
# Non-Faculty Academic Personnel Handbook

Approved by the Academic Policy Council

October 2001

Updated February, 2006

# ACKNOWLEDGMENT

[To be returned to the Office of the Dean]

I hereby acknowledge that I have received a copy of the Morehouse School of Medicine *Non-Faculty Academic Personnel Handbook,* revised February, 2006. I understand that I am to promptly read the contents of this handbook which set forth the terms and conditions of my appointment, including development of intellectual properties and where applicable my employment. This handbook supersedes and replaces any previous handbooks. I understand that if I have any questions regarding the contents of this handbook, I should discuss them with my supervisor or the Associate Dean for Administration.

I understand that circumstances will undoubtedly require that the policies, procedures, rules, and benefits described in this handbook change from time to time as the medical school deems necessary or appropriate in its discretion, and that those changes will be valid when approved by the appropriate authorities. I understand if any changes occur with this document, I will be notified of these changes in writing by formal memo or other correspondence, and that such changes will be incorporated in future editions of the *Non-Faculty Academic Personnel Handbook*.

_____
Employee's Name (Print or Type)

Date: _____ _____
Employee's Signature

## PURPOSE OF HANDBOOK

This handbook is an informational guide outlining some of the most important policies, programs, and benefits afforded employees who have academic titles without faculty status (non-faculty academic personnel) at Morehouse School of Medicine. Non-faculty academic personnel are expected to read this document and use it for future reference. Information contained in this Handbook is qualified in its entirety by reference to statements of official MSM policy set forth in the MSM Administrative Policy and Procedure Manual, the MSM Faculty Bylaws and related Appendices and the MSM Employee Handbook. The Non-Faculty Academic Personnel Handbook will make references to other documents to address specific issues for any particular non-faculty academic personnel group. These documents should be consulted if specific questions arise. All MSM policies are available in your departmental offices or the Library.

## *Table of Contents*

# 1. HISTORY, MISSION, GENERAL ORGANIZATION

## 1.1 Brief History

The Morehouse School of Medicine has a unique history. In 1973, Morehouse College received a federal grant to conduct a feasibility study. The study focused on the development of a two-year program to train students for careers as primary care physicians who would work in medically underserved areas. The study revealed the severe shortage of African-American and other minority physicians in the United States, and particularly in Georgia. In addition, the study highlighted a general shortage of physicians for rural areas and the inner cities of the nation. To address the critical health manpower needs of the citizens of Georgia and those who reside in medically underserved areas of the nation, the National Medical Association endorsed the development of a new medical school at Morehouse College. Other organizations, including the Georgia State Medical Association, the Georgia General Assembly, and the Carnegie Council also supported the development of a new medical school at the College. Morehouse College accepted this challenge. It was established as a two-year educational program in the basic sciences in April 1975 as The School of Medicine at Morehouse College.

The charter class of twenty-four students entered a two-year basic science program in September 1978. Those students, and the subsequent two classes, transferred from The School of Medicine at Morehouse College to other medical schools elsewhere in the country to complete their clinical training.

The School of Medicine became independent of Morehouse College in 1981. Morehouse School of Medicine received authorization from the Liaison Committee on Medical Education (LCME) in July of that same year, to begin planning for expansion to a four-year degree granting institution. The initial four-year program included a contractual arrangement with Emory University School of Medicine for the teaching of all required third-year clinical clerkships. In April 1985, the LCME granted MSM the authorization to award the Doctor of Medicine degree. The first class of students receiving the M.D. degree from the Morehouse School of Medicine graduated on May 17, 1985. Beginning in August 1990, MSM assumed full responsibility for teaching third-year clerkships in family medicine, surgery, and psychiatry. In 1991, LCME extended the accreditation of MSM for the maximum period of seven years. By 1997, the clinical faculty had assumed responsibility for all clinical courses. In 1998, Morehouse School of Medicine was again reviewed by the LCME and received full accreditation for another period of seven years.

The Graduate Medical Education program was initiated in 1981 when the Family Practice Residency program received accreditation from the Accrediting Council for Graduate Medical Education (ACGME). A Preventive Medicine Residency program is operated in cooperation with the Georgia Department of Human Resources, The Centers for Disease Control and Prevention and the Rollins School of Public Health of Emory University. The program was accredited in 1986. Since 1991, five additional residency programs have been accredited: psychiatry, internal medicine, surgery, obstetrics & gynecology, and pediatrics.

Morehouse School of Medicine is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools (1866 Southern Lane, Decatur, Georgia 30033-4097, 404-679- 4501) to award the degrees, Doctor of Medicine (M.D.), Doctor of Philosophy (Ph.D.) in Biomedical Science, and the Master of Public Health (M.P.H.). The initial class of students in the Ph.D. program entered in July 1992. The first students were enrolled in the Master of Public Health Program in September 1995. The first M.P.H. degree was conferred in May 1997 and the first two Ph.D. degrees were conferred in May 1998.

## 1.2 Mission

The Morehouse School of Medicine is a historically black institution established to recruit and train minority and other students as physicians, biomedical scientists, and public health professionals committed to the primary healthcare needs of the undeserved.

## 1.3 Accreditation

MSM is accredited to award the M.D. degree by the Liaison Committee on Medical Education (LCME), a joint committee representing the American Medical Association and the Association of American Medical Colleges. The LCME has been delegated the authority to accredit U.S. medical schools by the U.S. Department of Education. MSM is certified by the Department of Education of the State of Georgia to award the M.D. degree.

MSM is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools (1866 Southern Lane, Decatur, Georgia 30033-4097: Telephone number 404-679-4501) to award the M.D. degree, the Ph.D. degree in Biomedical Science, and the MPH degree. It is also accredited by the Council on Education for Public Health.

The seven residency programs currently sponsored by MSM (family practice, preventive medicine, psychiatry, internal medicine, general surgery, obstetrics and gynecology, and pediatrics), are accredited by the Accreditation Council on Graduate Medical Education (ACGME).

The Accreditation Council on Continuing Medical Education (ACCME) accredits the Continuing Medical Education Program.

| Accrediting Organization | First Accredited | Last Accredited | Next Review |
|---|---|---|---|
| **Liaison Committee on Medical Education (LCME)** | | | |
| • M.D. | 1985 | 2005 | 2012 |
| ***Southern Association of Colleges and Schools (SACS)** | | | |
| • Medical Education<br>• Ph.D. in Biomedical Sciences<br>• Master of Public Health<br>• Master of Science in Clinical Research | 1991 | 2001 | 2011 |
| **Council on Education for Public Health (CEPH)** | | | |
| • Master of Public Health Program | 1999 | 2004 | 2007 |
| **Accreditation Council on Continuing Medical Education (ACCME)** | | | |
| • Continuing Medical Education | 1986 | 2004 | 2007 |
| **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)** | | | |
| • Clinical Research Center | 1997 | 2003 | 2006 |
| **Accreditation Council for Graduate Medical Education (ACGME)** | | | |
| ***Residency Programs*** | | | |
| • MSM Program Institutional Review | | November 2004 | 2009 |
| • Family Practice | 1981 | May 2005 | 2007 |
| • Internal Medicine | 1992 | June 2002 | 2006 |
| • Obstetrics and Gynecology | 1997 | January 2005 | 2008 |
| • Pediatrics | 2000 | October 2004 | 2009 |
| • Public Health and Preventive Medicine | 1986 | April 2002 | 2007 |
| • Psychiatry | 1990 | Pending Report | 2009 |
| • Surgery | 1993 | February 2004 | 2007 |

For more information on accreditations, contact Mrs. Andrea Fox or the respective program director.

### 1.4 Administrative Organization

| Administrative Officers | |
|---|---|
| Angela W. Franklin, Ph.D. | Vice Dean and Associate Vice President for Academic and Student Affairs |
| Gary Key | Vice President for Institutional Advancement |
| Sylvia Nealy | Vice President for Human Resources |
| Eli Phillips | Vice President for Business and Finance |

| Administrative Officers | |
|---|---|
| David Satcher, M.D., Ph.D. | Interim President and Chief Executive Officer |
| Marjorie Smith, M.D. | Interim Dean and Senior Vice President for Academic Affairs |
| Walter W. Sullivan, Ph.D. | Vice President for Operations and Planning |
| **Academic Officers** | |
| Samuel Aguayo, M.D. | Associate Dean for Veteran Affairs |
| Daniel S. Blumenthal, M.D | Associate Dean for Community Programs |
| Martha Elks, M.D | Associate Dean for Medical Education |
| Sandra Harris-Hooker, Ph.D. | Associate Dean for Research Development |
| Elizabeth Ofili, Ph.D. | Associate Dean for Clinical Research |
| Doug Paulsen, Ph.D. | Assistant Dean for Graduate Studies |
| Lawrence Sanders, M.D. | Associate Dean for Clinical Affairs |
| Marjorie Smith, M.D. | Interim Dean and Senior Vice President for Academic Affairs |
| Angela W. Franklin, Ph.D. | Vice Dean and Associate Vice President for Academic and Student Affairs |
| Sandra E. Watson, MHA | Associate Dean for Administration |

| Academic Units |
|---|
| *The academic units of MSM are categorized, in accord with the Association of American Medical Colleges, as "basic science" or "clinical" units.* |
| *The following academic units are part of the basic science components of MSM:*<br>The Department of Anatomy and Neurobiology<br>The Department of Microbiology, Biochemistry and Immunology<br>The Department of Pharmacology & Toxicology<br>The Department of Physiology |
| *The clinical academic units of MSM are:*<br>The Department of Community Health and Preventive Medicine<br>The Department of Family Medicine<br>The Department of Medicine<br>The Department of Obstetrics and Gynecology<br>The Department of Pathology<br>The Department of Pediatrics<br>The Department of Psychiatry and Behavioral Sciences<br>The Department of Surgery |

In addition, MSM has a Department of Medical Education.

***There are also free-standing multi-disciplinary Centers or Institutes, which include*:**

| Name | Director |
|---|---|
| Cardiovascular Research Institute | Gary Gibbons, M.D. |
| Center of Excellence on Health Disparities | David Satcher, M.D. |
| Clinical Research Center | Elizabeth Ofili, M.D. |
| Cooperative Reproductive Science Research Center | David Mann, Ph.D. |
| NASA Space Medicine & Life Sciences Research Center | Myrtle Thierry-Palmer, Ph.D. |
| National Center for Primary Care | George Rust, M.D. |
| Neuroscience Research Institute | Peter MacLeish, P.h.D |
| Prevention Research Center | Elleen Yancy, Ph.D. |
| Research Centers in Minority Institutions | Vincent Bond, Ph.D. |
| Social Epidemiology Research Center | Sharon Davis, Ph.D. |

## 2. DEFINITION OF NON-FACULTY ACADEMIC PERSONNEL

Employees who have academic titles without faculty status are referred to as non-faculty academic personnel. They are assigned the titles of Research Associate, Clinical Associate, Teaching Associate, Research Scholar, Visiting Scholar, Senior Scientist or Lecturer. (See Appendix I) The minimum qualifications of each title of non-faculty academic personnel are as follows:

### 2.1 Research Associate

The appointee will generally possess a doctoral degree. On rare occasions, the appointee will not have a doctoral degree but will have an extensive amount of experience and/or specialized skill set. When one does not meet the doctoral degree requirement, the recommendation for appointment must be specifically justified as an exception subject to the final approval of the dean. The main effort for this appointment is research on particular grants. Research Associates must have a demonstrated ability to carry out independent research.

### 2.2 Teaching Associate

The appointee must possess a graduate degree and two years experience. The main effort for this appointment is significant contributions to departmental teaching and service programs.

### 2.3 Clinical Associate:

The appointee must possess a graduate degree and/or professional licensure in the State of Georgia. The main effort for this appointment is to be an assistant to the physician faculty as a physician's assistant or a nurse practitioner.

## 2.4 Research Scholar:

The title of Research Scholar is reserved for foreign researchers who have been invited to participate in MSM's Exchange Visitor Program. The exchange visitors are not considered employees but rather are part of a program designed to foster educational and cultural exchange between the United States and people around the world (see Exchange Visitor handbook or contact the Office for International Program Services for more information).

## 2.5 Visiting Scholar:

The title of Visiting Scholar is used for individuals who join MSM on full time basis while on sabbatical or educational leave from another institution. The duration for this appointment must be specifically defined but is usually one year or less. The details of the obligations and responsibilities of the Visiting Scholar are negotiated with the department chairperson with the approval of the dean. A Visiting Scholar may participate in teaching, research and/or patient care and must have any licensure required by the state of Georgia.

## 2.6 Post Doctoral Fellow:

The definition below serves to differentiate between the Research Associate and Post Doctoral Fellow.

The Post Doctoral Fellow appointment is part of the educational program and is appropriate for individuals recently awarded a Ph.D. or equivalent doctoral in appropriate fields. The postdoctoral fellow will work under the supervision of a senior scholar. The appointment effort is full-time research or scholarship and is considered a continuation of professional training. The appointee has the freedom and is expected to publish, within the guidelines of the institution, the results of his/her research or scholarship during the period of the appointment. This appointment is considered temporary and is viewed as preparatory for a full-time academic and/or research career. Therefore, after completion of a two-year appointment, the postdoctoral fellow is eligible for consideration of employment in a research associate or junior faculty position vacancy. A postdoctoral fellow should not be re-appointed to this classification after four years of service. For more information regarding the postdoctoral program, you may contact the Graduate Education in the Biomedical Sciences (GEBS) office at (404) 752-1580.

