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Research Affairs

**RE:** Annual Report (July 1, 2008– June 30, 2009)  
Office of Sponsored Research Administration

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## **YEAR'S OVERVIEW**

### **Activities and Initiatives (July 1, 2008 – June 30, 2009)**

This report highlights the activities and initiatives within the Office of Sponsored Research Administration as we work to promote research at Morehouse School of Medicine by:

- Providing high quality service
- Fostering new research initiatives
- Assisting with translating discoveries into public benefit

### **Research and Scholarly Activities:**

**Dean's Round Table** –A series of roundtable discussions to explore opportunities for faculty to engage with industry leaders through translational research has been launched. The emphasis of the series is to delineate steps for faculty members to take in moving from research to patents, publication, and commercialization. The series included Danube Pharmaceuticals, The National Eye Institute, and The Medicine Company.

**Rowe Foundation Funding** – The institution has received a generous endowment (via former Dean Eve Higginbotham) from the Rowe Family Foundation. The Teaching Academy received \$800,000 of the initial endowment. We have augmented our funding for intramural pilot projects with \$200,000 from the Rowe Foundation contribution. This funding provides opportunities for our faculty to strengthen their grant proposal submissions by developing pilot data. The Research Advisory Committee (RAC) has created a Request for Applications for pilot project funding. The faculty responded with more than 40 Letters of Intent and 26 proposals. Dr. Brenda Hayes is a co-chair for the management of the review process.

**CLAR Accreditation and Institutional Safety Officer** – Mr. James “Robbie” Champion was hired as Director of our Center for Laboratory Animal Research (CLAR) in March 2009. Mr. Champion has 17+ years of experience in animal care and is a certified Laboratory Animal Technologist and Registered Veterinary Technician.

In response to the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) Accreditation Team and the MSM Biohazard and Biosafety Committee's recommendation for a full-time Institutional Safety Officer we have retained Mr. Harry Jones for this position. Mr. Jones is an Environmental Health and Safety (EHS) professional with more than 20 years of successful EHS management experience. He is certified as a Hazardous Material Manager, Industrial Hygienist, Safety Professional and Professional Environmental Auditor.

**Incentive Plan** – The Research Advisory Council (RAC) was tasked with developing a Faculty Research Incentive Plan. There are a number of important reasons for considering incentives in an institutional compensation formula. These include but not limited to: 1) flattening of funding from the NIH and other

funding agencies; 2) more collaborative research initiatives; 3) shifts in curricula and 4) disappearance of the “triple threat”. The Faculty Incentive Plan is completed and has been presented to the President.(Attached)

Science of Disease Seminar Series –The second Science of Disease Seminar Series was expanded to include presentations from persons external to the institution that are either collaborating with our faculty or served as keynote speaker for a featured event (see Table III).

**Institutional Strategic Plan** – A five-year Institutional Strategic Plan has been developed. The Research component of the Plan includes four goals which in summary are: 1) to strengthen research support systems and enhance recruitment, retention and the productivity of investigators; 2) to strengthen and fully develop a select number of collaborative, multidisciplinary research programs; 3) to establish a more structured and systematic program of mentorship; 4) to establish a unique niche in disparities related community-based participatory research.

**Georgia Bio 2009** – Drs. Eve Higginbotham and Sandra Harris-Hooker participated in the planning of the 2009 Bio International Convention, held in Atlanta May 18-May 21, 2009. The convention marked the first appearance of Morehouse School of Medicine (MSM) at this international meeting. There were over 15,000 attendees and MSM was one of 30 exhibitors in the Georgia Pavilion, the host pavilion for the convention. The other Georgia exhibitors included five other educational institutions and various biotech companies.

The MSM exhibit booth was managed by a rotation of MSM staff and faculty throughout the week. The booth was well stocked with informational literature about MSM, various institutes, centers and programs as well as unique MSM incentives. The following MSM institutes, centers and programs were represented in the exhibit: Cardiovascular Research Institute (CVRI), Center of Excellence on Health Disparities Research, Clinical Research Center (CRC), M.S. in Biomedical Technology, Neuroscience Institute, Cancer Research Program, Global Health Program, HIV/AIDS Program, Reproductive Health Program and the RCMI Core Research Facilities.

There were 250+ visitors to the MSM booth resulting in 250+ contacts from various entities (biotech companies, educational institutions, law firms and marketing research firms). One notable visitor was Georgia Governor Sonny Purdue. A database with contact information has been generated and is currently under review for marketing purposes. MSM received excellent reviews from all visitors and from the Georgia Department of Economic Development (GDEcD), the host organization for the Georgia Pavilion.

