EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Office of the Dean

Date: July 5, 2011

To: Principal Investigators, Research Nurses, Clinical Research Coordinators and Regulatory Coordinators Involved in Clinical Research

Subject: Inclusion of Key Research Information in the Electronic Medical Record (EeMR), and new policy for Exception of Sensitive Clinical Research Information from Inclusion in the EeMR

Dear Study Team,

We are writing to inform you of a new policy that went into effect July 1, 2011. As part of our efforts to ensure the safety of clinical research participants, Emory Healthcare (EHC) has launched a safety-driven initiative for clinical research studies conducted in EHC facilities (see policy in Appendix A). This initiative requires that key information about the clinical research is made available in the study volunteer's Emory electronic medical record (EeMR). Principal Investigators (PI) will be required to complete and upload a "Clinical Research Key Points" document in the Data and Safety Monitoring Plan section of the eIRB smartform for any clinical drug or device study conducted in an EHC facility. The form (see attached Appendix B entitled "Clinical Research Key Points") will be available on the Emory IRB website, Researchers/Forms & Tools page (http://www.irb.emory.edu/researchers/formstools/formstools.cfm#oth). The Office for Clinical Research will link this summary in EeMR for each participant enrolling in qualifying studies. The purpose of this document is to make key study drug/device information, qualifying/disqualifying criteria, and emergency contact information available at a glance to EHC providers caring for patient-subjects. PIs are responsible for the accuracy and content of information provided on the form. For new applications submitted on or after July 1, 2011, IRB staff will ensure that a completed form is submitted before releasing approved informed consent and HIPAA documents for new applications. Failure to submit this form will delay the ability to enroll subjects.

For certain studies, providing information in the volunteer's EeMR about participation in clinical research might reveal information about the individual that would be stigmatizing. Examples of such research are studies of an HIV vaccine in persons who practice high-risk sexual behaviors or of a new treatment for drug abuse. For such studies, inclusion of sensitive information in the EeMR may further discourage participation in clinical research of populations who have been underrepresented due to past discrimination. A policy regarding the exemption of certain study-related information from the EeMR is attached (Appendix A). We hope that this policy will protect the privacy of individuals participating in

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clinical research, while at the same time facilitating their inclusion in clinical research. For investigators requesting a status of "sensitive study", a de-identified version of the "Clinical Research Key Points" form, the "Clinical Research Key Points for a *Sensitive Study*" form must be submitted (see attached Appendix C). The "Clinical Research Key Points for a *Sensitive Study*" form will only provide limited information sufficient for emergency management of the participant. Questions about this initiative should be directed to Dr. William Bornstein in the EHC Office of Quality and Risk at wbornst@emory.edu.

Sincerely,

Wright Caughman, MD	David Stephens, MD	Thomas Lawley, MD
Executive Vice President	Vice President, Research	Dean, Emory University
for Health Affairs, HSC	Woodruff Health Sciences	School of Medicine

Appendix A: Policy for Exception of Sensitive Clinical Research Information
Appendix B: Clinical Research Key Points
Appendix C: Clinical Research Key Points for a *Sensitive Study*