## 2.7 Senior Scientist:

The title of Senior Scientist is intended for individuals who independently undertakes or collaborates in the planning, development, and implementation of a laboratory, clinical, and/or field research study of an advanced nature requiring mastery of a line of research that is unique and/or in particularly high demand within an area of health sciences. A senior scientist provides leadership in the design and execution of leading research methods, protocols, and procedures that constitute a principal component of an integrated

research program. The appointee also provides technical consultation to research faculty and others in the interpretation and summation of data, and in the development of reports, presentations, and manuscripts associated with research findings.
(See appendix I for a detailed job description).

### 2.8 Lecturer

The academic title, Lecturer, will be used for academically qualified individuals whose responsibilities are limited in scope. Such individuals may provide a series of lectures or render occasional or regular lecture service, but otherwise are not affiliated with the medical school. This is a one-year renewable appointment.

## 3. CLASSIFICATION/APPOINTMENT

Non-faculty academic personnel are staff employees and not eligible to be members of the faculty assembly. Accordingly, non-faculty academic personnel are subject to all policies and procedures that govern other staff employees except where explicitly noted otherwise. Non-faculty academic personnel receive an annual letter of appointment from the Dean outlining title, salary, reporting structure and other pertinent information germane to the appointment.

### 3.1 Appointment Process

**3.1. a** The chairperson of an established department shall submit to the dean the qualifications of persons to be considered for appointment including the recommended title. Documented appropriate special skills, training or experience as demonstrated by an updated Curriculum Vitae (CV) in MSM format that includes degrees, diplomas, certificates or documents providing evidence of past experiences are required. At least one letter of reference from the individual or individuals who supervised the postdoctoral experience is also highly desirable. (See attached checklist) Unless specifically stated otherwise, an Academic Personnel Application for Employment is also required.

**3.1. b** The dean shall review the recommendation and the material supporting the recommendation. If the dean approves the recommendation, he/she will notify the candidate in writing in the form of an appointment letter, with a copy to the department chairperson. If the dean does not approve the proposal, he/she will return it to the department chairperson with a statement of the basis for disapproval. Review by the Faculty Appointment and Promotion Committee is not required.

# FORMAT FOR ORGANIZATION OF NON-FACULTY ACADEMIC PERSONNEL APPLICATIONS

NAME _____ TITLE _____

DEPARTMENT _____

**PLEASE COMPLETE THE FOLLOWING REQUIREMENTS AND SUBMIT PACKAGE TO THE OFFICE OF THE DEAN IN THE ORDER LISTED**

- Copy of fully executed REQUEST TO RECRUIT PERSONNEL (RP) form: No. _____ (RP not required for J-1 Applicants)
- PERSONNEL ACTION (PA) Form No. _____
- Copy of Office of International Program Services Checklist (required for J-1 Applicants)
- Letter of nomination for initial appointment from chairperson to dean
- Copy of "Letter of Intent" from the department chairperson or principal investigator to the candidate (if applicable)
- Application for Employment (Application not required for J-1 Applicants)
- A current Curriculum Vitae in an academic format (Use recommended MSM format)
- At least one letter of recommendation and reference, preferably from the person or persons who supervised the postdoctoral work or other qualified individual is highly desirable. **Original documentation is required and should address candidate's qualifications.**
- Copies of highest Graduate Training Certificates
- Copy of licensure and Certification (if applicable)
- Copy of ECFMG Certificate (if applicable)

- Copy of citizenship status (if applicable)

# FORMAT FOR ORGANIZATION OF J-1 APPLICANTS

NAME _____ TITLE _____

DEPARTMENT _____

**PLEASE COMPLETE THE FOLLOWING REQUIREMENTS AND SUBMIT PACKAGE TO THE OFFICE OF THE DEAN IN THE ORDER LISTED**

- (RP not required for J-1 Applicants)
- PERSONNEL ACTION (PA) Form No. _____
- Office of International Program Services Checklist (including copy of ALL documents)
- Letter of nomination for initial appointment from chairperson to dean
- Application for Employment
- Copies of highest Graduate Training Certificates or Diploma (English translation)

## 4. COMPENSATION

Compensation for non-faculty academic personnel is comprised of a competitive salary and a generous benefit package that is reviewed on an annual basis. Funding for these positions is completely contingent upon continuation of grant or other source of funds that provide for the salary. MSM salary ranges for non-faculty academic personnel are determined based on a number of criterions including, but not limited to, regional and national schedules set forth by recognized research bodies such as the National Institutes of Health (NIH) and reviewed on an annual basis. You may contact your supervisor for detailed information. Merit increases, consistent with MSM guidelines, may be given on an annual basis. When non-faculty academic personnel positions are funded entirely from a single grant-funding source, all salary adjustments are given in accordance with the grant anniversary year from which the position is funded, and not the institutional fiscal year. When the position is funded from several funding sources with varying renewal dates, salary adjustments are given in accordance with the institutional fiscal year. Merit increases shall occur one time per year based on the results of a performance evaluation.

See Employment Handbook, page 22 for benefits information.

## 5. PAY SCHEDULE

All employees hired after June 1993 are paid on a semi monthly basis: on the fifteenth (15) and the last workday of the month. When the fifteenth (15) or the last workday of the month falls on a Saturday or Sunday, paychecks are issued on the proceeding Friday.

See MSM Employee Handbook, page 10.

## 6. HOURS OF WORK

Non-faculty academic personnel are classified as exempt employees and therefore not entitled to overtime pay. It is the responsibility of the supervisor to establish and advise employees of specific work schedules. The normal work hours at Morehouse School of Medicine are Monday through Friday from 9:00a.m. - 5:00p.m. for regular employees, however, research and clinical department schedules are based on specific research or clinical requirements.

See MSM Employee Handbook, page 13.

## 7. VACATION

Vacation leave is accrued at a monthly rate for employees who occupy a position with a fifty percent (50%) or more full-time equivalency (FTE). Vacation is to be used after satisfactory completion of the probationary employment period.

See MSM Employee Handbook, page 24 for Vacation Accrual/Allowance Schedule.

## 8. TRANSFERS

Non-faculty academic personnel are required to complete six months of consecutive service before they can be considered for a transfer to another position within the institution. Employees should give their supervisors adequate notice (four to six weeks), to allow for satisfactory completion of projects.

See MSM Employee Handbook, page 12.

## 9. RESIGNATIONS

Non-faculty academic personnel are required to provide at least twenty (20) working days written notice of intent to resign. When possible, employees are requested to provide sufficient time (four to six weeks) to satisfactorily complete projects. Failure to provide required notice may forfeit any right to payment of unused vacation pay. Resignations should not be subject to any rights of reconsideration or review at the instance of either party without the concurrence of the other. See MSM Employee Handbook.

## 10. INVOLUNTARY SEPARATION

When the school terminates your employment, such action is called, "involuntary separation" (discharge).

## 11. GRIEVANCE PROCEDURE

Non-faculty academic personnel who are discharged involuntarily have appeal rights in accordance with the school's general grievance procedures that govern staff employees. These provisions do not apply to termination due to expiration of grant funding.

See MSM Employee Handbook, page 20.

## 12. ETHICAL STANDARDS IN THE CONDUCT OF RESEARCH

The maintenance of high ethical standards in research is a critical responsibility of the faculty and administration of Morehouse School of Medicine. Non-faculty academic personnel and faculty are held accountable for conducting research according to the high standards universally understood. Appropriate action will be taken when misconduct is research is substantiated.

See Appendix II.

## 13. ACADEMIC FREEDOM

Non-faculty academic personnel are entitled to exercise academic freedom and are expected to publish the results of his or her research or scholarship in the conduct of research and in the publications of results, subject to the adequate performance of other academic obligations and the approval of the principal investigator.

## 14. CONSULTING AND TEACHING ACTIVITIES

Full time non-faculty academic personnel who are salaried by MSM must obtain approval from the dean through their supervisor and/or department chair before engaging in teaching, research or consultation for monetary return paid by individuals or organizations other than MSM.

Research Scholars participating in the MSM Visitor Exchange Program may not engage in outside employment or activities that interfere with efficient performance of their responsibilities.

## 15. MSM RESEARCH RELATIONS WITH INDUSTRY

Morehouse School of Medicine believes that it has much to contribute to and to gain from appropriate relationships with private enterprise, and these relationships can be developed in a manner that preserves the institution's important academic and research principles and traditions. An additional goal is to protect the intellectual property of faculty.

See Appendix IV - Policy Statement on Faculty-Industry Research Relations.

## 16. PATENT POLICY

Non-faculty academic personnel are governed by the same patent policy as other employees. The aim of the patent policy of Morehouse School of Medicine is to promote the progress of science and the useful arts by utilizing the benefits of the U.S. patent system. The policy also clarifies the rights to ownership of patents among the parties involved.

See Appendix V - Patent Policy.

## 17. INTELLECTUAL PROPERTY

The aim of the copyright policy of MSM is to promote and protect the traditional academic freedom of the institution's faculty, non-faculty academic personnel, staff, and students

concerning publication. The policy also serves to protect the intellectual property of the faculty.

See Appendix III – Intellectual Property: Copyrights and Royalties.

## 18. RESPONSIBLE CONDUCT OF SCHOLARSHIP AND RESEARCH

Non-faculty academic personnel are governed by the same responsible conduct of scholarship and research as other MSM employees. Scientific achievement and progress are bound by the standards of honesty, integrity, objectivity and collegiality. The policy for responsible conduct of scholarship and research addresses safeguarding the research process and the increasing social expectations about the accountability of scientists and their institutions for research supported by public funds.

See Appendix VI - Policy for the Responsible Conduct of Scholarship and Research.

## 19. SERVICE CENTERS

Morehouse School of Medicine offers several specific technical or administrative services primarily for the internal operations. The users are charged a fee the services provided. Examples of such services include core research laboratories, animal care, telecommunications, network services, and graphics.

See Appendix VII - Service Center Recharge Policy.

## 20. EVALUATION OF NON-FACULTY ACADEMIC PERSONNEL

The performance of non-faculty academic personnel is evaluated on an annual basis using the non-faculty evaluation form.

See MSM Employee Handbook, page 12.

## 21. DISCRIMINATION/DISCRIMINATORY HARASSMENT POLICY

Non-faculty academic personnel are subject to the same discrimination/discriminatory harassment policy that governs all employees.

See MSM Employee Handbook, page 4.

## APPENDIX 1 - Job Descriptions

### Job Description of the Senior Scientist in MSM

**SUMMARY:**

Independently undertakes or collaborates in the planning, development, and implementation of a laboratory, clinical, and/or field research study of an advanced nature requiring mastery of a line of research that is unique and/or in particularly high demand within an area of health sciences. Provides leadership in the design and execution of leading research methods, protocols, and procedures that constitute a principal component of an integrated research program. Provides technical consultation to research faculty and others in the interpretation and summation of data, and in the development of reports, presentations, and manuscripts associated with research findings.

**DUTIES AND RESPONSIBILITIES:**

1. Independently undertakes or collaborates in the planning, development, and implementation of advanced laboratory, clinical, and/or field research studies.
2. Provides professional leadership in the design and development of broad research concepts, and in the establishment of new research methods, protocols, procedures, and techniques.
3. Provides technical consultation and professional leadership to research faculty and others in the interpretation and summation of data, and independently develops reports, presentations, and manuscripts associated with research findings.
4. Develops comprehensive data analyses and summary interpretations, and provides leadership and coordination in the development and delivery of reports, presentations, and manuscripts associated with research findings.
5. Provides day-to-day technical leadership and functional supervision to lower level professionals and/or paraprofessionals in the execution of study protocol.
6. Ensures proper care in the use and maintenance of equipment and supplies; promotes continuous improvement of workplace safety and environmental practices; may manage or oversee a complete research laboratory.
7. Performs miscellaneous job-related duties as assigned.

**KNOWLEDGE, SKILLS, AND ABILITIES REQUIRED:**

- Ability to supervise and train staff, including organizing, prioritizing, and scheduling work assignments.
- Demonstrated mastery of research methods, protocols, procedures, techniques, and equipment within an advanced area of specialty.
- Ability to lead and guide technical and professional staff in the performance of research.
- Ability to utilize advanced analytical techniques and programs to develop scientific models.
- Ability to develop creative solutions to unique, unprecedented operational research problems.
- Skill in organizing resources and establishing priorities.

