

## CLINICAL RESEARCH BUDGET AND COVERAGE ANALYSIS

Clinical Research Policy/Procedure	
Approved: October 2008	Next Review: October 2009

### Purpose

To establish a process for developing a clinical research budget for all research studies conducted through the Swedish Research Center (SRC). To help Swedish adhere to applicable laws, regulations, and requirements regarding payment and reimbursement from payors for costs associated with participation in research.

### Responsible Persons

Principal Investigators, Research Managers, Grants & Contracts Analysts, and Clinical Trials Budget & Claims Analysts.

## Policy

Billing for clinical items and services provided to research subjects can be complex due to the fact that multiple entities may be accountable for paying the costs incurred throughout the subject's participation in the research study. For instance, a research protocol may involve both medical procedures that are covered by governmental or private insurers and investigational items or services that are paid for with funds provided by research sponsors. Additionally, federal rules and regulations as well as contractual obligations and procedural requirements of insurers or sponsors mandate the conditions by which the insurers/sponsors will pay for the costs associated with participation in research.

It is SRC policy that SRC researchers, providers, and staff collaborate and work together with other appropriate Swedish Medical Center departments and staff to ensure that clinical items and services associated with research studies are properly billed in compliance with applicable laws, regulations, rules, and contractual obligations. The Principal Investigator (PI) is responsible for developing a budget and conducting a billing coverage analysis, as specified in this Policy/Procedure, for each research study that has potentially billable items or services. The PI shall ensure that research subjects are adequately and accurately informed of the costs to the subject that may result from his/her participation in the research. Neither the PI nor the institution may accept extraordinary payments for time or effort not expended on a research study (e.g., referral fees, finder's fees, recruitment incentives, etc.).

## Procedure

1. At the outset of a proposed research study that involves potentially billable items or services, the PI is responsible for establishing a Research Billing Plan for the study. See Addendum 1.
  - ➔ **NOTE: Comparable to prospective IRB review and approval requirements, the Research Billing Plan must be reviewed and approved by the SRC before the research can be conducted.**
  - a. Templates for the Research Billing Plan are available at:  
T:\RSCH\Shared\FinMgmtTools\Clinical Trial Billing.
2. Prepare and forward the following documents to the Clinical Trials Budget & Claims Analyst (CTBCA) for review, as available:
  - a. A Research Billing Plan for the study;
  - b. For studies involving investigational devices (IDE), a copy of the study protocol delineating the Medicare-billed services. For *each* service or procedure in the protocol, indicate next to the service or procedure either the word “study” to indicate the service or procedure is a cost and responsibility of the study (and will *not* be billed to Medicare) or the word “Medicare” for a service or procedure which (a) is medically necessary for the patient’s care, (b) would have been incurred in the absence of the study and (c) is an Medicare-covered benefit/service.
  - c. A copy of the FDA approval letter for the IDE or IND for the study (as available or provided by the sponsor); and,
  - d. Copies of all proposed contracts or agreements between the sponsor and the PI / SRC (e.g., clinical trial agreements, master research agreements, etc.).
3. A Grants & Contracts Analyst (GCA) and CTBCA confirm the billing coverage analysis by reviewing the documents for consistency of terms and to ensure that the billing to appropriate payors is correctly assigned for all items and services anticipated throughout the course of the research study.
  - a. The coverage analysis involves consideration of pertinent rules and regulations including the CMS National Coverage Decision for Routine Costs in Clinical Trials, 42 CFR Part 405 Subpart B – Medical Services Coverage Decisions That Relate to Health Care Technology, applicable Local Coverage Decisions, and contractual obligations and requirements of other private insurers.
  - a. The GCA and CTBCA will review and verify that the consent forms for the study are consistent with the terms of reimbursement and payment identified in the coverage analysis.
4. In consideration of any grant/contract negotiations being undertaken, the GCA and Research Manager will collaborate in (1) resolving any variance in payment sources for bills of items and services identified throughout the coverage analysis, and (2) negotiating the research budget and the contract with the sponsor. The Research Manager is primarily responsible for negotiating the budget. The GCA is primarily responsible for negotiating the contract and ensuring that the terms of the final contract correspond to the terms of the negotiated budget.

