

RESEARCH *administration* NEWS



Fall 2008

Conflicts of Interest

News headlines across the United States are covering a Congressional inquiry, led by Senator Charles E. Grassley, Republican of Iowa. This inquiry is systematically asking some of the nation's leading researchers to provide their conflict-of-interest disclosures, and Senator Grassley is comparing those documents with records of actual payments from drug companies.

Conflicts of interest that may create bias in work performed for MCG must be disclosed and managed.

For many years, federal agencies have required that conflicts of interest of funding applicants be disclosed and managed. MCG recently expanded its "Individual Conflicts of Interest Policy" to apply not only in the research setting, but also to conflicts of interest in any work performed for MCG. MCG also adopted a new policy requiring the disclosure and management of institutional conflicts of interest.

For the **Investigator** conducting research at MCG, there are several areas in which disclosure of conflicts of interest will be required. Some of these include:

Institutional Review Board (IRB) when submitting human subject protocols for review

Sponsored Program Administration (SPA) when a research grant, contract, or other extramural proposal is submitted for review

There are even conflict of interest policies of disclosure for individuals who serve on the Human Assurance Committee (HAC) and the Institutional Animal Care and Use Committee (IACUC).

An online training course concerning these policies will be provided to everyone on campus in November. Certain employees—faculty, investigators and senior leadership—now must certify annually the absence or disclosure of their individual conflicts of interest.

When reviewing the various policies on conflict of interest, with regards to human subjects research, please note that a financial conflict of interest in **any** amount above \$0 creates a responsibility to disclose the conflict. (This is as opposed to financial conflicts in other business for MCG, which have dollar thresholds for reporting such as \$10,000 per year and/or 5% interest in a company, etc.)

To read the MCG policies for individual and institutional conflicts, go to www.mcg.edu/policies/documents/IndivConflicts.pdf (and) www.mcg.edu/policies/documents/InstConflicts.pdf

To read the MCG policies for HAC members and IACUC members, go to www.mcg.edu/research/ohrp/irb/hac/documents/PP45.pdf (and) www.mcg.edu/research/iacuc/IACUC.HTM.

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Division of Sponsored Program Administration (DSPA)



MCG's Division of Sponsored Program Administration is developing a comprehensive certificate training program entitled Research Administration Certification and Education (RACE). RACE is being designed to meet the research needs of the Medical College of Georgia by offering an improved understanding of regulations, policies and procedures. RACE will also provide staff access to important resources and contacts for further assistance. "It is important for an institution of our size to have a training program in place so that members of the research community, their support staff and regulatory divisions will have a better working relationship" said Wendy Arbuckle, Director of Post Award Services.

Drawing on the collaborative resources of the Division of Sponsored Program Administration Pre-Award and Post-Award Services, the finance department, Department Administrators, Business Managers, and Administrative Assistants from across MCG, RACE will offer quarterly breakfasts and a certificate program for the entire research community. RACE breakfasts will serve as networking sessions where the MCG research community will be able to discuss hot topics and issues developing in their areas. The certificate program will cover important sponsored award

processes. It will be comprised of a set of core classes which will include information such as Proposal Development, Basic Budgets and Research Compliance, as well as electives that will delve deeper into the core areas such as Clinical Trials, NIH and Training Grants.

A core team has been put together to assist in the development of the curriculum and class content. The majority of this team will also be the "pilot" class for RACE to begin in January, 2009. After completing the program, this group will fine-tune it for others. DSPA is currently taking applicants for its first formal class of RACE set to begin September, 2009. It will offer its graduates an expertise in the field of research administration as well as demonstrate their commitment to advancing the University's research profile.

We expect RACE will improve the sponsored award process at MCG, training both the researchers and personnel who support them in the grant application and awards administration process. Through RACE we should be able to minimize procedural errors, increase the number of personnel qualified to administer research grants and build MCG's reputation as a University that achieves the goals set forth in its proposals. "This should increase communication as well as compliance," Arbuckle said. "With an improvement in these areas the researchers at MCG should experience a smoother process in the development and management of their awards."