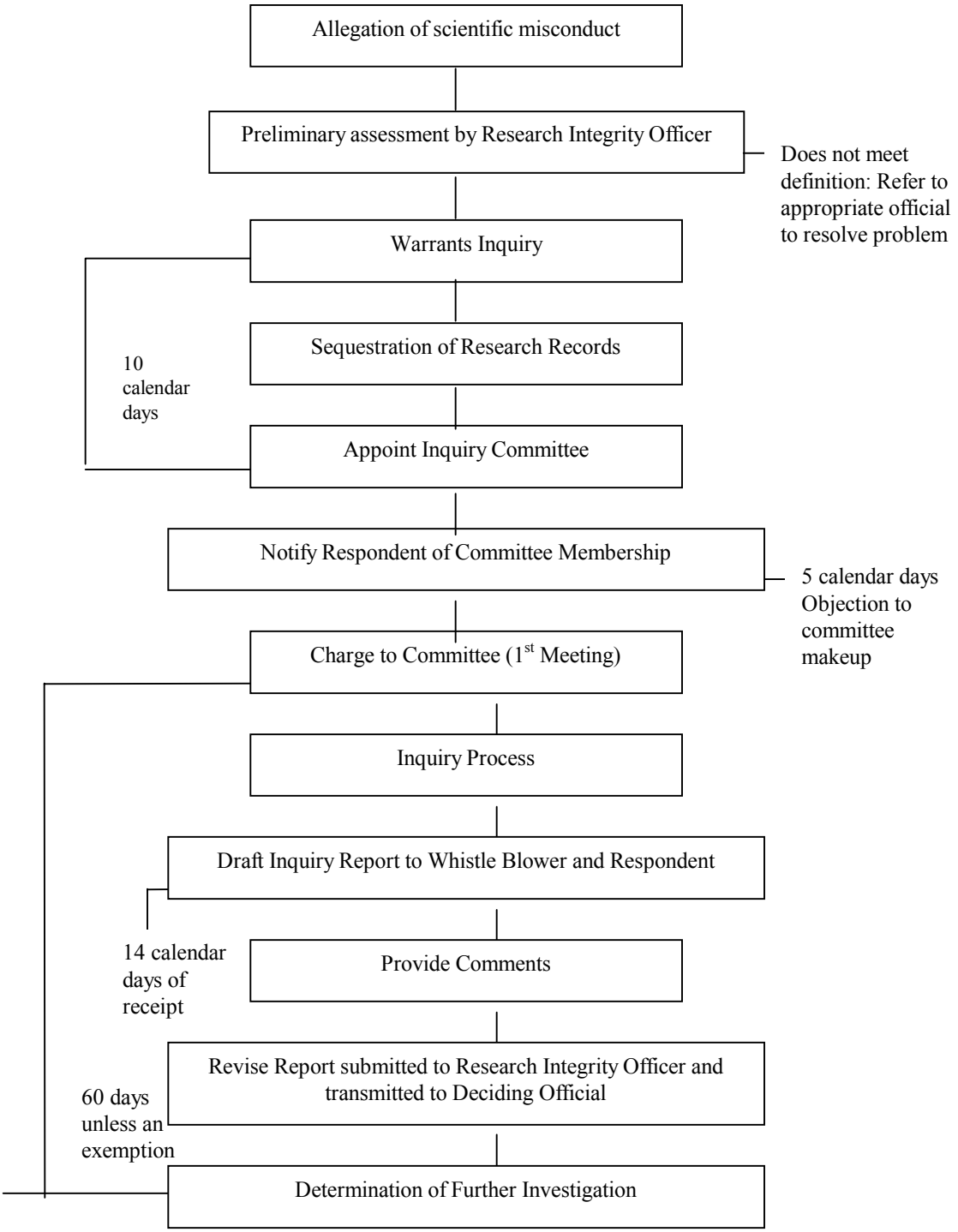
**MINIMUM EDUCATION and/or JOB REQUIREMENTS:**
Doctorate degree in appropriate field with at least 1 to 3 years experience directly related to the duties and responsibilities and ability to function as an independent investigator **OR**
Master's degree in appropriate field with at least 5 to 7 years research experience directly related to the duties and responsibilities specified; documented record of scholarly achievement and independent investigations.

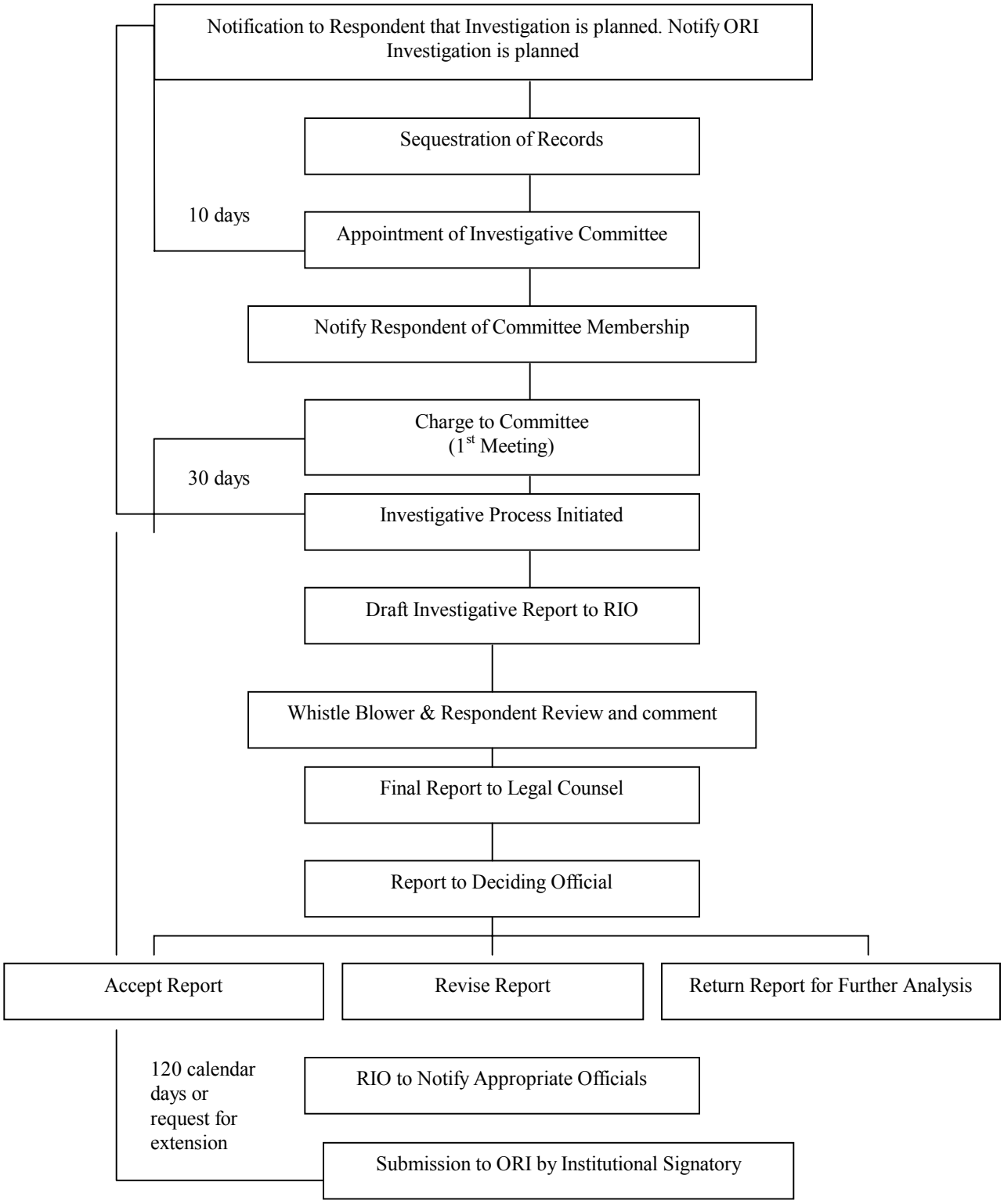
## APPENDIX II—Research Integrity Policy

### For Responding to Allegations of Scientific Misconduct

### Table of Contents

## Procedures for Responding to Allegation of Scientific Misconduct




Notification to Respondent that Investigation is planned. Notify ORI Investigation is planned
Sequestration of Records
10 days
Appointment of Investigative Committee
Notify Respondent of Committee Membership
Charge to Committee (1st Meeting)
30 days
Investigative Process Initiated
Draft Investigative Report to RIO
Whistle Blower & Respondent Review and comment
Final Report to Legal Counsel
Report to Deciding Official
Accept Report
Revise Report
Return Report for Further Analysis
120 calendar days or request for extension
RIO to Notify Appropriate Officials
Submission to ORI by Institutional Signatory

## I. Introduction

### A. General Policy

Morehouse School of Medicine (MSM) is committed to excellence in the discovery and dissemination of knowledge. This requires that faculty and staff adhere to the highest standards of integrity with regards to research. This is important to ensure that the discovery and dissemination of knowledge is done with the highest standards of ethics possible. It is important that we realize that such activities require responsibilities of researchers with regards to work of colleagues, including junior faculty, research associates, staff and students.

Further, Morehouse School of Medicine recognizes that federal regulations include policies and procedures which the institution must follow for dealing with possible misconduct in science. All persons involved in research should recognize the value to the institution of calling its attention to possible research misconduct and the possible lack of integrity involving scholarly endeavors.

If the conduct of research or the reporting of research information is challenged on the grounds of misconduct, by any member of the institution's community or outside the institution, there is a framework for resolution of such grievances that must involve the Dean and Senior Vice President for Academic Affairs and the Vice President and Associate Dean for Sponsored Research Administration. These persons are responsible for working within a process of peer and administrative review. Throughout the process, the protection of individuals (whistle blower and respondent) against unnecessary public disclosure of unproven allegations is paramount.

The Institution can suffer great harm in cases where research misconduct occurs. Therefore, it is important that institutional members exercise active leadership in roles of supervision, mentoring, and collaboration.

The policy found here shall be followed in responding to all allegations of research misconduct. The procedures described are steps involving academic peer review and fact finding and are not intended or designed to represent rules of law. It is of further importance that we safeguard, where possible, against retaliation to the respondent or whistle blower and to ensure that a fair and objective process is observed in examining and resolving allegations.

### B. Scope

This policy and the associated procedures apply to all individuals at Morehouse School of Medicine engaged in research supported by or for which support is requested from the U.S. Public Health Service (PHS). The PHS regulation at 42 C.F.R. part 50, Subpart A applies to any research, research-training or research-related grant or cooperative agreement with PHS. This policy applies to any person paid by, under the control of, or affiliated with MSM, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or

collaborators at MSM.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interest of MSM and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be reviewed in advance by the Vice President and Associate Dean for Sponsored Research Administration of MSM and approved by the dean.

## II. Definitions

*A.* *Allegations* means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

*B.* *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

*C.* *Deciding Official (Dean and Senior Vice President for Academic Affairs)* means the institution official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

*D.* *Good faith allegation* means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

*E.* *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.[1]

*F.* *Institutional Signatory (Vice President of Operations and Planning)* means the institutional official who shall notify the Office for Research Integrity of all research integrity-related investigations.

*G.* *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.[2]

*H.* *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

*I.* *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

*J.* *PHS regulations* mean the Public Health Service regulations establishing standards for institutional inquiries and investigations into allegation of scientific misconduct, which

is set forth at 42 C.F.R. part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

*K.* *PHS support* means PHS grants, contracts, cooperative agreements or applications thereof.

*L.* *Research Integrity Officer (Vice President and Associate Dean for Sponsored Research Administration)* means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

*M.* *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts, and patient research files.

*N.* *Respondent* means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

*O.* *Retaliation* means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation. **The institution will ensure that retaliation does not take place by having a person who takes such action to thoroughly document and prove why action is necessary and valid and is not connected to the allegation.**

*P.* *Scientific misconduct or misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.[3]

*Q.* *Whistleblower* means a person who makes an allegation of scientific misconduct.

## III. Rights and Responsibilities

A. Research Integrity Officer

The Vice President and Associate Dean for Sponsored Research Administration will serve as the Research Integrity Officer (RIO), who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist inquiry and investigating committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or other external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and security of the files.

The RIO will inform the Institutional Signatory as appropriate, who will report to ORI as required by regulation and keep ORI appraised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.[4]

B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.

The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees and to review the draft inquiry and investigation reports.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.[5]

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions. Any variation from these procedures must be approved by the dean.

E. Institutional Signatory

The Institutional Signatory is the institutional official who shall notify the Office for Research Integrity of all research integrity-related investigations or inquiries as appropriately defined in section IX.E.

## IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with MSM should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Research Integrity Officer at 404-752-1725 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At anytime, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Whistleblower

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will receive instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also the institution will protect the privacy of those who report misconduct in good faith[6] to the maximum extent possible. For example, if the whistleblower requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.[7]

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.[8]

Institutional employees accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice, but may not bring the counsel or personal adviser to interviews or meetings on the case.

D. Cooperation with Inquiries and Investigation

Institutional employees will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.

## V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science and involves PHS funding, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials (such as the Dean and Vice President of Academic Affairs, Vice President of Operations and Planning, and Department Chairs) as appropriate, will appoint an inquiry committee and committee chair within ten (10) calendar days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

The Research Integrity Officer will notify the respondent of the proposed committee membership within five calendar days of appointing the Inquiry Committee. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within five (5) calendar days, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation

assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The Research Integrity Officer will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The inquiry committee will normally interview the whistleblower, the respondent and key witnesses as well as examine relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

## VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Whistleblower

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review

to protect the confidentiality of the draft report.

2. Receipt of Comments

Within fourteen (14) calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record.[9] Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decisions by Deciding Official

The Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes the determination, which will be made within sixty (60) calendar days of the first meeting of the inquiry committee. Any extension of the period will be based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer will notify both the respondent and the whistleblower in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than sixty (60) calendar days following its first meeting,[10] unless the Research Integrity Officer approves an extension. The reason for an extension will be entered into the records of the case and the report.[11] The respondent also will be notified of the extension.

## VI. Conducting the Investigation

A. Purpose of the Investigation

If the initial inquiry results in the need for an investigation, the RIO will give written notification of the investigation to the Institutional Signatory. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involved clinical trials or potential harm to human subjects of the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process not previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within ten (10) days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation.[12] These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Research Integrity Officer will notify the respondent of the proposed committee membership within five (5) days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, define scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Research Integrity Officer, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee will be appointed and the process initiated within thirty (30) calendar days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.[13] Notification of the Inquiry Committee's decision will be sent to the Respondent.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls.[14] Whenever possible, the committee should interview the whistleblower(s), the respondent(s), and other individuals who might have information regarding aspects of the allegations.[15] Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comments or revision, and included as part of the investigatory file.[16]

## VII. The Investigation Report

A. Elements of the Investigation Report

The final report submitted to ORI must describe the policies and procedures, under

which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.[17]

B. Comments of the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed five (5) days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Whistleblower

The Research Integrity Officer will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The whistleblower will have five (5) days to review and comment on the draft report. The report should be modified, as appropriate, based on the whistleblower's comments.

