/ResearchResources/job22.htm>

### Appendix 1 Detoxification Checklist

If person is intoxicated from participation in a research study:

- Allow the participant to wait and rest in a comfortable area with bathroom facilities nearby that do not require unnecessary effort to access. Provide food and water as needed.
- Monitor the participant on a continuous or near-continuous basis in a way that is non-intrusive.
- Take a breathalyzer reading every 30 minutes until their BAL = .000. Release BAC values should be confirmed by at least two readings.

BAL	Time	Level
30 min		
60 min		
90 min		
120 min		

NOTE: Participants are not to drive home; in NM, you can get arrested for driving with a BAL >.000. It is important to not leave the participant unsupervised until the individual is sober.

If their BAL increases, they are not willing to retake a breathalyzer, or if their BAL does not decrease in the allotted timeframe:

- Document that the following were suggested by initialing each option:
  - \_\_\_\_\_ 1. Have a friend or family member pick them up.
  - \_\_\_\_\_ 2. Wait until their BAL is .000 and then drive home.
  - \_\_\_\_\_ 3. Provide them with a cab ride home.
  - \_\_\_\_\_ 4. (If medically indicated), walk them to UNM Hospital Emergency Room or call 911.
- Document which option the participant has chosen:

**If the participant has a BAL  $\geq$  .08 and insists on driving home and/or leaves unadvised, and/or is belligerent and you are worried about your safety and/or the safety of others, you must call campus security or the police. This is the only time you can violate confidentiality.**

If this step is necessary, explain what happened and why this step was taken.

\_\_\_\_\_

\_\_\_\_\_

Researcher Signature/Date: \_\_\_\_\_

## **When do activities need Institutional Review Board (IRB) review and approval?**

(If there are any questions regarding what does or does not require UNM IRB review, contact OIRB at 505-277-2644)

Any activity that meets either (a) the Department of Health and Human Services (DHHS) definition of both “research” and “human subjects” or (b) the Food and Drug Administration (FDA) definitions of both “clinical research” and “human subjects” requires review and approval by the University of New Mexico (UNM) Main Campus IRB (or deferral to an appropriate IRB).

**Research:** “A systematic investigation designed to develop or contribute to generalizable knowledge” [[45 CFR 46.102\(d\)](#)].

**Human Subjects (DHHS):** “A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [[45 CFR 46.102\(f\)](#)].

- **Intervention:** includes physical procedures such as blood samples, MRI, x-rays; or the manipulation of the environment in order to stimulate certain types of behavior.
- **Interaction:** includes interpersonal communication between the investigator and subject through surveys, interviews, administration of educational tests, etc.
- **Identifiable:** the identity of the subject is or may readily be ascertained by the investigator with the information obtained as part of the research.
- **Private information:** a context in which an individual can reasonably expect that no observation or recording is taking place or information that is provided for specific purposes by an individual and which the individual can reasonable expect will not be made public.

**Clinical Investigation:** “Involves use of a test article (i.e. drug, device, food substance or biologic), one or more human subjects, meets requirements for prior submission to FDA , or results are intended to be part of an application for research or marketing permit” [[21CFR 56.102](#)].

**Human Subjects (FDA):** “An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.” [[21CFR 56.102\(e\)](#)] (Drug, Food, Biologic)

**Human Subjects (FDA for medical devices):** “A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.” [[21 CFR 812.3\(p\)](#)] (Medical Devices) NOTE: This definition includes use of tissue specimens even if they are deidentified.

In cases in which any other federal agency apply, institutional oversight of the activity follows the definitions for “research” and “human subjects” as defined by the relevant agency as appropriate. For Department of Defense-supported research, institutional oversight of the activity follows the definitions of “research” and “experimental subject” as defined by Department of Defense regulations [[DoD Directive 3216.02](#)].