**Research Endowment** – Our competitive research endowment application has been funded by the National Center on Minority Health and Health Disparities. The funding which is based on our current endowment budget and the number of underrepresented minority students is approximately \$14.6 million over a three- year period. The expendable interest on these funds will support focused research areas and research training programs (Ph.D., MPH and MSCR).

#### **Regulatory Services:**

**Institutional Safety Committee** - The Institutional Safety Committee was established to provide a safe and healthy campus for our students, faculty, researchers and staff. The Institutional Safety Committee coordinates its activities with those of the Radiation Safety Committee, the Biohazard Committee, and the Environmental Health Committee. It will also interact closely with the Human Subjects Committee, for human subject research, and the Institutional Animal Care and Use Committee, for research in animals, to ensure that such research is conducted in a manner consistent with the biosafety practices outlined in the *National Institutes of Health Guidelines*.

An Institutional Safety Officer (ISO) was hired in February 2009. The ISO has Board Certifications in Safety, Industrial Hygiene, Hazardous Materials Management, and Environmental Auditing. From February – June

2009 the ISO focused on compliance with Federal (e.g., OSHA and EPA), State (GA DNR-EPD), and Local (e.g., Atlanta Fire Department) regulations.

*Compliance Efforts* – A peer audit was conducted at MSM (April 2008) in accordance with the Audit Agreement and EPA’s final policy on “Incentives for Self-Policing: Discover, Disclosure, Correction and Prevention of Violations” (Audit Policy). MSM worked on completing *Corrective Actions* for all Environmental Compliance Violations discovered during the Peer Audit. The final report will be submitted to Ms. Kelly Sisario, USEPA Region IV by Halloran & Sage LLP. The corrective actions were 99% completed by June 30, 2009.

MSM agreed to establish and implement an Environmental Management System (EMS) as part of the “Incentives for Self-Policing: Discover, Disclosure, Correction and Prevention of Violations”. The ISO attended the first of the four required training classes in February 2009.

*Other Compliance Efforts:*

- The ISO established and implemented an Emergency Safety Shower inspection program (February 2009) that includes monthly flow testing of these devices (29 CFR 1910.1450 – OSHA Laboratory Standard).
- The ISO established and implemented a Hazardous Waste Program that includes training for handling hazardous wastes, documents weekly inspections of the hazardous storage area, hazardous waste generation reports, the development of a Universal Waste Training program, and hazardous waste profiles for all MSM waste streams (February 2009–ongoing).

*Education and Training:*

- The ISO conducted *respiratory fit testing* using OSHA protocols for thirty-four employees in the Clinical Research Center (CRC) for a Joint Commission Accreditation site visit (February and May 2009)
- The ISO developed and implemented safety orientation training for students involved in the Benjamin Carson Science Academy and the Vivien Thomas Summer Research program in June 2009. This training included laboratory safety as well as biosafety elements.
- The ISO completed the following required regulatory training classes: EPA Hazardous Waste Training, DOT/Hazmat Training, FEMA Emergency Management Training, and OSHA Training for Laboratory Safety, Bloodborne Pathogens, and Respiratory Protection (February–March 2009).

**Institutional Review Board - *IRB Accreditation (Self-Study)*** Morehouse School of Medicine (MSM) and the Institutional Review Board (IRB) continue to work toward becoming accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP accredits high-quality human research protection programs in order to promote excellent, ethically sound research. Through partnerships with research organizations, researchers, sponsors, and the public, AAHRPP encourages effective, efficient, and innovative systems of protection for human research participants. An MSM AAHRPP Task Force has been established which contains faculty and staff members knowledgeable in at least 1 of the 5 areas (Domains) included in the self study. A first draft of the self study was completed in October. This draft identified several items that were lacking, needed to be modified, updated or enhanced. The Task Force is working to fill in those gaps before the accreditation application is submitted.

***MSM IRB Electronic Submission System*** The MSM IRB moved to an electronic submission system using IRBNet in late 2008. The first year of using this system has proven beneficial to the IRB Office as well as to faculty and staff. IRBNet has provided the ability for researchers to collaborate and develop protocols, consent forms and other study materials in an online format. The system allows a greater ease for the IRB Office to assist researchers during study design and preparation of their submission materials. It has allowed the IRB Office to route those study materials to specific IRB members for review, share reviewer comments within the

IRB, and communicate IRB decisions to researchers. Several group trainings have been provided to the MSM community as well as one-on-one sessions and assistance.

