To: School of Medicine Faculty and Administrators

From: Thomas Lawley, M.D.  
Dean, School of Medicine

Date: May 24, 2007

Re: Mandatory Review Required for New Clinical Trials and Certain Other New Research Studies Involving Human Subjects (Effective June 11, 2007)

As you know, Emory has been working for quite some time on improving its policies and procedures for compliance with federal billing guidelines related to items and services provided to patients enrolled in research studies. In January, we implemented a mandatory policy that all new Cardiology clinical trials and certain other research studies involving human subjects must have a coverage analysis completed before they will be approved. This policy is now being extended to all School of Medicine Departments. The attached memo from David Stephens, M.D., Executive Associate Dean for Research and Strategic Initiatives, spells out more specifically which research studies fall under this new policy.

A coverage analysis involves a thorough review of the protocol, the draft study agreement, and the informed consent document in order to reach an objective determination regarding which items and services required under the protocol can and cannot be billed to third party payers (such as Medicare or commercial insurance).

The goal for conducting the coverage analysis is to produce a single document that can serve multiple purposes, chiefly:

- Assisting the Clinical Trials Office ("CTO") and investigator in negotiating a financially viable budget;
- Creating a tool that conveys consistent billing information to the healthcare facilities where the research subjects receive treatment and services; and
- Disclosing to the subjects which items and services will be billed to the subject's insurer and which will be the subject's responsibility.

The School of Medicine is instituting a mandatory policy whereby any new clinical trial or other research study that requires any intervention with a human subject involving drugs, devices, services or procedures must have a coverage analysis completed before it will be approved by the Office of Sponsored Programs (OSP). The intent is to ensure
that any drugs, devices, services or procedures provided to subjects in a clinical setting are not billed to a third party payer if those interventions are done for research purposes and/or are being paid for by the sponsor. Even if you as the researcher do not intend for these interventions to be billed to a third party, the interventions could be billed automatically if the coverage analysis is not done. Consequently, the review is required whether or not you intend for the interventions to be billed to any third party payer. This new policy applies to all research studies described above that have not been approved by OSP as of June 11, 2007, whether or not they have already been submitted to OSP for approval as of that date.

In addition, this new policy applies to any research study described above as long as the protocol is required to be routed through OSP, even if the site for the research/patient care is a non-Emory facility.

Because there are significant costs involved in doing these coverage analyses, we are planning to institute a new policy requiring industry sponsors to agree to pay a non-refundable $3000 fee per trial for administrative costs. This fee will only apply to industry sponsored trials that are not cooperative group trials. It will not apply to any federally funded trials. Beginning September 1, 2007, this $3000 fee will be required in all industry sponsored clinical trial budgets and contracts, other than cooperative group trials. The indirect cost rate for industry sponsored trials will also be increased on September 1 from a minimum of 25% to a minimum of 30%, with 3% of this increase going back to the Departments and 2% going to the School of Medicine, to offset costs of the Clinical Trials Office.

Attached is a memorandum from David Stephens setting forth specific directions for investigators to follow in complying with this new policy.

I appreciate your cooperation in this important effort.