

Table of Contents

ON ACADEMIC AUTHORSHIP	6
GUIDELINES FOR AUTHORSHIP AT THE UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE	6
<i>Purpose</i>	6
<i>Scope</i>	6
<i>Background</i>	6
<i>Guidelines:</i>	6
CONTACT.....	8
GUIDELINES FOR AUTHORSHIP AT THE UNIVERSITY OF MIAMI SCHOOL OF NURSING AND HEALTH STUDIES (ADAPTED FROM MILLER SCHOOL OF MEDICINE GUIDELINES).....	9
<i>Purpose</i>	9
<i>Scope</i>	9
<i>Background</i>	9
<i>Guidelines</i>	9
CONTACT.....	12
DISCIPLINARY/PROFESSIONAL CONDUCT IN THE COURSE OF COMPLIANCE OPERATIONS.....	13
CONTACT.....	13
POLICIES AND PROCEDURES OF THE UNIVERSITY OF MIAMI RELATING TO ALLEGATIONS OF MISCONDUCT IN RESEARCH	14
INTRODUCTION	14
APPLICABILITY.....	14
DEFINITIONS.....	15
<i>Research Misconduct</i>	15
<i>Research record</i>	16
<i>Research support</i>	16
THE COMMITTEE TO INVESTIGATE MISCONDUCT IN RESEARCH.....	16
PROCEDURES FOR THE INVESTIGATION OF ALLEGED MISCONDUCT	17
FORMAL INVESTIGATION OF MISCONDUCT	19
COMMITTEE REPORT AND RECOMMENDATIONS.....	20
NOTIFICATION DURING INQUIRY OR INVESTIGATION.....	22
INTERIM ACTION	22
NOTIFICATION OF THIRD PARTIES AFTER INVESTIGATION	23
CONTACT.....	23
DISCLOSURES & CONFLICT OF INTEREST MANAGEMENT	24
DEFINITIONS:	24
<i>Conflict of interest (COI)</i>	24
<i>Contractor</i>	24
<i>Disclosure of financial interests</i>	24
<i>Financial interest</i>	24
<i>Financial conflict of interest (FCOI)</i>	25
<i>FCOI report</i>	25

<i>Governmental agency</i>	25
<i>Institutional responsibilities</i>	25
<i>Intellectual Property</i>	25
<i>Investigator</i>	26
<i>Manage</i>	26
<i>Obligatory interest</i>	26
<i>Obligatory conflict of interest (OCOI)</i>	26
<i>Research</i>	26
<i>Senior/key personnel</i>	26
<i>Significant financial interest</i>	26
POLICY:	27
<i>Investigator</i>	27
<i>Sub-awardees, sub-contractor, and consultant Responsibilities</i>	29
<i>University</i>	29
REFERENCES AND RELATED RESOURCES:	32
CONTACT.....	33
CONSULTING AND COMPENSATION FOR NON-UNIVERSITY ACTIVITIES	34
DISTRIBUTION OF EFFORT	34
CONSULTING	34
<i>Consulting for Government Agencies or Other Contractors</i>	34
<i>Outside Consulting</i>	35
<i>Intra-University Consulting</i>	35
<i>Private Professional Services</i>	35
<i>Use of University Facilities, Staff or Equipment</i>	35
<i>Relationships with Private Enterprises</i>	35
<i>Use of the Name of the University of Miami</i>	35
CONTACT.....	35
HUMAN RESEARCH PROTECTION PROGRAM	36
INTRODUCTION	36
AUTHORITY AND RESPONSIBILITY	36
UNIVERSITY OF MIAMI HSRO PROGRAM POLICIES	36
CONTACT.....	37
HUMAN STEM CELL RESEARCH	38
I. INSTITUTIONAL OVERSIGHT OF HUMAN EMBRYONIC STEM CELL AND RELATED RESEARCH AT THE UNIVERSITY OF MIAMI	38
II. PURPOSE OF THE UM ESCRO COMMITTEE.....	38
III. THE AUTHORITY OF THE UM ESCRO COMMITTEE.....	38
A. <i>Initial Approval of Human Stem Cell Research</i>	38
B. <i>Continuing Oversight</i>	38
C. <i>Monitoring of UM ESCRO Committee Approved Research</i>	39
D. <i>Restrictions, Suspension, and Termination of Research</i>	39
E. <i>Review of Research within the Jurisdiction of the UM ESCRO Committee by Other University Committees or Officials</i>	39
F. <i>Education and Training</i>	40

IV. CONFLICTS OF INTEREST – UM ESCRO COMMITTEE CHAIRMAN, MEMBERS AND CONSULTANTS	40
A. Disclosure	40
B. Abstention from Deliberations and Absence from the Meeting Room	40
C. Consultants and Conflict of Interest Disclosure	40
V. RESEARCH REQUIRING REVIEW AND APPROVAL BY THE UM ESCRO COMMITTEE	40
VI. PROHIBITED RESEARCH.....	40
VII. STANDARDS FOR UM ESCRO COMMITTEE REVIEW.....	41
A. Procurement of Gametes, Blastocysts, or Somatic Cells for hESC Generation	41
B. Transfer of Human Materials from Outside Entities	42
C. Derivation of hESCs	42
D. Transfer of hESCs into Non-human Animals	42
E. Safety Considerations in Trials with Humans	43
F. Justice	43
G. International Collaboration	43
VIII. PROCEDURES FOR RESEARCH REQUIRING UM ESCRO COMMITTEE REVIEW	43
A. UM ESCRO Committee Review of Research Proposals	43
IX. PROCESS FOR PROTOCOLS FOLLOWING UM ESCRO COMMITTEE VOTE	45
A. Protocols Granted Full Approval	45
B. Protocols Approved Subject to Concurrence with UM ESCRO Committee-Directed Changes	45
C. Protocols Reconsidered or Not Approved	46
X. UM ESCRO COMMITTEE MEETINGS	46
CONTACT.....	47
LABORATORY ANIMALS IN RESEARCH	48
ANIMAL WELFARE COMPLIANCE AND THE UNIVERSITY OF MIAMI ANIMAL CARE PROGRAM	48
INTRODUCTION	48
AUTHORITY AND RESPONSIBILITY FOR ENSURING COMPLIANCE/LINES OF AUTHORITY AND RESPONSIBILITY FOR ADMINISTERING THE PROGRAM	48
INSTITUTIONAL OFFICIAL.....	49
ANIMAL CARE AND USE COMMITTEE (IACUC)	49
ATTENDING VETERINARIAN (AV).....	49
DIVISION OF VETERINARY RESOURCES (DVR)	49
ENVIRONMENTAL HEALTH & SAFETY OFFICE	49
ANIMAL WELFARE ASSURANCE OF COMPLIANCE	50
ANIMAL WELFARE REGISTRATION OF COMPLIANCE.....	50
ASSOCIATION FOR ASSESSMENT AND ACCREDITATION OF LABORATORY ANIMAL CARE INTERNATIONAL (AAALAC).....	50
AUTHORITY AND RESPONSIBILITIES OF THE ANIMAL CARE PROGRAM.....	50
Review At Least Once Every Six Months the Institution's Program	50
Inspect the Institution's Animal Facilities	51
Prepare Reports of the IACUC Evaluations	51
Review Concerns	51
Make Written Recommendations to the Institutional Official	52
PROCEDURES FOR PROTOCOL REVIEW	52
Receipt of Protocols and Pre-review	52
D. Methods of Protocol Review	53
Review Significant Changes	55

<i>Notify Investigators and the Institution</i>	55
<i>Conduct Continuing Review</i>	56
BE AUTHORIZED TO SUSPEND ACTIVITIES	56
THE INSTITUTION'S PROCEDURES FOR OFF-SITE ACTIVITIES INVOLVING RESEARCH ANIMALS	56
USE OF VERTEBRATE ANIMALS IN TEACHING ACTIVITIES.....	57
THE LABORATORY ANIMAL OCCUPATIONAL HEALTH PROGRAM	58
OHS ADMINISTRATION	58
SCOPE.....	58
FOR DVR PERSONNEL:	58
FOR OTHER PERSONNEL WITH ANIMAL CONTACT.....	58
HAZARD IDENTIFICATION AND RISK ASSESSMENT.....	58
HEALTH HISTORIES AND EVALUATIONS	58
COMMON IDENTIFIED HAZARDS AND RISKS	59
PROCEDURES IN PLACE TO ALLEVIATE HAZARDS AND MINIMIZE RISKS	59
IMMUNIZATIONS.....	59
PRECAUTIONS TAKEN DURING PREGNANCY, ILLNESS OR DECREASED IMMUNOCOMPETENCE.....	59
PROVISIONS FOR PERSONNEL WHO ARE NOT INVOLVED IN ANIMAL CARE AND/OR USE BUT NEVERTHELESS NEED TO ENTER AREAS WHEN ANIMALS ARE HOUSED OR USED.....	59
AVAILABILITY AND PROCEDURES FOR TREATMENT IN THE EVENT OF BITES, SCRATCHES, ILLNESS OR INJURY	59
PROCEDURES/PROGRAM FOR REPORTING AND TRACKING INJURIES AND ILLNESSES.....	59
OTHER PERTINENT INFORMATION REGARDING THE OH&S PROGRAM.....	59
ANIMAL WELFARE/ANIMAL CARE AND HANDLING TRAINING PROGRAM	60
GENERAL	60
TRAINING OF UM RESEARCH PERSONNEL	60
TRAINING AND EDUCATION FOR DVR PERSONNEL	61
EVALUATION OF PROTOCOL PERSONNEL TRAINING	61
TRAINING AND EDUCATION FOR IACUC MEMBERS	61
ADDITIONAL TRAINING RESOURCES.....	62
INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION.....	62
RECORD KEEPING REQUIREMENTS	62
REPORTING REQUIREMENTS	63
CONTACT.....	63
ENVIRONMENTAL HEALTH AND SAFETY	64
EMERGENCY AND NON-EMERGENCY HAZARDOUS MATERIAL RELEASE RESPONSE.....	64
UNIVERSITY LABORATORY ANIMAL OCCUPATIONAL HEALTH PROGRAM	65
CHEMICAL HYGIENE PLAN AND CHEMICAL HAZARD COMMUNICATION	65
RADIOLOGICAL HAZARDS	66
LASER SAFETY.....	66
LABORATORY SAFETY MANUAL	66
CONTACT.....	66
EXPORT CONTROL & TECHNOLOGY MANAGEMENT	67
DEFINITIONS.....	67

EXPORT COMPLIANCE POLICY.....	67
EXPORT LICENSES FOR OVERSEAS SHIPMENTS	71
SHIPMENT OF DANGEROUS GOODS	71
SELECT AGENTS	71
PURCHASE REQUISITION EXPORT COMPLIANCE REVIEW	71
DATA CLASSIFICATION	72
PEER-TO-PEER.....	72
ELECTRONIC DATA PROTECTION AND ENCRYPTION.....	72
EXPORT CLASSIFICATIONS.....	72
EXPORT CONTROLS AND UNIVERSITY OF MIAMI’S OPENNESS IN RESEARCH POLICY	72
EXPORT CONTROLS AND AN INDIVIDUAL’S ELIGIBILITY AS A RECIPIENT OF EXPORT CONTROLLED ITEMS, SOFTWARE CODE, OR INFORMATION	72
RECORDKEEPING REQUIREMENTS	73
CONTACT.....	73
INVENTIONS, INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER.....	74
I GENERAL	74
II DEFINITIONS AND ABBREVIATIONS	75
III OWNERSHIP	76
IV ADMINISTRATION OF THE POLICY	77
V DISCLOSURE, REVIEW AND PROTECTION OF INNOVATIONS.....	78
VI DISTRIBUTION OF REVENUE DERIVED FROM COMMERCIALIZATION OF INNOVATIONS.....	81
CONTACT.....	833
LINKS TO OTHER POLICIES/GUIDELINES:	844
SPONSORED PROGRAMS POLICIES AND PROCEDURES	844
CLINICAL RESEARCH PARTICIPANT ENROLLMENT & TRACKING POLICY.....	84
ELECTRONIC DATA QUALITY POLICY FOR CLINICAL RESEARCH.....	844
CLINICAL RESEARCH TRIAL MONITORING	844
EXTERNAL AUDITS	84
FDA AUDIT GUIDELINES.....	84
F&A Distribution guidelines for inter-school research.....	844

On Academic Authorship

Defines the expectations and standards of the University of Miami Miller School of Medicine (UMMSM) and School of Nursing relating to authorship.

Guidelines for Authorship at the University of Miami Miller School of Medicine

Purpose:

To define the expectations and standards of the University of Miami Miller School of Medicine (UMMSM) relating to authorship.

Scope:

These guidelines cover authorship in books, scientific journals, conference proceedings, published abstracts, scientific posters, grant proposals, and other scholarly works by UMMSM faculty, staff, and trainees.

Background:

Authorship has important implications and carries substantial responsibilities. Authorship of books and journal articles is used in evaluation of researchers for jobs, promotions, grants/fellowships, and awards. In turn, authors are those who can be assigned responsibility both for the accuracy of published data and conclusions and for any ethical or scientific concerns that arise; they may also own or control data, tissues, reagents and other scientific materials discussed in the published work. As commonly understood, an author is someone who is an originator of a novel written work. In biomedical journals and other outlets for scholarly publication, an author is understood as someone who has made a substantial intellectual contribution to the published work.

Guidelines:

Fabrication, falsification, or plagiarism in scholarly works is prohibited, as are the practices known as “guest authorship”, “courtesy authorship”, and “ghost authorship” (or ghostwriting). Criteria for authorship can be summarized as follows:

Authorship should be based on 1) substantial contributions to conception and design of research, or to the gathering, analysis or interpretation of data; 2) drafting the article or reviewing it for intellectual content; and 3) approval of the final version to be published. Authors should meet each of the 3 criteria.

When a large group is involved, the members should identify the individuals who accept direct responsibility for the manuscript. Each of these individuals should meet the criteria for authorship defined above. When submitting a manuscript authored by a group, the lead/corresponding author should identify all individual authors as well as the group name, if applicable.

Acquisition/provision of funding, collection of data, or supervision of the research group does not, by itself, suffice for authorship.

All persons named as authors should qualify for authorship, and all persons who qualify should be listed as authors.

Each author should have sufficient knowledge of the work to take public responsibility for at least those portions of the work in which he/she was involved. Where feasible, a summary of author contributions (e.g., conceived and designed research, performed research, analyzed results, wrote initial draft, edited manuscript) should be clearly and explicitly listed in the publication.

Those who contribute to the research in a published work but who do not meet the criteria for authorship should be listed in the Acknowledgments. Examples include persons who provided purely technical help, (such as performing experiments under direction), writing assistance, or financial support. If assistance is provided with study design, data collection or analysis, or preparation of the manuscript, the authors should disclose the identities of the individuals who provided such assistance and the entity providing financial support for this assistance (if any) in the Acknowledgments. Individuals, such as students, fellows, and research assistants, who provide substantial technical support for the research should be given the opportunity to contribute intellectually as well, so as to qualify for authorship.

Persons and groups who have made substantial contributions to the work but whose contributions do not rise to the level of authorship may be listed under descriptions such as “participating investigators,” and their functions or contributions should be described—for example, “provided advice on study design”, “critically reviewed the initial proposal”, “provided technical assistance”, or “enrolled study patients.” Persons listed in the Acknowledgements should be asked for permission to be listed, since acknowledgement of contributions to an article may imply agreement with or endorsement of the article’s findings or conclusions.

Authorship decisions

Decisions about inclusion/exclusion of authors, and their listed order in the published work, should be made jointly by the authors. A person may refuse to be listed as an author despite having made substantial intellectual contributions; this however may not be done deliberately to subvert the prohibition on “ghost authorship” described below. Discussions about authorship and author order should occur as early in the research process as feasible, to reduce the probability of later disputes. The “lead” or corresponding author should lead authorship discussions. Each research group leader should ensure that all members of the research team understand the group’s authorship policies and practices. This information should ideally be conveyed at the time that a person joins the research group.

When disputes about author inclusion or author order arise, they should be handled by consensus among the group of authors, or, if necessary, by disinterested individuals chosen as arbiters by the group, such as the consult service offered by the University of Miami Ethics Programs. If the arbiters selected by the author group cannot provide a resolution acceptable to the group, the dispute should be brought to research leadership for arbitration.

“Ghost Authorship”

The practice of “ghost authorship” or “ghostwriting”, in which a person who has made substantial intellectual contributions to the writing of a submitted article is not listed as an author, is prohibited. Persons who make substantial intellectual contributions to the writing of a manuscript should be allowed to approve the final version and thus to qualify for authorship.

“Guest Authorship”

The practice of “guest authorship” or “courtesy authorship”, in which a person is listed as an author despite failing to meet the requirements for authorship, is prohibited.

Authorship of grant proposals

As with all research-related work, fabrication, falsification, or plagiarism in the writing of grant proposals is prohibited. “Self-plagiarism”, in which investigators “re-cycle” their own writing (previously used in other documents) may be acceptable in grant proposals. Data, written material, or figures originated by or obtained from another party may not be used in a grant proposal without explicit written permission from the individuals who originated the work. Agreements about who will be Principal Investigator(s), Co-Investigators, unpaid collaborators/consultants, etc, and their (paid and unpaid) efforts should be joint decisions of the investigators involved. Discussions about these issues should occur as early as possible in the grant writing process. Submittal of the same or substantially similar grant proposals to more than one funding agency is permissible, as long as 1) this is permitted by each of the involved funding agencies, 2) this is made clear in any “Other Support” sections of the relevant grant proposals, and 3) agencies are notified of any scientific/financial overlap in grant funding by the time of award(s). In the case of “limited submissions”, where there are limits on the number of proposals that may be submitted by the University or the UMMSM, investigators must make clear at the time of the competition whether they plan to submit a substantially similar grant to a different agency.

Simultaneous submission of manuscripts

It is inappropriate to submit the same or a substantially similar manuscript to more than one outlet at the same time, unless this practice is explicitly permitted or is disclosed and agreed to by each outlet. Editors generally assume that they are being given an exclusive opportunity to review and publish, which is necessary to avoid the possibility that they go to the trouble and expense of reviewing an article that is then withdrawn and published elsewhere.

Redundant publication

Various pressures have been known to lead some scholars to attempt to publish the same or a substantially similar document more than once – in different journals and/or under different titles. If this is done with the intent to inflate a scholar’s curriculum vitae (CV), or otherwise deceive supervisors, reviewers, or readers, it is inappropriate, constitutes research misconduct, and may also constitute a copyright violation. If a journal or book editor wants to include a closely related version of a previously published document, this may be permissible if it is adequately disclosed to readers and documented as such on the author’s CV.

Note: These guidelines, in part, closely adhere to principles developed by the International Committee of Medical Journal Editors. More information can be found in: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship;

<http://www.icmje.org/recommendations/browse/>

Revised 10/30/2012

Contact

Questions about these Guidelines can be answered by:

John L. Bixby, Ph.D.

Vice Provost for Research

305.243.9635

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Guidelines for Authorship at the University of Miami School of Nursing and Health Studies (Adapted from Miller School of Medicine Guidelines)

Purpose:

To define the expectations and standards of the University of Miami School of Nursing and Health Studies (SONHS) as they relate to authorship.

Scope:

These guidelines cover authorship in books, scientific journals, conference proceedings, published abstracts, scientific posters, grant proposals, and other scholarly works by SONHS faculty, staff, and students.