3. Institutional Counsel

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the

investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitted to ORI. The Deciding Official's explanation should be consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the whistleblower in writing. In addition, the Deciding Official in consultation with the Institutional Signatory and Institutional Counsel, will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborations of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI

After comments are received and necessary changes made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and whistleblower's comments, to the Deciding Official, through the Research Integrity Officer.

E. Time Line for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of the initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding official for approval, and submission by the Institutional Signatory of the report to the ORI.

## IX. Requirements for Reporting to ORI

A. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins.[20] At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.[21] ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.[22] Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

B. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will prepare a report of the planned termination, including a description of the reasons. for submission to the ORI.[23]

C. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to the Institutional Signatory for submission to the ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports via the Institutional Signatory as requested by the ORI.[24]

D. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific conduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.[25]

E. The Institution must notify the ORI at any stage of the inquiry or investigation if:

1. there is an immediate health hazard involved;[26]

2. there is an immediate need to protect the Federal funds or equipment;[27]

3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;[28]

4. it is probable that the alleged incident is going to be reported publicly;[29] or

5. the allegation involves a public health sensitive issue, e.g., a clinical trial or

6. there is reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.[30]

## X. Institutional Administrative Actions

MSM will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.[31]

If the Deciding Official determines that the alleged misconduct is substantiated by the

findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.

- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.

- Restitution of funds as appropriate.

## XI. Other Considerations

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the institution of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of al the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegations of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Whistleblower and Others[32]

Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblowers that made allegations of scientific misconduct in good faith and others

who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the whistleblower's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the whistleblower.

E. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.[33]

## XII. Record Retention

After completion of a case and all ensuring related actions, the Research Integrity Officer will prepare a complete file, including records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.[34]

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NOTES:

1. 42 C.F.R. 50.102.
2. 42 C.F.R. 50.102.
3. 42 C.F.R. 50.102.
4. 42 C.F.R. 50.103(d) (12).
5. 42 C.F.R. 50.103(d) (13).
6. 42 C.F.R. 50.103(d) (2).
7. 42 C.F.R. 50.103(d) (13).
8. 42 C.F.R. 50.103(d) (3).
9. 42 C.F.R. 50.103(d) (1).
10. 42 C.F.R. 50.103(d) (1).
11. 42 C.F.R. 50.103(d) (1).
12. 42 C.F.R. 50.103(d) (8).
13. 42 C.F.R. 50.103(d) (7).
14. 42 C.F.R. 50.103(d) (7).
15. 42 C.F.R. 50.103(d) (7).
16. 42 C.F.R. 50.103(d) (7).
17. 42 C.F.R. 50.104(a)(4); 42 C.F.R. 50.103(d)(15).
18. 42 C.F.R. 50.104(a)(2).
19. 42 C.F.R. 50.104(a)(2).
20. 42 C.F.R. 50.104(a)(1).
21. 42 C.F.R. 50.104(a)(1.
22. 42 C.F.R. 50.103 (d)(15).
23. 42 C.F.R. 50.104(a)(3).

24. 42 C.F.R. 50.104(a)(5).

25. 42 C.F.R. 50.104(a)(3).

26. 42 C.F.R. 50.104(b)(1).

27. 42 C.F.R. 50.104(b(2).

28. 42 C.F.R. 50.104(b)(3)

29. 42 C.F.R. 50.104(b)(4).

30. 42 C.F.R. 50.104(b)(5).

31. 42 C.F.R. 50.103(d)(14).

32. 42 C.F.R. 50.103(d)(14).

33. 42 C.F.R. 50.103(d)(11).

34. 42 C.F.R. 50.103(d)(10).

## APPENDIX III— Intellectual Property: Copyrights and Royalties

### PURPOSE

To set policy regarding copyrights and royalties for all copyrightable material created by Morehouse School of Medicine (MSM) personnel related to or within the scope of their employment with MSM.

### STATEMENT OF PRINCIPLES

Morehouse School of Medicine (School) encourages the dissemination of knowledge and development of creative work that fulfills its educational, research and service missions and benefits the public it serves. The School supports the preparation and publication of copyrightable works resulting from the teaching, research, scholarly and artistic endeavors of faculty, staff and students as part of their unique roles at the School. The School seeks to foster an intellectually stimulating environment in which creative efforts and innovations are encouraged and rewarded, the careers of its members are enhanced, and the School's reputation and prestige are furthered. The School respects, acknowledges and promotes the intellectual property rights in works created by its members. The School strives to maintain a balance among the interests of Creators, sponsoring bodies and the School in copyrightable material and income resulting from such works.

All Morehouse School of Medicine personnel are encouraged to retain ownership of the copyright to Traditional Works of Scholarship (as defined herein) or to obtain a perpetual license from the copyright owner to reproduce, distribute, perform, and/or display the work and to make Derivatives Works there from.
Scientific publications, including original articles, review of articles and books, for which copyright is normally transferred to the publisher and for which no revenue is obtained, are exempt from all reporting requirements of this document. In addition, works that generate less than $1,000 in revenue are also exempt from reporting requirements of this document.

### ACCOUNTABILITY

Under the direction of the President, the Dean and Senior Vice President for Academic Affairs, and the Senior Vice President and Chief Operating Officer shall ensure compliance with this policy. The Vice President and Associate Dean for Sponsored Research Administration shall implement this policy.

The Dean shall ensure that each new faculty member receives a copy of this policy or is directed to it on the MSM web site.

### APPLICABILITY

This policy applies to all faculty, staff, postdoctoral fellows, residents, students and any other person employed by the School.

### DEFINITIONS

1. The following terms are important for purposes of expressing the School's policy on Intellectual Property: Copyrights and Royalties.

a. "**Creator**": Individual or group of individuals who transforms ideas into a

tangible form of expression thereby creating Copyrightable Material.

b. "**Copyrightable Material**": Material that is subject to U.S. copyright laws, including, but not limited to, literary works, musical works, dramatic works, choreographic works, graphic works, photographic works, cardiographic, radiographic and pictorial works (e.g., - x-rays, images), sculptural works, audiovisual and videotaped works, sound recordings, films, theses, and works in electronic media (e.g., digitized works and network transmission of digitized works, multimedia broadcast, web-based products, recorded materials, remote transmission of information, instructional software, CDROMs).

c. "**Derivative Works**": Copyrightable Material based on or derived from one or more already existing copyrighted works. Derivative Works include, but are not limited to, new versions, translations, dramatizations, fictionalizations, reproductions, compilations, revisions and condensations.

d. "**Instructional Materials**": A type of "Institutional Work," including textbooks and study guides, used for the instruction of MSM students, residents and/or postdoctoral fellows.

e. "**Institutional Resources**": Tangible resources provided by the Institution to a Creator, including funds, office space, lab space, equipment, electronic network resources (hardware and software), support personnel, secretarial support, research, teaching and lab assistants, assistance from medical and graduate students or residents, media specialists or illustrators, supplies, utilities. Funds include grants and contracts or awards made to the Institution by an extramural sponsor.

f. "**Institutional Works**": Copyrightable Material created (1) specifically or predominantly for use by or at MSM, or (2) at the request or on behalf of MSM, or (3) under the specific direction of MSM, or (4) by a person acting within the scope of his or her employment at MSM, or (5) under a written contract between the Creator and MSM, or (6) under a contract between MSM and an external agency. "Traditional Works of Scholarship" will not be considered "Institutional Works" for the purposes of this policy.

g. "**Other Intellectual Property**": Any Copyrightable Material other than Traditional Works of Scholarship, Institutional Works, and Instructional Materials.

h. "**Traditional Works of Scholarship**": Copyrightable Material reflecting research and/or creativity which is considered evidence of accomplishment in the Creator's academic discipline or professional field, and is specifically created for predominate use by persons or entities other than MSM and/or its students. Such works include, but are not limited to, books, book chapters, journal articles, abstracts, student theses, plays, poems, pictorial and sculptural works, films, cassettes, musical compositions and other literary works.

## POLICY

### 1. Copyright Ownership

1.1. The terms of a sponsored research or other agreement may determine the ownership of all copyrightable material that a person creates in the course of or pursuant to such an agreement. If the agreement does not contain terms relating to the ownership of copyrightable material, the following provisions of this policy will govern ownership of the material.

**a**. Only a commissioned project shall be a "work made for hire", and accordingly, the School shall own all copyrightable material which a person creates as a commissioned project. If a question arises as to whether a person created copyrightable material pursuant to a commissioned project, the Intellectual Property Committee, after investigation into the appropriate facts shall formulate a recommendation for consideration by the president. In cases of a commissioned project, the Creator of the copyrightable materials shall execute an assignment of rights to the School in any copyrights or registration that may be obtained.

**b**. The Creator of all other copyrightable material not governed by the preceding paragraphs shall own such material notwithstanding any employment relationship with the School.

### 2. Marking and Disclosure

**a**. Copyrightable Material shall be marked at the earliest possible opportunity with the copyright symbol "©" or the word "copyright" or the abbreviation "**Copr**." the year of the first production or publication, and the name of the owner of the copyright in the work.

**b**. The Creator shall promptly file a copyright disclosure form (Exhibit A) with the Office for Research Development for any (i) School Research, (ii) Instructional Materials and (iii) Other Intellectual Property created with the use of School resources.

**c**. The School may release its ownership rights to the Creator when, as determined by the Intellectual Property Committee and Legal (i) there are no overriding special obligations to a sponsor or other third party, and/or (ii) the best interests of the School would be so served. The School shall make this decision within 30 days of receipt of the disclosure form.

**d**. If the Intellectual Property Committee denies the Creator's request that the School's ownership rights in the copyright be released to the Creator, the Creator may appeal this decision to Dean and Senior Vice President for Academic Affairs for final decision.

**e**. The Office for Research Development shall file an application to register the School's copyright interest in the disclosed work when copyright ownership remains with the School and the Creator is notified in writing.

**3. Use of School Resources**

3.1. When Works from School Research, including Instructional Materials and Other Intellectual Property are created with the use of School Resources:

**a.** The School, through the Office for Research Development shall have the right to determine the licensing, marketing and use of material for which the School has sought and obtained copyright ownership. This determination shall take into account the interests of the School, the public and the Creator, including the Creator's preferences.

**b**. The Creator shall have the right to be identified or to refuse to be identified as the Creator by the School and by subsequent licensees and assignees, except as required by law.

**4. Royalties and Revenue Distribution**

**a.** The School recognizes that, in cases in which the person who created copyrightable material assigns rights to the School, an equity in the material remains with the inventor, and in such cases, unless the Intellectual Property Committee recommends, and the President and Dean adopt, a different distribution warranted by the circumstances, the total net revenue derived from the copyrightable material shall be distributed as follows:

i. 10% of the accumulated gross royalties and milestones to the Institution. The Institution's distribution shall be divided:

1. 50% to the Office of the Dean; which shall be distributed at the discretion of the Dean to support research and teaching infrastructure; and

2. 50% to the Office for Research Development to help defray the cost of administering Intellectual Property-related activities.

ii. 90% of the accumulated gross royalties and/or milestones to the Creators. 5

**b**. In determining net revenue, the School shall deduct from gross royalty milestones or other revenue, documented expenses such as production costs, subventions, and litigation which may be incurred in enforcing or defending the copyright or in the licensing of the copyrightable material.

**c**. The School will credit to the Creator, prior to income distribution, any documented non-reimbursed expenses incurred in the course of developing the copyrighted material.

By Direction of the President_____ _____
Senior Vice President and Chief Operating Officer Date

_____ _____
Dean and Senior Vice President for Academic Affairs Date

**Materials Transfer Agreement**

**Between**

**Morehouse School of Medicine**

**And**

**COMPANY/INSTITUTION**

THIS MATERIALS TRANSFER AGREEMENT is made and entered into by and between Morehouse School Of Medicine, having principal offices at 720 Westview Drive, Atlanta, Georgia 30310-1495; and ("COMPANY/INSTITUTION") an academic institution having a principal place of business at ADDRESS.

WITNESSETH:

WHEREAS, Morehouse School of Medicine has developed ("BIOLOGICAL MATERIALS"), which are further described and defined herein below, and

WHEREAS, COMPANY/INSTITUTION wishes to use BIOLOGICAL MATERIALS in its own internal research programs without selling or otherwise directly commercializing BIOLOGICAL MATERIALS, and

WHEREAS, Morehouse School Of Medicine are desirous to provide reasonable quantities of BIOLOGICAL MATERIALS to COMPANY/INSTITUTION to assure application of BIOLOGICAL MATERIALS for public benefit.

NOW THEREFORE, in consideration of the mutual covenants and premises contained herein, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE I - DEFINITIONS

1.01 "BIOLOGICAL MATERIALS" shall specifically mean (DEFINITION OF MATERIALS) any progeny, any derivatives (such as, but not limited to, LIMITATIONS), and any modifications there from, specifically modifications substantially based on, or incorporating, a substantial element of BIOLOGICAL MATERIAL; or any modifications which are not new or not obviously distinct from BIOLOGICAL MATERIAL.