**Table 1: Examples of What Does and Does Not Require UNM IRB Review and Approval Prior to Initiation of Research**

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
<b>Repositories</b> (e.g. data, specimen, etc.)	Preliminary activities designed to help the Investigator refine data collection procedures. This data is to be included in the publication.	YES
	A storage site or mechanism by which identifiable human tissue, blood, genetic material or data (transcriptions/audio/video recordings) are stored or archived for research by multiple Investigators or multiple research projects.	YES
	Activities (e.g. review of medical or educational data, queries, etc.) intended only to assess the feasibility of future research. <i>Note that UNM or other “covered entity” might need to obtain researcher certifications for a review preparatory to research for HIPAA compliance purposes.</i>	NO
<b>Research Involving Only Decedents</b>	Research involving only data or tissue obtained from individuals who are deceased prior to the conduct of the research. There must not be any interaction or intervention with living individuals, or collection of private data or specimens associated with living individuals. Under HIPAA regulations, researchers with UNM or other “covered entity” must obtain a HIPAA waiver of authorization for review of identifiable protected health information (PHI).	NO <i>(contact Privacy Officer for HIPAA requirements)</i>
<b>Standard Diagnostic, Therapeutic, or Teaching Procedures</b>	The collection of data about a series of established and accepted diagnostic or therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.	YES
	An alteration in standard patient care or assignment for research purposes.	YES
	A diagnostic or experimental procedure added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a student or patient but not for the purposes of research.	NO
<b>Case Report – Clinical</b>	Report about three or less clinical experiences/ observations identified in the course of clinical care (including therapy), not involving biospecimens or FDA regulated products (e.g. drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE. Case reports are generally done by retrospective review of medical records and highlights a unique treatment, case or outcome. Please note: UNM HIPAA policies apply to this project. Contact UNM’s Privacy Officer ( <a href="http://hsc.unm.edu/admin/compliance/HIPAA.html">http://hsc.unm.edu/admin/compliance/HIPAA.html</a> ) for assistance in complying with UNM’s HIPAA policies.	NO



<b>Case Report – Other</b>	Report about experiences or observations associated with three or less individuals with no intent to generalize information.	NO
<b>Quality Assurance and Quality Improvement Activities – Clinical or Procedures</b>	Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operation. The activity is designed to bring about immediate positive changes in the delivery of health care, programs, or business practices at the University of New Mexico. There must be no plans to disseminate the knowledge beyond UNM.	NO
<b>Quality Assurance and Quality Improvement Activities – Non-Clinical</b>	Data collected with the limited intent of evaluation and improving existing services and programs or for developing new services or programs at the University of New Mexico. There must be no plans to disseminate the knowledge beyond UNM. Examples include teaching evaluations or customer service surveys.	NO
<b>Innovative Procedures, Treatment, or Instructional Methods</b>	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants [more than three (3)]. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.	YES
	The use of innovative interventions that are designed solely to enhance the wellbeing of an individual patient or client and have a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the particular individual.	NO*
<b>UNM functioning as the Coordinating Center for a Multi-Center Research Project</b>	UNM <i>in not</i> an enrolling site and the UNM PI has agreed to serve as the coordinating center for a multi-center project, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
	UNM <i>is</i> an enrolling site and the UNM PI has agreed to serve as the coordinating center for a multi-center project, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
<b>Establishing Subject Pools</b>	Activities with the purpose of recruiting subjects for future research studies.	YES
<b>Pilot Studies</b>	Pilot studies involving human subjects are considered human subject research studies.	YES
<b>Research Using Publicly Available Data Sets</b>	Use of publicly available data sets that do not include information that can be used to identify individuals. “Publicly available” is defined as information shared without conditions on use. This may include data sets that require payment of a fee to gain access to the data.	NO
<b>Research on Organizations</b>	Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources. Does not	NO

	include identifiable private information about individual members, employees, or staff of the organization.	
<b>Community Service Projects</b>	Donated service or activity that is performed by someone or a group of people solely for the benefit of the public or its institutions.	NO <i>(but if human subject data are collected during the activity to be used for research protocols, submission to the IRB is required)</i>
<b>Secondary use of research data</b>	Analysis of data gathered for a previous research protocol not related to current proposal and the data are de-identified. De-identified means removal of the 18 identifiers recognized by the HIPAA regulations with can be found at the following link: <a href="http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#standard">http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#standard</a>	NO <i>(but if data has direct or indirect identifiers, submission is required to the IRB)</i>
<b>Behavioral and Social Sciences Research</b>	Focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.	YES
<b>Oral History</b>	Interviews concerning the past that collect and interpret the voices and memories of people as a method of historical documentation and that are preserved by placement in some form of repository or archive for access by other researchers. Research activities conform to the Principles of Best Practices of the Oral History Association: <a href="http://www.oralhistory.org/about/principles-and-practices">http://www.oralhistory.org/about/principles-and-practices</a>	NO If interviews are not intended to draw conclusions, inform policy, generalize findings or be used for future research
<b>Journalism</b>	Activities focused on the collection, verification, reporting, and analysis of information or facts on current events, trends, issues or individuals involved in such events or issues. There is no intent to test hypotheses, and activities cannot reasonably be characterized as a systematic investigation. Research activities should be consistent with the Code of Ethics of the Society of Professional Journalists <a href="http://www.spj.org/ethicscode.asp">http://www.spj.org/ethicscode.asp</a>	NO <i>(but exercise of professional ethics is expected)</i>
<b>Master's Thesis/Doctoral Dissertation/Capstone</b>	Graduate studies which involve human subjects or a clinical investigation which results in a thesis, a dissertation research or a capstone.	YES

