

# Billing and Registration Plan Communication Process

## Responsibilities

### **IRB Coordinator:**

- Provide a blank copy of the Billing and Registration Plan to all principle investigators
- Ensure that the Billing and Registration Plan is received for all clinical trial studies (regardless of full or expedited review and regardless of type of study)
- Do not place study on agenda unless all documents and payment as outlined within the IRB bylaws are received
- Ensure that the Billing and Registration Plan is sent to Greg Balasus in Patient Financial Services
- Include new statement in all approval letters regarding separate hospital approval

*Note: This study has been approved by the GBMC IRB; however, that does not guarantee that Greater Baltimore Medical Center (GBMC) will approve this study. The hospital must ensure that all coding and reimbursement guidelines are arranged prior to the onset of any study that involves a hospital charge. To ensure that the hospital is notified of your intent to conduct a study that involves incurring a hospital charge, you must contact Greg Balasus in Patient Financial Services, (410) 560-5025.*

*Medicare requires a letter with supporting documentation be submitted to the FI and approval received from the FI prior to scheduling the procedure with GBMC. If the study that you are to conduct involves an IDE or HDE device, the PI must send a letter to the Medicare Fiscal Intermediary (FI) along with supporting documentation in order for the facility to obtain reimbursement for the device. The IRB website contains the details as to what must be included within the letter and to whom the letter should be sent.*

- Send copy of all study approval letters (including those for full and expedited review) to Greg Balasus in Patient Financial Services

### **IRB:**

- Do not review study unless all documents have been received and are noted on the agenda as having been received (this includes but is not limited to the Billing and Registration Plan, the Conflict of Interest Statement, and payment for the review)

### **PI:**

- Contact PFS with questions relating to completing the Billing and Registration Plan

### **FOR IDE/HDE STUDIES**

- Write and send letter and supporting documentation to Medicare Fiscal Intermediary
- Provide copy of FI approval response once received from the FI to PFS

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- Contact PFS with any billing, coding, or registration questions relating to the IDE/HDE study
- Do not schedule cases until you receive approval via email from PFS
- Once approval from PFS has been obtained, you may begin to schedule cases, **BUT** you must also send an email to “Surgical Clinical Trials” for each patient with the name, demographics, scheduled date of surgery and clinical trial that the patient is enrolled in. If this is a randomized study, the PI must only email the info on the patient(s) who is to receive the device

### **PFS Director:**

- Receive and review the Billing and Registration Plan
- Match up IRB approval letter with Billing and Registration Plan
- Communicate hospital billing and registration requirements with the principle investigator and/or sponsor
- Communicate important issues with the Finance Rates and Reimbursement Department
- Provide approval to begin the study to the principle investigator via email correspondence once all hospital billing and registration requirements have been addressed, met and documented
- Monitor the “Surgical Clinical Trial” billing email group for coordination of clinical trial billing
- Answer questions from the PI as they relate to the IDE/HDE request for approval letter that the PI will write and send to the Medicare FI
- Obtain a copy of the IDE/HDE Medicare FI approval letter from the PI

### **ABBREVIATIONS**

IRB	Institutional Review Board
FI	Fiscal Intermediary
HDE	Humanitarian Device Exemption
IDE	Investigational Device Exemption
PFS	Patient Financial Services
PI	Principle Investigator