1.02 "KNOW-HOW" shall mean any information related to BIOLOGICAL MATERIALS such as sequences, formulas, protocols, compilations of data, specifications or any other information that may be provided by Morehouse School of Medicine to COMPANY/INSTITUTION, in a tangible form, and in connection with BIOLOGICAL MATERIALS.

1.03 "EFFECTIVE DATE" shall mean the date this Agreement is last executed by a signatory hereto.

ARTICLE II - SUPPLY OF MATERIALS AND OBLIGATIONS OF INSTITUTION

2.01 Supply of Materials. Upon execution of this Agreement, Morehouse School of Medicine shall supply to COMPANY/INSTITUTION a reasonable such quantity of BIOLOGICAL MATERIALS as is reasonably requested by INSTITUTION, which shall be delivered to COMPANY/INSTITUTION according to federal and/or state shipping guidelines as prescribed for such BIOLOGICAL MATERIALS.

2.02 Obligations of COMPANY/INSTITUTION. COMPANY/INSTITUTION agrees that its use of BIOLOGICAL MATERIALS shall be subject to the following terms and conditions:

a. Safety. COMPANY/INSTITUTION agrees to use the BIOLOGICAL MATERIALS in a safe manner and in compliance with all applicable laws and regulations, including National Institutes of Health (NIH) guidelines. BIOLOGICAL MATERIALS shall not be used in humans in any way, including for purposes of diagnostic testing.

b. Storage. Upon COMPANY/INSTITUTION'S receipt of supply of BIOLOGICAL MATERIALS as provided for in paragraph 2.01 hereinabove, BIOLOGICAL MATERIALS shall be stored under DEFINE PROPER CONDITIONS until use by COMPANY/INSTITUTION.

c. Integrity of Materials. COMPANY/INSTITUTION agrees not to analyze, or have analyzed the composition or formulation of the BIOLOGICAL MATERIALS received hereunder.

d. COMPANY/INSTITUTION Use. BIOLOGICAL MATERIALS shall be used only at COMPANY/INSTITUTION's facilities for the research purposes described in Attachment A, hereby attached and made part of this Agreement. No option or commercial license is implied or granted to COMPANY/INSTITUTION herein.

e. No Transfer. COMPANY/INSTITUTION shall not transfer or provide BIOLOGICAL MATERIALS or KNOW-HOW or any portion thereof to any other organization or individual without the prior written consent of Morehouse School Of Medicine. Furthermore, COMPANY/INSTITUTION acknowledges that the BIOLOGICAL MATERIALS and KNOW-HOW are the valuable and proprietary properties of Morehouse School Of Medicine; COMPANY/INSTITUTION shall to the best of its ability utilize the BIOLOGICAL MATERIALS and KNOW-HOW in a manner that serves to protect the Morehouse School Of Medicine's proprietary interests.

f. Confidentiality. COMPANY/INSTITUTION agrees to maintain the confidentiality of any KNOW-HOW transferred to COMPANY/INSTITUTION with BIOLOGICAL MATERIALS.

g. Publications. COMPANY/INSTITUTION agrees to notify Morehouse School Of Medicine of any presentation or publication that results from use of BIOLOGICAL MATERIALS. COMPANY/INSTITUTION shall state in the presentation or publication that BIOLOGICAL MATERIALS were supplied by NAME OF FACULTY TRANSFERRING MATERIALS, a faculty member of Morehouse School Of Medicine. The foregoing does not in any way preclude or restrict COMPANY/INSTITUTION from making public presentations or publications.

## ARTICLE III - CONSIDERATION

3.01 Transfer Fee. COMPANY/INSTITUTION shall pay the packing and shipping costs associated with the transfer of BIOLOGICAL MATERIALS to COMPANY/INSTITUTION from Morehouse School Of Medicine, not to exceed one hundred dollars ($100) without the prior written consent of COMPANY/INSTITUTION.

## ARTICLE IV - TERMINATION

4.01 Expiration. This Agreement, unless sooner terminated as provided herein, shall remain in effect for a period of five (5) years from the EFFECTIVE DATE.

4.02 Termination by COMPANY/INSTITITION. COMPANY/INSTITUTION may terminate this Agreement at any time by providing written notice to Morehouse School Of Medicine at least sixty (60) days before the termination is to take effect.

4.03 Termination by Morehouse School Of Medicine. Should COMPANY/INSTITUTION materially breach this Agreement, Morehouse School Of Medicine may give COMPANY/INSTITUTION written notice of the breach. COMPANY/INSTITUTION shall have thirty (30) days from receipt of the notice to cure the breach. If COMPANY/INSTITUTION does not cure the breach within this period, Morehouse School Of Medicine may terminate this Agreement by giving written notice of its election to do so.

4.04 COMPANY/INSTITUTION's Financial Condition. If COMPANY/INSTITUTION: (a) ceases to carry on its business, (b) becomes "insolvent" (as such term is defined in the United States Bankruptcy Code, as amended from time to time), (c) fails to pay its debts in the ordinary course of business under conditions indicating insolvency, or (d) voluntarily seeks, consents to or acquiesces in the benefits of any bankruptcy or similar debtor-relief laws, then Morehouse School Of Medicine may terminate this Agreement without prejudice to any other remedy to which COMPANY/INSTITUTION may be entitled at law or in equity or elsewhere under this Agreement, by giving written notice of termination to COMPANY/INSTITUTION.

4.05 Disposal of Biological Materials. Should this Agreement expire or be terminated under paragraphs 4.01, 4.02, 4.03 or 4.04 above, COMPANY/INSTITUTION agrees to immediately discontinue its use of BIOLOGICAL MATERIALS, and destroy or return, at Morehouse School Of Medicine's request, all quantities of BIOLOGICAL MATERIALS and derivatives there from in COMPANY/INSTITUTION'S possession.

4.06 Other Matters Surviving Termination. All accrued obligations and claims, including claims or causes of action for breach of this Agreement, shall survive termination of this Agreement. Obligations of confidentiality shall survive termination of this Agreement. This section controls in the case of a conflict with any other section of this Agreement.

## ARTICLE V - LIABILITY AND REPRESENTATIONS

5.01 Infringement Indemnification. COMPANY/INSTITUTION shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold harmless, Morehouse School Of Medicine, its regents, officers, employees, and affiliates, against any claim, proceeding, demand, liability, or expense (including legal expenses and reasonable attorney's fees) which relates to any action brought by a third party alleging infringement of a domestic or foreign patent or trademark as a result of the activities of COMPANY/INSTITUTION hereunder.

5.02 Liability Indemnification. COMPANY/INSTITUTION shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold harmless Morehouse School Of Medicine, its regents, officers, employees, and affiliates, against any claim, proceeding, demand, liability, or expenses (including legal expenses and reasonable attorney's fees) which relates to injury to persons or property, or against any other claim, proceeding, demand, expense and liability of any kind whatsoever resulting from the use of BIOLOGICAL MATERIALS by COMPANY/INSTITUTION, or arising from any obligation of COMPANY/INSTITUTION hereunder.

5.03 In no event shall either party be liable to the other for exemplary, incidental, indirect, special or consequential damages of any kind, including without limitation, loss of profit, savings or revenue, whether or not such party has been advised of the possibility of such damages, however caused, and on any theory of liability arising out of this Agreement. In no event will either party be liable to the other for direct damages in excess of One Hundred Thousand Dollars ($100,000.00).

5.04 Representation. Morehouse School Of Medicine represents that it owns and has title to the BIOLOGICAL MATERIALS and KNOW-HOW, and that there are no outstanding agreements, assignments, or encumbrances inconsistent with the provisions of this Agreement. **MOREHOUSE SCHOOL OF MEDICINE MAKES NO OTHER REPRESENTATIONS AND EXTENDS NO OTHER WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR DOES MOREHOUSE SCHOOL OF MEDICINE ASSUME ANY OBLIGATIONS WITH RESPECT TO INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OR OTHER RIGHTS OF THIRD PARTIES DUE TO COMPANY/INSTITUTION'S ACTIVITIES UNDER THIS AGREEMENT.**

5.05 Nature of the Materials. All BIOLOGICAL MATERIALS provided hereunder should be considered experimental in nature and should be handled by COMPANY/INSTITUTION with appropriate safety precautions as provided in paragraph 2.02(a). However, in cases where a Material Safety Data Sheet is available for the BIOLOGICAL MATERIALS it will be supplied by Morehouse School of Medicine to COMPANY/INSTITUTION and the handling precautions contained therein should be followed.

## ARTICLE VI - NOTICES

6.01 Notices. Payments, notices, or other communications required by this Agreement shall be sufficiently made or given if mailed by certified First Class United States mail, postage pre-paid, or by commercial carrier (e.g., Federal Express, Airborne, etc.) when such carrier maintains receipt or record of delivery, addressed to the address stated below, or to the last address specified in writing by the intended recipient.

a. If to Morehouse School Of Medicine:

Sandra Harris-Hooker, Ph.D.
Associate Dean for Research Development
Morehouse School Of Medicine
720 Westview Drive, SW
Atlanta, GA 30310-1495

With copy to:

Scientist
Morehouse School Of Medicine
720 Westview Drive, SW
Atlanta, GA 30310-1495

b. If to COMPANY/INSTITUTION:

NAME
TITLE
ADDRESS
PHONE; FAX

With copy to:

SCIENTIST

ADDRESS
PHONE; FAX

## ARTICLE VII - MISCELLANEOUS PROVISIONS

7.01 Non-Use of Names. Except as set forth in paragraph 2.02(g) hereof, COMPANY/INSTITUTION shall not use the names of Morehouse School Of Medicine, nor of any of its employees or components, nor any adaptation thereof, in any advertising, promotional or sales literature without the prior written consent obtained from Morehouse School Of Medicine in each case, except that COMPANY/INSTITUTION may state that it has an Agreement with Morehouse School Of Medicine to use the BIOLOGICAL MATERIALS.

7.02 Assignment. This Agreement, with the rights and privileges it creates, is assignable only with the written consent of both parties.

7.03 Force Majeure. Each party shall be excused from any breach of this Agreement which is proximately caused by government regulation, war, strike, act of God, or other similar circumstance normally deemed outside the control of well-managed businesses.

7.04 Execution and Modification. This Agreement will become binding only when signed by both parties. It may be modified or amended only by a written document signed by the parties.

7.05 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the BIOLOGICAL MATERIALS and supersedes all other written and oral agreements between the parties with respect to the BIOLOGICAL MATERIALS.

7.06 Governing Law. This Agreement shall be construed under the Constitution and laws of the State of Georgia.

7.07 Headings. Headings appear solely for convenience of reference. Such headings are not part of this Agreement and shall not be used to construe it.

7.08 Provisions. If any provision or provisions of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

IN WITNESS WHEREOF, the parties have caused this Agreement to become effective as of the date last executed below by a signatory to this Agreement.

| MOREHOUSE SCHOOL OF MEDICINE, INC. | COMPANY/ INSTITUTION |
|---|---|
| _____ | _____ |
| Sandra Harris-Hooker, Ph.D.<br>Associate Dean for Research Development<br>Date: | NAME<br>TITLE<br>Date: |
| _____ | _____ |
| _____ | _____ |
| (Provider) Scientist | COMPANY/INSTITUTION (Recipient) Scientist |
| Date: | Date: |
| _____ | _____ |

**ATTACHMENT A**

The DEFINITION OF MATERIALS provided by Morehouse School Of Medicine, will be utilized for DETAILS OF USAGE GIVEN BY INVESTIGATOR.

## APPENDIX IV—Policy Statement on Faculty-Industry Research Relations

Introduction

Universities and Health Science Center have established successful cooperative relationships with industry which have been mutually beneficial and which have been helpful to the general society. These relationships have fostered an increase in knowledge, an increase in sabbatical opportunities and the economically productive application of technology.

Morehouse School of Medicine believes that it has much to contribute to and gain from appropriate relationships with private enterprise and that these relationships can be developed in a manner which preserves the School's important academic and research principles and traditions.

In order to clarify such principles and traditions, the School wishes to clearly state the policies which the faculty have determined should govern the School's relationships with industry.

The purpose of this statement of policies by the School is to foster those health and creative partnerships with the free enterprise sector of society which contributes new knowledge while maintaining the integrity of the School, its faculty and its students.

**Statement of Policies**

**Nature of the Research Affiliation**
Other academic institutions have experienced situations where it would be useful to have an investigator conduct a given research program for a sponsor and, in the absence of clear policy, have had to deal with pressures felt by investigators to conduct such research. The Task Force has felt it important to articulate a policy which will preserve the right of investigators to select the research in which they will be involved.

**Policy No. 1**
The Morehouse School of Medicine shall not require a principal investigator to participate in a particular research program as a condition of employment.

It is important for there to be close and open communication between sponsors and principal investigators during all phases of research and sponsors must, of course, have the privilege to define the nature of the project they intend to support. Principal Investigators expect to be able to design, modify and control the research which they will direct.

**Policy No. 2**
Whereas a sponsor must have the privilege to define the subject of research it wishes to fund, the Principal Investigator must have final authority over the design and control of that research.

Universities which have established legally freestanding research institutes in cooperation with sponsors wherein faculty may serve as staff have advised the Medical School to express a policy which preserves the academic freedom of such faculty.

**Policy No. 3**

Before the Medical School decides to enter into an agreement to participate in a freestanding research unit, the Dean shall request the Research Development Committee to advise him/her on whether there is risk of restriction to academic freedom of faculty which is unacceptable.