<b>Student Practicum and Internship</b> (Professional schools within UNM which actively seek opportunities for their students to become involved in “real world” activities or work assignments that will introduce them to and, in some cases, provide practical experiences in their chosen profession)	A practicum/internship that falls within the work scope of a local, state, or federal agency (e.g. Public Health Agency) or employment by private industry involving data collection for non-research purposes. No <i>a priori</i> research design or intent.	NO
	Use of or access to human subjects data previously collected for non-research purposes (perhaps through a circumstance like the one above) in a systematic investigation designed to contribute to generalizable knowledge, one indicator of which is publication.	YES
	Independent research project not falling within the scope of a previously approved project.	YES
	Participation with or providing services to a UNM PI conducting IRB-approved research. No work outside the scope of the IRB approval.	YES <i>(amendment to add student if providing research assistance at level of study personnel)</i>
<b>Classroom Assignments/Research Methods Classes</b>	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge or contribute to generalizable knowledge (e.g. published or disseminated at a capstone or conference).	NO <i>(instructors have an obligation to ensure students meet professional and ethical standards)</i>
<b>Internet Research</b>	Research involving online interactions with human subjects where identifiers are known or can be ascertained such as email addresses, certain websites and bulletin boards. Also includes data collected where an individual cannot be directly identified but data are collected through intervention or interaction with research subjects.	YES
	Research involving online interactions with/data collection from human subject internet community members that may expect a level of privacy and confidentiality such as vulnerable populations (HIV patients, alcoholics anonymous, sexual abuse survivors, etc.). Also includes data collected where an individual cannot be directly identified but data are collected through intervention or interaction with research subjects.	YES

\* Unless FDA regulations requiring IRB approval apply such as use of: articles (e.g. drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE.

**Standard  
C190 #1****Lecturer Annual and Promotion Reviews:  
Main and Branch Campus Implementation  
Standard**

Approved By: Faculty Senate Policy Committee

Effective Date: **Draft December 19, 2015**

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Policy Committee. Collaboration on revisions with relevant administration and other interested parties is expected.

This document provides standards and guidelines applicable to main campus and branch campuses to ensure compliance with Policy C190 “Lecturer Annual and Promotion Reviews.”

**Guiding Principles**

The following principles should be followed regarding annual and promotion reviews for lecturers:

Promotion Eligibility

A specified number of years of continuing service are required for promotion eligibility within the Lecturer ranks. Academic Affairs has interpreted this to include prior years of service as a visiting lecturer (or similar) at UNM. C190 also states that years of service at other institutions of higher learning may be counted, at the discretion of the department chair and/or associate chair. Similar years of service may be considered in offering an initial UNM faculty appointment.

There has been some confusion regarding when a lecturer is reviewed for promotion to Senior lecturer; is it in year five or in year six. Academic Affairs advises that the earliest a Lecturer can be considered for promotion to senior lecturer is during the sixth year.

**Promotion Procedures and Standards**

Policy C190 states that “each college or school is responsible for developing detailed procedures for implementation of C190. These procedures require approval by the college/school faculty members and dean, with final approval by the Provost.” C190 anticipates that procedures will be “similar to the process used to evaluate tenure-track and clinician educator (CE) faculty promotions, and should include input from departmental faculty members, including other lecturers, the department chair, and the school or college dean, who may use an ad-hoc advisory committee.” As is the case for the professoriate, the Provost or Chancellor for Health Sciences makes the final decision on promotion.