Background:

Authorship has important implications and carries substantial responsibilities. Authorship of books and journal articles is used in evaluation of researchers for jobs, promotions, grants/fellowships, and awards. In turn, authors are those who can be assigned responsibility both for the accuracy of published data and conclusions and for any ethical or scientific concerns that arise; they may also own or control data, tissues, reagents, interventions, and other scientific materials discussed in the published work. As commonly understood, an author is someone who is an originator of a novel written work. In scientific journals and other outlets for scholarly publication, an author is understood as someone who has made a substantial intellectual contribution to the published work.

Guidelines:

Fabrication, falsification, or plagiarism in scholarly works is prohibited, as are the practices known as “guest authorship”, “courtesy authorship”, and “ghost authorship” (or ghostwriting). Criteria for authorship can be summarized as follows:

Authorship should be based on 1) substantial contributions to conception and design of research, or to the gathering, analysis or interpretation of data; 2) drafting the article or reviewing it for intellectual content; and 3) approval of the final version to be published. Authors should meet all 3 criteria.

When a large group is involved, the members should identify the individuals who accept direct responsibility for the manuscript. Each of these individuals should meet the criteria for authorship defined above. When submitting a manuscript authored by a group, the lead/corresponding author should identify all individual authors as well as the group name, if applicable.

Acquisition/provision of funding, collection of data, or supervision of the research group does not, by itself, suffice for authorship. However, if a manuscript is based upon secondary analysis of data collected by a colleague or mentor, the principal investigator of the parent study should be given the opportunity to contribute to the manuscript, so as to qualify for authorship.

All persons named as authors should qualify for authorship, and all persons who qualify should be listed as authors.

Each author should have sufficient knowledge of the work to take public responsibility for at least those portions of the work in which he/she was involved. Where feasible, a

summary of author contributions (e.g., conceived and designed research, performed research, analyzed results, wrote initial draft, edited manuscript) should be clearly and explicitly listed in the publication.

Those who contribute to the research in a published work but who do not meet the criteria for authorship should be listed in the Acknowledgments. Examples include persons who provided purely technical help, (such as performing experiments under direction, participant assessments, intervention delivery, and supervision), writing assistance (review/editing), or financial support. If assistance is provided with study design, data collection or analysis, or preparation of the manuscript, the authors should disclose the identities of the individuals who provided such assistance and the entity providing financial or material support for this assistance (if any) in the Acknowledgements. Individuals, such as students, fellows, community partners and research assistants, who provide substantial technical support for the research should be given the opportunity to contribute intellectually as well, so as to qualify for authorship.

Persons and groups who have made substantial contributions to the work but whose contributions do not rise to the level of authorship may be listed under descriptions such as “participating investigators,” and their functions or contributions should be described—for example, “provided advice on study design”, “critically reviewed the initial proposal”, “provided technical assistance”, or “enrolled study patients.” Persons listed in the Acknowledgements should be asked for permission to be listed, since acknowledgement of contributions to an article may imply agreement with or endorsement of the article’s findings or conclusions.

Authorship decisions

Decisions about inclusion/exclusion of authors, and their listed order in the published work, should be made jointly by the authors. A person may refuse to be listed as an author despite having made substantial intellectual contributions; this however may not be done deliberately to subvert the prohibition on “ghost authorship” described below. Discussions about authorship and author order should occur as early in the research process as feasible, to reduce the probability of later disputes. The “lead” or corresponding author should lead authorship discussions. Each research group leader should ensure that all members of the research team understand the group’s authorship policies and practices. This information should ideally be conveyed at the time that a person joins the research group.

When disputes about author inclusion or author order arise, they should be handled by consensus among the group of authors, or, if necessary, by disinterested individuals chosen as arbiters by the group, such as the consult service offered by the University of Miami Ethics Programs. If the arbiters selected by the author group cannot provide a resolution acceptable to the group, the dispute should be brought to the Associate Dean for Research or other SONHS leadership for arbitration.

“Ghost Authorship”

The practice of “ghost authorship” or “ghostwriting”, in which a person who has made substantial intellectual contributions to the writing of a submitted article is not listed as an author, is prohibited. Persons who make substantial intellectual contributions to the writing of a manuscript should be allowed to approve the final version and thus to qualify for authorship.

“Guest Authorship”

The practice of “guest authorship” or “courtesy authorship”, in which a person is listed as an author despite failing to meet the requirements for authorship, is prohibited.

Authorship of grant proposals

As with all research-related work, fabrication, falsification, or plagiarism in the writing of grant proposals is prohibited. “Self-plagiarism”, in which investigators “re-cycle” their own writing (previously used in other documents) may be acceptable in grant proposals, but citation should be used when feasible. Material developed for a grant application may be used in a publication; however the usual authorship guidelines apply. Data, written material, or figures originated by or obtained from another party may not be used in a grant proposal without explicit written permission from the individuals who originated the work. Agreements about who will be Principal Investigator(s), Co-Investigators, unpaid collaborators/consultants, etc, and their (paid and unpaid) efforts should be joint decisions of the investigators involved. Discussions about these issues should occur as early as possible in the grant writing process. Submittal of the same or substantially similar grant proposals to more than one funding agency is permissible, as long as 1) this is permitted by each of the involved funding agencies, 2) this is made clear in any “Other Support” sections of the relevant grant proposals, and 3) agencies are notified of any scientific/financial overlap in grant funding by the time of award(s). In the case of “limited submissions”, where there are limits on the number of proposals that may be submitted by the University or SONHS, investigators must make clear at the time of the competition whether they plan to submit a substantially similar grant to a different agency.

Students as First Authors

Students publishing manuscripts that are principally derived from a course assignment, doctoral dissertation or capstone should be the first author. Faculty members and others must meet the same criteria for authorship as stated above. Merely reviewing and editing does not qualify for authorship. Further, faculty members should not assume that they will be invited to be an author on their students’ manuscripts.

Simultaneous submission of manuscripts

It is inappropriate to submit the same or a substantially similar manuscript to more than one outlet at the same time, unless this practice is explicitly permitted or is disclosed and agreed to by each outlet. Editors generally assume that they are being given an exclusive opportunity to review and publish, which is necessary to avoid the possibility that they go to the trouble and expense of reviewing an article that is then withdrawn and published elsewhere.

Redundant publication

Various pressures have been known to lead some scholars to attempt to publish the same or a substantially similar document more than once – in different journals and/or under different titles. If this is done with the intent to inflate a scholar’s curriculum vitae (CV), or otherwise deceive supervisors, reviewers, or readers, it is inappropriate, constitutes research misconduct, and may also constitute a copyright violation. If a journal or book editor wants to include a closely related version of a previously published document, this may be permissible if it is adequately disclosed to readers and documented as such on the author’s CV.

For the most part, abstract/poster/oral presentations will not rule out future publication of material presented. However, some conference presentations may be published in “proceedings” of that conference, in paper form or online, which some journals may view as a publication. Authors should always review conference policies regarding publication of presentations and/or posters prior to submitting abstracts for conferences.

It is the responsibility of the authors to know the requirements and standards of the journal to which they are submitting, as they differ by journal and discipline. Authors should make a

journal editor aware, as part of the submission process, of any prior presentation that has occurred.

Note: These guidelines, in part, closely adhere to principles developed by the International Committee of Medical Journal Editors. More information can be found in: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship;
<http://www.icmje.org/recommendations/browse/>

Revised 12/20/2012

Contact

Questions about these Guidelines can be answered by:
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School of Nursing and Health Studies
305.284.9139
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Disciplinary/Professional Conduct in the Course of Compliance Operations

Policy to define interactions between UM faculty, staff and Research Compliance officials

The University of Miami's Disciplinary/Professional Conduct policy applies to all interactions during the conduct of compliance operations (IACUC/IBC/ESCRO audits; export control, research misconduct and conflict of interest investigations) between University of Miami faculty, staff, trainees, and Research Compliance officials. All UM employees, trainees and faculty are expected to maintain standards of professional conduct and performance as required by the employing department and the University. Unacceptable conduct including, but not limited to, use of insulting or abusive language, intimidation, acting in a manner that can be perceived as threatening, explicit aggression, assault, and/or battery to any Research Compliance official, or personal conduct that adversely affects the work environment and/or the Research Compliance official's ability to perform his/her job duties, will be immediately reported to the appropriate UM officials. These may include the offending individual's supervisor, department chair, Dean, the UM Director of Human Resources, Vice Provost for Faculty Affairs, and Vice Provost for Research.

Contact

Questions about this policy can be answered by:

John L. Bixby, Ph.D.

Vice Provost for Research

305-243-9635

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Policies and Procedures of the University of Miami Relating to Allegations of Misconduct in Research

Presents the policies and procedures that will be followed in the investigation and reporting of allegations of research misconduct at the University of Miami.

Introduction

Research in an institution such as the University of Miami is grounded upon the principles of academic freedom and mutual trust. The fostering of inquiry and creativity requires an atmosphere in which all are presumed to adhere to high ethical standards in the conduct of research and other academic pursuits. Misconduct in research is a fundamental violation of this trust and represents an assault upon the integrity of the University community.

Acts of misconduct are fortunately rare events, but because of the seriousness of allegations and the special responsibilities of the University in such circumstances, both to individual researchers and to society, it is recognized that explicit procedures must be provided for dealing with instances of alleged misconduct. It is the purpose of this document to outline the policies and procedures that will be followed in the investigation and reporting of allegations of research misconduct at the University of Miami.

In establishing these procedures, however, it must be emphasized that the best mechanism for dealing with misconduct is to prevent it. Thus it is imperative that those who participate in research reaffirm their responsibility for the ethical conduct of all research activities with which they are associated. Principal investigators, laboratory supervisors and others who lead research must recognize their ultimate responsibility for the authenticity of research conducted and published in their names and realize that they must provide adequate supervision for their trainees and research teams. It is also their responsibility to see that all persons who have contributed to the research receive appropriate credit for their work. It is incumbent upon collaborators and other contributors to research to understand that the inclusion of their names as co-authors of publications reflects a genuine contribution to the work, and signifies that they have approved the publication and are prepared to accept responsibility for the work reported.

Applicability

This policy is applicable to research misconduct arising from research conducted at the University, and/or conducted by University faculty and employees, including misconduct involving:

- Applications or proposals for support for extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information.
- Supported extramural or intramural research.
- Supported extramural or intramural research training programs.
- Supported extramural or intramural activities that are related to research or research training, such as the operation of tissue and data banks or the dissemination of research information.
- Plagiarism of research records produced in the course of supported research, research training or activities related to that research or research training. This includes any

research proposed, performed, reviewed, or reported or any research record generated from that research, regardless of whether an application or proposal for funds resulted in a grant, contract, cooperative agreement, or other form of extramural or intramural support.

This policy applies only to research misconduct occurring within six years of the date the University receives an allegation of research misconduct, unless (1) the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use, for the potential benefit of the respondent, of the research record that is alleged to have been fabricated, falsified, or plagiarized, or (2) the University, following consultation with the Office of Research Integrity (hereinafter "ORI"), determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public. In the event the alleged misconduct occurred outside the time limit described above, the matter should be referred to the Committee on Professional Conduct.

Definitions

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research). Research, as used herein, includes all basic and applied research in all disciplines. This includes, but is not limited to, research in economics, education, the humanities, linguistics, medicine, nursing, psychology, the natural and social sciences, engineering, mathematics and statistics, and includes any research involving human subjects or animals.

Research Misconduct

"Research misconduct" means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism may also include self-plagiarism. Self-plagiarism refers to the author's re-use of their earlier work and passing it off as new or original material.

Research misconduct does not include honest error or honest differences of opinion.

A finding of research misconduct requires that:

- there was a significant departure from accepted practices of the relevant research community
- the misconduct was committed intentionally, knowingly, or recklessly
- the allegation was proven by a preponderance of the evidence. Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research record

The record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, chapters, books, audio or video tapes, CDs, internal reports, journal articles, and any documents and materials provided to the University or to a University official by a respondent in the course of the research misconduct proceeding.

Research support

Funding, or applications or proposals, for research, research training, or activities related to that research or training, that may be provided through: (1) funding for intramural or extramural research by grants, cooperative agreements, or contracts; or (2) subgrants or subcontracts under those funding instruments; or (3) salary or other payments under those grants, cooperative agreements, or contracts.

The Committee to Investigate Misconduct in Research

The Committee to Investigate Misconduct in Research (hereinafter referred to as the Committee) is charged with the responsibility of investigating allegations of research misconduct by members of the academic community of the University of Miami. It is the Committee's responsibility to determine if allegations of research misconduct can be substantiated, to ensure that the relevant authorities are informed of the existence and progress of any formal investigations, to make a final report on the findings of investigations, and to recommend appropriate action to the dean of the School or College and to the Provost.

The Committee shall be drawn from a standing body (the "pool") consisting of thirty-two tenured members of the faculty appointed by the Provost. There shall be at least six members from each of the three major campuses represented in the pool. Membership terms in the pool are for three years and shall be staggered. Members whose terms are ending while a specific matter is under consideration shall continue to serve for the duration of that matter. The Vice Provost for Research shall select six members from that pool to serve as the Committee for each investigation. Members of a Committee shall continue to serve for the duration of that matter. The Assistant Provost for Research Standards shall be a non-voting ex-officio member of the Committee. The members of the Committee will elect a chair to conduct the proceedings. Additional ad hoc members of the Committee with special expertise in the area of investigation may be appointed to the Committee from within or outside the full-time faculty of the University at the request of the Committee or by the Vice Provost for Research. Only those ad hoc members who are full-time University faculty may vote. In accordance with federal law, reasonable steps shall be taken to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation. Members of the Committee whose participation in the investigation of allegations against a specific individual could be construed as inappropriate or who are involved in the research in question will be expected to recuse themselves from such proceedings. In case of doubt, the Vice Provost for Research, or the Committee by majority vote, may require a member to recuse himself or herself.

In the event the Vice Provost for Research has a conflict of interest related to an allegation, he or she will recuse himself or herself. The Provost will appoint an appropriate individual to act for the Vice Provost for Research under these circumstances.

Procedures for the Investigation of Alleged Misconduct

The goal of the procedures is to investigate and resolve allegations of research misconduct in an expeditious, responsible and fair manner. The responsibility of protecting the rights and reputations of all who are involved in any investigation of research misconduct is recognized as very important. For this reason, disclosure of the identity of respondents and complainants in research misconduct proceedings shall be limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as required or allowed by statute or regulation.. The University shall protect, to the extent possible, the privacy of those who in good faith report apparent research misconduct and shall undertake all reasonable and practical efforts to protect the positions and reputations of any complainant, witness, or Committee member and to prevent potential or actual retaliation against these complainants, witnesses, and Committee members. Individuals responsible for carrying out any part of the research misconduct proceeding must not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses. The University and Committee shall afford the respondents, complainants and research subjects identifiable from research records or evidence confidential treatment to the extent possible. Persons accused of misconduct may consult with legal counsel, but legal counsel for neither the accused nor for the University may participate in any hearing or interview.

Steps in an investigation:

1. Allegation – Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional official. Allegations of misconduct should normally be directed to the Vice Provost for Research or designee, who shall determine if an inquiry is warranted. Others who receive an allegation of misconduct should immediately forward it to the Vice Provost for Research.
2. An inquiry is warranted if the Vice Provost for Research determines that the allegation (1) falls within the definition of research misconduct and (2) is sufficiently credible and specific so that potential evidence of possible research misconduct may be identified.
3. Inquiry - An inquiry is an information gathering and initial fact finding process to determine if a formal investigation of misconduct should be undertaken. An inquiry will be conducted by an Inquiry Panel, made up of three tenured faculty members chosen by the Vice Provost for Research from the pool. Members who serve on the Inquiry Panel may not serve on the Investigation Committee for the same matter. The Assistant Provost for Research Standards shall be a non-voting ex-officio member of the Inquiry Panel. At the time of or before beginning an inquiry, the Vice Provost for Research must make a good faith effort to notify in writing the presumed respondent. If the Inquiry Panel subsequently identifies additional respondents, the Inquiry Panel will notify the Vice Provost for Research who in turn will notify them in writing.

To the extent it has not already done so at the allegation stage, the University must, on or before the date on which the respondent is notified or inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to:

1. Obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding.
2. Inventory the records and evidence.

3. Sequester them in a secure manner, except that, where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent in evidentiary value to the original data or evidence on the instruments. The University shall, where appropriate, give the respondent copies of, or reasonable, supervised access to, the research record. The University shall undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding.

An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A draft written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the Inquiry Panel as to whether an investigation is warranted. An investigation is warranted if there is:

1. A reasonable basis for concluding that the allegation falls within the definition of research misconduct.
2. Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The individual(s) against whom the allegations were made shall be given a copy of the draft report. If they wish to comment on that report, their comments must be submitted in writing to the Inquiry Panel within 14 calendar days of the date on which the individual(s) received the draft report and will be made part of the record. If the inquiry takes longer than 60 calendar days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

The final report of the Inquiry Panel, including any comments received from the individual(s) against whom the allegations were made, shall be sent to the Vice Provost for Research. The reasons for the decision whether an investigation is warranted should be documented in that report.

The Vice Provost for Research shall maintain sufficiently detailed documentation of inquiries to permit a later assessment of the reason for that decision. Such records shall be maintained in a secure manner for a period of at least seven years after the termination of the inquiry, and shall, upon request, be provided to authorized federal agency personnel as may be required by law.

Within 30 calendar days of finding that an investigation regarding research involving federal agency support is warranted the University shall provide ORI with the written findings and a copy of the report of the Inquiry Panel which shall include the following information:

1. The name and position of the respondent
2. A description of the allegations of research misconduct
3. The federal agency support, including for example, grant numbers, grant applications, contracts, and publications listing federal agency support
4. The basis for recommending that the alleged actions warrant an investigation
5. Any comments on the report by the respondent.

The University shall provide the following information to ORI upon request:

1. The institutional policies and procedures under which the inquiry was conducted

2. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents
3. The charges for the investigation to consider.

Formal investigation of misconduct

If findings from the inquiry provide a sufficient basis for conducting an investigation by the Committee, the Vice Provost for Research will initiate an investigation within 30 calendar days following receipt of the Inquiry Panel report.

An investigation means the formal development of a factual record and the examination of that record leading to a decision either to make a finding that research misconduct was not shown or to recommend a finding of research misconduct; the latter finding may include a recommendation for appropriate actions, including administrative actions. The Vice Provost for Research will inform the respondent and any collaborators promptly, in writing, of the allegations, of the decision to initiate a formal investigation, and of the procedures that will be followed. The Committee shall give the respondent and the Vice Provost for Research written notice of any new allegations of research misconduct within a reasonable amount of time after deciding to pursue any such allegations not addressed during the inquiry or included in the initial notice of investigation.

The Committee is empowered to call for and examine all relevant documentation, including, but not limited to, research data and proposals, laboratory notebooks, grant applications, publications, correspondence, memoranda of telephone calls and computer data, files and programs. These materials may relate to any research with which the accused is involved. To the extent the University has not already done so at the allegation or inquiry stages, the Committee shall take all reasonable and practical steps to (1) obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, (2) inventory the records and evidence, and (3) sequester them in a secure manner, except that, where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent in evidentiary value to the data or evidence on the instruments. Whenever possible, the University shall take custody of the records (1) before or at the time the Vice Provost for Research notifies the respondent; and (2) promptly thereafter, whenever additional items become known or relevant to the investigation. The University shall, where appropriate, give the respondent copies of or reasonable, supervised access to, the research record.