**Policy No. 4**
In cases where a given sponsor may wish to restrict an investigator's freedom to conduct similar research for a second sponsor, the Medical School will only consider such a restriction if there is a reasonable possibility that the proprietary rights of the first sponsor, as defined by a pre-existing agreement, will be infringed by work sponsored by the second.

In return for a financial commitment a sponsor may wish to state expected results to be delivered by a given date. Because of the nature of research, specific results cannot be guaranteed, although the School does commit to using its best efforts in conducting research and agrees to comply with sponsor's requirements that reports be generated on schedule.

**Policy No. 5**
Although the Medical School cannot guarantee the success of a particular research project, it is the policy of the School to organize and conduct research projects on a best effort basis and to be sensitive to special needs and time constraints of sponsors.

**Publication and Dissemination of Research Findings**
The freedom to publish and to otherwise disseminate research findings through formal and informal means is an important principle to academic institutions. Industries must, on the other hand, protect proprietary, trade secret or other confidential information. The policies adopted by the Medical School should meet the nondisclosure requirements of sponsors while preserving academic freedom.

**Policy No. 6**
Sponsors may review materials resulting from research they have sponsored prior to the publication of the materials. However, such reviews should not delay publication for more than 60 days unless recommended by the investigator and approved by the Dean.

**Policy No. 7**
The final determination of what may be published shall remain with the Medical School.

**Policy No. 8**
Ordinarily, agreements to treat confidentially information resulting from sponsored research are not acceptable. Exceptions which are consistent with the School's principles may be granted by the Dean after review by the Research Development Committee.

Each individual investigator has the responsibility to protect freedom of communication with colleagues and to refuse to enter into agreements which would restrict that freedom unacceptably.

**Involvement of Students**

Universities with experience in the involvement of students in research in which proprietary information is involved or in which faculty may have an outside professional interest, advise that any such arrangements should be monitored by a third, disinterested party.

**Policy No. 9**
Students shall not take part in research projects in which their right to publish or otherwise Communicate the results are constrained. Exceptions to this policy must be approved by the Dean upon the recommendation of the Research Development Committee.

Specific approval in writing by the Dean is required by the Medical School in any involvement of students in the outside professional activities of faculty. The student shall also sign such a document.

**Conflict of Interest or Commitment and Outside Professional Activities**
A conflict of interest exists when a Medical School employee has a relationship with an outside organization such that his or her activities with the medical school could be biased in a direction which would ultimately provide direct financial benefit to the individual or a close family member.

A conflict of commitment exists when a medical school employee has a relationship which requires a commitment of time or effort such that the employee, either implicitly or explicitly, cannot meet his/her usual obligations to the Medical School. Any relationship with an outside organization which requires frequent and/or prolonged absence from the Medical School may present a conflict of interest.

Examples of situations which may create a conflict of interest or commitment include ownership by a faculty member or his/her immediate family (spouse and minor children) of a significant interest in an outside concern or management responsibilities.

**Policy No. 10**
Faculty members shall avoid entering into relationships which constitute a conflict of interest or a conflict of commitment.

**Policy No. 11**
Faculty members shall disclose annually to their chairperson and to the Dean in writing their outside relationships with corporations and other business entities as members of boards, consultants, advisors or managers. The name of the company and the nature and scope of the relationship shall be provided. No information about financial arrangements need be provided.

**Policy No. 12**
In cases where a faculty member wishes to appeal an interpretation or decision made under this policy by a chairperson or the Dean, or where the chairperson or the Dean wishes to consult others for advice before making such a decision, the case may be brought to the Research Development Committee. On request from a faculty member, chairperson or the Dean, the Committee shall review the status of the faculty member's (or his/her immediate family's) financial interest or managerial relations with a private enterprise. The Committee shall report its findings to the Dean.

**Definition of Terms**

***Significant Financial Interest in a private enterprise*** means holding more than 20% of the equity, options or other types of corporate security. Such interests, if held by a faculty member's immediate family, shall fall within this definition.

***Direct and active management obligations*** include serving as a member of the Board of Directors, Chief Executive Officer, Chief Operating Officer, Director of Research, Treasurer or other senior line management officer.

## APPENDIX V— Patent Policy

I. PURPOSE

To set Morehouse School of Medicine (MSM) policy for patenting any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereon made by MSM faculty, staff, and/or students, while using MSM facilities and/or funds, and to establish policy for the distribution of patent income.

II. ACCOUNTABILITY

Under the direction of the President, Senior Vice President and Chief Operating Officer shall ensure compliance with this policy. The Associate Dean for Research Development shall implement this policy.

III. APPLICABILITY

A. All MSM personnel, including every person holding any form of teaching or research appointment, fellows, and non-academic staff holding appointments at or employed by the MSM.

B. All students enrolled at the MSM.

IV. DEFINITIONS

A. **Inventor** - Any individual named in Section III above who makes or develops any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereon.

B. **Invention Developed With MSM Support** - Any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereon made or developed upon the time of and while in the pay of; or during appointment by or enrollment as a student; or in the laboratory of or with the facilities of the Institution.

C. Patent Management Organization - A corporation or foundation (e.g., Research Corporation) which may be designated as the MSM agent in the handling of certain patent matters.

D. Patent Income - All income arising directly from the licensing or sale of the patent to either a third party or to a company in which the inventor has a financial interest. Such income shall include, but shall not be limited to, cash payments, minimum royalties, running royalties dividends, stocks, stock options, capital gains or payments in kind.

V. POLICY

A. Requirements:

1. The Morehouse School of Medicine is committed to fostering research, educational and technical endeavors related to the advancement of scientific knowledge and to the publication and the use of the results of such research. While

such research activities performed with the facilities and/or funds of MSM by faculty, staff and students are not intended to be profit making, MSM recognizes that some activities may lead to inventions which should be patented for one or more of the following reasons:

a. to protect the public interest;

b. to comply with the requirements of research grants, awards, and contracts for research;

c. to comply with the requirements agreed upon by MSM and non-research entities;

d. to promote the development of useful apparatus and processes which would not be developed without patent protection;

d. to encourage invention and assure adequate rewards as incentive for the inventor; and

e. to support facilities and programs at MSM for research, education and advance technology by means of income derived from royalties.

2. The MSM Patents policy is intended to be consistent with these principles and philosophy and with the purposes of MSM. It is intended to encourage patenting of potentially valuable inventions made by members of the MSM community while using MSM facilities and/or funds.

3. Ownership of Inventions

a. (Does this date match the initial policy date?) Since April 12, 1973, a condition of appointment or continued employment by or enrollment in the Institution has been the agreement to assign to the Institution all inventions developed with Institution support. Notebooks and other documents pertaining to research activities and all data (including written and computerized material and photographs, etc.) leading to an invention is the property of the Institution and will be retained in the files of the Institution.

4. Administration of Patents

a. The Office for Research Development shall be responsible for providing information and assistance on patent matters to inventors, and for managing the patenting of inventions under this policy after consultation with the inventors.

5. Disclosure Responsibilities of Inventors

a. Every inventor shall promptly disclose to the Office for Research Development as described under "PROCEDURE" all inventions developed with MSM support in order that they may be evaluated as to patentability and commercial and scientific utility, and so that timely

decisions can be made regarding the filing of patent applications thereon.

6. Inventions made Jointly with Outside Inventors

    a. Where an invention covered by this policy has been developed jointly with individuals not covered by this policy, the terms of any contractual agreement previously entered into by MSM with the non-MSM inventors will govern. If no agreement exists or the terms of the existing agreement are not complete, an agreement regarding patent rights and obligations shall be negotiated with the co-inventor(s)'s or the appropriate institution or corporation by the Associate Dean for Research Development.

7. Compliance with Contractual Patent Restrictions

    a. All inventions or disclosures thereof resulting from research performed under grants or contracts entered into by MSM with specific patent restrictions shall be subject in the first instance to the restrictions, but, even when governed by contract or grant, all inventions must be submitted for review and evaluation as provided in paragraph V.A.5. above.

8. Distribution of Patent Income

    a. A portion of patent income shall be paid to the inventor according to the schedule set forth herein.

## V. PROCEDURES

A. Disclosure of Inventions to the Director of Patents and Licensing

1. Inventors shall submit a full disclosure of any invention to the Associate Dean for Research Development using the Invention Disclosure Form (ATTACHMENT A).

2. Disclosures should be made as early as possible in the development of an invention.

3. When any question exists as to whether an invention is covered by this policy, the invention must be disclosed through the usual disclosure mechanism described above, with a request for a determination of whether the invention is covered. In cases where an inventor seeks to establish that an invention is not covered by this policy, the burden of proof shall be with the inventor.

4. An Invention Disclosure must be submitted prior to any negotiations by any inventor with outside companies with regard to further support or licensing of the invention. Disclosure shall be made even if the inventor

seeks additional support to complete the invention or to enter into a collaborative arrangement to complete the invention. This is imperative in order to ensure confidentiality of the potential invention.

B. Patent Protocol

1. Once disclosure has been made to the Office for Research and Development, the Associate Dean for Research Development shall promptly submit the disclosure to the Intellectual Property Committee for review. When a disclosure containing sufficient technical information to permit an effective patent study has been made, the Associate Dean for Research Development shall notify the inventor in writing, within 90 days, of MSM's intentions with regard to the invention.

2. Options Available to the Institution

MSM may after consultation with the inventor:

a. undertake the timely filing of patent prosecution, development, and marketing of the invention and shall bear all related costs. Any income to be distributed shall be income received, less costs incurred by the Institution in obtaining and protecting the patent rights;

b. seek support for the costs of patent prosecution through a licensing or other agreement. Any income to be distributed shall, in this instance, be income received less costs incurred by the Institution in obtaining and protecting the patent rights;

c. cause the invention to be assigned to a patent management organization. The domestic or foreign patent rights, or both, may be assigned to a patent management organization. Any income to be distributed shall be the income received after the patent management organization has received its portion of the income, less additional costs borne by the Institution;

d. release to the inventor all rights to the invention unless such rights revert to the sponsor of the program or the Federal Government; and

e. the Institution has the obligation to make a good faith effort to commercialize the invention within a reasonable period of time. If, for any reason, the Institution is unwilling or unable to carry out this obligation, the Institution will then offer to release the invention to the inventor(s), as in Option VI.B.2.d., under conditions acceptable to all parties.

3. Continuing Option

a. Notwithstanding any previous decision to support an invention, the Institution may at any time elect to release all rights to the invention to the inventor, as in VI.B.2.d. above.

C. Distribution of Invention Related Income

1. Formula for Distribution of Income

   a. 50% to inventor(s); and

   b. 50% to the Institution. The Institution's distribution shall be divided:

      i. 50% to the Office of the Dean; which shall be distributed at the discretion of the Dean to support the research infrastructure; and

      ii. 50% to the Research Development Fund to help defray the cost of administrating Intellectual Property –related activities (i.e., provisional patents, full patents, legal services, marketing, etc.).

2. Additionally the inventor(s) may at his/her option at the time of the allocation of funds allocate up to 25% of the inventor's distribution under this policy to support his/her own research in his/her department.

3. Where the Institution has released the rights to an invention to the inventor, the inventor shall pay the Institution 10% of any patent income later derived from the invention.

By Direction of the President:

_____

Senior Vice President and Chief Operating Officer

_____

Dean and Senior Vice President for Academic Affairs

## Confidentiality Agreement

Effective _____, 20___ (the "Effective Date"), "Corporation Name" and Morehouse School of Medicine agree as follows:

1. Confidential Information means: (a) any information in written or tangible form of the type described in the List of Definitions at the end of this Agreement, communication to "Corporation Name" by Morehouse School of Medicine, and marked confidential; and (b) information of the type described in the List of Definitions, communicated orally or visually to "Corporation Name" by Morehouse School of Medicine, if it is reduced to writing or tangible form by Morehouse School Of Medicine on or before the date thirty days after the date of such communication, marked confidential, and promptly delivered to "Corporation Name". Other italicized terms in this Agreement are defined in the List of Definitions.

2. After Morehouse School of Medicine receives a fully-signed copy of this Agreement, Morehouse School of Medicine shall disclose to "Corporation Name" Confidential Information solely for use by "Corporation Name" in its internal evaluation of the Confidential Information's commercial prospects.

3. "Corporation Name" agrees that, for a period of five years after the date of its receipt of each Confidential Information disclosed under this Agreement, it shall: (i) keep Confidential Information confidential; and (ii) not use the Confidential Information for any commercial purpose. The foregoing shall not apply to that part of any Confidential Information that:

   (a) is disclosed or used by "CORPORATION NAME" in accordance with any written consent granted by Morehouse School Of Medicine, or

   (b) at any time becomes generally known to the public through no fault of "Corporation Name"; or

   (c) has been or is made available to "Corporation Name" by a third party having the lawful right to do so without breaching any obligation of nonuse or confidentiality to Morehouse School Of Medicine; or

   (d) has been or is disclosed to others by Morehouse School Of Medicine without similar restrictions on disclosure and use; or

   (e) "Corporation Name" is required to disclose pursuant to an order of a judicial or administrative authority.

4. Morehouse School Of Medicine authorizes "Corporation Name" to disclose the Confidential Information to those employees and consultants who require the Confidential Information for the evaluation hereunder, and to potential

# CONFIDENTIAL

# MOREHOUSE SCHOOL OF MEDICINE

## INVENTION DISCLOSURE

Please provide as much information as possible on this form. Attempt to answer all of the questions and be as accurate as you can be, providing as much information as you can to answer the question. If you need more space, use separate pages and attach them to this form. Please feel free to use photocopies of lab notebooks (showing dates), data sheets, drawings or any other rough document(s). If you have questions, please contact the MSM Office for Research Development at 404-752-1050.

