## New Research Insurance Carrier Request for SDK

**Date of Request:**

Form initiated by:

Phone:

**Admin/Study Coordinator:**

**Email:**

#### Study/Grant Title:

#### PI:

#### IRB #

#### Department:       Section:

**What would you like to name this study/grant in SDK? (up to 16 characters):**

#### Is this Inpatient, Outpatient or Both? Choose an item.

#### Is this a Federal agreement? Choose an item.

**Payor ID#** (the7-digit AU for BMC or 10-digit Internal Order# for BU)**:**

**Effective Start Date:** **Effective End Date:**

**Where will study take place?**

**Builidng:       Floor:       Room:**

**\*\*Please attach a copy of the Final Approved Budget and Billing Grid with all the clinical tests being performed \*\***

***Email a copy of the form to Raymond Jaro (******Raymond.Jaro@bmc.org******) so all applicable forms may be updated.***

**For FIS Use Only:**

 **Carrier: Research Grant/Study No: (check one) 1 2 3**

####  Research Plan Mnemonic (Primary Insurance Plan): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Date Completed in SDK: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

###### **Revised 07-08-2014**

###### **Clinical Trial Patient Enrollment Guide**

This form is to set up an insurance plan in SDK for patient enrollment in a clinical research study. In order to set up your grant properly in SDK, you must fill out this form in its entirety and have the following items completed:

* A fully executed Clinical Trial Agreement
* An approved IRB Protocol number (an SDK account will not be set up without an IRB approval)
* A negotiated budget and Medicare Coverage Analysis (MCA) that falls in line with the hospital research fee schedule for all clinical testing being performed at a Boston Medical Center service area
* A BMC/BU account number

#### When is a visit considered Standard of Care (SOC) or research related?

It is sometimes difficult to determine whether a subject is coming in for a SOC visit or a research visit. This should have been determined at the time the contract was being negotiated and should be easily referenced in the Medicare Coverage Analysis (MCA) and its associated Billing Grid.

1. In general, patients/third party payers should not be charged for the investigational item or service, itself. Costs of procedures and services performed solely for research purposes are charged to the study/grant, unless preauthorized by the patient/third party payer.
2. If procedures and services considered to be standard of care are within the scope of the research study, and are to be billed to the patient/third party payer, these visits must not be registered under the research grant, but should be registered to the patient/third party payer for reimbursement.
3. Patients and third-party payers must not be billed for research costs that are paid by another entity, such as a grant or study sponsor.
4. If a subject comes in for a research visit, and has a standard of care visit afterwards, there should be 2 separate visit numbers in the system in order for services to be billed accurately. One visit number can not contain charges for both SOC and research visits.

**How do patient care costs get charged to the grant?**

Once a subject has completed their visit and charges have been entered into the system, a file will be downloaded once a month by the Clinical Research Accountant and sent to the Study Coordinator/ Department Administrator and the Principal Investigator for review and payment confirmation. The file will include amounts to be charged to the study/grant and information such as insurance carrier, insurance plan, account number, admit date, patient name, amount, payment by BU/BMC grant, adjustment, comment, CPT code, CPT code description, revenue code, revenue code description, etc. After the file has been reviewed for accuracy, the Study Coordinator/Department Administrator/Principal Investigator will then send back confirmation to the Clinical Research Accountant to charge the study/grant.

If at any time you have questions regarding the financial aspect of a clinical trial, please contact the Clinical Trial Financial Analysts in the Clinical Trial Office.

**Allisson Dugan, Senior Clinical Trial Financial Analyst.**

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