A first round of hearings will be conducted in which those who have brought the charges, those alleged to have committed research misconduct, and any others who might have knowledge relevant to the alleged misconduct will be interviewed individually in closed-door sessions. A transcription or recording of these interviews shall be prepared and given to each interviewed party for comment or revision, and included as part of the investigatory file. Comments by any interviewed party or the accused must be made within 30 calendar days of receipt of the transcription or recording. The Committee shall consider and address any comments of the interviewed parties and the respondent before issuing a final report. The Committee shall use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research, records and evidence relevant to reaching a decision on the merits of the allegations. The Committee shall pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

At the conclusion of these hearings, the Committee will review the evidence and apprise all those who may bear some responsibility for the alleged misconduct of the results of the investigation to that point. These individuals will then be granted the right of rebuttal and the opportunity to present additional evidence to the Committee. Following this, the Committee may recall earlier witnesses for re-examination, call new witnesses, or close the investigative phase. In any case, before the Committee moves toward final deliberations, those bearing potential responsibility will always be given an opportunity to review and comment upon any new evidence uncovered subsequent to their last appearance before the Committee.

The Committee must complete within 120 calendar days all aspects of investigation, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to the appropriate University officials in order that the final report can be submitted to ORI where required. If unable to complete the investigation in 120 calendar days, the Committee must provide the reasons for the delay to the Vice Provost for Research who must ask ORI for an extension in writing, where required.

Committee Report and Recommendations

The Committee will evaluate all evidence and testimony in order to determine if the allegations of misconduct are substantiated and, if so, who must bear responsibility. Because of the negative impact of charges of misconduct, whether ultimately substantiated or not, on the research career of an individual, it is important that the Committee's final decision be rendered in clear terms. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the University establishes by a preponderance of the evidence that the respondent had research records and intentionally, knowingly, or recklessly failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community. In determining whether the University has carried the burden of proof imposed by this part, the Committee shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent. The respondent has the burden of going forward with and proving by a preponderance of the evidence any and all affirmative defenses raised and any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

A finding of research misconduct requires a determination by the Committee by an eighty percent (80%) majority vote that (1) there was a significant departure from accepted practices of the relevant research community; (2) the misconduct was committed intentionally, knowingly, or recklessly; and (3) the allegation was proven by a preponderance of the evidence. Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. If the Committee cannot reach this conclusion, then it will report that the individual(s) under investigation have been exonerated. A minority report by a Committee member may be written which will be included with the final report. The Committee may make other relevant recommendations for action to be taken by the University, including, but not limited to, referring the matter to the Committee on Professional Conduct.

At the close of its investigation, the Committee will prepare a draft written report, and make that draft report available for comment by the respondent(s). The comments of the respondent(s), if any, must be submitted in writing to the Committee within 30 days of the date on which the respondent(s) received the draft report. If they can be identified, the complainant(s) should be provided with those portions of the report that address their role and opinions in the investigation. The comments of the complainant, if any, must be submitted in writing to the

Committee within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it. The Committee will submit the final report including any comments received from the respondent(s) or the complainant to the Provost, Dean of the School or College at which the respondent has an appointment, and the Vice Provost for Research.

The final Committee report must be in writing and must:

- (1) Describe the nature of the allegations of research misconduct;
- (2) Describe and document the funding support, if any, including for example, any grant numbers, grant applications, contracts, and publications listing funding agency support;
- (3) Describe the specific allegations of research misconduct for consideration in the investigation;
- (4) If not already provided where required to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted;
- (5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed;
- (6) For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so,
 - (a) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard.
 - (b) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - (c) Identify the specific funding agency support, if any,
 - (d) Identify whether any publication needs correction or retraction;
 - (e) Identify the person(s) responsible for the misconduct; and
 - (f) For research involving federal agency funding, list any current support or known applications or proposals for support that the respondent has pending with Federal agencies.
- (7) Include and consider any comments made by the respondent and complainant on the draft investigation report.

For studies involving federal agency funding, the University must maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

All recommendations of the Committee shall be considered as advisory to the dean of the School or College and to the Provost, who shall be responsible for further action consistent with University policy. In principle, anyone found to have committed research misconduct should, in the absence of extenuating circumstances, be recommended for dismissal from the University. In the case of tenured faculty, this is consistent with initiation of termination for cause proceedings as a consequence of dishonesty in research as defined in the Faculty Manual. If it is found that misconduct was committed by a collaborator or other member of a research team, and the supervisor of the research is found to have failed to make reasonable and periodic inquiry as to the authenticity of the data, and if this inquiry would have been likely to prevent or uncover the fraudulent research, the supervisor should be recommended for appropriate sanction. The Provost will determine what sanctions and/or corrective action will be taken in accordance with University policy (including the provisions of the Faculty Manual) and ensure that the report is submitted to any appropriate agencies.

If the Committee determines that the allegations of misconduct were made in bad faith, the Committee may recommend sanctions be imposed against those making bad faith allegations. This recommendation will be forwarded to the appropriate human resource department and to the Provost.

Notification During Inquiry or Investigation

The relevant governmental agency shall be notified by the Provost or designee when the University determines that an investigation involving federally funded research is warranted. For all research, a determination of the need to inform other interested parties including the dean and the chair will also be made at this time. A determination as to whether other interested parties, such as collaborators, supervisors, and officials of sponsoring or funding agencies or institutions, shall be notified will normally be made only after a formal investigation is initiated.

The Provost or designee is responsible for immediately notifying the ORI if the Provost or designee ascertains at any stage of the inquiry or investigation of research misconduct involving federally sponsored research activities that there is reason to believe that any of the following conditions exist:

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

In such circumstances, consideration may be given to the advisability of notifying a funding agency as well.

For federally funded studies, the Vice Provost for Research will keep ORI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential agency funding for the individual(s) under investigation or that the agency needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest or as may be required by federal law or regulations.

Interim Action

If at any time during the formal investigation, the Committee feels that interim action by the administration is needed in order to safeguard the interests of any of the involved parties or funding agencies or to expedite the investigation, it may recommend appropriate measures to the Vice Provost for Research. It will be the responsibility of the Vice Provost for Research to consult regularly with the Committee during the investigation and to apprise appropriate agencies of any developments material to their interests, and take appropriate action to protect sponsoring agency funds.

Notification of Third Parties after Investigation

The Committee shall identify and advise the Vice Provost for Research of all parties who should be notified of its findings; these may include the Faculty Senate, editors of journals or officers of societies where research papers or abstracts related to the research have appeared or are pending, and the officials of current or past granting agencies involved in funding or otherwise sponsoring any compromised research. The Vice Provost for Research shall notify the Institutional Review Board or Institutional Animal Care and Use Committee where appropriate. The Committee may also recommend actions concerning the release of information regarding the incident to the media and corrective actions to prevent further instances of misconduct in light of the experience gained from the investigation.

For research involving Public Health Service (PHS) funding, the Vice Provost for Research shall provide the ORI with a copy of the investigative report, including all attachments; a statement of whether the University found research misconduct and if so, who committed the misconduct; a statement whether the University accepts the Committee's findings; and a description of any pending or completed administrative actions against the respondent.

In the event the research is funded by a federal agency other than PHS agencies with scientific misconduct rules different from those of PHS, the University shall comply with the other funding agency rules and reporting requirements if they differ from this policy.

If the charges of misconduct are not substantiated, those under investigation shall be so notified in writing, and the University shall undertake diligent efforts to ensure that the reputations of those involved are restored as fully as possible. This may require, with approval of the accused, notification of collaborators, granting agencies, and any others who might have become aware of the investigation.

The University agrees to cooperate fully with ORI during its oversight review or any subsequent administrative hearings or appeals as may be authorized by federal regulations. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

Dissemination of This Statement of Policies and Procedures

This document shall be distributed to each faculty member on initial appointment and the faculty at large shall be notified through posting on the University website and through appropriate University list servers whenever changes are made.

Questions about this Policy can be answered by:

Contact

Jerome (Jerry) Engel, J.D., CHRC
Research Compliance Officer, Office of Research Compliance
Phone: 305.243.4054
Email: JEngel@med.miami.edu

Conflict of Interest

To establish the University of Miami's position in regards to the conflicts of interest of academic researchers, research teams and educators.

The increasing involvement of academic researchers, research teams and educators with industry and private entrepreneurial ventures has raised the potential for conflict of interest. These conflicts arise from an individual's opportunities to benefit financially from the outcome of his/her research or other activities conducted as a University researcher, educator, or as part of a University research team. This policy is designed to promote objectivity in research, scholarly and educational activities funded under external grants, contracts or cooperative agreements. By requiring the review of disclosures of interests made by our investigators (faculty, trainees, students, staff and subcontractors) relating to their institutional responsibilities, the policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of such activities will be free from bias resulting from individual financial and obligatory conflicts of interest.

The Vice Provost for Research is responsible to the Executive Vice President and Provost for the overall coordination of research at the University. The Vice Provost for Research is the chief administrative officer of the University of Miami Office for Research and has been designated by the Provost to solicit and review disclosures of potential conflicts of interest related to externally funded research, scholarly and educational activities at the University of Miami.

This policy supplements the existing university policy contained in the University of Miami Faculty Manual and other University policies and procedures on this subject. In the event of conflict as it relates to funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements, the provisions of this policy will apply.

Definitions:

Conflict of interest (COI)

An actual or potential interest that could *directly and substantially* (as determined by the Vice Provost for Research and/or his/her designee, acting on behalf of the Provost), affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.

Contractor

An entity providing property or services under contract for the direct benefit or use of an awarding component.

Disclosure of financial interests

An Investigator's (collectively, an educator, researcher, etc; see below) disclosure of financial interests to the University.

Financial interest

Anything of monetary value, whether or not the quantitative value is readily ascertainable.

- A. With regard to any publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure or the value of any equity interest in the entity as of the date of disclosure exceeds \$600.

For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- B. With regard to any non-publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds \$600, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options (vested or unvested), or other ownership interest); or
- C. With regard to Intellectual property (IP) rights and interests (e.g., patents, copyrights), a financial interest is considered to be present as soon as protection is sought (e.g., filing an invention disclosure, patent application, etc).

The term *financial interest* does not include the following types of interests: salary, royalties, or other remuneration paid by the University of Miami to the Investigator if the Investigator is currently employed or otherwise appointed by the University of Miami, including intellectual property rights assigned to the University of Miami and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, service on advisory committees or review panels for, or sponsored by a United States Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial conflict of interest (FCOI)

A financial interest that could *directly and substantially* affect the design, conduct, or reporting of funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

FCOI report

The University's report of a financial conflict of interest to a funding component.

Governmental agency

Any governmental agency that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts.

Institutional responsibilities

An Investigator's professional responsibilities on behalf of the Institution. These may include for example: activities such as research, research consultation, consulting, lecturing, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Data and Safety Monitoring Boards, or external advisory boards. Income from, or obligations arising from any outside activity that is related to the Investigator's institutional responsibilities must be disclosed to the University.

Intellectual Property

The filing of a thought or idea that could be protected.

Investigator

The project director (PD), principal investigator (PI), co-principal investigators, and any other person who could be responsible for the design, conduct, or reporting of

- 1) research irrespective of funding source, or
- 2) scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

“Investigator” is used for the purpose of this policy to collectively indicate individuals whose role could be described as an educator, researcher or investigator.

This includes sub-awardees, sub-contractor(s), consultants and "to be appointed" positions as well as any individual whose biographical sketch is included in the proposal or whose name appears in the budget (including subcontract budgets). The Investigator, as referred to within this policy, includes the investigator's spouse and dependent children. The phrase “team member” is used interchangeably with Investigator.

Manage

Taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Obligatory interest

A relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, or holding scientific advisory or governing board membership.

Obligatory conflict of interest (OCOI)

A responsibility or commitment that could *directly and substantially* affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

Research

A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic “bench,” “clinical” or applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term also includes any scholarly or educational activity for which external funding is available through a contract, grant or cooperative agreement.

Senior/key personnel

The PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the funding agency by the University.

Significant financial interest

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related (associated with a common idea or practice) to the Investigator's institutional responsibilities:

- A. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel); equity interest includes any stock,

stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- B. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- C. Intellectual property rights and interests (e.g., patents, copyrights) become SFIs when an individual receives an aggregated income of \$5,000 or more from one entity for said rights and interests.

(2) The term significant financial interest *does not include* the following types of interests: salary, travel, royalties, or other remuneration paid by the University of Miami to the Investigator if the Investigator is currently employed or otherwise appointed by the University of Miami, including intellectual property rights assigned to the University of Miami and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, service on advisory committees or review panels for or sponsored by a United States Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(3) For PHS funded Investigators this also includes any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to an Investigator's institutional responsibilities that the Vice Provost for Research and/or his/her designee determines constitutes an FCOI with the Investigator's funded research.

Policy:

This policy is divided into sections to describe the responsibilities of the University Investigator; the Sub-awardee/subcontractor/consultant that is not a member of the University of Miami community; and finally those of the University Vice Provost for Research, and/or his/her designees.

Investigator

Required Training:

Each Investigator (any University faculty member, staff, or student who could be involved in the design, conduct or reporting of research irrespective of funding source, or in educational activities funded by an external entity) is required to complete conflict of interest training prior to engaging in research or externally-funded educational activities, at least every four years, and immediately when any of the following circumstances apply:

- A. the University revises its COI policies or procedures in any manner that affects the requirements of University Investigators;
- B. an Investigator is new to the University; or
- C. the University finds that a University Investigator is not in compliance with the University's COI policy or management plan.

Responsibility to Disclose:

A. Financial and Obligatory Interests

All Investigators who could be involved in sponsored work must disclose annually to the Vice Provost for Research and/or his/her designee their institutional responsibilities and financial and obligatory interests that could be perceived to be related to any of their institutional responsibilities. In addition, the Investigator must list financial and obligatory interests of his/her spouse and dependent children that are related to the Investigators institutional responsibilities.

Such disclosures must be made, updated, or certified to the Vice Provost for Research and/or his/her designee:

- at least annually, prior to the close of the calendar year
- prior to an application, project or contract being submitted for proposed funding
- prior to expending funds for a new award (grant or contract)
- upon joining a project/award/contract team engaged in funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements
- if a new financial interest is discovered or acquired (e.g., through activity, purchase, marriage, or inheritance)
- upon transfer to the University of an externally funded award, contract or cooperative agreement from another institution or entity.

During the pendency or the term of an award or contract, Investigators are required to update disclosures within **thirty (30) days** of discovering or acquiring new financial or obligatory interests (e.g., through activity, purchase, marriage, or inheritance).

B. Reimbursed or sponsored travel:

PHS funded Investigators must also disclose the occurrence of any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities.

The details of this disclosure include:

- the purpose of the trip,
- the identity of the sponsor/organizer,
- the monetary value,
- the destination, and
- the duration.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The Vice Provost for Research and/or his/her designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

During the pendency or the term of an award or contract, investigators are required to update disclosures regarding reimbursed or sponsored travel within **thirty (30) days** of the occurrence of the travel.

Sub-awardees, sub-contractor, and consultant Responsibilities

Responsibility to Comply:

Sub-awardees, sub-contractors, and consultants on sponsored awards, contracts or cooperative agreements are required to comply with all aspects of the PHS FCOI regulations. In instances that the sub-awardee, sub-contractor, or consultant's organization does not have a federally compliant COI program, they must comply with the University's COI policies and procedures. Failure to comply with this policy or adhere to a COI Committee management plan may result in termination of participation in the associated project.

Methods of Compliance:

The University (as an awardee Institution) takes reasonable steps to ensure that any subrecipient Investigator complies with the PHS conflict of interest policy by written agreement with the subrecipient with terms that establish whether the FCOI policy of the University or that of the subrecipient will apply to the subrecipient's Investigators.

- A. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the Federal Regulation on FCOI, specifically Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the University's FCOI policy for disclosing significant financial interests that are directly related to the subrecipient's work for the University;
- B. Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, per the agreement referenced above the subrecipient will report all identified FCOI to the Vice Provost for Research and/or his/her designees within twenty (20) days. This time period is required to enable the University to provide timely FCOI reports, as necessary, to the awarding component.
- C. Alternatively, if the subrecipient's Investigators must comply with the University's COI policy, the agreement referenced above shall specify that the subrecipient must submit to the University of Miami all disclosures of financial and obligatory interests related to the Investigator's institutional responsibilities within fifteen (15) business days of submission of the grant or contract proposal. Disclosures are to be submitted directly to the Vice Provost for Research and/or his/her designees. This time period is required to enable the University to comply timely with its review, management, and reporting obligations.

University

Review of Disclosures:

Disclosures of financial and obligatory interests and level of significance will be reviewed by the Vice Provost for Research and/or his/her designees to determine whether an actual or potential COI exists, and to determine what conditions or restrictions, if any, should be imposed by the University to manage or eliminate such COIs. The Vice Provost for Research and/or his/her designees are responsible for assuring that determinations are the result of consistently applied guidelines, including but not limited to, a review of

- A. the nature of the personal relationship between the Investigator and the research;
- B. a risk/benefit analysis of patients if involved in the research;
- C. the specific role (e.g. patient screening and enrollment; data acquisition, analysis and interpretation) of the Investigator and consideration of how that role can affect the outcome of the research; and

- D. the expertise of the Investigator and extenuating circumstances as to why he or she should be involved in the research.

An interest will be determined to be a COI if it exceeds the threshold limits put forth by this policy or if it could directly and significantly affect, or be affected by the design, conduct, reporting or outcome of the funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

Management

Management of an identified COI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Examples of conditions or restrictions that might be imposed to manage or eliminate actual or potential conflicts of interest include, but are not limited to:

- Public disclosure of COIs;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in specific portion (s) of the funded research that would be affected by the COI;
- Divestiture or reduction of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.

The Investigator will affirm in writing that he/she agrees to comply with the condition (s) and/or restriction (s) imposed by the Vice Provost for Research and/or his/her designees within ten (10) days of receiving the determination letter or management plan.

Management plans are distributed to all relevant individuals, administrative offices and other units as required by the conditions of the plan including but not limited to the Investigator, the Investigator's supervisor, the Principal Investigator, Human Subjects Research Office, IACUC, the IP Strategy and Licensing office, General Counsel, and Research Administration.

Investigator compliance with the management plan is subject to monitoring and review by the Office of Research Compliance and/or other University compliance offices, including the Human Subject Research Office.

Appeals:

If an Investigator does not agree with the decision of the Vice Provost for Research and/or his/her designees, the Investigator may appeal the decision once to the Vice Provost for Research. If the Investigator remains unsatisfied with the subsequent ruling, he or she can further appeal the determination to the Provost, whose decision will be final. For an appeal to be valid, the Investigator must file each appeal with the Vice Provost for Research and/or his/her designees in writing within 10 business days of receiving the management plan.

Retrospective Review:

Whenever an interest related to funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements is not identified or managed in a timely manner including failure by the Investigator to disclose a financial or obligatory interest, or failure by the University to review or manage an interest, the Vice Provost for Research and/or his/her designee has sixty (60) days to determine if the disclosure constitutes a COI.

If determined to be an FCOI related to PHS funding, or upon learning that an Investigator failed to comply with a prior FCOI management plan for PHS-funded research, the University shall complete a retrospective review of the Investigator's activities within one hundred and twenty **(120) days** of the discovery of nondisclosure/ determination of noncompliance in order to determine whether the research or scholarly activity, or any portion thereof, conducted during the time period of noncompliance, was biased in design, conduct, or reporting.