With regard to standards, in the absence of developing specific criteria for these appointments, academic units may wish to look to their professorial promotion and tenure procedures and standards, while eliminating requirements for creation and dissemination of new knowledge (research and scholarship). The remaining standards for teaching and service would be adequate and appropriate.

### **Promotion Packages due March 1<sup>st</sup>**

Academic Affairs has determined that a deadline for submittal of recommendations and review materials for lecturer promotion in rank to the Provost should occur no later than March 1<sup>st</sup> of each academic year, if promotions are to take effect in the subsequent academic year. However, academic units are encouraged to submit promotion packages by the end of the fall semester to avoid Lecturer promotion files arriving at the same time as the professoriate review files later in the spring semester.

### **Progression through Ranks**

The eligibility statement for promotion to principal lecturer states that “upon the completion of a minimum of eleven years of service, a senior lecturer will be eligible to apply for promotion to principal lecturer.” This implies one must proceed through the ranks in sequence and the rank of senior lecturer could not be skipped, even if 11 years of service are identifiable. However, Academic Affairs has not held lecturers to a requirement that they must first stand for promotion in rank to senior lecturer before seeking promotion in rank to principal lecturer. To do so would be inconsistent with other aspects of eligibility requires described above.

### **Promotion Compensation Increases**

Policy C190 states that upon promotion in rank, a lecturer may expect “a salary increase that is consistent with the policy and practices of the HSC, the College or School, and the Department.” However, Academic Affairs currently provides a recurring revenue allocation to its academic units to ensure a minimum of \$3,000 for a promotional increase attaining senior lecturer, and a minimum of \$4,000 for principal lecturer.

### **Lecturer Appointments vs. Lecturer Ranks**

Three distinct appointments are available for lecturers: lecturer I, lecturer II, and lecturer III. The criteria for holding these lecturer appointments are found in the *Faculty Handbook* Section B2.3.2. It may be appropriate from time to time for someone to move to a different lecturer appointment if it better reflects their current credentials, experience, and/or role. For example, it might be justifiable for someone to move from lecturer II to lecturer III upon obtaining a terminal degree. Changes in appointment title present opportunities for academic unit to do a compensation equity analysis and seek approval to make salary adjustments; however, Academic Affairs does not currently provide new recurring revenue for salary increases for this reason. Currently Academic Affairs only provides new recurring revenue for certain promotions in rank. These include promotions through the professorial and lecturer ranks.

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## **DRAFT HISTORY**

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## HISTORY

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[handbook@unm.edu](mailto:handbook@unm.edu)

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## C05: Rights and Responsibilities at the University of New Mexico

### Policy

*(Adopted by the Regents, October 1965; revised August 1970, September 1975, November 1981, and July 1982)*



Section 6 as follows is added to the Statement as an interim measure pending further study and the adoption of a permanent policy:

6. One of the important aspects of academic due process is a clear statement of the kinds of conduct that will lead to University disciplinary action. It is deemed important, therefore, to clarify the type of conduct which shall be considered to affect adversely the University's educational function, to disrupt community living on campus, or to interfere with the right of others to the pursuit of their education or to conduct their University duties and responsibilities. In an effort to accomplish this, but without intending the statement to be all-inclusive, the following is hereby set forth:

(a) Any member of the University community—student or member of the faculty or staff—who commits or attempts to commit any of the following acts of misconduct shall be subject to appropriate disciplinary procedures and sanctions:

(i) Obstruction or disruption, by any means, of teaching, research, administration, disciplinary procedures, or other University or University-authorized functions, events, or activities.

(ii) Unauthorized or prohibited entry into or onto, or unauthorized or prohibited occupation or use of, any University facility, building, vehicle, or other University property.

(iii) Physical abuse, the threat of physical abuse, or intimidation of any person on campus or at any University-authorized function or event, or other conduct which threatens or endangers the health, freedom of action, or safety of any such person.

(iv) Theft of, damage to, or defacement of property of the University or the property of any person on campus. (Any student or member of the faculty or staff who steals, damages, or defaces University property shall reimburse the University to the full extent of the University's loss.)

(v) Denial of, or interference with, any person's lawful right of, access to, use of, or exit from any University facility or with any other lawful right of any person on the campus.

(vi) The destruction of, or damage to, property of the University or of others on campus by setting a fire without proper authority.