**1. Title of Invention**

_____

_____

**2. Investigator to whom communications should be addressed.**

Name: _____

Address: _____

Phone #: _____ Fax #: _____ E-mail: _____

Date: _____

## DESCRIPTION OF THE INVENTION

**3. Describe the characteristics/specifications of the invention**

a. Please give a complete technical description of the invention and its advantages over what was known previously. If necessary, use drawings, diagrams, pathways, etc.

b. What is the technology that presently exists in the area of this invention? What are the advantages of this technology over existing inventions and practices?

## APPENDIX VI— POLICY FOR INTEGRITY AND THE RESPONSIBLE CONDUCT OF SCHOLARSHIP AND RESEARCH: GUIDELINES TO ENCOURAGE RESPONSIBLE RESEARCH PRACTICES

Introduction

The community of scientists is bound by a set of values, traditions, and standards that embody honesty, integrity, objectivity, and collegiality. The diversity, flexibility, and creativity of the research community are strengths that have contributed to decades of scientific achievement and progress in the United States.

For centuries scientists have relied on each other, on the self-correcting mechanisms intrinsic to the nature of science and on the traditions of their community to safeguard the integrity of the research process. Recent and dramatic increase in the size and influence of the research enterprise, and in the amounts and patterns of funding, have led to changing social expectations about the accountability of scientists and their institutions for research supported by public funds. In addition, the changing nature of collaborative efforts, the quickening pace and increasing complexity of research endeavors, and the growing emphasis on commercialization of research results have combined to exacerbate stresses that have always been apparent to some extent in scientific research.

The self-regulatory system in science, which has evolved over the centuries to foster creativity and scientific achievement, may need to evolve further to meet the demands for public accountability that accompany government, foundation, and industrial support of scientific research. To respond to the need for more visible, explicit mechanisms to ensure integrity in the research process, and to handle allegations of misconduct in science, the following objectives should be addressed.

1. To develop vigorous approaches to protect and enhance knowledge of scientific traditions and sound research practices, and mechanisms to penalize those who engage in misconduct.

2. To foster responsible research conduct in a period of increasing diversification of funding sources, growing demands on limited research resources, and greater incentives for financial gain in the research environment.

3. To ensure fairness and balance in efforts to establish individual and institutional accountability in scientific research activities.

In concert with these objectives, the institution is obligated to protect and foster the academic freedom and intellectual integrity of all members of the institutions community in the pursuit of knowledge.

Scientists engaged in work involving human subjects should refer to the MSM IRB policy, and the "Code of federal regulations Title 45-Part 46-Protection of Human subjects".

A. Framework for Fostering Responsible Research Conduct

Integrity of the research process is defined as the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities. Science is not only a body of information composed of current knowledge, theories, and observations, but also the process by which this body of knowledge is developed. Three categories of behaviors in the research environment warrant specific attention.

1. Misconduct in Science

Fabrication, falsification, or plagiarism in proposing, performing, or reporting research. This does not include errors of judgment; errors in the recording, selection, or analysis of data; differences in opinions involving the interpretation of data; or misconduct unrelated to the research process. ***Fabrication*** is making up data or results, ***falsification*** is changing data or results, and ***plagiarism*** is using the ideas or words of another person without giving the appropriate credit.

2. Questionable Research Practices

Actions that violate traditional values of the research enterprise and that may be detrimental to the research process.

These do not directly damage the integrity of the research process, however, they can erode confidence in the integrity of the research process, violate traditions associated with science, affect scientific conclusions, waste time and resources, and weaken the education of new scientists.

Questionable research practices include:

- Failing to retain significant research data for a reasonable period
- Maintaining inadequate research records
- Conferring authorship for a contribution that is not significantly related to the research reported in the paper
- Refusing to give peers reasonable access to unique material or data
- Using inappropriate statistical analysis to enhance the significance of research findings
- Inadequately supervising research subordinates

3. Other Misconduct

These practices include behavior which is clearly not unique to the conduct of science, i.e. sexual and other forms of harassment of individuals, misuse of funds, vandalism, including tampering with research experiments or instrumentation, and violations of government research regulations, such as those dealing with radioactive materials, recombinant DNA research, and the use of human or animal subjects.

Recommendations

As science becomes more closely linked to economic and political objectives, the processes by which scientists formulate and adhere to responsible research practices will be the subject of increasing public scrutiny. Scientists and research institutions thus need to clarify and strengthen the methods by which they foster responsible research practices. Ensuring the integrity of the research process requires that scientists and research institutions give systematic attention to the fundamental values, principles, and traditions that foster responsible research conduct. All who participate in the research

enterprise share responsibility for the integrity of the research process. The following recommendations are aimed at strengthening the research enterprise, as well as clarifying the nature of the responsibilities of scientists, research institutions, and government agencies in this area.

1. Scientists in cooperation with officials of research institutions should accept formal responsibility for ensuring the integrity of the research process. They should foster an environment, a reward system (i.e. when assessing promotion), and a training process that encourages responsible research practices.

2. Educational programs that foster faculty and student awareness of concerns related to the integrity of the research process should be integrated into the current educational program.

3. Adoption of formal guidelines for the conduct of research. This should include a common framework of definitions, distinguishing among misconduct in science, questionable research practices, and other forms of misconduct.

4. Policies and procedures should be formulated to address other misconduct that may occur in the research environment such as theft, harassment, or vandalism.

B. Current Policies and Procedures at Morehouse School of Medicine

The Public Health Service implemented regulations (effective January 1, 1990) stating that any institution that applies for, or receives assistance under the Public Health Service Act, for any project or program which involves the conduct of biomedical or behavioral research, is required to complete and submit to the Office of Research Integrity (ORI) an assurance regarding procedures for dealing with and reporting possible misconduct in science. In compliance with Public Health Service regulations, MSM has adopted a document entitled, "Research Integrity Policy for Responding to Allegations of Scientific Misconduct" (See current MSM Bylaws of the Faculty). This policy was approved by the Academic Policy Council on July 1, 1983 and modified administratively in July, 2005 in order to comply with these regulations. The procedures outlined in this document are sufficient to handle reports of initial misconduct,

however, MSM has not formulated an "official framework for defining misconduct, nor has it established guidelines to encourage responsible research practices. To be effective, guidelines must be incorporated into the process of research and education and become an operational part of day-to-day activities. It would thus seem appropriate that if such policies should be formulated, they should be under the supervision of those who will be directly affected. We therefore set for the following general principles to provide a common frame of reference. The following guidelines are proposed for defining misconduct.

1. Data Handling

   Data handling refers to the acquisition, management, and storage of research results. Scientific experiments and measurements are typically transformed into research data. Research data are the basis for reporting discoveries and experimental results. When a scientist communicates a set of results and a related piece of theory or interpretation in any form, it is assumed that the research has been conducted as reported. It is a violation of the most fundamental aspect of the scientific research process to set forth measurements that have not, in fact, been performed (fabrication) or to ignore or change relevant data that contradict the reported findings (falsification).

   On occasion what is actually proper research practice may be confused with misconduct in science. Responsible practice requires that scientists disclose the basis for omitting or modifying data in their analysis of research results, especially when such omissions or modifications could alter the interpretation or significance of their work.

   Concerns about misconduct in science have raised questions about the roles of research investigators and of institutions in maintaining and providing access to primary data. Scientists are generally expected to exchange research data as well as unique research materials that are essential to the replication or extension of reported findings. However, it is well recognized that in the academic environment, centralized research records raise complex problems of ownership, control, and assess.

Recommendation in Data Handling

Research data, including the primary experimental results, should be retained for five years. Custody of all original primary laboratory data should be retained by the unit in which they are generated. All data, even from observations and experiments not leading directly to publication, should be treated in a likely manner. Research data should always be immediately available to scientific collaborators and supervisors for review.

C. Communication and Publication

In a publication, all data pertinent to the project should be reported, whether supportive or unsupportive of the thesis or conclusions. Except for review articles, publishing the same material in more than one paper should be avoided.

Plagiarism is using the ideas or words of another person without giving appropriate credit. Plagiarism includes the unacknowledged use of text and ideas from published work, as well as the misuse of privileged information obtained from peer review is not acceptable because the reviewer is in a privileged position.

Peer review is the process by which editors and journals seek to be advised by knowledgeable colleagues about the quality and suitability of a manuscript for publication in a journal. The proliferation of research journals and the rewards associated with publication and obtaining research grants have put substantial stress on the peer review system.

The reviewer has the responsibility for preserving the integrity of the review process. In reviewing a manuscript or a grant proposal, she or he is entrusted with privileged information that is unavailable to anyone outside of the laboratory of the submitting scientists. It is of obvious importance for the reviewer not to make use of information gained in the review for her or his own purposes until it is published or prior to that, only by consent of the author.

Recommendation on Communication and Publication

Authorship of original research reports is an important indicator of accomplishment, priority, and prestige within the scientific community. Authorship practices are guided by disciplinary traditions, customary practices within research groups, and professional and journal standards and policies. A general rule is that an author must have participated sufficiently in the work to take responsibility for its content and vouch for its validity. Credit for authorship should be contingent on substantial participation in one or more of the following categories: 1) conception and design of the experiment, 2) execution of the experiment and collection and storage of the supporting data, 3) analysis and interpretation of the primary data, and 4) preparation and revision of the manuscript.

D. Correction of Errors

At some level, all scientific reports, even those that mark profound advances, contain errors of fact or interpretation. In part, such errors reflect uncertainties intrinsic to the research process itself--a hypothesis is formulated, an experimental test is devised and based on the interpretation of the results, the hypothesis is refined, revised, or discarded. Errors are an integral aspect of progress in attaining scientific knowledge.

Science is self correcting, and errors whether honest or products of misconduct, will be exposed in future experiments. Scientific truth is founded on the principal that results must be verifiable and reproducible. Publication of a scientific report provides an opportunity for the community at large to critique and build on the substance of the report, and serves as one stage at which errors and misinterpretations can be detected and corrected. The research endeavor can therefore be viewed as a two-tiered process: first, hypotheses are formulated, tested, and modified; second, results and conclusions are re-evaluated in the course of additional study.

Recommendation on Correction of Errors

In accordance with established principles of science, scientists have the responsibility to replicate and reconfirm their results as a normal part of the research process. The cycles of theoretical and methodological formulation, testing, and reevaluation, both within and between laboratories, produce an ongoing process of revision and refinement that corrects errors and strengthens the fabric of research.

E. Research Training, Supervision and Mentorship

A mentor, as a research advisor, is generally expected to supervise the work of the trainee and ensure that the trainee's research is completed in a sound, honest, and timely manner. The ideal mentor challenges the trainee, spurs the trainee to higher scientific achievement, and helps socialize the trainee into the community of scientists by demonstrating and discussing methods and practices that are not well understood. It is important to recognize that junior investigators may be particularly at risk in failing to distinguish, or prevent, unacceptable research practices.

Mentors should limit the number of trainees in their laboratory to the number for whom they can provide an appropriate research experience. Mentors should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting and storing data.

The principles of science and the practices of the specific scientific disciplines are transmitted by scientists in classroom settings, and, perhaps more importantly in research groups and teams. The dynamics of research groups can foster or inhibit innovation, creativity, education, and collaboration. The laboratory director or group leader is the primary determinant of a group's practices. Individuals in positions of authority are visible and are also influential in determining funding and other support for the career paths of their associates and students. Research directors and department chairs, by virtue of personal example, thus can reinforce, or weaken the power of disciplinary standards and scientific norms to affect research practices.

To the extent that the behavior of senior-scientists conforms to general expectations for appropriate scientific and disciplinary practices, the research system is coherent and mutually reinforcing. Thus, personal example and the perceived behavior of role models and leaders in the research community can be powerful stimuli in shaping the research practices of colleagues, associates, and students.

Recently, the demands of obtaining sufficient resources to maintain a laboratory in the contemporary research environment often separate faculty from their trainees. When laboratory heads fail to participate in the everyday workings of the laboratory, their inattention may harm their trainee's education. In addition, problems arise when faculty members are not directly rewarded for their graduate teaching or training skills. When institutional policies fail to recognize and reward the value of good teaching and mentorship, the pressures to maintain stable funding for research teams in a competitive environment can overwhelm the time allocated to teaching and mentorship by an investigator.

Research supervisors must devote attention to maintaining an atmosphere of open communication and cooperation in their research groups, with opportunity for appropriate participation by and recognition of all parties. Considering human relationships and interactions is an important aspect of good research practice.

Recommendation on Research Training, Supervision and Mentorship

Research mentors, laboratory directors, department heads, and senior faculty are responsible for defining, explaining, exemplifying, and requiring adherence to the value systems of their institutions. A mentor is defined as that person directly responsible for the professional development of a research trainee. Professional development includes both technical training and socialization in basic research practices (i.e. authorship practices and sharing of research data). The mentor has the responsibility to supervise the trainee's progress closely and to interact personally with the trainee on a regular basis in such a way as to make the training experience a meaningful one. The neglect of sound training in a mentor's laboratory will over time compromise the integrity of the research process.

F. Conclusions

The self-regulatory system that characterizes the research process has evolved from a diverse set of principles, traditions, standards, and customs transmitted from senior scientists, research directors, and department chairs to younger scientists by example,

discussion, and informal education. The principles of honesty, collegiality, respect for others, and commitment to dissemination, critical evaluation, and rigorous training are characteristic of all the sciences.