#### Reciprocity agreements with other IRBs

The involvement of MSM in the ACTSI program has necessitated an interaction between the IRBs of the participating institutions. Reciprocity agreements are being developed between MSM, Emory, Georgia Tech and Children's Healthcare of Atlanta. These agreements will help determine which institution has oversight for human subjects research that involves collaborations between multiple institutions.

#### Agreement with ACS and ITC Established

The MSM IRB is now the IRB of record for the American Cancer Society and the Interdenominational Theological Center. The IRB will review research protocols from these 2 institutions on a fee for service basis. A representative from ACS also serves as a Board member.

**MSM/AUC Radiation Safety Program** - The MSM/AUC Radiation Safety Program exists in order to ensure that radioactive materials and radiation sources at the MSM and AUC member Institutions comply with all Federal and State regulations. The Radiation Safety Program achieves this goal by protecting the health and Safety of the members of the MSM/AUC community and the public from potentially harmful effects of radiation through maintaining both external and internal exposures as low as reasonably achievable (ALARA).

#### Education and Training

Staff provided education and training activities throughout the MSM and AUC member institutions for the period of January 1, 2009 – December 31, 2009. During this period a total of one hundred and three 103 faculty, staff, students and ancillary personnel received radiation safety training.

#### Operational Activities

During the past twelve months the Radiation Safety Officer completed the following task: conducted inspections of twenty seven (27) laboratories, supervised one off campus shipment of radioactive waste, facilitated the calibration of 19 Survey Meters. Performed Department of Homeland Security surveillance, inspection and inventory reporting of Increased Control high level radioactive source material. Responded to 2 radioactive spills, completed decontamination of two laboratories containing low level radioactive contamination.

#### FY '10 Expectations

The Radiation Safety Program will continue to operate at a high level of efficiency, with great emphasis on health and safety as well as maintaining regulatory compliance by all MSM and all AUC member institutions.

**Office of International Programs** - The Office of International Program Services provides a three-pronged service to MSM. First, it works with departments who desire to hire foreign nationals, issuing or filing the appropriate paperwork for those foreign nationals to come to the US to be employed at MSM; second, it provides continuing services (orientation, cross-cultural adjustment, maintenance of legal status) for foreign nationals while they are employed at our institution; and third, it maintains the institution's compliance with regard to regulations (US Depts. of State, Homeland Security, and Labor) covering the employment and education of foreign nationals at MSM, and the maintenance of MSM's Exchange Visitor Program designated by the U.S. Dept. of State.

The OIPS works primarily with the nonimmigrant classifications of H-1B (specialty occupation), J-1 (Exchange Visitor), and F-1 (students), and adjustors to Permanent Residency status. For FY2008-2009, the office worked with 30 H-1Bs, 13 J-1s, and 8 F-1s, and filed one labor certification for permanent employment. For all newly arriving non-immigrants, OIPS meets with the foreign national individually for an orientation service. Additionally, OIPS provides tax help—in individual sessions—for all non-resident aliens. OIPS is available for

on-demand immigration advising and cross-cultural adjustment issues to all foreign nationals (including the 16 J-1 alien physicians sponsored by the ECFMG, but on our campus for the duration of their residency program).

## **Research Highlights:**

**Informatics for Integrating Biology and the Bedside** – We are also excited about a new initiative in biomedical informatics lead by the collaborative efforts of the Dean’s office and several departments, centers and institutes to establish the i2b2 Clinical/Translational Research Data Repository. The NIH-funded Informatics for Integrating Biology and the Bedside (i2b2) at Harvard is one of 7 National Centers for Biomedical Computing which are designing tools for accelerating the translation of genomic discoveries into clinical treatment of patients. Morehouse School of Medicine (MSM) has the unique opportunity to apply this technology to the field of minority health by implementing the i2b2 software to integrate our research databases with clinical data from the medical clinics affiliated with MSM.

## **Other Research Highlights**

### **Georgia Cancer Coalition**

- Dr. Gonzalez named Distinguished Cancer Scholar
- \$50,000 per year for five years
- Joins previous MSM honorees: Drs. Kaplan, Matthews, Rao, Reddy, Shamsa, and Yao

### **Sponsored Research with Pharma**

- Takeda Pharmaceuticals
- Acorda Pharmaceuticals

## **Research Funding Highlights**

Drs. Reddy and Bumpers

- Department of Defense grants
- Total of nearly \$1 million

Dr. Braithwaite

- National Institute on Drug Abuse
- \$2.1 million

Dr. Dunston, in collaboration with Emory

- National Children’s Study
- \$1.2 million

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**Research Publications** - The research faculty (Basic, Clinical and Community-Based) published approximately 352 peer-reviewed manuscripts for 2008-2009.