(vii) Use or possession on the campus of firearms, ammunition, or other dangerous weapons, substances, or materials, or of bombs, explosives, or incendiary devices, except as authorized.

(viii) Aid to others in committing or inciting others to commit any act of misconduct set forth in 6(a)(i) through 6(a)(vii).

(ix) Any act that demonstrates the probability that the person constitutes a physical danger to himself or others on campus.

(x) Willfully refusing or failing to leave the property of, or any building or other facility owned, operated, or controlled by the Board of Regents upon being requested to do so by the President, if the person is committing, threatening to commit, or inciting others to commit, any act which would disrupt, impair, interfere with or obstruct the lawful mission, processes, procedures or functions of the University. As used herein, "President" means the President (or acting President) of the University or any person or persons designated by him to act on his behalf.

(xi) Any other acts or omissions which affect adversely the University's educational function, disrupt community living on campus, interfere with the rights of others to the pursuit of their education, or affect adversely the processes of the University.

(b) Sanctions:

(i) Any student who violates any of the rules set forth in 6(a)(i) through 6(a)(xi) shall be subject to censure, warning, disciplinary

probation, suspension, or expulsion.

(ii) Any member of the faculty or staff who violates any of the rules set forth in 6(a)(i) through 6(a)(xi) shall be subject to censure, warning, disciplinary probation, or dismissal.

(iii) As used in 6(b)(i) and (ii),

a) "Censure" means a written reprimand or expression of disapproval.

b) "Warning" means an oral censure.

c) "Disciplinary probation" means the establishment of a time period during which further acts of misconduct may or will result in more severe disciplinary sanctions depending on the conditions of the probation.

d) "Suspension" means losing student status for a period of time specified in the terms of the suspension. A suspension may commence immediately upon a finding of a violation or it may be deferred to a later time.

e) "Expulsion" means losing student status for an indefinite period of time. Readmission may not be sought before the expiration of two years from the date of expulsion.

f) "Dismissal" means a termination of employment, either for a stated time period or indefinitely.

(c) If any of the acts of misconduct set forth in 6(a)(i) through 6(a)(xi) are committed by a person who is not a student or member of the faculty or staff, such person may be denied admission, readmission, or employment by the University.

As noted above, the Regents and the vast majority of students, faculty, staff, alumni, and citizens share the same goal for the University—that it be a stable and peaceful center of teaching, research, discussion, learning, and service, free from coercion and unlawful use of force. In situations where the stability and peace of the institution are threatened, extraordinary measures are required. The Regents are determined to use all lawful means to assure the continuity and the integrity of the educational process at the University. As part of this effort, we adopt the following as an interim measure pending further study and adoption of permanent policy:

#### **STATE OF EMERGENCY**

1. As used in this Policy:

a) "President" means the President (or acting President) of the University or any person or persons designated to act in his behalf for purposes of these rules.

b) "Official" means any person authorized by the President to act on behalf of the University.

c) "Student" means a person who is a student at the University in an undergraduate, graduate, or professional program on campus, whether for credit or no credit, full- or part-time.

d) "Visitor" means any person on campus who is not a student or member of the faculty or staff.

e) "Person" means any student, member of the faculty or staff, or visitor.

2. The President is authorized to declare a State of Emergency at the University upon finding by him that the orderly processes of the University are seriously threatened. In making such a finding the President shall consider whether disruptive activities are such as to require immediate, extraordinary measures to safeguard persons or property or to maintain the University's educational function. As soon as reasonably possible after the Declaration of Emergency, the President shall inform available Regents of his action. When the President determines that the serious threat has passed, he shall, after consultation with available Regents, declare the State of Emergency to be at an end.

3. a) During a State of Emergency, the President, in the exercise of reasonable judgment in the circumstances, is authorized to take whatever actions he finds necessary in order to safeguard persons or property or to maintain the University's educational function. Such actions shall remain in effect during the State of Emergency unless sooner canceled by the President. During a State of Emergency, the President may, if in his judgment the circumstances warrant it, suspend University activities for a day or a portion thereof.

b) During a State of Emergency, the violation by any person of a presidential order or ruling under 3(a) of this Policy, or the commission during such State of Emergency of any act or acts of misconduct of the kind set forth in Section 6(a)(i) through 6(a)(xi) of the Regents' Statement on Rights and Responsibilities will be considered an offense of the graves nature, and sanctions (as listed in Section 6 of the Statement on Rights and Responsibilities) appropriate to the gravity of such offense or offenses shall be imposed.

c) A visitor who, after appropriate hearing, is found to have violated a presidential order authorized by Section 3 of this Policy may be denied admission to and employment by the University.