Further, regardless of type of COI or origin of funding, the University has the option to conduct a similar retrospective review in order to determine if the design, conduct, or reporting of the research or scholarly activity was biased.

Depending on the nature of the interest, the Vice Provost for Research and/or his/her designee may determine that additional interim measures are necessary with regard to the Investigator's participation in the funded research project or scholarly activity until the completion of the Institution's review.

If bias is found, the University will notify and submit a mitigation report to the awarding component (as required). The mitigation report will include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the PHS funded research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the University will submit FCOI reports **annually** for the duration of the funded project, including extensions with or without additional funding.

Further, if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Enforcement and Sanctions:

Regardless of funding source, failure to comply with a determination of the Vice Provost for Research and/or his/her designees or failure to comply with this policy will be brought to the attention of the Investigator's supervisor, Dean, and the Provost. The Provost will have the option of taking appropriate action(s) including but not limited to withdrawal of pending proposals and/or placing a hold on, or terminating, an active award, contract or cooperative agreement. In addition, if required, the University will notify the awarding component of the Investigator's failure to comply with the determination and/or policy.

Public Access:

The University will maintain a website to ensure public accessibility to this policy and information concerning any significant financial interest disclosed to the University that meets the following three criteria:

- A. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;
- B. The University determines that the significant financial interest is related to funded research or to scholarly and/or educational activities funded under external grants, contracts or cooperative agreements; and
- C. The University determines that the significant financial interest is a FCOI.

The information presented includes the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

This information will be provided on the website prior to the University's expenditure of any funds under the relevant funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

The University will update the website within sixty (60) days of the University's receipt or identification of information concerning:

- any additional significant financial interest that was not previously disclosed held by the senior/key personnel for the funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements project, or
- upon the disclosure of a significant financial interest of senior/ key personnel new to the funded research project or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

The information will remain publically available for three years from the date on which the information was most recently updated.

Advising External Funding Entity:

The Vice Provost for Research and/or his/her designee will be responsible for advising an external funding entity regarding actual or potential conflicts of interest according to the policies/requirements of the external entity. The University does not disclose information related to potential or actual conflicts of interest unless it is required by the awarding component.

Record Retention:

Records of financial interests, significant financial interests, determinations of the Vice Provost for Research and/or his/her designees, appeals and compliance documents, and documents regarding all actions taken to resolve actual or potential conflicts of interest will be maintained by the Vice Provost for Research and/or his/her designees for at least three years following the submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

Compliance with Federal Regulations:

Any regulations promulgated by a governmental agency on conflict of interests will be incorporated by reference in this policy.

References and Related Resources:

University of Miami, Faculty Manual.

University of Miami Policy on Audits, 6.3

PHS Grants Policy Statement and Code of Federal Regulations 42CFR50, 42CFR94

NSF Grants Policy Manual.

The University of Miami Medical Group "Interactions with Health Industry Entities" policy

Office of Research Conflict of Interest webpage located at: <http://uresearch.miami.edu/?p=173&s=4>

Contact

Questions about this policy can be answered by:

Lory A. Hayes, Ph.D., CHRC

Associate Director

Office of Research Compliance

305.243.5036

l.hayes@miami.edu

Consulting and Compensation for Non-University Activities

This policy on consulting does not apply to faculty members who are participants in the Miller School of Medicine's professional practice group.

Opportunities for outside consulting are normally looked on with favor when they (1) contribute to the professional development of a faculty member, (2) contribute expertise not commonly available for the solution of a problem of society or industry, or (3) provide carry-over into the instructional program of the professor involved. The following general guidelines apply to consulting activities. (See also the Conflict of Interest Policy following this section.)

(1) Time spent on such consulting must be in addition to rather than a part of the normal full-time effort expected of the members of the faculty for University responsibilities. If a faculty member is engaged in any work for which extra compensation is received from the University, the number of hours devoted to outside professional activities shall be correspondingly reduced.

(2) A faculty member shall keep the department chair and the dean of the college or school, through the department chair, informed of the nature and extent of consulting and related activities by annual submission of a report as required by the Executive Vice President and Provost. The Office of the Executive Vice President and Provost provides forms for annual reporting of consulting activities.

Distribution of Effort

There are competing demands on the energies of a University faculty member (for example, research, teaching, administering, committee work, and outside consulting). The way in which employees divide their effort among these various functions does not raise ethical questions unless the agency supporting research is misled in its understanding of the amount of professional effort actually devoted to the research in question. If the research agreement contemplates that a faculty member will devote a certain fraction of effort to sponsored research or agrees to assume a responsibility in relation to this research, a demonstrable relationship between the indicated effort or responsibility and the actual extent of involvement is to be expected. The University, therefore, through joint consultation of administration and faculty, has developed procedures to assure responsible compliance with the terms of these agreements.

Consulting

Consulting for Government Agencies or Other Contractors

When University members engaged in Government sponsored-research also serve as consultants to a Federal agency, their conduct is subject to the provisions of the federal Conflict of Interest Statutes and the President's memorandum of May 2, 1963, Preventing Conflicts of Interest on the Part of Special Government Employees. When members consult for one or more Government agencies or other contractors, or prospective contractors, in the same technical field as their research projects, care must be taken to avoid giving advice that may be of questionable objectivity because of its possible bearing on their other interests. In undertaking and performing consulting services, members should make full disclosure of these interests to the University and to the contractor insofar as they may appear to relate to the work at the University or for the contractor. Conflict of interest problems could arise, for example, in the participation by members of the University in an evaluation for the Government or other agency of its contractor of some technical aspect of the work of another organization with which they

have a consulting or employment relationship or a significant financial interest, or in an evaluation of a competitor to that other organization.

Outside Consulting

Faculty may accept opportunities for outside consulting and similar services in their fields of specialization provided this work does not interfere or conflict with their teaching, research, examining, counseling, and other University responsibilities. No faculty member may profit from private services while receiving monies from the University for the performance of these same services. The receipt of honoraria, lecture fees, and monies for expert testimony is permitted provided the services performed for such fees do not interfere or conflict with University responsibilities and the University has not provided or agreed to provide funds to the faculty member for performing those same services. The time involved in consulting activities shall not amount to more than an average of one day a week during the faculty member's period of appointment.

Intra-University Consulting

When intra-University consulting is permitted under established University policy, University faculty members may not be paid a retainer fee. Compensation is to be based upon regular daily rates established by University policy. Any variation from these rates requires authorization from the appropriate vice-president. Intra-university consulting requires the prior approval of the immediate supervisor of the faculty member undertaking the consulting.

Private Professional Services

The University assumes no responsibility for private professional services rendered by members of the faculty. When faculty members do work in a private capacity, they must make it clear to those who employ them or may use the results that their work is not performed as agents of the University.

Use of University Facilities, Staff or Equipment

If University facilities, staff, or equipment are used in any activity, the activity must be a University-authorized function and must be conducted either (1) under contract with the University or (2) under an agreement that provides for reimbursement to the University for facilities, staff, or equipment used by the faculty member in the conduct of this activity.

Relationships with Private Enterprises

Faculty members should not acquire a relationship with private enterprise that either (1) requires in excess of one day per week of their time during their period of appointment, or (2) presents the possibility of competition between the private enterprise and the University in terms of the services each could provide.

Use of the Name of the University of Miami

University faculty members should not use the University of Miami name in any manner when advertising for consulting work.

Contact

Questions about this Policy can be answered by:

Faculty Senate Office

305.284.3721

facsen@miami.edu

Human Research Protection Program

The mission of the University of Miami Human Subject Research Office (HSRO) is to facilitate human subject research among the faculty, staff, and students from all schools and departments within the University of Miami and the Jackson Health System and to support the UM IRB in conducting its reviews and other responsibilities. The HSRO shall be committed to ensuring that University research is conducted according to the University's high ethical standards and in compliance with federal, state and local regulations.

Introduction

This policy for the protection of Human Subjects in Research is provided in an effort to give comprehensive information about the organization and focus of the Human Subjects Research Office to the members of the research community at University of Miami and affiliated organizations. Its Policies and Procedures are written and organized to teach and to provide reference to the requirements and best practices in meeting the high ethical standards of the University of Miami and in carrying out federal, state and local regulations. The Declaration of Helsinki and the Belmont Report provide the ethical foundation for these Written Policies and Procedures. Written policies and procedures are required by federal regulations (Code of Federal Regulations: Title 45, Part 46.103 (b)(4) and Title 21, Part 56.108(a)). [NOTE – Further such references to federal codes will be made in a shortened manner such as 45 CFR 46.103].

Equally important is that written policies and procedures are essential to:

- a. Establish consistency in decisions and decision-making
- b. Promote predictability to investigators and others on the process that the Institutional Review Board (IRB) and HSRO will follow
- c. Reduce errors by providing a framework for careful conduct
- d. Give clarity to authorities and responsibilities
- e. Facilitate the training of, and serve as a reference manual for IRB members, investigators, HSRO staff and others
- f. Ensure that human studies research and IRB matters are managed appropriately and equitably

Authority and Responsibility

The HSRO is supervised by the Associate Vice Provost for Human Subject Research and the Vice Provost for Research who is the Institutional Officer of the University. The Associate Vice Provost for Human Subject Research shall ensure that adequate resources (i.e. staff support, equipment, space and other resources) are available and appropriately allocated to and within the HSRO for the HSRO to accomplish its mission. The Vice Provost for Human Subject Research is also responsible for the effective allocation of resources to various activities of the IRB.

University of Miami Compliance Helpline

<https://secure.ethicspoint.com/domain/media/en/gui/32533/index.html>

University of Miami HSRO Program Policies

The complete Human Research Protection Program Policies is available on the Human Subjects website

<http://hsro.med.miami.edu/>

Contact

Questions about HSRO can be answered by:

Khemraj Hirani, MPharm, Ph.D., CPH, RPh, CCRP, CIP, RAC, MBA

Associate Provost for Human Subjects Research

Phone: 305-243-3195

Email: KHirani@med.miami.edu

Human Stem Cell Research

I. Institutional Oversight of Human Embryonic Stem Cell and Related Research at the University of Miami

It is the policy of the University of Miami (UM) that all research using human embryonic stem cells (hESCs) or somatic cell nuclear transfer (SCNT) involving human cells being conducted by UM faculty, staff or students or involving the use of UM facilities or resources shall be subject to review and oversight by the UM Embryonic Stem Cell Research Oversight (ESCRO) committee. Any and all such research must be conducted according to the specific ESCRO protocol as reviewed and approved in advance by the UM ESCRO committee.

II. Purpose of the UM ESCRO Committee

Under the ESCRO Committee Charge issued by the Vice Provost for Research, the primary purpose of the committee is to provide oversight of all issues related to derivation and use of hES cells and SCNT involving human cells and to facilitate education of investigators involved in such research.

Specifically, the UM ESCRO Committee provides oversight over all issues related to derivation and use of hESCs and hSCNT, including establishing and modifying policies and procedures; assures all research involving hESCs and hSCNT conducted at the University or by University investigators is compliant with all relevant regulations and is within the guidelines presented in the NAS/IOM report "Guidelines for Human Embryonic Stem Cell Research." (2005 and subsequent updates), or any subsequent revisions or replacements of those guidelines.

The committee also maintains registries of hESC and hSCNT research conducted at the University and of hESCs derived or imported by University investigators; ensures MTA's are on file; reviews and approves the scientific merit of hESC and hSCNT research protocols; reviews derivation details and ensures appropriate informed consent is obtained; coordinates with other University regulatory and oversight committees (i.e., IACUC, IRB, IBC, etc.); and assures that University investigators and trainees are educated regarding the responsible conduct of research with hESC and hSCNT, including University, State, and Federal regulations governing such research. In addition, the committee also serves as a consultative body for researchers working with human embryonic germ (EG) cells, human adult stem (AS) cells, human umbilical cord blood (UCB) stem cells, and/or human/non-human chimeras.

III. The Authority of the UM ESCRO Committee

A. Initial Approval of Human Stem Cell Research

The UM ESCRO committee shall have the authority to approve, require modifications of, or withhold approval of all research activities that fall under its jurisdiction within UM, (see UM ESCRO Committee Charge). In addition, other Divisions of the University may refer research protocols to the UM ESCRO committee for review.

B. Continuing Oversight

1. Approved research shall be reviewed by the UM ESCRO committee every three years, or more frequently, as determined by the committee on a case-by-case basis. The

investigator is responsible for submitting the renewal application in a timely manner. Failure to submit the application by the deadline will result in withdrawal of approval.

2. Progress Reports and Adverse Event Reports pertaining to UM ESCRO committee approved research and submitted to a University IRB, IACUC, and/or IBC must also be submitted to the UM ESCRO committee.
3. No modifications to a UM ESCRO committee approved research protocol shall be implemented prior to committee approval of the modifications, except when a deviation is necessary to prevent imminent harm. Such deviations should be reported to the committee within 3 business days. The committee has the authority to review and approve, require modifications of, or withhold approval of all proposed modifications to the approved research protocol prior to the implementation of such modifications by the investigator.

C. Monitoring of UM ESCRO Committee Approved Research

The UM ESCRO committee or its representatives shall have the authority to observe the conduct of any research activity subject to committee oversight. This function includes the authority to review all records associated with the conduct of the research.

D. Restrictions, Suspension, and Termination of Research

1. The UM ESCRO committee shall have the authority to place restrictions on research activities that fall under its jurisdiction. The committee will notify the Vice Provost for Research and any other relevant committees (e.g., IRB, IACUC, IBC, and other applicable Committees and Boards) of any such restrictions.
2. The UM ESCRO committee shall have the authority to suspend or terminate its approval of research that falls under its jurisdiction and that is not being performed in compliance with committee requirements, applicable governmental regulations, and/or University policies. The committee will notify all UM Institutional Official(s), as well as other relevant committees (e.g., IRB, IACUC, IBC, etc.) of any suspension or termination.
3. If the UM sponsors research at a site outside the University, or a UM researcher¹ participates as a co-investigator in research at a site outside the University, the UM ESCRO committee shall have the authority to terminate the participation of UM researchers in the research. In such cases, the UM ESCRO committee chairman will inform the responsible Institutional Official(s) at UM and at each institution involved in the research of the termination.

¹ UM researchers are UM faculty, staff or students acting in their capacity as UM faculty, staff, or students.

E. Review of Research within the Jurisdiction of the UM ESCRO Committee by Other University Committees or Officials

1. Research requiring UM ESCRO committee review ordinarily will be submitted for review and approval concurrently with submission of the research to any other UM entity (e.g., IRB, IACUC, IBC, etc.) that may have responsibility for oversight of other aspects of the research.

2. Research activities approved by the UM ESCRO committee may be subject to further review, modification of, approval and/or disapproval by all relevant bodies, such as IRB; IBC; IACUC; and the UM Vice Provost for Research. However, those committees and officials may not approve the conduct of research within the UM ESCRO committee's jurisdiction if approval was previously withheld by the committee.

F. Education and Training

All study team members engaged in research, subject to oversight by the UM ESCRO committee shall complete educational activities related to the responsible conduct of such research, as specified by the committee.

IV. Conflicts of Interest – UM ESCRO Committee Chairman, Members and Consultants

A. Disclosure

UM ESCRO committee chairman and committee members are required to disclose conflicts of interest at the beginning of each committee meeting or when assigned as a reviewer. Conflicts of interest include being a listed investigator, having a financial interest in the sponsor of the research or the technology being evaluated, as defined by the faculty manual, UM Policy on Conflict of Interest, or having any other interest or relationship that might reasonably be perceived to inhibit or impede a fair and unbiased review of the research.

B. Abstention from Deliberations and Absence from the Meeting Room

UM ESCRO committee members who have conflicts of interest with respect to protocols submitted for review will abstain from participating in committee deliberations and decisions relative to those protocols. Such members may be consulted on the research.

C. Consultants and Conflict of Interest Disclosure

Consultants shall be asked and are required to disclose, at the time they are contacted to review a research study, if they have a conflict of interest with the study on which they are being asked to consult. Such conflicts shall generally be considered disqualifying.

V. Research Requiring Review and Approval by the UM ESCRO Committee

All research under the jurisdiction of the UM ESCRO committee shall be subject to review by the committee, in addition to all other relevant bodies with oversight, such as the IRB and the IACUC.

VI. Prohibited Research

In accordance with prevailing ethical and policy guidance and applicable law, the following categories of research are currently prohibited at UM:

- a. Research involving the introduction of ESCs into human blastocysts;
- b. Research involving the introduction of hESCs into non-human blastocysts;
- c. Research involving in vitro culture of any intact human embryo for longer than 14 days or until formation of the primitive streak begins, whichever occurs first; and
- d. Breeding of animals that have had hESCs introduced into the germ line.

Note: The above list of prohibited research does not imply that similar research with human pluripotent stem (hPS) cells or induced pluripotent stem cells (iPSC) is allowed by default. Such research while not under ESCRO Committee jurisdiction still requires IRB and/or IACUC approval. The IRB and IACUC may refer cases to ESCRO for review prior to granting approval. This list may be revised to reflect changes in prevailing ethical and policy guidance and applicable law.

VII. Standards for UM ESCRO Committee Review

In conducting review of proposed research, the UM ESCRO committee will take into account considerations that include the following.

A. Procurement of Gametes, Blastocysts, or Somatic Cells for hESC Generation

For the purposes of UM ESCRO committee review, sources of human embryonic stem cell materials will be considered human research subjects (per 45 CFR 46), regardless of the context in which the materials are procured. Human subject research is required to have IRB approval.

The ethical and legal issues related to hESC research will depend in part on the context in which human materials are procured (for example, infertility treatment, research, clinical care). The context of procurement will involve established standards of care that will be taken into consideration during committee deliberations. Therefore, protocols must describe:

1. Ethical considerations for procurement of human materials in the context of clinical care:
 - a. Plans to ensure that an individual's decision about donation will not affect the quality of care s/he receives;
 - b. Plans to ensure that infertility treatment teams will not generate more oocytes than clinically necessary.
2. Voluntariness of Consent:
 - a. Plans to ensure that undue inducements will not be provided for donation (e.g., financial or special considerations for services);
 - b. Plans to ensure that decisions to donate are made free from undue influence (e.g., the investigator and the attending physician responsible for the infertility treatment are not the same person).
3. Informed Consent:

In addition to the required elements of informed consent specified in 45 CFR 46. 116, the informed consent process and document must disclose the following:

- a. That blastocysts or gametes will be used to derive hESCs for research that may include research on human transplantation;
- b. That embryos will be destroyed in the process of deriving hESCs;
- c. That embryos will not be used to produce a pregnancy and will not be allowed to develop in culture for longer than 14 days from fertilization;
- d. That resulting cell lines will be genetically similar or identical to the donor;
- e. That restricted and/or directed donation (e.g., to individuals or groups) are/is not permitted;
- f. Whether the donors' identities will be ascertainable;
- g. If the donors' identities are retained (even if coded), whether donors can elect to be contacted to receive information obtained through studies of the cell lines;
- h. That derived hESCs and/or cell lines might be kept for many years;

- i. That the hESCs and/or cell lines might be used in research involving genetic manipulation of the cells or the mixing of human and non-human cells in animal models;
- j. That the results of study of the hESCs may have commercial potential and that the investigator and institution may benefit; however, the donor will not receive financial or any other benefits from any commercial development;
- k. That the research is not intended to provide direct medical benefit to the donors;
- l. That neither consenting nor refusing to donate embryos for research will affect the quality of any care provided to potential donors;
- m. Risks to donors.