For more information about the RACE program or to apply for the fall, 2009 session contact Kerry Cartledge at kcartledge@mcg.edu or 706-721-8239.



P-card Use for Study Subjects

To all Principal Investigators, Study Coordinators and Departmental Administrators using gift cards as a form of reimbursement to Study Subjects:

In response to the recent State prohibition against using p-cards to purchase gift cards, we recently released a business process to permit project-specific cash funds with which gift cards may be purchased.

Several principal investigators provided useful feedback which prompted us to revisit and streamline this business process and the associated forms. These are available on the Controller's Website at: www.mcg.edu/comptroller/ap.htm.

For questions or additional information, please contact the Financial Operations Accountant, Justin Hensley, at extension 0912.

Division of Sponsored Program Administration (DSPA)

NIH Announces Transition Schedule to Adobe Forms

The National Institutes of Health (NIH), Aging for Healthcare Research and Quality (AHRQ), the Center for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) and the U.S. Food and Drug Administration (FDA) have issued a transition schedule from PureEdge to Adobe-based forms for the electronic submissions of SF 424 Research and Related (R&R) applications.

Most electronic submissions to the NIH must use Adobe applications forms on or after **January 1, 2009**. Award mechanisms for small businesses (R41, R42, R43, R44) and Conference Grants (R13/U13) will not transition until January 7, 2009. Funding Opportunity Announcements (FOAs) with non-standard submission dates expiring on or before January 31, 2009 will also be allowed to use PureEdge until the FOA expires.

The NIH deliberately decided to delay the transition to the Adobe format until all remaining changes under the PureEdge format were issued by Grants.gov and validated by the NIH thus, enabling the NIH to issue one complete set of changes.

The new Adobe forms look very similar to the PureEdge forms. The bulk of the changes are cosmetic. Menus are now available for fields such as State, Country, Title Prefix, etc. Calendars are also available to select dates. The "Cover Page" remains open when opening other forms. This enables the writer to know at all times what project is being worked on.

The overall electronic submission process will remain the same:

- Find opportunity announcement
- Download application package
- Develop research plan and other attachments in PDF format
- Complete the Adobe forms (formally PureEdge)
- Submit application
- Check assembled application in eRA Commons

Adobe software is needed to access the form set. Adobe Reader 8.1.2 or 9.0 is required to open the form. The software is free and available from the Grants.gov website www.grants.gov/help/download_software.jsp. Please note that there are a few adjustments that you may need to make when uploading the required software.



- The upload of the required versions does not override other versions of Adobe already installed on the PC. If there are other Adobe versions on the PC you must do the following to open the forms:
 - Right click on the form
 - Select "Save Target As"
 - Save Forms to the desktop, thumb drive, etc.
 - Right click and select "Open With Version 8"
- Print problems may result when there are multiple versions of Adobe on the PC.

An alternative is to purchase Adobe Professional Version 8. This will eliminate the concerns identified above.

Important Note: Opening the forms with a non-compatible version of Adobe can potentially corrupt the application. Also, anyone opening the forms (including the subaward budget forms) must use a compatible Adobe Reader version.

There are slight differences in the look and size of the assembled application image when using the Adobe Forms. The Adobe files are much larger than the PureEdge.

It is anticipated that the NIH will not release the Adobe Forms until December. For those submitting applications in January and February, the NIH suggests the following:

- Review the current Funding Opportunity
- Begin working on the research plan.
- Download the Adobe software
- Check the site periodically during December for the release of the Adobe forms.
- Download the Adobe application package when available.
- Complete the Adobe forms
- Work with Sponsored Programs to submit your application.

Contact your Grant and Contract Officer with questions/concerns, www.mcg.edu/spa/preaward.htm. The complete announcement can be accessed at the following link: grants.nih.gov/grants/guide/notice-files/NOT-OD-08-117.htm.

Proper Management of Aerosol Cans

Aerosol cans are used by many departments on a daily basis at MCG. They are used for numerous products including paints, cleaners, degreasers, disinfectants, and pesticides. Aerosols work by coupling a product (e.g. paint) with a propellant (e.g. propane) which dispenses both the product and propellant from the container when the nozzle of the can is pressed.