4. During a State of Emergency, any person who, after being requested to do so by a properly identified official and after being advised by such official of the sanction for failure to identify oneself, fails to identify himself by name and status as a student, member of the faculty or staff, or visitor to such official shall have imposed upon him, after appropriate hearing, the sanctions set forth in Section 6 of the Statement on Rights and Responsibilities.

State law establishes the second Monday in March for the Regents' annual organization meeting, at which time officers are elected for the ensuing year. Quarterly meetings are required by law, but in actual practice the Regents convene on an average of ten times annually.

The University, largest of the seven state institutions of higher learning, is supported chiefly by appropriations made by the State Legislature, by income from the rental of lands granted to it by the Federal Government, by the income from royalties on the oil taken from these lands, and by student fees.

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New Mexico's Flagship University

## C05: Rights and Responsibilities of UNM Faculty

Approved By: Faculty Senate

Effective Date: **Draft 12/31/15**

Responsible Faculty Committee: [Operations Committee](#)

Office Responsible for Administration: [Office of the Provost](#)

Legend: Text in Blue: Language copied from AAUP Statement of Professional Ethics

Revisions to the Policy Rationale, Policy Statement, and Applicability sections of this document must be approved by the full Faculty Senate

### POLICY RATIONALE

Membership in the academic profession carries with it special responsibilities. This Policy document lists a variety of faculty responsibilities based on Statement of Professional Ethics published by the American Association of University Professors.

### POLICY STATEMENT

The rights and responsibilities defined in this document assist faculty in the [exercise of their responsibilities to students and colleagues, their conduct when undertaking sponsored research, speaking as citizens, or resigning](#) from UNM. The enforcement of these responsibilities will be made in accordance with Policy C07 “Faculty Discipline.”

1. As academic professionals, faculty [seek and state the truth as they see it](#), and are responsible for:

- [developing and improving their scholarly competence;](#)
- [exercising critical self-discipline and judgment in using, extending, and transmitting knowledge, and](#)
- [ensuring that any subsidiary interests do not seriously hamper or compromise their freedom of inquiry.](#)

2. As teachers, faculty shall [encourage the free pursuit of learning in their students](#) and are responsible for:

- [demonstrating respect for students as individuals;](#)
- [adhering to their proper roles as intellectual guides and counselors;](#)
- [making every reasonable effort to foster honest academic conduct;](#)
- [ensuring that their evaluations of students reflect each student’s true merit;](#)
- [respecting the confidential nature of the faculty/student relationship;](#)

- avoiding any exploitation, harassment, or discriminatory treatment of students;
- acknowledging significant academic or scholarly assistance provided by students; and
- protecting students' academic freedom.

3. As colleagues, faculty are members of a community of scholars and are responsible for:

- avoiding discrimination or harassment of colleagues;
- respecting and defending the free inquiry of associates, even when it leads to finding and conclusions that differ from their own;
- acknowledging academic debt and string to be objective in their professional judgment of colleagues; and
- sharing responsibilities for shared governance.

4. As members of an academic institution, faculty seek to be effective teachers and scholars and are responsible for:

- observing the published policies of the institution, provided the policies do not contravene academic freedom, they may maintain the right to criticize and see revision;
- giving due regard to their paramount responsibilities within their institution in determining the amount and character of work done outside it;
- recognizing the effect of any decision to interrupt or terminate their service on the program or institution, and giving due notice of their intentions.

5. As members of their community, faculty have the rights and obligations of other citizens and are responsible for:

- measuring the urgency of these obligations in the light of their responsibilities to their subject, to their students, to their profession, and to their institution; and
- avoiding creating the impression of speaking or acting for their institution when they are speaking or acting as private person.

As citizens engaged in a profession that depends upon freedom for its health and integrity, professors have a particular obligation to promote conditions of free inquiry and to further public understanding of academic freedom.

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## APPLICABILITY

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All UNM academic faculty.

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## DEFINITIONS

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No specific definitions are required for the Policy Statement.