- a. The Research Manager is responsible for developing a budget for the study. The PI must review and sign the budget. The Research Manager forwards the signed budget to the GCA.
    - b. Upon resolution of the budget and contract negotiations with sponsor, the GCA delivers the budget and proposed final contract to the Research Operations Coordinator (ROC).
  5. The ROC coordinates and secures execution of the contract by the PI, SRC Director, and sponsor. Upon final execution of the contract, the ROC scans and files the contract and notifies the Research Manager and the Grants and Contracts Staff that the contracts have been executed. See Clinical Research Policy/Procedure: RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION.
  6. The PI is responsible for ensuring that appropriate documentation is provided to fiscal intermediaries, Medicare carriers, and other Medicare contractors as required.
  7. The PI is responsible for promptly notifying the GCA and the CTBCA of any proposed changes to the research that could potentially affect a change to the billing for the study (e.g., protocol amendment adding/deleting clinical procedures or ancillary services).
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## Forms

- ◆ Research Billing Plan

## Supplemental Information

N/A

## Expert Consultants

Grants & Contracts Analysts, Lead  
Clinical Trials Budget & Claims Analyst  
Research Education & Compliance Officer

## Author

Peter Kim, JD CIP, Research Education & Compliance Officer

## Regulatory Requirement

CMS National Coverage Decision for Routine Costs in Clinical Trials

42 CFR Part 405 Subpart B – Medical Services Coverage Decisions That Relate to Health Care Technology

## References

N/A

## **Addenda**

### 1. Research Billing Plan

pk:Clinical Research Budget and Coverage Analysis - v. 1.0.doc (10/7/08)

**CLINICAL RESEARCH BUDGET AND COVERAGE ANALYSIS****ADDENDUM 1****Research Billing Plan**



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RESEARCH BILLING PLAN

Form with fields: PRINCIPAL INVESTIGATOR, DATE, PROTOCOL TITLE, PROTOCOL NUMBER, SPONSOR, SPONSOR CONTACT NAME AND INFO, phone/email.

PROTOCOL INFORMATION

1. The research protocol involves an:
- investigational drug (IND) - IND#
- investigational device (IDE) - IDE#
- approved drug (IND exempt) - name of drug
- approved device - name of drug/device
2. Has the Sponsor provided an informed consent form for the study?

FINANCIAL INFORMATION

3. Has the Sponsor proposed any agreements?
4. Has the Sponsor proposed a budget for the study?

MEDICARE QUALIFICATION INFORMATION

5. Is the subject or purpose of the protocol an evaluation of an item or service that falls within a Medicare benefit category...
6. Does the protocol have therapeutic intent?
7. Does the protocol involve a patient population with diagnosed disease...
8. Do any of the following apply to the research?
- Research is funded by NIH, CDC, AHRQ, CMS, DOD, or VA;
- Research is funded by centers or cooperative groups...
- Research will be conducted under and IND reviewed by the FDA;
- Research is exempt from having an IND under 21 CFR 312.21(b)(1).

- 9.** If “none of the above” was your answer to Question 8, answer the following questions:
- a. Is the principal purpose of the research to test whether the intervention potentially improves the participants’ health outcomes?  Yes.  No.
  - b. Is the research well-supported by available scientific and medical information or is it intended to clarify or establish the health outcomes of interventions already in common clinical use?  Yes.  No.
  - c. The research does not unjustifiably duplicate existing studies.  Yes.  No.
  - d. The research design is appropriate to answer the research question being asked?  Yes.  No.
  - e. The research is sponsored by a credible organization or individual capable of executing the trial successfully.  
 Yes.  No.
  - f. The research will be conducted in compliance with federal regulations relating to the protection of human subjects.  
 Yes.  No.
  - g. All aspects of the research will be conducted according to appropriate standards of scientific integrity.  
 Yes.  No.

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**Signature of Principal Investigator**

<b>SWEDISH RESEARCH CENTER APPROVAL</b>		
Name and Title	Signature	Date