B. Transfer of Human Materials from Outside Entities

To determine the scientific and ethical integrity of hESC research the UM ESCRO committee must examine the circumstances under which human materials were (or will be) procured for use in hESC research and the details of the derivation of hESC lines. The applications must include documentation of the provenance of all hESC lines, whether the cell lines were imported into the institution or derived locally. Such documentation must include evidence of IRB-approval of the procurement process, a copy of the original informed consent for obtaining the embryos, evidence of and adherence to basic ethical and legal principles of procurement, and compliance with applicable laws.

C. Derivation of hESCs

Protocols must describe:

1. Appropriate expertise of the research team in the derivation or culture of either human or non-human ESCs;
2. The scientific rationale for the need to generate new hESCs, as well as the basis for the number of blastocysts used in the derivation process;
3. Any plans for compliance with an established set of good manufacturing practices (GMPs), and if so with which GMPs;
4. How any new hESC lines will be characterized, validated, stored, and distributed.

D. Transfer of hESCs into Non-human Animals

Protocols must describe:

1. Why hESCs are required in lieu of ESCs from primates or other animals;
2. Relevant animal work that precedes the proposed work involving hESCs;
3. Quality control of ESC lines and their derivatives, (such as genetic stability, freedom from contamination);
4. The part of the non-human animal's body to which the cells will be transferred;
5. The developmental stage of the non-human animal to which the cells will be transferred;

6. When the proposed research involves potential for neural grafting, describe procedures that will assess whether the animal may acquire cognitive characteristics that are thought of as distinctly human, as well as how non-human primates will be evaluated (pre- and post-transplant).

E. Safety Considerations in Trials with Humans

Protocols must comply with all FDA, IRB and any other relevant Federal, State and local laws and must describe:

1. Pre-clinical testing with animal models;
2. Quality control of ESC lines and their derivatives;
3. Selection of subjects (e.g., the appropriateness of using healthy volunteers in early human trials);
4. Risk of infectious disease (e.g., from cells cultured in mouse feeder layers);
5. Risk of transfer of genetic disorders;
6. Risks of misdifferentiation, mistargeting, tumor formation, and immune rejection;
7. Risk of uncontrolled cell growth.

F. Justice

Protocols must describe mechanisms established for subject selection. The process for selection among groups and individuals to participate must be equitable.

G. International Collaboration

Where UM faculty, staff or students acting in their capacity as faculty, staff or students respectively, collaborate with a researcher at a foreign institution, protocols must describe protections afforded and procedures prescribed by the foreign institution.

VIII. Procedures for Research Requiring UM ESCRO Committee Review

The review process and the records of the UM ESCRO committee will be maintained as confidential to the extent permitted by law.

A. UM ESCRO Committee Review of Research Proposals

1. Each research study requiring review and approval by the convened UM ESCRO committee shall be addressed separately at the committee meeting.
2. The Principal Investigator must be a University of Miami faculty member. May be waived under University policy. All waivers must be approved in writing by the Vice Provost for Research.

3. Submitted protocols will be made available to UM ESCRO committee members in advance of committee meetings to allow sufficient time for review.
4. The primary reviewer for each protocol shall summarize the proposed research followed by an open discussion of the research by the UM ESCRO committee members.
5. All proposals will have a secondary reviewer assigned.
6. The primary and secondary reviewers may direct questions about the submitted protocol to the Principal Investigator via ESCRO administration. In such cases, the Principal Investigator will have an opportunity to submit revisions before full UM ESCRO committee review.
7. Reviewers who are absent from a full UM ESCRO committee meeting may provide written comments regarding the proposed research, but absent members shall not be counted in the UM ESCRO committee vote.
8. Following open discussion, the UM ESCRO committee chairman shall call for a vote of the committee to grant:
 - a. **Full Approval:** No changes are required to the proposed research;
 - b. **Approval Pending Concurrence with UM ESCRO committee-directed Changes:** The proposed research may be granted full approval by the UM ESCRO committee chairman pending principal investigator concurrence with specific revisions stipulated by the committee. The research may not receive full approval until such time that the research procedures have been modified to comply with the specific revisions stipulated by the committee and such revisions have been reviewed and approved by the UM ESCRO committee chairman or their designee;
 - c. **Reconsideration:** Approval of the proposed research requires substantive clarifications or modifications of the research design or procedures. The principal investigator must respond to the identified clarifications, modifications, or revisions and resubmit the revised research protocol for re-review by the UM ESCRO committee; or
 - d. **Approval withheld:** The proposed research has fundamental design problems and/or presents significant ethical, legal or regulatory compliance concerns. The principal investigator must undertake a major revision of the proposed research before it can be resubmitted for re-review by the UM ESCRO committee.
9. The vote of the majority of the UM ESCRO committee members present at the meeting shall determine the final determination status (i.e., full approval, approval pending concurrence with UM ESCRO committee-directed changes, reconsideration, or approval withheld) of the proposed research. The UM Vice Provost for Research may impose additional restrictions on approved research, but may not approve research for which approval was withheld by the UM ESCRO committee.

10. Following an UM ESCRO committee vote for full approval or approval pending concurrence with UM ESCRO committee directed changes:
 - a. UM ESCRO committee members voting to reconsider or withhold approval of the research in the face of a majority vote for full approval or approval pending concurrence with committee-directed changes shall be requested to summarize the reasons for their contravention.
11. The UM ESCRO committee shall notify the investigators in writing of the committee's decision to approve, reconsider, or withhold approval of the research, or of the committee -directed changes required to secure committee approval of the research.

IX. Process for Protocols Following UM ESCRO Committee Vote

A. Protocols Granted Full Approval

For research granted full approval by the UM ESCRO committee, the Principal Investigator will be notified. The Principal Investigator shall be responsible for ensuring that all other applicable institutional requirements are met (e.g., IRB, IACUC, or IBC approval).

B. Protocols Approved Subject to Concurrence with UM ESCRO Committee-Directed Changes

If the convened UM ESCRO committee decides to approve the proposed research pending concurrence with committee-directed changes, the principal investigator will be provided:

1. Notification addressing the specific revisions stipulated by the committee in order to obtain full approval of the research.
2. Notification instructing the investigator to revise the research protocol to concur with the specific revisions stipulated by the committee and to resubmit for full approval.
3. Notification specifying that the principal investigator must respond to the committee's request for revisions within six (6) weeks of the date of the notification, and that failure to respond within this six (6) week period may result in termination of the respective research submission.

For research approved by the UM ESCRO committee pending concurrence with committee-directed changes, the revised research submitted in response to the specific revisions stipulated shall be reviewed by the committee chair or his/her designee and, based on an appropriate response, granted full approval. Any problems or concerns related to the principal investigator's response shall be communicated, in writing or by e-mail, to the principal investigator. In the event that the principal investigator does not agree with certain specific revisions stipulated by the UM ESCRO committee, the research proposal (to include any directed changes agreed on by the principal investigator) and the investigator's justification for not complying with certain change(s) shall be referred to convened meeting review. The investigator shall be notified that s/he will be afforded an opportunity to appear in person at the committee meeting during which the research will be reconsidered.

C. Protocols Reconsidered or Not Approved

If the UM ESCRO committee decides to reconsider or disapprove the proposed research, the principal investigator will be provided:

1. The primary reason(s) for the committee's decision to reconsider or withhold approval of the research;
2. A listing of additional problems or deficiencies identified by the committee;
3. Instructions regarding resubmission of the research for review by the committee including a requirement to address the statements and concerns emanating from the initial review;
4. Notification that s/he may appear in person at the meeting of the committee wherein the research will be reconsidered, to address any additional questions or concerns of the committee; and
5. Notification that s/he must respond to the committee's request for revisions within six (6) weeks of the date of the notification, and that failure to respond within this six (6) week period may result in termination of the respective research submission.

X. UM ESCRO Committee Meetings

The minutes of the UM ESCRO committee meetings shall include but not be limited to the following items: record of attendance, declared conflicts of interest, protocols reviewed (including controverted issues), documentation of approval intervals (if applicable), and committee votes.

Documentation shall include UM ESCRO committee members voting for and against the action taken and the number of members abstaining from the vote (e.g., 7-for, 1-against, 1-abstain), including the name(s) of any voting member(s) who abstained from the vote due to conflict-of-interest or other considerations.

The minutes shall be reviewed and accepted by the UM ESCRO committee chairman prior to generating investigator correspondence.

The minutes shall be distributed to UM ESCRO committee members. At each meeting, a vote of shall be taken to approve the minutes of the previous meeting. The minutes may be modified as necessary to obtain approval of the UM ESCRO committee.

Portions of this document were derived from:

The Policies and Procedures of the Johns Hopkins University School of Medicine ESCRO Committee <http://www.hopkinsmedicine.org/Research/escro/Policies/PoliciesProcedures.html>

University of Pittsburgh *UM ESCRO Committee Policies and Procedures Manual*
[http://www.rcco.pitt.edu/UM ESCRO committee/policy_053106.pdf](http://www.rcco.pitt.edu/UM%20ESCRO%20committee/policy_053106.pdf)

National Academy of Sciences *Guidelines for Human Embryonic Stem Cell Research*
<http://darwin.nap.edu/books/0309096537/html>

Contact

Questions about this Policy can be answered by:

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Chair, ESCRO Committee

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Laboratory Animals in Research

Animal Welfare Compliance and the University of Miami Animal Care Program

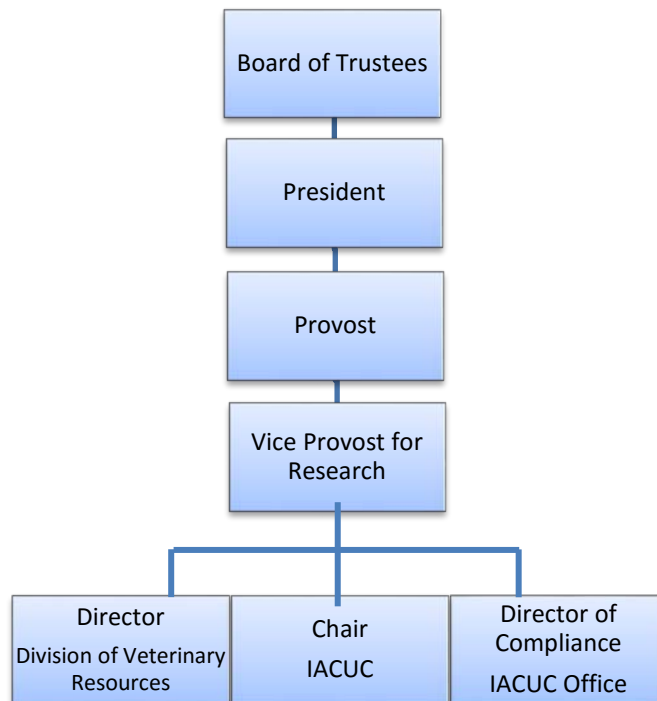
This policy describes and outlines the University of Miami's compliance with all relevant laws and regulations governing the humane care and use of laboratory animals. The University of Miami (UM) complies with the Animal Welfare Act and the PHS Policy on Humane Care and Use of Laboratory Animals. Additionally, the University is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Introduction

It is University of Miami policy that all faculty, staff, visiting scholars and students comply with the applicable provisions of the US Department of Agriculture (USDA) Animal Welfare Act, the University's Assurance of Compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, 8th edition (*Guide*), other Federal and State statutes, local regulations, and all other University policies and procedures relating to laboratory animals (living or dead). Failure to comply may result in a suspension of privileges to use laboratory animals in teaching and research activities.

Authority and Responsibility for Ensuring Compliance/Lines of Authority and Responsibility for Administering the Program

The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows:



Institutional Official

The Vice Provost for Research is the institutional official responsible for ensuring that activities using laboratory animals at UM are humane and in compliance with all applicable external regulations. To achieve that end, s/he is responsible for establishing and enforcing relevant University policies and procedures.

Animal Care and Use Committee (IACUC)

The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy and the Animal Welfare Act (the University President has delegated authority for IACUC appointments, specifically and in writing to the Institutional Official) and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy and as applicable, the Animal Welfare Act. The IACUC Chair reports directly to the Institutional Official.

The IACUC Chair reports directly to the Institutional Official. The IACUC is charged with reviewing and approving all teaching and research activities involving laboratory animals. A protocol application form, i.e., the "long form" must be submitted to the IACUC for its review and approval before a project is initiated. The IACUC is also responsible for semi-annual inspections of all laboratory animal housing areas at UM and a semi-annual evaluation of the overall program for the care and use of laboratory animals.

Attending Veterinarian (AV)

The Attending Veterinarian reports directly to the Institutional Official. The AV is the Director of the Division of Veterinary Resources (DVR) and has oversight authority for all activities involving laboratory animals. That individual, or designee, is a voting member of the IACUC. Investigators are encouraged to call upon the Attending Veterinarian or other DVR staff for guidance in protocol development and consultation on experimental procedures.

The veterinarians under the Attending Veterinarian's direction carry out their duties as part of the Animal Care Program via the Division of Veterinary Resources (DVR). The DVR is a division of the Office of the Vice Provost for Research (VPR). Therefore, the authority of the veterinarians is derived from the Board of Trustees, through the President, through the Provost, through the Vice Provost, to Attending Veterinarian. The Attending Veterinarian reports directly to the Institutional Official.

Division of Veterinary Resources (DVR)

The DVR is responsible for the procurement of laboratory animals, providing housing and care of laboratory animals, providing and maintaining certain facilities for animal research such as surgery suites, overseeing transportation of laboratory animals onto or off of the UM campus or from site to site on the campus, and providing veterinary services for laboratory animals and veterinary consultation for investigators.

Environmental Health & Safety Office

The Environmental Health & Safety office (EH&S) is responsible for implementing an IACUC approved Laboratory Animal Occupational Health Program (OHS) for individuals working in laboratory animal facilities and having substantial animal contact

Animal Welfare Assurance of Compliance

The assurance ensures UM compliance with PHS Policy on Humane Care and Use of Laboratory Animals; includes a description of UM's policies and procedures for the animal program. This Assurance renewal, identified as #A3224-01, is approved for a five year period, and will expire on November 23, 2015. See [DHHS Assurance Renewal Letter](#)

Animal Welfare Registration of Compliance

The registration ensures UM compliance with the Animal Welfare Act Policy regarding regulated live animals in research facilities. This registration refers to all USDA regulations and standards regarding regulated animal research.

This USDA registration renewal, identified as #58-R-0007-01, is approved for a three year period, and will expire on December 3, 2014. See [USDA Certificate of Registration](#)

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)

This voluntary accreditation program evaluates institutional animal research programs. Those that meet or exceed AAALAC standards are awarded accreditation; UM has been accredited since 2005. On-site visits evaluations of the animal program occur every three years. See [AAALAC Accreditation Letter](#)

Authority and Responsibilities of the Animal Care Program

To ensure UM's compliance with the Animal Welfare Act, PHS Policy and the recommendations of the Guide for the Care and Use of Laboratory Animals, 8th edition (*Guide*), the following occur:

Review At Least Once Every Six Months the Institution's Program

The IACUC reviews at least once every six months, the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations are as follows:

- Review semiannually the University's Program for Laboratory Animal Care and Use at convened IACUC meetings. The Committee uses the *Guide* and other pertinent resources, e.g., PHS Policy, and as applicable, 9 CFR Chapter I, subchapter A as a basis for the review. To facilitate the evaluation, the Committee uses a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website and the AAALAC application.
- The evaluation includes, but is not necessarily limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care; d) Personnel Qualifications (Experience and Training); and d) Occupational Health and Safety. In addition, the evaluation includes a review of the Institution's PHS Assurance and AAALAC application.
- Categorize any program deficiencies as minor or significant and develop a plan and schedule for correction for any deficiencies

Inspect the Institution's Animal Facilities

The IACUC inspects at least once every six months, all of the Institution's animal facilities, including satellite facilities, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

- Inspect every six months all of the University's animal facilities, including satellite holding facilities and areas in which surgical manipulations are performed, using the *Guide*, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation, with at least two IACUC members inspecting all facilities animal species are housed or used. Facility inspection findings are presented at convened IACUC meetings. Any IACUC member can attend an inspection of any facility.
- To facilitate the evaluation, the Committee uses a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. If deficiencies are noted during the inspection, they are categorized as significant or minor and the Committee develops a reasonable and specific plan and schedule for correcting each deficiency.

Prepare Reports of the IACUC Evaluations

The IACUC prepares reports of the IACUC evaluations as set forth in the PHS Policy and submit the reports to the Institutional Official. The IACUC procedure for developing reports and submitting them to the Institutional Official are as follows:

- The IACUC develops reports of the IACUC evaluations, addressing the requirements outlined in the "Sample Format for the Semiannual Report to the Institutional Official," and as applicable, 9 CFR Chapter I, subchapter A; listing the dates when program evaluation and facilities inspections were conducted and provides any minority views or a statement that there were no minority views; the IACUC evaluations are reviewed and approved at an IACUC meeting; the IACUC submits reports to the Institutional Official via the IACUC Chair/IACUC office.
- The IACUC identifies and discusses departures from the *Guide*, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, during their program evaluations, facilities inspections and protocol review; any departure is designated in IACUC minutes, and if new, reported in the Semiannual Reports to the Institutional Official.
- The IACUC ensures through their facilities inspections and program evaluations processes that any deficiencies are characterized as significant or minor, and assigns reasonable and specific plans and schedules for the correction of each deficiency.

Review Concerns

The IACUC review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

- The IACUC facilitates and enables individuals' abilities to report concerns involving animal care and use by posting the website/telephone number for reporting concerns anonymously; a compliance hotline 'Cane Watch', an external

third-party vendor, independent of the University. The 'Cane Watch Phone Number is: 877-415-4357;'Cane Watch Website: www.canewatch.ethicspoint.com. This posting is in multiple locations throughout the main animal facilities, where the majority of animal users pass through;

- Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC or DVR staff.
- The IACUC reviews all concerns with safeguards to protect the individual's identity, and if needed, appoints a subcommittee to perform an IACUC investigation; reviews any subcommittee investigation findings at a convened meeting and takes appropriate action, if warranted, up to and including suspension of a protocol.
- The IACUC reports concerns and related IACUC findings and recommendations, via the IACUC Chair, Attending Veterinarian or IACUC office to the Institutional Official.

Make Written Recommendations to the Institutional Official

The IACUC may make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- Evaluate, usually by subcommittee, a particular aspect of the University's animal program, facilities, or personnel training
- Review subcommittee reports at a convened meeting and vote to approve the report
- Submit written recommendations for review, via the IACUC Chair to the Institutional Official

Procedures for Protocol Review

In accord with the PHS Policy and the Animal Welfare Act, the IACUC reviews and approves, requires modifications in (to secure approval), or withholds approval of activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

Receipt of Protocols and Pre-review

Protocols are received electronically in the IACUC office via PDF-fillable form. IACUC staff pre-review all protocols for completeness and adherence to animal welfare standards, and write routine comments to comply with federal regulations and University policies/practices.

A. Notification of Members

All protocols are posted on the online secured site (Black Board). The IACUC Chair assigns all protocols for review and members are notified of IACUC assignments by an email when protocols are assigned to IACUC members (primary IACUC reviewers).

B. Distribution

Protocol activities are distributed via both email and the online secured site (Black

Board) for primary IACUC review as either: 1) full committee review; or 2) designated member review, (descriptions below under “Methods of Protocol Review”) based on established criteria. Only after all members have received a list of proposed research protocols, had written descriptions of those protocols available to them, and decided that full committee review is not necessary, can the designated reviewers review and approve the protocols.