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Policy and Operations Committee in consultation with the responsible Faculty Senate Committee listed in Policy Heading.

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## WHO SHOULD READ THIS POLICY

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- [Faculty](#)
- [Department Chairs](#)
- [Academic deans and other academic administrators and executives](#)

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## RELATED DOCUMENTS

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### *UNM Regents' Policy Manual*

[Policy 2.1](#) "Free Expression and Advocacy"

[Policy 2.4](#) "Diversity and Campus Climate"

[Policy 4.2](#) "Student Code of Conduct"

[Policy 4.8](#) "Academic Dishonesty"

[Policy 5.1](#) "The Faculty's Role in the University's Mission"

[Policy 5.5](#) "Outside Employment"

[Policy 6.4](#) "Employee Code of Conduct and Conflicts of Interest"

[Policy 6.5](#) "Political Activity by Employees"

### *Faculty Handbook*

[A50](#) "The Faculty's Role in the University's Mission"

[C07](#) "Faculty Discipline"

[C09](#) "Respectful Campus"

[C130](#) "Outside Employment"

[C150](#) "Political Activity"

### *University Administrative Policies*

[Policy 2200](#) "Whistleblower Protection and Reporting Misconduct and Retaliation"

[Policy 2060](#) "Political Activity"

Policy 3720 "Conflicts of Interest"

Policy 3740 "Media Response"

### *Pathfinder*

Student Code of Conduct

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## CONTACTS

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[Direct any questions about this policy to the Office of the Provost.](#)

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## PROCEDURES

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[There are no procedures at this time.](#)

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## DRAFT HISTORY

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December 31, 2015—Revised draft in new format with references added.

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## HISTORY

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\_\_\_\_\_ first part of policy removed  
July 1982—Revised  
November 1981--Revised  
September 1975--Revised  
August 1970--Revised  
October 1965 – Adopted by the Board of Regents

COMMENTS TO: <a href="mailto:handbook@unm.edu">handbook@unm.edu</a>	<a href="#">FACULTY HANDBOOK HOME</a>	<a href="#">TABLE OF CONTENTS</a>	<a href="#">TABLE OF POLICIES</a>	<a href="#">UNM HOME</a>
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# Statement on Professional Ethics

*The statement that follows was originally adopted in 1966. Revisions were made and approved by the Association's Council in 1987 and 2009.*

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## Introduction

From its inception, the American Association of University Professors has recognized that membership in the academic profession carries with it special responsibilities. The Association has consistently affirmed these responsibilities in major policy statements, providing guidance to professors in such matters as their utterances as citizens, the exercise of their responsibilities to students and colleagues, and their conduct when resigning from an institution or when undertaking sponsored research. The *Statement on Professional Ethics* that follows sets forth those general standards that serve as a reminder of the variety of responsibilities assumed by all members of the profession.

In the enforcement of ethical standards, the academic profession differs from those of law and medicine, whose associations act to ensure the integrity of members engaged in private practice. In the academic profession the individual institution of higher learning provides this assurance and so should normally handle questions concerning propriety of conduct within its own framework by reference to a faculty group. The Association supports such local action and stands ready, through the general secretary and the Committee on Professional Ethics, to counsel with members of the academic community concerning questions of professional ethics and to inquire into complaints when local consideration is impossible or inappropriate. If the alleged offense is deemed sufficiently serious to raise the possibility of adverse action, the procedures should be in accordance with the [1940 Statement of Principles on Academic Freedom and Tenure](#), the 1958 [Statement on Procedural Standards in Faculty Dismissal Proceedings](#),<sup>1</sup> or the applicable provisions of the Association's [Recommended Institutional Regulations on Academic Freedom and Tenure](#).<sup>2</sup>

## The Statement

1. Professors, guided by a deep conviction of the worth and dignity of the advancement of knowledge, recognize the special responsibilities placed upon them. Their primary responsibility to their subject is to seek and to state the truth as they see it. To this end professors devote their energies to developing and improving their scholarly competence. They accept the obligation to exercise critical self-discipline and judgment in using, extending, and transmitting knowledge. They practice intellectual honesty. Although professors may follow subsidiary interests, these interests must never seriously hamper or compromise their freedom of inquiry.
2. As teachers, professors encourage the free pursuit of learning in their students. They hold before them the best scholarly and ethical standards of their discipline. Professors

demonstrate respect for students as individuals and adhere to their proper roles as intellectual guides and counselors. Professors make every reasonable effort to foster honest academic conduct and to ensure that their evaluations of students reflect each student's true merit. They respect the confidential nature of the relationship between professor and student. They avoid any exploitation, harassment, or discriminatory treatment of students. They acknowledge significant academic or scholarly assistance from them. They protect their academic freedom.