## **PHILOSOPHY OF THE DEPARTMENT**

### **Purpose and mission of the unit**

The Office for Research Development was created in 1998 as a unit within the Office of the Dean to foster research excellence by supporting the scholarly activities of faculty, students and staff. The function of the Office of Sponsored Programs was to assist faculty in the identification of funding sources and the procurement of funds to support research, instruction and outreach. In April 2006, the Office for Research Development was merged with the Office of Sponsored Programs and is now the Office of Sponsored Research Administration.

### **Narrative description of essential functions and Organizational chart**

The OSRA contains three units: Research Development, Research Resources and Regulatory. (See Table I for Organizational Chart)

**Research Development** is the central unit of OSRA that 1) supports the creation of an environment in which research excellence is fostered. To this end Research and Development collaborates with faculty to identify, obtain and administer extramural and internal research funding in support of the mission of the Institution 2) administers sponsored programs activities including pre and post-award grant submission and administration.

**Research Resources** is responsible for the coordination, implementation and maintenance of shared-use facilities and services which exist to relieve the burden of investigators attempting to purchase large pieces of equipment on individual grants. These services are available to all MSM researchers on a fee-for-service basis.

The **Regulatory** unit in the Office for Research Development exists to assist research faculty and personnel through the development of coordinated compliance efforts and strategies. MSM research investigators must comply with various federal and state and institutional regulations. Compliance with these regulations is essential to maintaining a research program that seeks to ensure the safety of research subjects and the integrity of research data. This unit also serves as a resource for the MSM research community providing regulatory analysis and interpretation; compliance policy development; training; education and enforcement as well as research policy development and implementation.

### **Primary and secondary activities of units and key drivers**

The primary activities under this unit include:

- Enhancing the research capability of MSM faculty by supporting biomedical, clinical and community-based research related to disease processes that disproportionately affect minorities and underserved populations;
- Working with other units of the institution to provide a supportive environment for the conduct of research at MSM;
- Serving as a liaison between investigators and institutional administrative units to facilitate and seek optimal procedures for processing and managing grants;
- Managing and identifying sources for establishing an institutionally-based research fund that will support research development;
- Resolution and reconciliation of research-related faculty issues on a daily basis;

- Facilitating the upgrade/maintenance to obsolete or current resources in order to maintain research capabilities;
- Establishing and maintaining relationships with external agencies and organizations to facilitate the research capacity.
- Working with faculty and staff to match research interests with opportunities for external support;
- Identifying, securing and managing external funds for programs that provide training and financial support for research students, faculty development and career enhancement;
- Identifying, securing and managing external funds for programs that enhance the research infrastructure;
- Processing and maintaining Material Transfer Agreements, Patent Policies and other Intellectual Property-related documents;
- Administering all aspects of the International Services program (processing entrance documents, transfer and extension forms, mandated quarterly activities, annual reports); and developing and maintaining the Student and Exchange Visitor Information System (SEVIS), a database administered by the Immigration and Naturalization Service (INS) to track and record the entry and presence in the U.S. of foreign students and exchange visitors;

The secondary activities under this unit include:

- Designing and disseminating materials that will advertise and promote research activities at MSM;
- Developing and maintaining MSM Research Websites;
- Working to develop various research-related Institutional Policies and Procedures;
- Serving on the Advisory Committees of other units within MSM.
- Providing leadership/oversight to the Research Core Facility Directors;
- Assisting the institutional Research Centers with the submission and implementation of their respective awards;
- Assisting with securing and managing external funds for programs that provide for the endowment of research at the institution;
- Assisting with the logistics of hiring new research faculty; administer internal funds for start-up packages;

### **Key drivers associated with functions of the unit**

- To establish preeminence in selected research areas
- To develop appropriate links with the private sector to seek support funding
- The enhancement of the research technological infrastructure and operational efficiency
- A perpetual source of support for the research enterprise
- To increase and maintain scholarly products
- To provide the mechanisms to address major research-related issue
- To develop or secure electronic systems to facilitate the procurement and administration of awards
- To recruit, retain and build a critical mass of talented research faculty and staff
- To develop an internal “pipeline” of talented future faculty from within the MSM graduate programs
- To comply with national and international regulatory guidelines.