C. Meetings and Attendance Requirements

The IACUC meets at least monthly; the IACUC proceedings are confidential. A quorum of the IACUC must be present to conduct its business. Alternates are encouraged to attend all meetings. All agendas and minutes are sent to all IACUC members, and a copy is sent to Institutional Official.

D. Methods of Protocol Review:

Full Committee Review

Protocol activities that have been referred for Full Committee Review are assigned to IACUC primary reviewers, (a minimum of two IACUC members) by the IACUC Chair who also assigns other expert reviewers to protocols when applicable; Radiation Safety when a project involves radioisotope use and/or OHS when a project involves a biological agent or recombinant DNA vectors.

1. The IACUC primary and expert reviewers review the protocol on the online secured site (Black Board) system; IACUC reviewers submit their comments and requests for modification to the IACUC office via email to the IACUC office.
2. The IACUC office reviews all comments and requests for modification received for consistency and any duplication, and then send the comments and requests for modification to the principal investigators.
3. Principal investigators are notified via email that comments have been made on the protocol. All comments and requests for modification are sent without referencing the author of the comments and requests for modification, thus preserving IACUC reviewer anonymity.
4. Upon return receipt of the Principal investigators’ responses to the comments and required modifications to the protocol, the IACUC staff reviews the responses and modifications, then forwards responses and modifications to the IACUC reviewers. Comments and modifications within the protocol are then reviewed by the reviewer. If additional questions arise or modifications need to be made, another round of comments is generated and sent to the Principal investigators for responses. This process is repeated as often as necessary, until all reviewer questions have been answered and requested modifications to the protocol have been made. The protocol is then assigned to a convened IACUC meeting agenda.

A protocol assigned to full committee review will be presented at a convened meeting by IACUC primary reviewers and/or discussed collectively at the meeting with direction from the IACUC Chair, prior to a vote to approve with or without further modifications to secure approval or withhold approval. If approval is withheld, the

IACUC will provide written notification to the principal investigator and provide the principal investigator with an opportunity to respond in person and/or in writing. If substantive modifications are required, the IACUC will vote to return the modified protocol for full committee review or send the modified protocol for designated member review, as described below in the designated member review section. If designated member review is selected, then all IACUC members agree that the primary reviewers shall review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols.

Several days prior to any convened meeting, a list of all protocol activities is sent to all IACUC members via an email. Complete written descriptions of these protocols are available to all IACUC members on the online secured site (Black Board) system.

Designated Member Review:

Protocol activities referred for designated review are assigned by the IACUC Chair to IACUC primary reviewers, (a minimum of one IACUC member); the IACUC Chair also assigns other expert reviewers to protocols when applicable, e.g., Radiation Safety when a project involves radioisotope use and/or OHS/IBC when a project involves a biological agent or recombinant DNA vectors.

1. The IACUC designated and expert reviewers review the protocol via email and/or the online secured site (Black Board) system.
2. IACUC reviewers submit their comments and requests for modification to the IACUC office via email.
3. The IACUC office reviews all comments and requests for modification received for consistency and any duplication, and then send the comments and requests for modification to the principal investigators.
4. Principal investigators are notified via email that comments have been sent on the protocol. All comments and requests for modification are sent without referencing the author of the comments and requests for modification, thus preserving IACUC reviewer anonymity.
5. Upon return receipt of the principal investigators' responses to the comments and required modifications to the protocol, the IACUC staff reviews the responses and modifications, then forwards responses and modifications to the IACUC reviewers. Comments and modifications within the protocol are then reviewed by the reviewer. If additional questions arise or modifications need to be made, another round of comments is generated and sent to the principal investigators for responses. This process is repeated as often as necessary, until all reviewer questions have been answered and requested modifications to the protocol have been made. Once this process has been concluded, the designated member can indicate the protocol activity is ready for approval or that full committee review is needed. Prior to designated member approval release, a list of all designated member protocol activities is sent to all IACUC members via email. Complete written descriptions of these protocols are available to all IACUC members on the online secured site (Black Board) system. Any member of the IACUC may request full

committee review of those protocols that had been reviewed by designated member review. If full committee review of those protocols reviewed by designated members is not requested prior to the IACUC committee meeting, then the protocol is considered approved by the designated member review process once the convened meeting has completed business. In an emergency situation, the predetermined time period for review may be shortened, but the procedures for designated review as outlined above will be followed.

E. Conflicts of Interest

Protocol activities that disclose a potential Investigator Conflict of Interest or potential Institutional Conflict of Interest are referred to the appropriate campus entities for follow up review.

The IACUC requires members to decline participation in any type of IACUC review and/or voting, in which the member has a conflicting interest. The definition of Conflict of interest includes participation in the project, involvement in competing projects, a financial interest, a personal relationship, or other situation giving rise to a conflicting interest as defined by the Conflict of Interest Committee and in the COI section of this policy handbook. Any member having a conflicting interest must leave the meeting during the discussion of and vote on the protocol. No member leaving the room because of a conflicting interest or any other reason will be counted as part of the quorum for any vote taking place while the member is out of the room.

F. Voting

The IACUC requires a quorum to conduct its business. Voting occurs after IACUC review and deliberations at a convened meeting. An approval vote of a majority of the quorum present is needed for any IACUC action.

The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity of vote with the IACUC unless they are also members of the IACUC.

Review Significant Changes

The IACUC reviews and approves, requires modifications in (to secure approval), or withholds approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy and the Animal Welfare Act. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

The IACUC processes significant changes for IACUC review under either: Full Committee Review or Designated Member Review, as described above.

Notify Investigators and the Institution

Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy and the Animal Welfare Act.

The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows: The IACUC notifies principal investigators by email reports of IACUC decisions regarding protocol review.

Conduct Continuing Review

Conducts continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy and as applicable, the Animal Welfare at least once every year. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC procedures for conducting complete review of continuing activities require at least annual review:

1. Principal investigators complete and submit an annual report/renewal application (via the "short form").
2. At least one IACUC member reviews the annual report/renewal applications, along with the initial protocol submission and any subsequent revised versions of the protocol (on the online secured site Black Board system) that conforms to the *Guide*, PHS Policy, and as applicable, 9CFR Chapter I, subchapter A, under either: Full Committee Review or Designated Member Review, as described above.

The IACUC monitors ongoing activities through their post-approval monitoring program, including:

- Veterinary walk-through or veterinary assignments to animal use areas where protocol activities take place.
- Assignment of protocols (during protocol review process) for specific veterinary /IACUC research compliance officer in-person monitoring. This monitoring is followed up by subsequent reporting during IACUC meetings.
- IACUC semiannual inspections and follow up inspections.

Be Authorized to Suspend Activities

Be authorized to suspend an activity involving animals as set forth in the PHS Policy and the Animal Welfare Act. The IACUC procedures for suspending an ongoing activity are as follows:

- The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of PHS Policy, the Animal Welfare Act, the *Guide*, or the institution's Assurance. Suspension of any protocol or approved activity involving animals occurs after review of the matter at a convened meeting of a quorum of the IACUC and through a vote of a majority of the quorum present.
- Review of the reasons for suspension with the Institutional Official and implementation of appropriate corrective action.
- Submission of a full report to the Institutional Official, who then submits a written report to OLAW, for PHS supported research, or if applicable to USDA, and other relevant entities.

The Institution's Procedures for Off-site Activities Involving Research Animals

The institution's procedures for offsite activities involving research animals are:

- Off-site research, involving animal studies and institutional protocol directors conducting vertebrate animal research, teaching, or research training protocols at an off-site facility must provide: a letter of approval from the host IACUC; and, if applicable, proof of a currently approved PHS Assurance and a USDA registration number. Additionally, appropriate research agreements and/or Memoranda of Understanding must be in place between UM and the off-site facility.

Use of Vertebrate Animals in Teaching Activities

It is the policy of University of Miami that the use of either live or deceased vertebrate animals for solely instructional purposes is permitted when:

1. The cognizant instructor(s) judges that the educational goals of the program or course will be best achieved by such usage.
2. The IACUC determines that such usage is humane, proper, and appropriate, consistent with government principles and regulations for the utilization and care of vertebrate animals used in teaching and research. Only the minimum number of animals essential to instructional objectives should be used. Instructors should be encouraged to use alternatives to animals whenever possible.
3. Any faculty member who intends to use vertebrate animals for teaching purposes must submit an Animal Use Protocol signed by the department chairperson to the IACUC. Reuse of previously approved preserved material requires no approval. Courses taught each year with no significant changes in animal usage must submit an annual report via the "short form" each year.
4. The protocol must include information about the source from which animals are procured. In addition, the protocol must explain why animals are needed to achieve the goals of the course, and justify the species and the number of animals to be used. If the IACUC questions the species of animal chosen, the procurement process, the number of animals to be used or other related matters, such questions need to be resolved before the animals may be ordered.
5. Live vertebrate animals must be cared for according to the Division of Veterinary policies and procedures governing the use of laboratory animals. Disposal of animal tissue must be in compliance with relevant health and safety regulations.

The Laboratory Animal Occupational Health Program

The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows:

OHS Administration

The Director of Environmental Health and Safety is responsible for the overall management of UM's Occupational Health and Safety Program (OHS) for personnel involved in the care and/or use of laboratory animals in research and teaching. The EHS office keeps records of participation and compliance with OHS policies. The IACUC provides monthly lists to EHS of new personnel or personnel with potentially changing animal use risks (e.g., change in species use). EHS follows up these individuals and reports back to the IACUC regarding compliance.

Scope

The university of Miami's OHS program for animal research covers all employees performing work duties that involve contact with animals (e.g., all DVR staff, principal investigators, their staff and students), Physical Plant and Facilities and Security staff personnel that service buildings with animal facilities).

For DVR personnel:

The basic components of the OHS program are: entry/baseline health assessment, annual health questionnaire, annual audiograms (if indicated), annual respiratory protection training or respiratory fit testing, biannual tuberculosis screening, counseling as needed for pregnancy or other health-related issues (e.g., immunosuppression), vaccinations (as indicated) and annual training and education modules (e.g., zoonotic diseases, nonhuman primate disease/safety, etc). DVR personnel are required to participate in the program as outlined above.

For other personnel with animal contact:

The basic components of the OHS program are: entry/baseline health assessment, annual health questionnaires, training module in occupational health and safety for animal users (renewed every 3 years), participation in the occupational health program, semi-annual TB testing (if exposed to non-human primates), annual audiograms (if indicated), respiratory protection training or respirator fit testing (if warranted because of biohazard use or non-human primate work), vaccinations (if indicated) and educational modules are available as described previously. Annual questionnaires include questions regarding changes in animal usage, hazardous agent usage, and changes in personnel health status. The EHS office reviews all questionnaires to ensure appropriate follow up actions.

Hazard Identification and Risk Assessment

In addition to current OHS program, any new project involving hazardous chemicals or biologic agents must have a risk assessment conducted prior to initiation of the project. These risk assessments include the EHS officer, the clinical veterinarian, husbandry supervisor, principal investigator and their staff. At these assessments, the hazards of using the agent, disposal procedures, drug or compound elimination and excretion, exposed animal handling and, proper use of PPE, and use of proper primary containment equipment (e.g., biosafety cabinets) is discussed.

Health Histories and Evaluations

Entry/baseline health assessment and annual health questionnaires are used to

evaluate potential risks to personnel working with or near animals. This assessment is performed by the OHS office.

Common Identified Hazards and Risks

The most common species group is rodents, thus rodent bites and allergy are common hazards. The most common risks include allergy to animals, bedding, etc and physical hazards of large cages and equipment. Specific species (e.g., non human primates) and/or use of biohazardous agents or chemicals comprise the secondary potential risks or hazards. Zoonotic disease transmission is a less common risk.

Procedures in Place to Alleviate Hazards and Minimize Risks

Risk assessments and training are provided to mitigate hazards/risks encountered on the job. Use of primary and secondary containment equipment/items are included as part of the risk assessments and mitigation plan. Training in proper use of these items is given annually in addition to zoonoses training.

Immunizations

Vaccination against tetanus and rabies is provided and is required for all DVR personnel. Other vaccinations may be required depending on the specific experiment.

Precautions taken during pregnancy, illness or decreased immunocompetence

Individuals who are planning to be or are pregnant or have illness or decreased immunocompetence must meet with the EHS physician/nurse to discuss precautions to be taken. In general, the common recommendations given for pregnant women include but are not limited to avoidance of gas anesthetics, avoidance of animals with biohazards, avoidance of NHP, and avoidance of heavy lifting. Other precautions will depend on the individual situation.

Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used

Physical plant, facilities, and security personnel are included in the overall OHS plan as outlined above. This includes, but is not limited to, health assessment, TB screening, and training for PPE use.

Availability and procedures for treatment in the event of bites, scratches, illness or injury

Bite kits are available in every animal and procedure room within the DVR facility. Each kit contains a scrub sponge and iodine solution for cleaning of a bite area. Should the bite/needle stick be from a primate, additional instructions are provided in the bite kit. If the latter should occur, the supervisor and the veterinarian of the building should be contacted immediately. If there is a life threatening emergency or illness, 911 is called immediately. Accident reports are generated.

Procedures/program for reporting and tracking injuries and illnesses

Accidents/injuries, should they occur, require reporting to risk management office within 24 hours. These reports are followed by the risk management office and DVR office until resolved.

Other Pertinent Information Regarding the OH&S Program

Training and oversight is provided to researchers and DVR staff as needed based on protocol or species specific requirements and risk assessments. Training is available that includes particular attention to specific risks of utilizing non-human primates, specific hazards and the proper use of personal protective equipment.

Animal welfare/Animal Care and Handling Training Program

The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

General

It is a UM requirement that all faculty, researchers, students, and staff active in animal research at UM will complete core training via a web-based training program (www.citiprogram.org). We recognize that much relevant training occurs within each research unit, and that many individuals have background experience that qualifies them in certain aspects of the care and use of animals. However, we believe completion of introductory core training by all those involved in animal research at UM is essential.

This core training program, which has been reviewed and approved by the IACUC, is available online, and information regarding enrollment is available on the [IACUC website](#). Documentation of completion requires that personnel take and pass a brief quiz upon finishing each course. The DVR also offers an extensive list of seminars, workshops, and training, both didactic and hands-on, targeted for individuals whose use of animals in research and teaching creates special training needs (e.g., rodent handling and basic techniques, work with non-human primates, rodent survival surgery, introduction to stereotaxic surgery, breeding mice). OHS conducts classes in the use of biohazardous agents in animals. The IACUC office offers animal welfare compliance classes that provide supplementary information to complement the CITI training.

Principal Investigators (PIs) must keep in mind that it is their responsibility to guarantee the appropriate training of their students, associates, and staff, and to make sure that their research programs are in compliance with all regulations and policies governing the care and use of animals. The animal welfare training help PIs do this, and it enables the Division of Veterinary Resources (DVR) and the IACUC to document the delivery of this introduction to the care and use of animals in research and teaching at University of Miami.

Training of UM research personnel

All research personnel handling animals must be on an approved protocol, which includes completion of aforementioned CITI animal welfare courses. The CITI training (www.citiprogram.org) consists of reviewing two to three training modules (depending upon research animal models) and passing the respective quizzes. This includes all those who intend to file a protocol for the first time, or whose names are being added to existing protocols. The content of the animal use training program includes current regulations regarding housing, use, care, and euthanasia of research animals, humane practices of animal care, humane practices of animal use (e.g. research procedures, use of anesthesia, pre- & post-operative care), research/testing methods that minimize animal pain and distress, and the use of hazardous agents. In addition, training on the specific animal model used must also be completed.

In addition, the Principal Investigator validates that the personnel are trained in the specific procedures described in their protocol. For new personnel or personnel requiring additional training in any species, DVR provides a hands-on course in rodent handling and basic procedures, and didactic presentations on small and large animal surgery (basic techniques, sterile techniques, intra and post operative anesthesia, analgesia, monitoring and record keeping). Additional surgical training can be requested with a clinical veterinarian as needed.

Veterinarian oversight and hands on training is highly recommended for new personnel or new or complex surgical techniques.

The Principal Investigator ensures that all people working with animals under his or her jurisdiction fulfill all training requirements. Additionally, the IACUC office staff monitors training status of all participants and protocols will not be approved until ALL members of the research team have their training requirements up to date. A refresher course must be taken every four years. Additionally, the online Occupational Health and Safety course must be updated every four years. Those individuals who will be observing animals, without contact, will be given an orientation by certified trainers. Documentation of said orientation must be provided to the IACUC office.

The University also provides faculty/staff/student access to online resources available through the Library. Trained librarians within the Miller School of Medicine Calder library are available to assist with literature searches for alternatives.

Training and Education for DVR personnel

DVR personnel undergo a period of intense training in animal care, observation, husbandry and/or veterinary technical care upon hiring. Depending on need, handling and basic procedures are taught using training animals in house for this purpose. All DVR personnel receive annual training in blood borne pathogens, proper personal protective equipment usage (PPE), zoonoses and nonhuman primate safety and diseases. In addition, as needed, personnel are trained in specific procedures, PPE, or health issues associated with any biohazards that they may encounter. All DVR personnel are encouraged to strive for AALAS technician certification; to this end, the DVR education coordinator provides classes and materials for the ALAT certification exam. Additional instruction and/or materials are provided to those individuals studying for the higher levels of certification.

Evaluation of Protocol Personnel Training

All protocols submitted to the IACUC for review must describe experience/training personnel have had or will have with this specific animal model(s). The IACUC then performs an assessment of the personnel's ability to work humanely with animals. The IACUC may assign specific training to personnel as a condition of their approval.

Training and Education for IACUC members

Training of IACUC members includes, but is not limited to CITI program online animal welfare training modules; meeting with the IACUC Chair, Attending Veterinarian, and/or IACUC director to review responsibilities; and the opportunity to go to SCAW or PRM&R conferences. New materials or publications are discussed at IACUC meetings throughout the year. Modification of policies and procedures occurs regularly at IACUC meetings as the need arises.

All new IACUC members attend an orientation session given by the IACUC Chair, Attending Veterinarian, and/or IACUC director which covers the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's. The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in the *Guide*, AVMA Guidelines and federal regulations.

Each IACUC member will be provided with a current copy of the following:

- The PHS Policy for the Humane Care and Use of Laboratory Animals

- The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals
- The ARENA/OLAW IACUC Guidebook
- The AVMA Guidelines on Euthanasia

Additional Training Resources

Web Resources:

[DVR](#) and the [IACUC](#) maintain websites that includes resource information, training information, occupational health and safety information, IACUC/DVR guidelines, etc.

[The Environmental Health and Safety Office](#) maintains a website that provides information on safety, health (including the Laboratory Animal Occupational Health Program) and environmental practices and procedures.

Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category One (1)—accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. This Institution is Category One (1)—accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

Record Keeping Requirements

This institution will maintain for at least three years:

1. A copy of PHS Assurance and any modifications thereto, as approved by PHS
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official
5. Records of accrediting body determinations

This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

All records shall be accessible for inspection and copying by authorized USDA, OLAW or other PHS representatives at reasonable times and in a reasonable manner.

Reporting Requirements

This Institution's reporting period for OLAW is January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The report will include:

- Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
- Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Vice Provost of Research.
- Any minority views filed by members of the IACUC.

This Institution's reporting period for USDA is October 1– September 30. The IACUC, through the Institutional Official, will submit an annual report to USDA by December 1 of each year. The report will include:

- Animal usage for the time period and the designation of pain in which the studies were performed.
- Any exemptions and exceptions to the *Guide*.