In accordance with the Resource Conservation & Recovery Act (RCRA), aerosols can be considered a hazardous waste by the Environmental Protection Agency (EPA). Therefore, those aerosols that contain flammable, toxic, or corrosive chemicals **MUST** be managed and disposed of properly. Even “canned air,” often used in offices to clean computers, can contain hazardous chemicals. Below are some general guidelines to follow when managing aerosol cans in the MCG:

- Review the Material Safety Data Sheets (MSDSs) for the aerosol products commonly used in your laboratory or shop to identify those which are hazardous. Contact the Chemical Safety Office (CSO) at 1-2663 if you need assistance with this.
- Store all aerosol cans as instructed on the container label. Storing aerosols in areas of excessive heat can potentially cause them to explode due to the pressure of the expanding gas.

- Spent aerosol cans containing flammable, toxic, or corrosive chemicals should be placed in a box in the laboratory or shop’s “Satellite Accumulation Area.” The box needs to be labeled properly with the words “Hazardous Waste” along with the hazardous contents of the cans (e.g. Aerosol cans contain trichloroethylene).
- When the box has been filled with cans, schedule chemical pick-up through the chemical inventory database at: Chemical Inventory Database. Contact the CSO at 1-2663 if you do not have access to the database or need assistance scheduling pick up in the database.
- At **NO POINT** should aerosol cans generated from MCG containing hazardous chemicals be placed in the regular trash.

After the pick-up has been completed, the CSO will puncture each can, drain and collect the excess chemical contents for proper disposal and treat the empty cans as scrap metal. By taking the time to properly manage aerosol cans, we can further enhance our regulatory compliance and the overall safety of MCG community.

Human Assurance Committee (HAC)

Member Spotlight

Marjorie Shaw Phillips, M.S., FASHP Vice Chairperson, Human Assurance Committee

Marjorie Shaw Phillips, M.S., FASHP, is the Pharmacist Coordinator with the Medical College of Georgia Health System here in Augusta, as well as a Clinical Professor University of Georgia College of Pharmacy and an Adjunct Assistant Professor in the Department of Pharmacology at MCG. She is the Vice-Chair of the Medical College of Georgia Human Assurance Committee (Institutional Review Board). Her practice includes clinical research pharmacy, hospital inpatient services, nursing home consulting and medication use evaluation/improvement (MUE). She is also the Residency Program Director for MCG Health's PGY1 pharmacy residency program and precepts Pharm.D. rotations in Medication Safety/MUE and Clinical Research/ Investigational Drug Services. Since 1995, she has served as the Chair of the Medication Error Prevention Committee (MEPC) at MCG. The MEPC is an interdisciplinary group whose focus is review of local/national medication error reports and hospital efforts to improve medication safety and increase event reporting in a non-punitive environment.

Marjorie received her M.S. in Hospital Pharmacy from the University of Florida College of Pharmacy and completed a two-year hospital pharmacy residency at Shands Hospital at the University of Florida. The next six years were spent practicing hospital pharmacy, with an emphasis in quality and performance improvement, at two Florida hospitals (Shands-UF/Gainesville and Memorial Hospital-Ormond Beach). She joined the pharmacy staff at the Medical College of Georgia (MCG) Hospitals and Clinics (now part of MCG Health) in 1990.

ASHP service includes Chair of the House of Delegates (2003-2006), Board of Directors (2002-2006), House of Delegates, Council on Organizational Affairs (1991-1994), Ad Hoc Committee on Policy Development, USP Advisory Committee, Section of Clinical Specialists Communication Committee and drafter for two ASHP Guidelines. She is Past President, Georgia Society of Health-System Pharmacists and Eastern Shores Florida Society of Hospital Pharmacists, and a past Board Member and Committee Chair for both FSHP and GSHP. In 1997, she was GSHP Pharmacist of the Year. Her professional contributions also include over 30 publications and 50 presentations (on topics varying from medication safety, performance improvement, team-building, and clinical trials compliance). She is currently serving a second five-year term on the USP Safe Medication Use Expert Committee and was elected Vice-Chair.

