

RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION

Clinical Research Policy/Procedure

Approved: September 2008

Next Review: September 2010

Purpose

To establish the process for initiating research studies to be conducted via the Swedish Research Center.

Responsible Persons

Research Managers, Grants and Contracts Data Coordinator, Grants and Contracts Analysts, Clinical Trials Reimbursement Analyst, and the Research Operations Coordinator.

Policy

Research Administration requires the establishment of an administrative and contract file for every research study initiated at the Swedish Research Center.

Procedure

PRE-CONTRACT SET-UP; ADMINISTRATIVE RECORDS

1. The Research Manager is responsible for initiating a research study by completing a Project Initiation Form (PIF) and submitting it to the Grants & Contracts Data Coordinator (GCDC). See Addendum 1.
2. The GCDC assigns a unique Swedish Research Center (SRC) study number and file name.
 - The convention for naming files is four alphanumeric blocks, separated by spaces. The first block is the study area (e.g. "PMS" for Pain Management Services); the second block is the first three letters of the last name followed by the first letter of the first name of the Principal Investigator (e.g. "DOEJ" for John Doe); the third block is the sponsor name entered as the letter "C" for commercial, followed generally by the first three letters of the sponsor's name (e.g. "CNOV" for Novartis); the fourth block is the SRC number, using the convention of the first two digits to designate the year (e.g. "08" for 2008) followed by two or three more digits to designate the next ascending number after the last study which was opened (e.g. if the latest file was "08001", the next one would be "08002," etc.)

- The convention for labeling files is by color corresponding to the study area:
Admin – Lt Grn; CVR – Lt Blu; EC – Grn; HD – Dk Blu; HIV – Brn; Misc – Grn; NI – Red; OT – Lt Blu; PEDS – Grn; PMS – Dk Blu; PN – Brn; RHM – Lt Blu; SLE – Red; TI – Lt Grn; TIFE – Lt Grn; TIRO – Red.
3. The GCDC creates a record for the study in the Programs 98 database (e.g., Projects Table, Sponsor Table, etc.)
 4. The GCDC creates a “study shell” record for the study in Study Manager™ (SM).
 5. The GCDC creates a record for the study on the New Research Status Report located at T:\RSCH\LimitedContracts\NEW RESEARCH STATUS REPORT. The report enables staff to track the progress of budget/contract negotiations and finalization.
 - ➔ **NOTE:** If the study never becomes an active study (e.g., the contract/grant is cancelled, the Research Manager notifies the GCDC. The GCDC changes the Contact Info for the study in Programs 98 to “ZZRL,” and marks the Project Status as cancelled. The GCDC also deletes (“Zdelete”) the study in SM, if appropriate, and changes the study from “Active” to “Inactive” by unchecking the Active Study box in the Edit Study field. Annually, the GCDC generates a list of remaining “Pending” studies and forwards the list to the appropriate Research Manager for review. The Research Manager notifies the CGDC if any of these studies can be cancelled.

BUDGET AND BILLING RECONCILIATION

6. The Clinical Trials Reimbursement Analyst (CTRA) compares the Visit Support by Sponsor for each Visit in SM with the Budget and Billing Matrix (BBM) and verifies that the correct reimbursement amount is recorded for each Visit in SM. See Addendum 2. The CTRA also confirms that standard of care items/services are properly identified in the BBM and that the BBM is complete.
7. Upon completion of the BBM, the CTRA forwards the reviewed and approved BBM to the Grants and Contracts Analyst for the opening of a cost center for the study. The CTRA also informs the Research Manager that review of the BBM is complete.
8. The Research Manager prints and signs the final BBM and also secures the review and signature of the PI. The Research Manager forwards the signed BBM to the Research Operations Coordinator (ROC).
9. The ROC scans and places an electronic copy of the BBM into the \Individual Study Budgets folder for the respective study area in T:\RSCH\Shared\FinMgmtTools\Final Version of Contracts – Repository. See Clinical Research Policy/Procedure: CLINICAL RESEARCH BUDGET AND COVERAGE ANALYSIS.
10. The ROC forwards the signed original BBM to the GCA. The GCA places the BBM in the administrative study file.

POST-CONTRACT SET-UP

11. Upon completion of the BBM and notification of final execution of the contract, the Grants & Contract Analyst (GCA) completes administrative set-up of the study.

- a. **SRC Project Listing.** The GCA enters a record for the study on the “a_SRC Listing of Projects in PeopleSoft.” See Administrative Set-Up Instructions at Addendum 3.
 - b. **Study Manager™.** The GCA enters financial information for the study in Study Manager. See Administrative Set-Up Instructions at Addendum 3.
 - c. **Programs 98.** The GCA enters project information and financial information in Programs 98. See Administrative Set-Up Instructions at Addendum 3.
 - d. **Cost Center.** The GCA emails the Swedish Finance Department with a request to open the new cost center. See Administrative Set-Up Instructions at Addendum 3.
 - Use the next available and unused cost center within the range appropriate to the department (e.g., Res Admin – 100000; CTU – 200000; CVR – 300000; TICO – 400000 / 490000; TIRO – 430000; NI – 500000; NI LABS – 570000; PN – 800000; TIFE – 900000).
12. The GCDC invoices the sponsor for the administrative set-up fees, placing a copy of the invoice into the file, and sending a copy to the Research Manager.
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Forms

- ◆ Project Initiation Form (PIF)
- ◆ Budget and Billing Matrix

Supplemental Information

- Administrative Set-Up Instructions
- Clinical Research Policy/Procedure: CLINICAL RESEARCH BUDGET AND COVERAGE ANALYSIS
- See Clinical Research Policy/Procedure: STANDARDS FOR THE USE OF STUDY MANAGER.