The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.
2. Any serious deviations from the provisions of the *Guide*
3. Any suspension of an activity by the IACUC.
4. The USDA will be informed of any IACUC mandated suspension of animal work for any USDA regulated species.

Contact

Questions about this Policy can be answered by:

Ellen Kapsalis, Ph.D.

Director, IACUC Committee

University of Miami

Phone: 305-243-9518

E-mail: EKapsali@med.miami.edu

Environmental Health and Safety

The UM [Office of Environmental Health and Safety's](#) mission is to help the University continuously improve its compliance with health, safety, and environmental regulations. We provide support and training in an effort to avoid occupational, biological, and chemical hazards.

Emergency and Non-Emergency Hazardous Material Release Response

Environmental Health and Safety oversees the collection and disposal of hazardous chemical waste on all UM campuses. Waste collected in the laboratories is picked up by EHS personnel and prepared for proper disposal.

The waste generated in the laboratories should be placed in the [Satellite Accumulation Area \(SAA\)](#)* designated for that laboratory. Waste should be placed in containers that are in good condition, sealed, and labeled with the exact contents. Always take the time to immediately label all containers in your laboratory. Unknowns pose an extreme safety problem for all and are very expensive to fingerprint. All chemical percentages should be placed on the label if there are compatible mixtures in same container. Where possible, waste chemicals should be collected in separate containers. Compatible non-halogenated solvents should be collected separately from compatible halogenated solvents. Each laboratory cannot accumulate more than 55-gallons of hazardous waste or 1-quart of acutely hazardous waste identified as [P-Listed Hazardous Wastes](#)*.

When a laboratory is ready for waste pickup, complete the [Chemical Waste Disposal Form](#) and call 305-243-3268. If further information or clarification is needed, please call EHS at your convenience.

Our Hazardous Waste Policy is designed to meet the disposal needs of all UM personnel in the safest, least time consuming, and economically feasible manner. It is also based on UM compliance with strict EPA regulations. UM employees who work with hazardous chemicals and generate hazardous waste need to dispose of them properly via the EHS office so that we may protect our working environment as well as our outside environment.

Related Links

- [Disposal of Inherently Wastelike Chemicals](#)
- [Emergency Response Guide](#)
- [Handbook of Chemistry and Physics](#)
- [MSDS Search](#)
- [Mercury Reduction](#)
- [MSDS - Seton \(Compliance Resource Center\)](#)
- [NIOSH Pocket Guide To Chemical Hazards \(NPG\)](#)
- [Waste Minimization](#)
- [SAA Training Documents](#)

University Laboratory Animal Occupational Health Program

Occupational health and safety is fundamentally important to work with laboratory animals. The potential physical and health hazards that may arise from animal use in research make it necessary for laboratory workers to have the appropriate preparation and training. The Office of Protection from Research Risks (OPRR), part of the National Institutes of Health, mandates that each institution working with research animals develop and maintain health and safety programs. **Principal Investigators (PIs) have the primary responsibility for implementing these programs in their research areas and for providing the preparation and training for employees under their supervision.**

Before beginning research with animals at the University of Miami, PIs must first have protocols and procedures approved by the [Animal Care and Use Committee](#). This Committee is responsible for assuring that the animals will be treated humanely and in compliance with federal guidelines as well as determining the completeness of a PI's Standard Operating Procedures (SOPs). Each PI is responsible for developing an SOP which will address the physical hazards (bites, scratches, accidental needle sticks, etc.), allergens, and zoonoses which may be involved in his or her research. The SOP should also define the potential use of hazardous chemicals (including radioisotopes), recombinant DNA, and infectious agents. Contact **EHS** and the [Division of Veterinary Resources \(DVR\)](#) for additional assistance.

Additional information for [Working with Animals in the Laboratory](#)

Chemical Hygiene Plan and Chemical Hazard Communication

The Office of Environmental Health and Safety (EHS) have developed a program to help Laboratory personnel in implementing good laboratory practices in their laboratory. Implementation of good lab practices creates a safe laboratory environment and promotes compliance with applicable local, state and federal regulations, standards and guidelines.

[The OSHA Lab Standard \(29 CFR§1910.1450\)](#) is the most relevant regulation applicable to the Laboratory activities. Compliance with this regulation is the primary directive of the Laboratory Safety Program and is mandatory for all laboratory personnel.

For more information on the laboratory safety program and policies please visit the University's Chemical Hygiene Plan. This plan includes the Chemical Hygiene plan document, the University of Miami Right To Know Law and Hazard Communication policies, and the OSHA Lab Standard.

To view the Chemical Hygiene Plan:

[CHEMICAL HYGIENE PLAN](#)

[BSD-045 - Laboratory Safety Program](#)

MEMORANDUM to ALL Laboratory Personnel for Hurricane Preparations for Laboratories:

[Hurricane Preparations for Laboratories](#)

To view the Biological Agent Registration Form:

[Biological Agent Registration Form](#)

To view the Laboratory Safety Self Assessment Worksheet:

[Laboratory Safety Self Assessment Worksheet](#)

University of Miami Freezer Facility in the Viciana Warehouse:

[University of Miami Freezer Facility](#)

Radiological Hazards

The use of radioactive materials and ionizing radiation producing devices at the University of Miami is regulated by the State of Florida under an agreement with the U. S. Nuclear Regulatory Commission. The responsible University agency for such activities is the University of Miami Radiation Control Center (RCC) and the document which details the rules and regulations which have been adopted to ensure both the safety and regulatory compliance of radiation use is the Radiation Control Manual.

All individuals who intend to use radiation in University of Miami facilities must contact the RCC, prior to initiating such work, for further information concerning required training and authorizations. It should be noted that all radioactive material is regulated at the University of Miami and no quantity, no matter how small, is considered exempt from these regulations. For additional information concerning the use of radioactive materials and ionizing radiation producing devices, please contact the RCC.

Laser Safety

The [Laser Safety Program](#) at the University of Miami is designed to help all laser users to undertake their laser activities, medical use or research, in complying with all applicable Federal, State, and local regulations, standards and guidelines, while working in the safest environment possible. These regulations include The State of Florida regulations, Chapter 64E, 21 CFR§ 1040 and the ANSI Standards (ANSI 136.1 and 136.3).

Essential compliance requirements are the required Basic Laser Safety Training seminar, the baseline eye examination for all laser users and the periodic laser safety inspections for all lasers, laser devices and systems.

[Laboratory Safety Manual](#)

Contact

Kenneth Capezzuto
Executive Director, Environmental Health and Safety
University of Miami
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E-mail: ken.capezzuto@miami.edu

Export Control & Technology Management

The University of Miami (UM) conducts focused research to advance knowledge, enhance student learning experiences, and build its reputation in the scientific and technical communities while providing positive returns on sponsoring partners' investments. While UM applies the principles of freedom of inquiry and open exchange of knowledge, we must also be mindful of the federal laws and regulations governing the exchange of research materials and results that are subject to export controls.

Definitions:

A [list of acronyms and terms](#) commonly found within U.S. export control laws and regulations and the University's Export Compliance program.

Export Compliance Policy:

This policy applies to all University of Miami personnel including administrators, faculty, staff, research associates and fellows, post-doctoral fellows, student employees, students, and volunteers in all units of the University.

Policy Statement

It is the policy of the University of Miami (UM) to comply with all U.S. export control laws and regulations, and to develop and maintain an export compliance program that enables UM employees, faculty, students, trainees, visiting scientists, and other persons, herein referred to as "UM personnel," retained by or working at or for UM to conduct business in accordance with these laws and regulations. No UM personnel may engage in any export activity that is prohibited by the U.S. Department of Commerce, the U.S. Department of State, the U.S. Department of Treasury's Office of Foreign Assets Control, or any other government agency that enforces export laws/regulations. Similarly no UM personnel may transfer any controlled item, including technology and technical data, without approved documentation.

Compliance with export control laws and regulations must be considered and achieved **before** traveling internationally, engaging in science or technology-based research, executing contracts or other agreements, purchasing high-technology devices or software, or engaging in any other activity that may be affected by export controls.

Export control requirements are constantly changing. Governmental and inter-governmental agencies in the U.S. and abroad are evaluating their regulations and protocols as a result of new laws and directives, as well as administrative and judicial experience. While this policy will be reviewed and revised on a regular basis, it is essential that all UM personnel keep current with information and training provided by the Export Compliance Office within the Office of the Vice Provost for Research.

The Vice Provost for Research (VPR) is UM's Empowered Official. UM's Export Compliance Officer (ECO) is the VPR's designee to oversee the export compliance program.

Purpose

UM employs foreign nationals and often hosts foreign visitors in connection with international exchange programs, degree-granting programs, and other business agreements. While UM welcomes the opportunity to employ foreign nationals¹ and host international visitors, it must also assure compliance with U.S. laws and regulations governing the export of certain commodities and technical data.

Export control laws and regulations apply to and affect the full range of UM activities including research and scholarly activity, software development, hiring, the selection and education of international students, scholars and graduate advisors, laboratory security, technology transfer, purchasing, receiving and shipping, international travel, exchanges of educational, research and technical information, and responsibility for the activities of visitors to the campus.

Failure to comply with export control laws and regulations affects both the individual(s) involved in the violation as well as UM. Criminal and Civil penalties can be financially severe and may also include imprisonment, deportation, or loss of licensure. Other administrative sanctions may include loss of research funding and export privileges. Failure to comply with export control laws and regulations affects both the individual(s) involved in the violation as well as UM. Criminal and Civil penalties can be financially severe and may also include imprisonment, deportation, or loss of licensure. Other administrative sanctions may include loss of research funding and export privileges.

This policy applies to all UM personnel, including:

- All faculty, including voluntary faculty and courtesy appointments
- Faculty emeriti engaged as active researchers on UM projects.
- Researchers, including research staff, postdoctoral fellows, and research associates.
- Graduate students, undergraduate students, and interns involved in research programs; for export control purposes, graduate students working as research assistants on research projects are *not* considered to be employees.
- Staff in departments, centers, and administrative offices charged with responsibilities under this policy.

Consultants, agents, and volunteers associated with research and scholarly activities as well as in departments and offices charged with responsibilities under this policy.

Overview

This policy addresses obligations every individual has with respect to actual and deemed export of what several agencies of the United States Government categorize as strategically important items. The controlled materials include: information, software, data and technology, as well as technical assistance rendered to foreign countries, entities, or individuals.

On January 3, 2013, the VPR issued a memo regarding UM's policy on U.S. export laws and regulations². UM conducts research to advance knowledge, enhance student learning, and build its reputation while providing positive returns on sponsoring partners' investments. Though UM's culture is built on the principles of freedom of inquiry and open exchange of

¹ A foreign national is any individual who is not a U.S. Citizen, Permanent Resident (green card holder), or protected under U.S. refugee or asylum status.

² "University Policy Regarding U.S. Export Laws and Regulations" memo dated 01/03/2013 may be found on UM's Export Compliance website.

knowledge, UM must also adhere to federal laws and regulations governing the exchange of research materials and results that are subject to export controls.

UM does not prohibit research that excludes participation by foreign nationals, but UM investigators are encouraged to explore removal of contract clauses that provide for such restrictions. Notwithstanding this policy, UM personnel are personally responsible for safeguarding export-controlled items from disclosure or release to foreign persons without prior **written** approval.

Export control laws and regulations are governed by the U.S. Department of State through its International Traffic in Arms Regulations (ITAR) of the Directorate of Defense Trade Controls (DDTC), and the U.S. Department of Commerce, through its Export Administration Regulations (EAR) of the Bureau of Industry and Security (BIS). The U.S. Department of Commerce regulates certain commercial and dual-use technologies, materials, and items specified in the EAR. The U.S. Department of State controls the export of defense articles, defense services and defense-related technical data through the ITAR.

In addition, the U.S. Department of Treasury, through its Office of Foreign Assets Control (OFAC), maintains targeted economic sanctions programs that restrict or prohibit a wide range of export and other transactions that may include educational services involving designated countries, entities, and individuals.

Export control laws can affect research and non-research areas. Examples include:

- Entering into a contract – such as to purchase items or services.
 - if the person or entity is on a restricted / denied party list
 - if the money to pay for items or services goes to a person or entity in an embargoed or restricted country
 - If there are export control restrictions noted in the End-User License Agreement (EULA) for software?
- Shipping ancient artifacts to a restricted foreign destination.
- Shipping robots outside the United States.
- Shipping plasmids to a Ph.D. student writing his/her dissertation at a foreign university.
- Using atmospheric recording equipment in international waters.

All departments within UM can be at risk. Areas that are more likely to trigger export control requirements than others include:

- Engineering
- Space Science
- Computer Science
- Biomedical research with lasers
- Research with controlled chemicals, biological agents and/or toxins
- Research with encrypted software
- Research in international or foreign waters.

Export control laws and regulations restrict the shipment, transmission or transfer of certain items, software, technology and services from the U.S. to foreign countries, as well as “deemed exports,” which are releases of controlled items to foreign nationals located in the United States.

Responsibility

All UM personnel must conduct their affairs in accordance with U.S. export control laws and regulations. While compliance with all applicable legal requirements is imperative, it is equally important to maintain an open research environment that welcomes the participation of researchers from around the world as part of UM's mission. To maintain this balance, UM personnel must be familiar with the U.S. export control laws and regulations, including important exclusions and exemptions, as they relate to their responsibilities. Depending on the nature of their activities and/or job functions, UM personnel may be required to participate in formal training as determined by the VPR.

UM personnel are responsible for safeguarding the items identified as export-controlled, confidential, restricted, proprietary or sensitive but unclassified (SBU)³. Violations of the Arms Export Control Act (AECA) can be attributed to the person(s) involved in the violation as well as to UM. Thus it is the responsibility of all UM personnel to be clear about UM policies and exercise reasonable care in using and sharing export controlled items and engaging in export controlled activities.

UM personnel with supervisory authority over foreign persons or projects involving controlled items are responsible for overseeing export compliance within their areas of administrative responsibility and for supporting UM's Export Compliance program by implementing the procedures set forth in this policy.

The Export Control & Technology Management Office, under the direction of the VPR, is responsible for helping UM personnel understand and comply with export control laws and regulations. All communications with U.S. licensing authorities shall be made through the ECO or the VPR.

Procedure

UM personnel are to use UM's Export Compliance website (<http://www.miami.edu/exportcompliance>) for guidance on matters pertaining to export controls.

UM personnel are to follow the Standard Operating Procedures (SOP) outlined as well as utilize the various required forms and templates that have been implemented for the activities that fall under the management of the ECO. (e.g., Purchase requisitions, hiring foreign nationals, observerships, technology control plan, federally funded research, shipping, international travel)

Where UM's Export Compliance website fails to provide the information or resources needed, UM personnel should contact the ECO directly for consultation. Contact information for the ECO can be found on UM's Export Compliance website.

Training

Export Compliance Basics. All UM personnel are encouraged to attend this live training session conducted by the ECO. This course gives a broad general overview on how export control laws and regulations affect day-to-day activities at UM. Training is approximately 1 hour in length.

³ The U.S. Department of State uses SBU as a document designation comparable to 'For Official Use Only' (FOUO).

Export Compliance for Researchers. This is a follow-up course to *Export Compliance Basics*, which goes deeper into the activities affected by export controls, and provides guidance on the various policies and procedures that must be followed to ensure compliance with UM policies and U.S. laws and regulations. This training is designed for the researcher who is more likely to need specific direction. Training is approximately 1.5 hours in length. Prerequisite: *Export Compliance Basics*.

Export Compliance for Researchers is mandatory for all UM personnel who have been identified as working on an export-controlled project.

UM personnel may register for the *Export Compliance Basics* and *Export Compliance for Researchers* training sessions through ULearn. (<http://ulearn.miami.edu>) UM personnel should renew their training every 24 months.

Export Licenses for Overseas Shipments

The University's ECO will determine which license type is appropriate. Items that have been determined to require an export license cannot be exported or released until the export license has been received by the University's ECO and reviewed with the Principal Investigator (PI) and/or department administrator. Only the University's ECO is able to submit license applications on behalf of the University, and only the Vice Provost for Research (VPR) will have signing authority.

Any shipment of Dangerous Goods, Hazardous Materials, Biological Products, Infectious Substances or Diagnostic Specimens must comply with International Air Transport Association (IATA) Dangerous Goods regulations and the U.S. Department of Transportation regulations on Shipment of Hazardous Materials and is coordinated through the University's Office of Environmental Health and Safety (EHS).

Shipment of Dangerous Goods

This policy applies to any employee at the University of Miami involved in any step of the shipment of any dangerous goods.

This policy covers all dangerous goods as per the International Air Transport Association (IATA) Dangerous Goods regulations and the United States Department of Transportation regulations (49 CFR 100-185) on Shipment of Hazardous Materials.

Select Agents

To comply with the Additional Requirements for Facilities Transferring or Receiving Select Agents (42 CFR § 73, 7 CFR Part 331, 9 CFR Part 121) and the USA Patriot Act (PL 107-56).

Purchase Requisitions and Export Compliance Review

UM offices and departments are often in need of importing and exporting supplies and equipment in support of the University's global research and teaching activities. Such supplies and equipment may be subject to U.S. export control laws and regulations. The University is committed to compliance with applicable laws and regulations pertaining to exports of items, services, and technology and technical data by or on behalf of UM. This policy applies both to tangible exports for which the ultimate destination is outside the United States borders, as well as "deemed exports" to foreign nationals within the United States. All purchases for which items may be subject to export controls must be cleared and approved for purchase by the University's ECO before acquisition or transfer is made. Other University offices, such as the

General Counsel and Environmental Health & Safety (EHS), may also need to be included in the approval process before the purchase requisition can be completed.

Data Classification

This policy applies to all electronic data stored on any media or system(s) throughout UM and applies to all individuals storing, accessing, or working with the data, in any way, including all University employees, students, contractors, guests, consultants, temporary employees, and any other users, including all personnel affiliated with third parties utilizing University resources.

Peer-to-Peer

The purpose of this policy is to provide information regarding the University's position involving any peer-to-peer application that promotes copyright infringement or the illegal sharing of copyrighted files without permission of the owner or distributor.

Electronic Data Protection and Encryption

Information Security exists to further the mission of the University. The University is comprised of large and diverse populations with evolving needs related to information technology resources and data. University management is committed to safeguarding those resources while protecting and promoting academic freedom.

This policy establishes a framework that outlines when encryption must be used to secure the University's data from risks including but not limited to, access, use, disclosure, and removal as well as to adhere to regulatory and compliance requirements.

Export Classifications

It is the responsibility of each UM employee to secure their research and technology, chemicals and biological materials they handle, and proprietary and Government articles or information entrusted against unauthorized use or theft. All items have an export classification. Identifying the export classification is key in understanding the restrictions to foreign nationals and exporting overseas. Thus, all items received by UM must be identified with the appropriate classification. The University is not in a position to understand the technical assessment of the item or the original design intent (ODI) in order to determine the correct export classification. Per 15 CFR 758.3, the vendor or manufacturer is to supply this information upon request. Items received by UM from a third-party must disclose prior to releasing items to UM export classifications or other restrictive identifications.

Export Controls and the University of Miami's Openness in Research Policy

The University currently does not prohibit restrictive research that would exclude the participation by foreign persons or publication. Thus, each UM employee is personally responsible for safeguarding export-controlled items from disclosure or release to foreign persons without prior approval.