How long have you been on HAC?

I've been an HAC member since 1992 (boy time flies...) and Vice Chair beginning July 2001.

Why did you initially decide to join the HAC?

I wanted a chance to have an impact on shaping the quality (and safety) of clinical research at MCG. I think a pharmacist, particularly one with a background in performance improvement, quality and medication safety in addition to clinical research can provide an important perspective.



What advice would you give researchers who are submitting protocols?

Remember that the main purpose of the HAC is to ensure the protection of human subjects. We need to have enough information in the submission to understand clearly how the research will be conducted, including how subjects will be completely informed and how their rights and safety will be protected. Follow the directions (such as the Description of Research Proposal Template) and answer all of the items on the forms - much of the delays are due to the committee not having enough information.

Do you have any hobbies or pastimes?

Absolutely! Actually, I spend a lot of evenings and weekends reviewing HAC protocols, but also enjoy traveling with my husband Bill (a Family Physician at MCG) and talking long walks with our terrier--Auggie (who is my "Personal Trainer"). I also am very active in a number of professional volunteer activities, including as the Vice-Chair of the USP Safe Medication Use Expert Committee, a past Board member of ASHP (the American Society of Health-system Pharmacists) and currently as one of their Practitioner-Accreditation surveyors for PGY1 residencies.

Office of Human Research Protection

Webinar Archives Available for Investigators and Research Team Members



Sponsored by the Office of Human Research Protection, this training series is strongly recommended for investigators and research team members. Webinars have taken place throughout 2008, with each webinar recorded and archived. These archived webinars are available now through the mid to late 2009 for access by any research team member.

Contact hours are earned for each webinar attended and completed, including archived sessions.

Archived Webinars Available:

- Informed Consent – The Process and the Documentation of the Process
- Levels of IRB Review – The Differences Between Exempt, Expedited, Full and Emergency Review

- Recognizing and Reporting Unanticipated Problems, Adverse Events and Serious Adverse Events”
- Conducting Research at Non MCG Health Systems Facilities
- What to Do If the IRB Suspends or Terminates Your Study
- Vulnerable Populations: Children, Pregnant Women and Prisoners
- Vulnerable Populations: Subjects with Diminished Capacity Resulting from Disease
- Vulnerable Populations: Subjects with Diminished Capacity Resulting from Trauma
- Investigational Drugs: INDs, NDAs, and the Role of the Clinical Investigational Pharmacy
- Privacy and Confidentiality in Clinical Research

- Data Safety Monitoring Plans and Data Safety Monitoring Boards
- Amendment and Continuation Submissions for the HAC

For complete, step-by-step instructions, go to the

- **Office of Human Research Protection** website,
- select the **Education and Training** tab
- select the **Webinar** tab
- this screen will have a link to the instructions

The url is www.mcg.edu/research/ohrp/training/webinar.html.

If you have any questions, or need additional information, please contact Kim Koss, Clinical Research Training Coordinator at kkoss@mcg.edu or (706) 721-1481.

Office of Human Research Protection

Coordinator University Fall 2008

Congratulations to the graduates of the Fall 2008 Coordinator University, which was held October 6th through 10th at MCG. Sponsored by the Office of Human Research Protection, this week-long conference is conducted twice annually (Spring and Fall) and provides new research team members an “overview” of human subject research compliance. The graduates from October’s class are:

Barbara Barton	Candelario (Andy)	Kate Sideman
Latanya Bowman	Laserna	Chris Turner
Kilwanna (Kiki) Bush- Brown	Jann Leverett	Sarah Wilson
Kerry Cartledge	Laura Logue	Christy Wise
Brian Close	Jody Madden	Kayla Woehler
Sandra Dollander	Steve McKinnon	Jerrilyn Wright
Becky Lambert	Sara Mobley	
	Christine O’Meara	

The dates for Spring 2009 Coordinator University are set for April 20-24, 2009. For more information about Coordinator University, go to www.mcg.edu/research/ohrp/training/cu.html or contact Kim Koss, Clinical Research Training Coordinator at 706.721.1481, or kkoss@mcg.edu.