3. As colleagues, professors have obligations that derive from common membership in the community of scholars. Professors do not discriminate against or harass colleagues. They respect and defend the free inquiry of associates, even when it leads to findings and conclusions that differ from their own. Professors acknowledge academic debt and strive to be objective in their professional judgment of colleagues. Professors accept their share of faculty responsibilities for the governance of their institution.
4. As members of an academic institution, professors seek above all to be effective teachers and scholars. Although professors observe the stated regulations of the institution, provided the regulations do not contravene academic freedom, they maintain their right to criticize and seek revision. Professors give due regard to their paramount responsibilities within their institution in determining the amount and character of work done outside it. When considering the interruption or termination of their service, professors recognize the effect of their decision upon the program of the institution and give due notice of their intentions.
5. As members of their community, professors have the rights and obligations of other citizens. Professors measure the urgency of these obligations in the light of their responsibilities to their subject, to their students, to their profession, and to their institution. When they speak or act as private persons, they avoid creating the impression of speaking or acting for their college or university. As citizens engaged in a profession that depends upon freedom for its health and integrity, professors have a particular obligation to promote conditions of free inquiry and to further public understanding of academic freedom.

## Notes

1. AAUP, *Policy Documents and Reports*, 11th ed. (Baltimore: Johns Hopkins University Press, 2015), 91–93. [Back to text](#)
2. Ibid., 79–90. [Back to text](#)



## C20: Employment of UNM Graduates

### *Policy*

*Approved by Faculty on March 12, 1951*

As a general policy, no person who has received a degree from the University of New Mexico shall hereafter be employed as a regular member of the faculty in a position which may lead to permanent tenure unless subsequent to the last degree at the University of New Mexico, he or she has taken at least one academic year of advanced work at another reputable institution or has established himself or herself professionally elsewhere. Such work or professional experience must be in his or her teaching field.

At the discretion of the Provost/Vice President for Academic Affairs or the Vice President for Health Sciences for Health Sciences faculty, an exception may be made to this general policy in the case of a person who has taken a master's degree, its equivalent, or pursued other substantial graduate work at another reputable institution before receiving a more advanced degree at the University of New Mexico.

In case of the above or any other exceptions to the general policy, it is recommended that the Provost/Vice President for Academic Affairs consult with the Academic Freedom and Tenure Committee before taking action. For further information refer to "Employment of UNM Graduates" Section [5.3](#), *Regents' Policy Manual*.





Rationale:

It is important that UNM's faculty composition reflect wide-ranging viewpoints relevant to the missions of creation and dissemination of knowledge. This is especially important at the level of graduate education [describe why].

Policy:

Faculty hired into professorial appointments which may lead to a tenured position should normally not include UNM's own terminal-degree graduates

As a general policy, no person who has received a degree from the University of New Mexico shall hereafter be employed as a regular member of the faculty in a position which may lead to permanent tenure unless subsequent to the last degree at the University of New Mexico, unless they have had he or she has taken at least one academic year of advanced work at another reputable institution or have s established himself or herself themselves professionally elsewhere. Such work or professional experience must be in his or her research (??) teaching field.

At the discretion of the Provost/Vice President for Academic Affairs or the Vice President for Health Sciences for Health Sciences faculty, an exception may be made to this general policy in the case of a person who has taken a master's degree, its equivalent, or pursued other substantial graduate work at another reputable institution before receiving a more advanced degree at the University of New Mexico; or if hiring one of UNM's terminal degree graduates will in and of itself further the rationale of this policy.-

This policy does not apply to other faculty appointments made in furtherance of other missions, e.g., branch faculty and lecturers serving UNM's teaching mission, research faculty, etc.

In case of the above or any other exceptions to the general policy, it is recommended that the Provost/Vice President for Academic Affairs consult with the Academic Freedom and Tenure Committee before taking action.

For further information refer to "Employment of UNM Graduates" Section [5.3](#), *Regents' Policy Manual*.