Guidelines for the conduct of research differ from institutional policies that are designed to address misconduct in science, conflict of interest, or that have been formulated in response to regulatory requirements governing research involving human subjects, hazardous materials, or recombinant DNA. Research conduct guidelines are intended to promote responsible conduct of research and, to the extent that questionable practices and misconduct in science are linked, to reduce the amount of misconduct in science.

Administrative officials within the research institution bear responsibility for ensuring that good scientific practices are observed in units of appropriate jurisdiction. In addition, they should balance reward systems appropriately to recognize research quality, integrity, teaching, and mentorship. Adherence to scientific principles and disciplinary standards is at the root of a vital and productive research environment. Institutions should strive to attain a research enterprise that emphasizes and rewards excellence in science, quality rather than quantity, openness rather than secrecy, and collegial obligations rather than opportunistic behavior in appointments, promotion, tenure, and other career decisions. The challenge is thus to aid faculty in establishing effective systems of values and social controls, to provide individuals with opportunities and incentives to develop and implement these systems, and to safeguard the traditions that foster scientific creativity.

## APPENDIX VII— Service Center Recharge Policy

Revised DRAFT 5/9/03

### I. PURPOSE

This Policy establishes Morehouse School of Medicine's (MSM) policies and procedures for developing billing rates for service centers.

### II. DEFINITIONS

***Service Center:*** An activity that performs specific technical or administrative services primarily for the internal operations of MSM and charges users for its services. Examples of such services include core research laboratories, animal care, telecommunications and network services, and graphics.

***Direct Operating Costs:*** All costs that can be specifically identified with a service provided by a service center. These costs include the salaries, wages and fringe benefits of faculty and staff directly involved in providing the service; materials and supplies; purchased services; travel expenses; equipment rental or depreciation; interest associated with equipment acquisitions; etc.

***Internal Service Center Overhead:*** All costs that can be specifically identified to a service center, but not with a particular service provide by the center, such the salary and fringe benefits of the service center director.

***Institutional Facilities and Administration (F&A) Costs:*** The costs of administrative and supporting functions of the School. Institutional F&A costs consist of executive management, payroll, accounting, personnel administration, and operations and maintenance expenses. Operations and maintenance expenses include utilities, building maintenance and custodial services; building depreciation and interest associated with the financing of buildings; administrative and supporting services provided by academic departments; libraries; and special administrative services provided to sponsored projects. Costs not allocable to service activities, such as the salary of unit administrative staff, operations and maintenance expenses paid by the institution, may not be recovered as a component of the user fee or markup charged to internal users. These costs are recovered as a component of the School's F&A cost rate.

***Unallowable Costs:*** Costs that cannot be charged directly or indirectly to federally sponsored programs. These costs are specified in Circular A-21 issued by the U.S. Office of Management and Budget. Common examples of unallowable costs include advertising (*except for recruitment of staff or trainees, procurement of goods and services, disposal of scrap or surplus materials, and other specific purposes necessary to meet the requirements of the grant-support project or activity*), alcoholic beverages, bad debts, charitable contributions, entertainment, fines and penalties, goods and services for personal use, interest (*except interest related to the purchase or construction of buildings and equipment*), selling and marketing expenses.

***Applicable Credits:*** Transactions that offset or reduce costs, such as purchase discounts, rebates, allowances, refunds, etc. For purposes of charging service center costs to federally sponsored programs, applicable credits also include any direct federal financing of service center assets or operations (e.g., the direct funding of service center equipment by a federal program).

***Equipment:*** An item of tangible personal property having a useful life exceeding one year and an acquisition cost of $1,000 or more. Purchases under this amount are considered consumable supplies.

***Billing Unit:*** The unit of service provided by a service center. Examples of billing units include hours of service, animal care days, tests performed, machine time used, etc.

***Billing Rate:*** The amount charged to a user for a unit of service. Billing rates are usually computed by dividing the total annual costs of a service by the total number of billing units expected to be provided to users of the service for the year.

***Program Income***: Gross income earned by a grantee that is directly generated by the grant supported project or activity or earned as a result of the award. An example of program income is user fees for core laboratories.

***Surplus:*** The amount that the revenue generated by a service exceeds the costs of providing the service during a fiscal year.

***Deficit:*** The amount that the costs of providing a service exceed the revenue generated by the service during a fiscal year.

## III. GENERAL POLICIES

1. Billing rates should be designed to recover the direct operating costs of providing the services and internal service center overhead, on an annual basis. No costs other than the costs incurred in providing the services should be included in the billing rates. The costs should exclude unallowable costs and be net of applicable credits. Whenever possible, service centers should attempt to recover all associated activity costs when calculating the billing rates. Requests for institutional support for services should be kept to a minimum.

2. Billing rates should be computed annually at the start of each fiscal year and adjusted where necessary. The rates should be based on a reasonable estimate of the costs of providing the services for the year and the projected number of billing units for the year. Billing rates are usually computed by dividing the total annual costs of a service by the total number of billing units expected to be provided to users of the service for the year. (See Exhibit A for an example of a rate calculation.)

3. The billing unit should logically represent the type of service provided.

4. The billing rate computation should be documented.

5. MSM users should be charged for the services they receive and be charged at the same rates. External users can be charged a premium.

6. Separate accounts should be established in MSM's accounting system to record the actual direct operating costs of the service center, internal service center overhead, revenues, billings, collections, and

surpluses or deficits. Documentation to support the costs of the service center and records of units of service should also be maintained.

7. Actual costs and revenues should be compared at the end of each fiscal year. Deficits or surpluses should be carried forward as an adjustment to the billing rates of the following year or the next succeeding year. Where feasible, the adjustments may be made by increasing or decreasing the charges made to users for the completed year, rather than through the "carry-forward" adjustment process.

## IV. SERVICE CENTERS THAT PROVIDE MULTIPLE SERVICES

Where a service center provides different types of services to users, separate billing rates should be established for each service that represents a significant activity of the service center. The costs, revenues, surpluses and deficits should also be separately identified for each service. The surplus or deficit related to each service should be carried forward as an adjustment to the billing rate for that service in the following year or the next succeeding year. The surplus from one service may be used to offset the deficit from another service only if the mix of users and level of services provided to each group of users is approximately the same.

## V. COST ALLOCATION

Where separate billing rates are used for different services provided by a service center, the costs related to each service must be separately identified through a cost allocation process. Cost allocations will also be needed where a cost partially relates to the operations of a service center and partially to other activities of a department or other organizational unit.

Depending on the specific circumstances involved, there may be three categories of cost that need to be allocated: (a) costs that are directly related to providing the services, such as the salaries of staff performing multiple services, (b) internal service center overhead, and (c) in the case of specialized service facilities, institutional F&A costs.

When cost allocations are necessary, they should be made on an equitable basis that reflects the relative benefits each activity receives from the cost. For example, if an individual provides multiple services, an equitable distribution of his or her salary among the services can usually be accomplished by using the proportional amount of time the individual spends on each service. Other cost allocation techniques may be used for service center overhead and institutional F&A costs, such as the proportional amount of direct costs associated with each service, space utilized, etc. Questions concerning appropriate cost allocation procedures should be directed to the Finance Office, which is also responsible for determining the amount of institutional F&A costs that is allocable to each specialized service facility.

## VI. EQUIPMENT PURCHASES

Expenditures for equipment purchases should not to be included in the costs used to establish service center billing

rates. The costs should, however, include depreciation of the equipment. When equipment is paid for with federal funds the depreciation on such equipment cannot be included in the service center rate calculation. Including non-federal equipment depreciation in the billing rates will generate funds that will enable service centers to purchase equipment needed in the future. The funds represented by the depreciation should be set-aside in an equipment replacement reserve account. When a service center needs to purchase a new item of equipment, a budget request form should be prepared and submitted to the Budget Office to allocate funds to the appropriate object code within the equipment replacement reserve account. If the amount in the equipment replacement reserve account is not sufficient to cover the cost of the new equipment, a request for funds to purchase the equipment should be submitted in accordance with normal MSM budgetary procedures.

## VII. VARIABLE BILLING RATES

All users should normally be charged the same rates for a service center's services. If some users are not charged for the services or are charged at reduced rates, the full amount of revenue related to their use of the services must be imputed in computing the service center's annual surplus or deficit. This is necessary to avoid having some users pay higher rates to make up for the reduced rates charged to other users. This requirement does not apply to alternative pricing structures related to the timeliness or quality of services. Pricing structures based on time-of-day, volume discounts, turn-around time, etc. are acceptable, provided that they have a sound management basis and do not result in recovering more than the costs of providing the services.

## VIII. SERVICES PROVIDED TO OUTSIDE PARTIES

Although service activities are established principally to serve the campus community, services are occasionally requested by external entities. If a service facility provides services to individuals or organizations outside of MSM, the billing rates may include institutional F&A costs even though these costs are not included in the rates for internal users. Where applicable, sales tax must also be charged to outside parties. Any amounts charged to outside parties in excess of the regular internal billing rates should be excluded from the computation of a service center's surpluses and deficits for purposes of making carry-forward adjustments to future billing rates.

Since revenue from outside parties may have Unrelated Business Income Tax (UBIT) implications, the Vice President of Finance must have prior written notice of these arrangements.

## IX. TRANSFERS OF FUNDS OUT OF SERVICE CENTERS

Except for transfers to the equipment replacement reserve account discussed in section VI., it is normally not appropriate to transfer funds out of a service center account to the institution's general funds or other accounts. If a transfer involves funds that have accumulated in a service center account because of prior or current year surpluses, an adjustment to user charges to compensate for the surpluses may be necessary. Any transfers (other than those to the equipment replacement reserve account discussed in section VI.) must be approved in advance by the Budget Office.

## X. INVENTORY ACCOUNTS FOR PRODUCTS HELD FOR SALE

If a service center sells products and has a significant amount of stock on hand, inventory records must be maintained. If the value of the inventory is expected to exceed $25,000 at any point in the year, a formal inventory

account should be established. If the inventory is not expected to exceed $25,000, internal inventory records may be used in lieu of a formal account. A physical inventory should be taken at least annually at the end of the fiscal year and be reconciled to the inventory records. Inventory valuations may be based on any generally recognized inventory valuation method as established by the Finance Office.

## XI. SUBSIDIZED SERVICE CENTERS

The institution may elect to subsidize the operations of a service center, either by charging billing rates that are intended to be lower than costs or by not making adjustments to future rates for a service center's deficits. Service center deficits caused by intentional subsidies cannot be carried forward as adjustments to future billing rates. Since subsidies can result in a loss of funds, they should be provided only when there is a sound programmatic reason. The ***newly established*** Research Planning Committee described in section XIV must approve subsidies involving service facilities and specialized service facilities.

## XII. RECORDS RETENTION

Financial, statistical and other records related to the operations of a service center must be retained for three years from the end of the fiscal year to which the records relate. Records supporting billing rate computations must be retained for three years from the end of the fiscal year covered by the computations. For example, if a billing rate computation covers the fiscal year ending June 30, 2003, the records supporting the computation must be retained until June 30, 2006.

## XIII. ESTABLISHMENT OF NEW SERVICE CENTERS

New recharge activities or new service facilities must be approved by the ***newly established*** Research Planning Committee described in section XIV. The requests for approval must contain the following information:

1. A description of the services to be provided and the users of the services.

2. The reasons why the services can best be provided by an internal service center, rather than by an external service provider.

3. A projection of the costs and utilization of the services.

4. A billing rate calculation and, where possible, a comparison of the internal rates with the rates charged by external service providers.

## XIV. REVIEW OF SERVICE CENTERS

MSM has recently established a Research Planning Committee to oversee implementation of this policy and to consider future changes to the policy. The Committee is composed of representatives from faculty and appropriate administrative staff. The Committee will be responsible for the review and approval of:

1. Exceptions and changes to the policy;

2. Establishment of new service facilities;

3. Establishment of new services;

4. Arrangements to provide services to outside parties; and

5. Subsidies to service centers.

The Finance Office will make periodic reviews of the financial operations of service centers. These reviews will focus on the development of billing rates, the handling of surpluses and deficits, and the adequacy of the service center's record keeping procedures. Any major problems or disagreements that arise in these reviews will be referred to the Research Planning Committee for resolution.

## XV. TECHNICAL ASSISTANCE

The Finance Office is available to provide technical assistance and advice on the financial management of service centers. This assistance may be requested in connection with the development of billing rates, cost allocation procedures, equipment depreciation, record keeping, etc.

**EXHIBIT A- EXAMPLE OF BILLING RATE COMPUTATIONS**

| | |
|---|---|
| **1. Revenue** | |
| External | $ 5,000 |
| Internal (MSM users) | 15,000 |
| Institutional Subsidy | 25,000 |
| Grant Agency Subsidy | 45,000 |
| **Total Revenue** | **$90,000** |
| **2. Expenses** | |
| Salaries and Wages | $30,000 |
| Fringe Benefits | 6,600 |
| Supplies | 14,400 |
| Maintenance and Repairs | 19,000 |
| Service Contracts | 9,000 |
| Telecommunications/Network | 1,000 |
| Equipment Depreciation -Non-federal | 10,000 |
| **Total Expenses** | **$90,000** |
| **2. Prior year (over)/under recovery** ***(#1 minus #2)*** | -0- |
| **3. Total Costs to be Recovered** ***(#2 plus #3)*** | **$90,000** |
| **4. Annual Utilization (billing units)** | **15,000 service units** |
| **5. Billing Rate (Total Costs/Annual Utilization)** ***(#4 divided by #5)*** | **$6.00 per unit** |