Michelle Christiano discusses audits with Coordinator University attendees



Becky Lambert, Jerrilyn Wright and Latanya Bowman during Coordinator University



Standing, l to r: Kilwanna (Kiki) Bush-Brown; Barbara Barton; Chris Turner; Kayla Woehler; Jann Leverette; Kate Sideman; Sandra Dollander; Laura Logue; Christy Wise **Seated/second row**, l to r: Christine O’Meara; Becky Lambert; Jody Madden; Jerrilyn Wright; Sarah Wilson; Latanya Bowman **Seated/bottom row**, l to r: Brian Close, Candelario (Andy) Laserna **Not pictured**: Kerry Cartledge, Steve McKinnon, Sara Mobley,

Research Administration Update

A Proactive Approach to Transitioning

Dr. Frank Treiber, Vice President for Research at the Medical College of Georgia, wants to make sure that prospective research faculty has a “head start” when transitioning to MCG.

Dr. Treiber and Program Directors in Research Administration, as well as Directors from other Divisions that provide research support services, meet with prospective research faculty on their second visits with MCG.

Along with Dr. Treiber, Program Directors from

- Sponsored Program Administration
- Office of Human Research Protection
- Division of Laboratory Animal Services
- International and Postdoctoral Services
- Office of Technology Transfer and Economic Development
- Information Technology Support and Services
- Environmental Health and Safety

meet in a group setting with the prospective faculty to assist with the transition and transfer of their research related activities to MCG.

Did You Know ?

The Office of Human Research Protection (OHRP) has three primary areas of responsibility in research:
Education and Training for Investigators and Research Team Members
Auditing and Compliance of Research Involving Human Subjects
Administrative Support to the Human Assurance Committee (HAC)

For each of these areas, in addition to the regularly scheduled functions and tasks, there are free services available to MCG research team members and departments that may come as a surprise.

Training and Education — OHRP can provide customized human research regulatory training for your staff or department, depending upon your needs. Some examples of sessions available include training on:

- HAC forms
- Requirements for initial, continual and amendment submissions;
- HAC policy training;
- Informed consent requirements
- Adverse events, serious adverse events and unanticipated problems
- Research levels of review and the documentation requirements for each level

Audit — The OHRP auditor not only performs “audits” but also provides the following services to research teams:

- Assistance with preparations for outside audits
- Assistance with preparations for accreditation visits
- Not-for-cause evaluation of study files
- Directed self assessments

HAC Administration — Anytime you need help with your protocol submission, OHRP will gladly

- Meet with you to answer questions and offer direction
- Pre-review your submissions (especially helpful for first-time submissions)

All of the services provided by the Office of Human Research Protection are free. *For more information, please contact Kim Koss, Clinical Research Training Coordinator at kkoss@mcg.edu, or call 706.721.1481. You can also visit the OHRP website at www.mcg.edu/research/ohrp.*

Prospective Research Faculty to MCG

When a researcher is relocating to MCG, there are several areas that require pre-planning. The candidate is asked to complete a form that addresses different segments of research. These areas of consideration include:

- Grants that may be transferring
- Use of laboratory animals
- Use of human subjects or human-derived materials
- Use of radioactive materials, chemicals, and biohazardous materials
- Recruitment of postdoctoral fellows or personnel currently on nonimmigrant visas

- Technology needs associated with research (electronic data storage, database support, etc.)

By making it a priority to connect with prospective research faculty, Dr. Treiber and his team of directors take a proactive approach in the process of transitioning research related activities. The faculty are given an opportunity to familiarize themselves with the processes and procedures associated with research at MCG. Researchers can begin working on research related requirements that may include compliance documentation, required training, space and resource allocation, etc., prior to their arrival on campus.



News from the NIH Office of Biotechnology Activities

OBA Launches Annual Reporting Tool for Human Gene Transfer Trials —The National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) has updated the Genetic Modification Clinical Research Information System (GeMCRIS) — a web-accessible database of human gene transfer clinical trials.