Export Controls and an Individual's Eligibility as a Recipient of Export Controlled Items, Software Code, or Information

Each UM employee is personally responsible for safeguarding the items identified as export controlled, confidential, restricted, proprietary or sensitive but unclassified (SBU). Violations of the Arms Export Control Act (AECA) can be issued to the person(s) involved in the violation as well as the University. Thus, it is the employee's responsibility to be clear about all University policies and exercise reasonable care in using and sharing export controlled items and activities.

Information that could be a target for espionage activity may include: proprietary formulas and processes, prototypes or blueprints, research data, technical components and plans, confidential documents, computer access protocols, passwords, employee data, manufacturing plans, equipment specifications, vendor information, customer data, access control information, computer network design, software (including source code), phone directories, negotiation strategies, etc. The tactics used range from computer hacking, on-site visits, theft, photography, going through trash, elicitation, surveillance, unsolicited requests for information or participation, obtaining surplus equipment, etc.

All University employees and students are responsible for protecting information that is not public knowledge and are to be familiar with the various University policies regarding information security found on the UM-IT website, such as (but not limited to):

POL-UMIT-EDQ-001-02: [Electronic Data Quality Policy for Clinical Research](#)

A055: [Use of Electronic Communications](#)

A110: [Data Classification Policy](#)

A131: [Password Security Policy](#)

A155: [Information Security Policy](#)

A175: [Electronic Data Protection and Encryption Policy](#)

Recordkeeping Requirements

Departments must keep copies of all documentation, including required licenses, financial records and shipping documentation such as invoices, Shippers Export Declarations (SEDs), Automated Export System (AES) records, and any internal campus forms related to export control regulations. (*Reference: 15 CFR §762 (EAR); 22 CFR §122.5, §123.22, and §123.25 (ITAR); and 31 CFR §501.601 (OFAC)*)

Records required to be maintained by export control laws and regulations will be kept for the longer of:

- (a) The record retention periods required by the applicable export control regulations, or
- (b) The period required for retention of records as set forth in the University's record retention policy.

Contact

Questions about these Policies/Guidelines can be answered by:

Phone: 305-243-9545

E-mail: exportcontrol@miami.edu

Inventions, Intellectual Property and Technology Transfer Policy:

The Faculty Senate, at its March 30, 2016 meeting, unanimously approved the revised Policy on Inventions, Intellectual Property and Technology Transfer, located in the Faculty Handbook section of the *Faculty Manual*. The Policy replaces the current section of the Faculty Handbook titled “Patent and Copyright Policy.” The purpose of replacing the previous policy is to outline rights and responsibilities of members of the University of Miami community regarding inventions, intellectual property and technology transfers and to provide guidelines for the protection, management and commercial application of innovations.

I. GENERAL

- 1.1 Although the University does not undertake research or developmental work principally for the purposes of commercialization, patentable inventions and other works with commercial application may result from activities carried out by Applicable Personnel. The University has an obligation to appropriately develop Innovations to both benefit the public and generate resources that further support the academic mission of the University. The purpose of this policy is to outline rights and responsibilities regarding inventions, intellectual property and technology transfer and to provide guidelines for the protection, management and commercial application of Innovations.
- 1.2 The policy is applicable to:
 - a) all full- and part-time faculty, staff and employees, students, fellows and non-employees who use University funds, facilities or other resources, or participate in University-administered research, including visiting faculty and industrial personnel, regardless of obligations to other companies or institutions;
 - b) Innovations conceived, created, made or disclosed on or after the Effective Date of this policy, and to those prior Innovations disclosed to the Office of Technology Transfer (OTT) as agreed by Applicable Personnel.
- 1.3 Responsible Official: The Provost is responsible for administration of this policy.

Policy Review: The Technology Transfer Policy Committee (TTPC) is responsible for review of proposed changes to the Faculty Manual in relation to this policy.

II. DEFINITIONS and ABBREVIATIONS

For the purposes of this policy, the following definitions shall apply.

Applicable Personnel: all full- and part-time faculty, staff and employees, students, fellows and non-employees who use University funds, facilities or other resources, or participate in University-administered research, including visiting faculty and industrial personnel, regardless of obligations to other companies or institutions.

Commercialization Costs: costs incurred by the University for evaluating, protecting, defending, enforcing, marketing, negotiating, licensing, assigning, transferring and otherwise commercializing Innovations and/or University owned Intellectual Property.

Courseware: course syllabi, assignments, assessments, and/or other materials that are first created and made available to students as part of the educational curriculum at the University.

Creations: copyrightable works created in the course of Applicable Personnel's scholarly and artistic pursuits, including literary works, textbooks, other scholarly books, journal articles, novels, poems, plays, musical compositions and other artistic works to disseminate for scholarly study or artistic expression; a student work created using student dedicated resources, as part of the educational curriculum at the University, including Capstone projects, papers, dissertations and articles.

Gross Revenue: the amount received by the University under a license or assignment of the University's rights in Innovations, including option or license fees, milestone payments, royalties and proceeds from sale of equity.

Incidental Use: use of none of the University's resources other than its library, limited secretarial or administrative resources, the University's computers and/or Applicable Personnel's office space. Use of University laboratories, clinics and equipment may also be construed as an incidental use in accordance with written policies jointly developed by a school or college and the TTPC.

Innovations: patentable or un-patentable inventions, discoveries, processes, compositions, research tools, data, ideas, databases, know-how, copyrightable works that are not scholarly or artistic Creations and tangible property, including biological organisms, engineering prototypes, drawings, and software created, conceived or made by Applicable Personnel within their normal duties (including clinical duties), course of studies, field of research or scholarly expertise or making more than Incidental Use of University's resources.

Intellectual Property (IP): patent applications and patents, copyright registrations and renewals, trade secrets and trademarks. IP may be categorized as Creations or Innovations as detailed in Section III.

Net Revenue: Gross Revenue, less all Commercialization Costs and a 15% deduction for administration of OTT.

CDA: Confidential Disclosure Agreement
IP: Intellectual Property
MTA: Material Transfer Agreement
OTT: Office of Technology Transfer
TTPC: Technology Transfer Policy Committee

III. OWNERSHIP

- 3.1 Consistent with long-standing academic tradition, Creations are owned by the author(s), unless otherwise agreed in a contract between the University and Applicable Personnel, including:
- a) the University has expressly commissioned the Applicable Personnel in writing to produce, or participate in production of, the work with University's funds for a specific University purpose;
 - b) the University has expressly assigned the Applicable Personnel in writing to produce or participate in the production of the work; or
 - c) the work is otherwise subject to contractual obligations.
- 3.2 Creations meeting one of the above criteria (a-c) will be treated as Innovations and shall be owned by the University.
- 3.3 Innovations are owned by the University; revenues derived from commercialization of Innovations will be shared with the Applicable Personnel as detailed in Section VI.
- a) Applicable Personnel are required to assign and hereby do assign to the University all Innovations. This assignment includes the right for the University to claim priority and recover for third party infringement or misappropriation.
 - b) This assignment and abiding by this policy are conditions of employment and continued employment, access to University's resources and/or receipt of funding by the University.
 - c) This policy governs in the event of any inconsistent obligation to which Applicable Personnel may agree, including in any consulting agreement.
- 3.4 Intellectual property made or developed with not more than Incidental Use of University resources and not within normal duties (including clinical duties), course of studies, field of research and scholarly expertise of Applicable Personnel will belong to the Applicable Personnel. If Applicable Personnel are uncertain about the disposition of rights, they should make full disclosure of the potential Innovation or Creation to the OTT for determination of rights, as further described in Section 5.2.
- 3.5 Criteria for ownership of Courseware developed by Applicable Personnel follow the guidelines for Creations and Innovations.

IV. ADMINISTRATION OF THE POLICY

- 4.1 The Provost is responsible for oversight and administration of this policy. The Director of the OTT reports to the Provost or Provost's designee.
- 4.2 The TTPC is a committee consisting of seven voting faculty members, including the Provost or Provost's designee, the Vice Provost for Research and 5 additional faculty members, chosen by the Provost in consultation with the Faculty Senate chair. The Director of OTT and a member of the Office of General Counsel will serve as advisors to the TTPC. The five faculty members will serve two-year terms, which may be renewed.
 - a) The TTPC is charged with review of proposed changes to the *Faculty Manual* in relation to this policy;
 - b) TTPC proposed changes must be approved by the Provost and subsequently undergo the standard procedure for changes to the Faculty Manual, with final approval by the President and the Board of Trustees; and
 - c) The TTPC will meet at least annually and otherwise as necessary and will be chaired by the Provost or Provost's designee.
- 4.3 The OTT:
 - a) Evaluates Disclosure Forms and determines the commercial potential and the most appropriate mechanism, if any, for protecting each Innovation;
 - b) Works with Applicable Personnel to identify and engage potential commercial partners for their Innovations;
 - c) Undertakes negotiation and execution of agreements pertaining to Innovations, including licenses, data transfers, assignments, Material Transfer Agreements (MTA) that cover transmission of Innovations (outbound MTA), as well as Confidential Disclosure Agreements (CDA);
 - d) Receives Gross Revenue and distributes Net Revenue received from commercialization of Innovations; and
 - e) Interacts with University's research, compliance and finance units, including the Office of the Vice Provost for Research, Office of General Counsel, Office of Research Administration, Business Services, University Advancement, University Compliance Services and other units to ensure appropriate conduct of business and protection of the University's interests and recommend contractual language related to all Innovations.
- 4.4 Appeal Process. Disagreements with decisions made pursuant to this policy should be addressed to the Provost for final resolution.

- 4.5 Failure by Applicable Personnel to comply with the requirements of this policy may constitute unprofessional conduct and may lead to penalties including:
- a) The individual being deemed ineligible to hold principal investigator status on sponsored projects;
 - b) The individual being deemed ineligible to enter into technology transfer agreements; and
 - c) In the case of University Faculty, referral to the Senate's Committee on Professional Conduct for such other sanctions as it may recommend to the President and/or the Senate.

V. DISCLOSURE, REVIEW AND PROTECTION OF INNOVATIONS

5.1 Disclosure.

- a) Applicable Personnel are required to make timely and complete disclosure of Innovations to the OTT via submission of a Disclosure Form, available on the OTT website; early disclosure facilitates engagement of the OTT and allows for specific discussion and guidance toward determination of commercial potential.
- b) In general, disclosure to the OTT should occur at least 45 days prior to public disclosure of the Innovations, including submitting an abstract, poster, article, grant application or talking about the Innovation outside the University; this allows time for the OTT to evaluate commercial potential and identify mechanisms for protection of the Innovation.
- c) On the Disclosure Form, the Applicable Personnel will report
 - 1) the percent contribution of each of the Applicable Personnel to the Innovation;
 - 2) primary department and school for each Applicable Personnel;
 - 3) any center, institute or other department that supported the work that led to the Innovation;
 - 4) any Intellectual Property or tangible materials of a third party, including those that were generated at a previous institution or place of employment that has relevance to the disclosure;
 - 5) any non-University inventors (i.e., inventors who are not Applicable Personnel as defined in this policy), including, individuals acting as independent contractors, or individuals at other universities, institutions, companies, foundations or other entities; and

- 6) the source of funding for the work that led to the Innovation and details regarding specific technology transfer language (for example, ownership of allocations, sharing of revenue or licensing of Intellectual Property) in the funding agreements.

5.2 Review and Protection of Innovations

- a) The OTT will evaluate each Innovation Disclosure Form to determine
 - 1) commercial potential;
 - 2) what Intellectual Property protection, if any, would be appropriate to facilitate the University's ability to incentivize investment in the commercial development of the Innovation; and
 - 3) whether or not the Disclosure Form is premature or incomplete, in which case, the Applicable Personnel may be asked to resubmit the Disclosure Form when additional information is obtained.
- b) Evaluation for such Innovation as described in Section 5.2(a) will be made to Applicable Personnel within 90 days of receipt of a complete Disclosure Form.
- c) Applicable Personnel will cooperate with the OTT in its efforts to evaluate, protect and transfer Innovations, including executing documents and taking other actions as reasonably requested by OTT. The University encourages Applicable Personnel to participate through the OTT in the process of commercialization.
- d) Applicable Personnel are required to consult with the OTT to ensure that appropriate agreements are in place prior to disclosing the University's Innovations or sending materials embodying Innovations outside the University (for example, to another university, institution, company, foundation or other entity).
- e) Lack of patentability need not eliminate commercial potential for an Innovation and will not alter the University's ownership of the Innovation.
- f) The OTT is responsible for directing the filing of University-owned Intellectual Property. The OTT may delegate this authority including by written agreement in connection with commercializing an Innovation. As an example, the University retains qualified law firms to draft, submit and prosecute patents.
- g) The OTT decides when and whether to enter into agreements conveying Innovations and the terms and conditions in such agreements.
- h) Applicable Personnel are required to record all research data and information accurately and clearly and to keep all such data in a permanent and retrievable form. In addition, with regard to a patentable Innovation, original

laboratory data must be kept for the life of the patent. Tangible property, including biological materials, chemical compounds, etc., must be securely stored. All of the foregoing are the University's property. Exceptions to these requirements may be adopted in writing by the TTPC.

- i) It is the University's policy to publish research results as soon as possible; however, if publication may reveal an Innovation, Applicable Personnel should seek advice from OTT as to how and when to publish the results in order that patent or other protection is not compromised.
- j) Applicable Personnel are obligated to refrain from any act that would impair the University's rights in any Innovations and must maintain the confidentiality of Innovations, along with custody of applicable data and tangible property, consistent with the University's decisions regarding protection and commercialization. This is especially important when the Innovations have been supported by outside entities through a grant or contract.
- k) If Applicable Personnel leaves the University, all the Innovations arising prior to their departure remain the property of the University, and cannot be practiced, including being commercialized, without the University's written agreement;

5.3 Release of Technology.

- a) In rare cases, the OTT may recommend that the University return the rights to an Innovation to the Applicable Personnel. When this situation occurs, the University will generally transfer its rights, and if so by in a written agreement that will allow the University to practice and have practiced the Innovation for research, education and/or patient care, at no cost, and may include other provisions to protect the University's interests;
- b) Such a release will not be given until all pre-existing commitments to third parties, including sponsoring agencies, with regard to Innovations have been cleared;
- c) Prior to conducting activities, including research and clinical trials, that could reasonably appear to influence the financial value of the released Innovation, the Applicable Personnel must disclose the potential conflict of interest.
- d) Improvements, new developments and modifications to these returned rights, otherwise satisfying the definition of Innovations, remain subject to this policy;
- e) Release may be conditioned upon reimbursement to the University for all Commercialization Costs and 10% of the Applicable Personnel's net income from the released Innovation.

VI. DISTRIBUTION OF REVENUE DERIVED FROM COMMERCIALIZATION OF INNOVATIONS

6.1 Sharing of Revenue - Guidelines

- a) Multiple units may contribute to the support of work that leads to an Innovation, including the departments and schools/colleges of Applicable Personnel, as well as centers or institutes of which the Applicable Personnel are members.
- b) Distribution of Net Revenue will follow the percent allocation for Applicable Personnel as agreed upon on the Disclosure Form. Absent agreement on the percent allocation among Applicable Personnel, and subject to notice of a dispute being resolved pursuant to Section 6.1(i), the Applicable Personnel will share equally.
- c) Distribution to departments will follow the percent allocation for Applicable Personnel. For those schools/colleges without departments, the department share will be distributed to the school/college.
- d) The Applicable Personnel are responsible for disclosing whether a center or institute has provided financial or other support for the work that led to the Innovation, including laboratory space, supplies or significant administrative support. In such cases, upon disclosure of the Innovation, the involved department (or school/college in the absence of departments) will work with the center or institute to agree upon sharing of the department Net Revenue with the center or institute. As centers and institutes often include faculty from more than one school or college, the Provost or Provost's designee will mediate disputes related to the department's share.
- e) In the event that departments, centers or institutes from different schools/colleges contribute to an Innovation, sharing of Net Revenue will follow the allocation as determined in 6.1(c) and (d).
- f) University may make alternative arrangements for distribution of Gross Revenue or Net Revenue, whether due to co-ownership, grant, funding contract, gift or other agreement, only after review and approval of the Provost or Provost's designee.
- g) The OTT is authorized to delay distribution where additional expenses are anticipated, including those associated with filing for patent protection in foreign countries.
- h) The University has no fiduciary or other duty regarding whether or when to liquidate equity. Unless equity is liquidated, there is no Net Revenue to distribute.
- i) Any dispute regarding the distribution of Net Revenue may be addressed as set forth in Section 4.4 of this policy.

6.2 Formula for Sharing of Revenue

- a) Accrued as a result of Innovations licensed or assigned **prior to** the effective date of this policy, and in the absence of special funding/gift agreements:
 - 1) Commercialization Costs will be deducted from Gross Revenue; this does not include 15% for administration of OTT; and
 - 2) The first \$1,000 of cumulative Net Revenue shall be paid to the Applicable Personnel
 - 3) Cumulative Net Revenue will then be distributed 1/3 to the Applicable Personnel; 1/3 to the departments of the Applicable Personnel and 1/3 to the University.

- b) Accrued as a result of Innovations licensed or assigned **on or after** the effective date of this policy, and in the absence of special funding/gift agreements:
 - 1) Commercialization Costs will be deducted from Gross Revenue; however, the 15% for administration of OTT will not be deducted from Gross Revenue until initial cumulative Net Revenue equal to \$25,000 has been distributed to the Applicable Personnel; after which
 - 2) Ongoing Commercialization Costs will be deducted from cumulative Gross Revenue, followed by deduction of 15% for administration of OTT;
 - 3) Cumulative Net Revenue greater than \$25,000 and up to \$2 million will be distributed 1/3 to the Applicable Personnel, 1/3 to the department(s), as well as institutes and centers, as described in Sections 6.1c - 6.1e and 1/3 to the University.
 - 4) Cumulative Net Revenue greater than \$2 million will be distributed 1/3 to Applicable Personnel; 1/3 to the school/college, with the Dean of the Applicable Personnel school/college having the authority to determine sharing of Net Revenue between department(s)/center(s)/institute(s) within the school/college; 1/3 to the University.

6.3 Additional Information

- a) In the absence of extenuating circumstances, distributions of Net Revenue will generally be made within three months of receipt but no less than semi-annually.

- b) If Applicable Personnel should change departments within the University, the department share of revenue will generally not follow the Applicable Personnel, except under special circumstances and only as agreed upon by the Dean of the school/college in which the original department resides.

- c) If an Applicable Personnel should leave the University, the portion allocated to the Applicable Personnel's department will remain with the department.
- d) Payments made to Applicable Personnel must be made to the Applicable Personnel and cannot be assigned by the Applicable Personnel to other parties or entities, except upon the Applicable Personnel's death, in which case the personal representative of the Applicable Personnel's estate will notify the University Controller's Office, in order to ensure that the appropriate paperwork and permissions are received for distribution of the revenue to the Applicable Personnel's estate/heirs.

Contact

Norma Kenyon, Ph.D.

Vice Provost for Innovation

Phone: 305-2435346

E-mail: nkenyon@miami.edu

Links to other Policies/Guidelines:

[Sponsored Programs Policies and Procedures](#)

[Clinical Research Participant Enrollment & Tracking Policy](#)

[Electronic Data Quality Policy for Clinical Research](#)

[Clinical Research Trial Monitoring](#)

[External Audits for Research Policy](#)

[FDA Audit Guidelines](#)

[Software Purchasing Policy](#)

[F&A Distribution guidelines for inter-school research](#)

REFERENCES AND RELATED RESOURCES:

University of Miami, Faculty Manual

Stanford University Research Policy Handbook