### **Criteria appropriate to use in measuring our unit’s effectiveness and efficiency**

- Publications
- Grants/contracts submitted and funded
- Invitations to serve as advisors or reviewers on boards, panels or committees
- Number of R01-like/investigator initiated grants
- Extramural support for graduate programs

- Development of resources that aid or enhance the research enterprise

## **DEPARTMENT ORGANIZATIONAL CHART** – see Table I

## **SEMINARS** – see Table III

## **GRANT ADMINISTRATION**

The Office of Sponsored Research Administration encompasses the activities related to Sponsored Programs and Research & Development. Under this organizational structure, Sponsored Programs is responsible for handling liaison activities between MSM and funding agencies, provides assistance in the proofreading, editing, and processing of grant proposals during preparation and submission. Sponsored Programs is also responsible for assuring that all intramural assurances have been provided prior to the submission of the proposal or application and the appropriate progress and final reports are submitted. The Research & Development component of the structure supports the creation of an environment in which research excellence is fostered. To this end Research and Development facilitates the procurement of external support through research grants, contracts, and technological assistance agreements; administers internal support for research; assists with documenting and publicizing the scholarly achievements of members of the research community.

## **GRANTS, AWARDS AND PROPOSALS**

**Current R0-1 Grants** – see Table IV

**Active Awards** (includes **Federal, Private & State**) – see Table V

## **ISSUES/CHALLENGES**

**The critical operational issues are divided into three segments:**

- Recruitment and Retention
- Nonfederal Funds
- Manpower/Personnel

## **RECRUITMENT/RETENTION**

### **Issues:**

- Lack of senior scientific leadership in select research areas
- Loss of intellectual/financial capital over past 5-6 years (R01 funded investigators); Not only loss of revenue, but loss of capital investments;
- Lack of coherent research space allocation/management policies and procedures

### **Recommendations:**

- 1) Identify critical area; assemble existing faculty with research in this area; fully support the selected area
- 2) Develop retention mechanisms such as incentives/rewards
- 3) Recruit, develop and retain the most talented and competitive scientists that MSM can attract
- 4) Re-invest ‘revenue’ from research enterprise back into research enterprise
- 5) Establish attractive recruitment packages
- 6) Establish faculty development mechanisms and provisions
- 7) Recruit additional “senior” investigators

### **Outcomes to Date**

- The first recommendation is being addressed by selecting signature research areas within the institutional strategic plan
- The second recommendation has been fully implemented by the development and approval of a Research Incentive Plan
- The third and fourth recommendation will be addressed via the Research Incentive Plan
- The faculty start-up package has been increased which begins to address the fifth recommendation

### **FEDERAL/NON-FEDERAL FUNDING**

#### **Issues:**

- Overdependence on federal funding
- Federal funding agencies depend on congressional oversight
- Lack of non-federal, private foundation/donor support

#### **Recommendations:**

- 1) Cultivate interchange with Private/Pharmaceutical Agencies
- 2) Increase MSM service on behalf of funding agencies
- 3) MSM leadership increase lobbying for a national research agenda that serves the best interest of minority institutions
- 4) Increase endowment for research enterprise
- 5) Develop a mechanism by which the research enterprise will link with Institutional Advancement to identify and secure resources via private donors and foundations

### **Outcomes to Date**

- The first recommendation is being addressed via the Dean's Round Tables
- President Maupin presented to Congress on behalf of AMHPS; this action is related to recommendation three
- Research endowment has been increased by \$14.6 million dollars

### **MANPOWER/PERSONNEL**

#### **Issues:**

- Lack of support to recruit, develop, and retain talented research staff
- Difficulty with promotion and compensation of research staff
- Need to enhance the research environment (physical, financial and continuing education) to attract competitive post-doctoral fellows and graduate students

#### **Recommendations:**

- 1) Develop mechanism to encourage/facilitate collaborative research efforts (internal/external, basic/clinical, across disciplines)
- 2) Recruit, develop and retain talented and competitive post-doctoral fellows and graduate students
- 3) Establish competitive support packages (salary/stipend, benefits, environment) for post-doctoral fellows and grad students
- 4) Implement a user-friendly process for promotion and compensation
- 5) Enhance faculty development mechanisms for post doctoral fellows

### **Outcomes to Date**

- Recommendation is being addressed via the funding of the Clinical Translational Science Award application. This is a partnership with Emory University and Georgia Tech which supports collaborative research efforts

### **LOOKING FORWARD - PLANS FOR FY 2010**

- Continue to establish research opportunities with the VA
- Implement faculty incentive plan
- Construct lab space versus grant funding
- Facilitate IRB accreditation
- Assist with commercialization of Byron Ford's patent
- Develop relationship with Enterprise/Tech Transfer Lab at GA Tech
- Complete addressing EPA citations
- Implement Science of Disease Seminar Series for 2008-2009
- Continue maintenance of Collexis database
- Continue to facilitate visits between faculty and industry
- Explore contracting with a tech transfer broker