A new feature has been added that allows investigators and sponsors conducting human gene transfer trials to create and submit annual reports via a secure electronic interface within GeMCRIS. With this tool, reports can be submitted instantaneously to NIH OBA. The annual reporting module allows for safety information to be uploaded directly into GeMCRIS using an excel spreadsheet template. The entire annual report can then be submitted electronically through GeMCRIS, or additional information can be submitted separately to NIH OBA.

Investigators and sponsors can save their NIH OBA submission on their own computer and send a copy to the FDA in accordance with 21 CFR 312.33.

The electronic reporting tool is key to efforts by both NIH and FDA to improve oversight and facilitate investigator reporting for human gene transfer trials

The public GeMCRIS site is available at: www.gemcris.od.nih.gov.

Investigators and sponsors who wish to use the system to submit annual reports and/or adverse events occurring on human gene transfer trials registered with NIH OBA should send a written request on institutional letterhead by U.S. mail or fax to: GeMCRIS Systems Administrator, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892; Fax: 301-496-9839



Human Assurance Committee (HAC)

HAC Policies and Forms – Revisions and Updates

All policy changes are effective November 1, 2008

The Office of Human Research Protection (OHRP) and the Human Assurance Committee (HAC) have implemented several policy and form revisions. These changes went into effect on November 1st.

To communicate the updates, OHRP organized seven classes that were held October 30th through November 7th, as well as recorded a webinar that is available now through the beginning of 2009.

*For webinar instructions, see the box at the bottom of this page

Below is a list of the changes and updates.

For a complete overview, go to the OHRP website and look for HAC Updates and Revisions 11/1/08.

I. Exempt Review

Additional criteria and guidance has been added regarding studies which **CANNOT** be reviewed as **EXEMPT**. **No Longer EXEMPT:**

1. Any research involving prisoners
2. Any research involving an FDA regulated product
3. Some research that involves children (**see OHRP website for details**)

II. Safety Events

Although nothing has changed with regards to Adverse Events (AEs), Serious Adverse Events (SAEs) and Unanticipated Problems (UAPs), the policies and deadlines have been edited to make them more “user friendly”. The deadlines are now on the same page in the HAC policies. See under OHRP/HAC website, under “Submission Deadlines”.

III. Investigational Drug Studies that involve an IND (Investigational New Drug Application to the FDA)

The biggest change in this policy is not the policy itself, but the changes in the execution of the policy. From November 1st, required documentation must be provided with the submission, otherwise the submission will not be granted approval.

IV. Investigational Device Studies that involve an IDE (Investigational Device Exemption Application to the FDA)

Like the IND policy above, the biggest change in this policy is not the policy itself, but the changes in the execution of the policy. From November 1st, required documentation must be provided with the submission, otherwise the submission will not be granted approval.

V. Emergency Use

Nothing changed, however the policy has been revised to read more clearly. To summarize, DHHS does not allow emergency use exemptions, therefore, federally funded research that is not regulated by the FDA does not allow emergency use exemptions. For details, see OHRP website, under “HAC Policies”.

VI. Continuing Review

The HAC Form 107 has been revised. There are several sections that now require additional, detailed information. Some of these changes to the 107 include:

- Under subject information in section 2, there is a new column that requires listing any subject changes since last review.
- There are columns that require listing the subject(s)' withdrawal dates and reason for withdrawal.
- A report on the progress of the study must be provided since the last review. This doesn't mean “study is going as expected.” This means an update on recruitment, payment to subjects, staffing changes, etc. are areas that must be addressed in this portion of the 107.
- Big change: The Principal Investigator is the only signature required and accepted on the Form 107.

To access the “Updates on HAC Forms and Procedures” webinar:

- go to <http://mcglive.wimba.com>
- run the “set up” wizard
- log in using your **first name_last name**
- select the “Archives” tab at the top of the next screen
- **scroll down** until you see “**Updates on HAC Forms and Procedures**”
- select that archive
- turn up the volume on your computer/speakers and wait for archive to begin

Human Assurance Committee (HAC)

VII. Waiver of Consent

Waiver of Consent requests no longer require review by the full HAC. However, the **Description of Research Proposal (DRP) must have all of the four below specifications addressed:**

1. The research involves no more than minimal risk to the subjects
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
3. The research could not practicably be carried out without the waiver or alteration
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation (include a description of the information that would be provided to subjects).