Expert Consultants

Grants and Contracts Analysts, Lead
Grants and Contracts Data Coordinator

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Regulatory Requirement

N/A

References

N/A

Addenda

1. Project Initiation Form (PIF)
2. Budget and Billing Matrix (BBM)
3. Administrative Set-Up Instructions

pk:Research Study Initiation Procedures - Administration - v. 1.0.doc (09/17/08)

RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION**ADDENDUM 1****Project Initiation Form (PIF)**

Project Initiation Form

Instructions: Please complete this form and forward it to the Clinical Research Center when requesting initiation activities of any new research project (budget, contract, IRB). *(This form is protected, to fill it out just tab to the field or place your cursor in the field to be filled out. The boxes are check boxes. Just click on the appropriate box.)*

Department:

Principal Investigator:

 PI Initiated Yes No

Funding Source: Federal Non-Profit Commercial Other (Please state below)

Sponsor Name:

Multi-Arm Study: Yes No **Please check box if Study uses a device**

Coordinator/SMC Contact Person:

Project Title: (To be completed by Administration Office)

Protocol Title:

Indication:

Protocol Number:

Comments/Notes: (To be completed by Administration Office)

cc: CRC Established

(To be completed by Administration Office)

CRC NUMBER ASSIGNED

RETURN ONE COPY TO COORDINATOR/CONTACT

RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION

ADDENDUM 2

Budget and Billing Matrix (BBM)

RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION**ADDENDUM 3****Administrative Set-Up Instructions**

Administrative Set-Up Instructions

per

Clinical Research Policy/Procedure: RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION

SRC Project Listing

- Open T:\RSCH\Limited\GCS Files\la_SRC Listing of Projects in PeopleSoft.xls
 - (1) “History of All Projects” tab
 - Scroll to most recent PID created for that department
 - Right click on field below that & Insert
 - Enter next number in sequence as the PID
 - Enter Project Title (from Programs98)
 - Enter Department
 - Start Date = PID opened or Contract Date
 - End Date = duration of study or approximate (2 years?)
 - (2) “Active CURRENT Studies” tab
 - Repeat above
 - Enter Overhead (OH) rate
 - (3) Update “As of:” date to current.
 - (4) Save changes and close file.

Study Manager™

- Logon to Study Manager (<http://fhiisu-ps03/sm%5Fwebedition%5Fnet>)
 - (1) Studies
 - Enter CRC# in Study ID
 - Choose Study in list
 - Edit Study and change name to following naming convention: PID P.I. CRC# Study Friendly Name (if any) → Submit & Okay
 - (2) Go to Financials Section of Study Manager
 - Select Module → Budgeting
 - Select Study by Study Name and Site
 - Select “View One Procedure Across All Visits”
 - Select “Visit Support by Sponsor”
 - Review Amount Due for Each Visit
 - Make sure Visit Support (each visit) in SM matches the Budget in Agreement or Contract in CRC file, and the Budget and Billing Matrix.
 - (3) Return to Studies
 - Add the contract value (the full potential revenue total) in the Studies\Participating Sites\Manage Study\General Info section of SM
 - Go To Study Sites
 - Select whatever Site study is in

Study Manager™ (cont.)

- Affirm the Patient Quota as entered for the Site by the Research Manager
- Enter Contract Value = Total Amount Due → Submit
- Enter Study Friendly Name, if known
- Close

Programs98:

- Open Projects table
 - (1) Find CRC#
 - Enter: PID, Start date, End Date, Agreement Status, Project Status = Active, Estimate Enrollment, Run_GSR = Yes, Indirect Rate.
 - Close
 - (2) Open New SRC File Form
 - Find study: drop-down CRC Number in Search Criteria
 - Click on BUDGET FORM
 - Account drop-down choose “510510 | Revenue”
 - Enter Per Case Amount = Total Amount Due (enter as negative)
 - ADD
 - Account drop-down choose “770850 | Other Misc Exp”
 - Enter Per Case Amount = Total Internal Cost (enter as positive)
 - Close
 - Close
 - (3) Open Budget table
 - Go to end of the table and double check what was just entered in the New SRC File Form.
 - Close table.

Cost Center:

- Send email to Account to request “New Project ID Setup Request: (Department – PID)”
 - Send to: Rebecca Chan, Mary Waller, Debora Scholz, Rod Suddreth, Richard Willette, Levita Suelen
 - Copy to: department manager, coordinator (if applicable), Chuck Buchanan, Jesse McNeece, Kjersti Hagman, Sean Ngo, James delAlcazar (if applicable), and the Claims Analyst.
 - Email should include: Department & Project ID's, CRC file name (copy & paste from Projects table in Programs98), Revenue, Benefits percentage, & Indirect Rate.
- Print email and file in section 2 of the study's CRC file.