

**HAC Policies and Procedures**

**Form FDA 1572 – Statement of Investigator**

## HAC Policies and Procedures

### **What Is The Form FDA 1572 “Statement of Investigator”?**

This document, signed by the PI, confirms their commitment to following federal regulations, state law, and institutional policies and procedures related to investigational test article research. A completed and signed Form [FDA 1572](#) Statement of Investigator is required for submission to the HAC for all Investigational New Drug (IND) studies. All investigators listed on the informed consent document (ICD) and/or children’s assent document (CAD), the [HAC Form 101](#), Protocol Information, and any Division of Sponsored Programs Administration (DSPA) documents must be listed on the Form FDA 1572.

### **What Is The Correct Address For Drug Shipment If At MCG Or MCGHI?**

The study sponsor must be informed that all medications used in clinical research studies are to be shipped directly to the respective pharmacy. This information must be noted on the Form [FDA 1572](#), Statement of Investigator. If the Medical College of Georgia (MCG) or Medical College of Georgia Health, Inc. (MCGHI) is a site, then a signed copy of the Form FDA1572 must include the address of the MCGHI Clinical Research Pharmacy in Section 3 as follows:

SHIP DRUG TO:

MCG Health System Pharmacy  
1120 15<sup>th</sup> Street, BI-2101  
Augusta, GA 30912

ATTENTION: Clinical Research Pharmacy

Contact Phone Number: (706) 721-0802

### **What Is The Correct Address For Drug Shipment If At the Augusta VAMC?**

Please see the VA section for additional information.

### **Is the Investigational Pharmacist a Sub-Investigator (Sub-I)?**

No. The Clinical Research Pharmacist should not be listed as a Sub-I simply due to a role in drug accountability and dispensing in compliance with the protocol.

### **What Is The Correct Address For The HAC?**

The correct address for the HAC/IRB is as follows:

Chairperson, Human Assurance Committee  
Medical College of Georgia

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1120 15<sup>th</sup> St., CJ-2103  
Augusta GA 30912

### **Should Study Coordinators (SC) Be Listed On The Form FDA 1572?**

Study coordinators (SC) should be listed on the Form [FDA 1572](#) if they are actively involved with the conduct of the study.

### **Is There A Web Link To The Most Current Form FDA 1572?**

There is a web link to the most current Form FDA 1572 from the OHRP web page.

### **Since The Form Expires Every Two Years, Do We Have To Re-Submit At That Time?**

No. The form should only be re-submitted when changes occur.