VIII. Description of Research Proposal

Additional information is now required on the DRP regarding:

A) The provisions to protect the privacy interests of the subjects

- i) How will subjects be approached about participating in the study in a private manner?
- ii) How will the study be conducted so that subjects will be treated in a private manner?
- iii) Include a plan to give subjects control of the release of private information, tissues, or biological specimens, as applicable?
- iv) If applicable, how will privacy be handled for any information which may be viewed by the subjects as unusually sensitive or objectionable?

B) For Multi-Center Trials in which the PI is the Lead Investigator:

Description of how the following information from sites will be managed:

- i) Unanticipated problems involving risks to subjects or others
- ii) Interim results
- iii) Protocol amendments

IX. Charlie Norwood VA Medical Center

The Charlie Norwood VA Medical Center now has a revised checklist. For more information, see their website at www.mcg.edu/research/ohrp/va/index.html.

X. HAC Procedural Changes:

Two-sided documents - Researchers may now submit two-sided documents.

Track changes - All amendments involving revisions to an HAC-approved document should include the following:

1. A copy of the revised document
2. A copy of the document using track changes to show the revisions

Informed Consent Document - The ICD template in the HAC Policies and Procedures has been revised to include the new contact number for subjects' rights **"The Office of Human Research Protection at (706) 721-1483."**

Revised HAC Roster - (version date 09/15/08) see www.mcg.edu/research/ohrp/irb/hac/documents/HACRoster09.15.08.pdf.

2009 HAC Submission Deadline and Meeting Dates

HAC Submission Dates	HAC Meeting Dates
for New, Full-Review Protocols and Full-Review Amendments by 4:00 pm	
January 12	January 26
February 9	February 23
March 9	March 23
April 13	April 27
May 4 <i>1st Monday</i>	May 18 <i>3rd Monday due to Memorial Day</i>
June 8	June 22
July 13	July 27
August 10	August 24
September 14	September 28
October 12	October 26
November 2 <i>1st Monday</i>	November 16 <i>3rd Monday due to Thanksgiving</i>
December 7 <i>1st Monday</i>	December 21 <i>3rd Monday due to Holidays</i>

International and Postdoctoral Services Office

IPSO Director to Attend 2008 Annual Biomedical Research Conference for Minority Students to Recruit Postdoctoral Fellows.

Following an Advisory Council recommendation to play a more active role in the recruitment of Postdoctoral Fellows, IPSO Director L.D. Newman will be attending the 2008 Annual Biomedical Research Conference for Minority Students (ABRCMS). Now in its seventh year, ABRCMS is the largest, professional conference for biomedical students, attracting approximately 2600 individuals. The conference, to be held in Orlando, Florida, will be offering a dedicated postdoctoral fellow recruitment exhibition area for the first time in its history. Ms. Newman will be staffing an exhibition booth for several days, delivering targeted recruitment materials provided by individual faculty mentors with plans to hire Postdoctoral Fellows in the coming months. Faculty should send postings for current postdoc vacancies as well as those likely to be available through summer 2009 to Sgaffney@mail.mcg.edu.

IPSO Implements Immigration Tracker

The International and Postdoctoral Services Office is phasing in a new case management software program called Immigration Tracker as part of our ongoing efforts to provide superior customer service and timely regulatory guidance. This comprehensive and multi-faceted system will improve IPSO's ability to stay abreast of regulatory changes, offer sound immigration advice and maintain an accurate database of foreign employees' status at the Medical College of Georgia.

Immigration Tracker is a market leader in immigration management software, used by a majority of top immigration law firms and a growing number of universities and



academic medical centers. This new software will allow department managers and employees direct online access to their cases while being processed in IPSO and adjudicated by USCIS. For more information on

Immigration Tracker and how it will impact future processing of foreign national employees, contact Jonathan Harwood, Coordinator of International Services at jharwood@mail.mcg.edu.