

Title: Budgeting Procedures for Clinical Research	No.:
	Effective: mm/dd/2008
	Revised:
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Entity: Health First

I. OBJECTIVE

The Objectives of This Policy Are

- To ensure proper budgeting of services rendered in connection with clinical research projects.
- To ensure that all items and services provided by Health First (HF) for research protocols are identified and reimbursed.
- To ensure that Health First is fairly and reasonably compensated for items and services.
- To assist Health First's overall compliance effort by avoiding any apparent or actual inducement to utilize its facilities.
- To ensure that items and services provided to research patients for routine care and for research are identified and that the correct payer is assigned to each.

II. DEFINITIONS

Items & Services:

Any service or item provided to a patient participating in a clinical research study, by any department in any HF facility. They include such services as laboratory tests, pharmacy services, any diagnostic procedure, any interventional procedure, IV treatments, hospital rooms, etc, and items such as dressings, syringes, drugs, catheters, implantable devices, sutures, etc. Also included in this definition is the time and effort and outside expenses incurred by Research Administration.

Budget Template:

The standard form used to create a budget for an industry-sponsored clinical trial. This document allows for recording all costs associated with a research project study in order to effectively establish a complete budget and account for the project.

Coverage Review:	A systematic review (sometimes referred to as a Medicare Coverage Analysis, or MSA) of clinical trial related documents to determine the billing eligibility of patient care services provided as part of a clinical trial.
Routine Care:	The treatment that experts agree is appropriate, accepted and widely used for a patient with a particular health condition. Determining Routine Care and assembling documentation to support the determinations are critical, because items that are non-Routine Care are typically not billable to insurance and therefore should be reimbursed by the PI or Practice.
Research Administration:	Individuals who develop budgets and help record all expenditures and revenue associated with a particular research project.

III. POLICY

It is the policy of HF to ensure that budgeting for items and services is both comprehensive and representative of all expenses emanating from a clinical research project at HF facilities. All individuals involved in initiating, conducting, facilitating and administering a research study are required to comply with this policy. Everyone involved in the process is expected to understand their roles and responsibilities and be accountable for the timeliness and correctness of the information provided by them. Disciplinary action will ensue for violations of this policy, including study suspension, budgeting suspension, suspension of research privileges, and/or employment action.

No study may commence until a budget template is developed and a budget is incorporated into a Study Agreement that is duly executed by the Chief Operating Officer of the HF facility or facilities in which the study will be conducted, and the Principal Investigator (and his or her Practice, if appropriate). For studies anticipating third-party health insurance payments for particular items and services, a Coverage Review will inform the budget template and categorize all items and services provided by HF for the study into one of two groups: payable by the Practice (or PI), vs. payable by the patient's insurance. Research Administration will facilitate and coordinate these activities.

Reimbursement rates paid by the PI or the PI's practice for budgeted items will be commensurate with rates paid by private third-party payers for the same services, with similar terms of payment. Although PIs and Practices may rely on Sponsor payments for items and services provided by HF, study budgets are an integral component of formal Agreements between HF and the PI and Practice and are thus, reimbursement for items and services provided by HF is the direct responsibility of the PI and Practice.

IV. PROCEDURE

1. The Research Administrative Liaison (RAL) retrieves necessary information to begin to build a budget. These items may consist of:
 - a. The investigator's proposed budget
 - b. The completed Coverage Analysis including the grid of all items and services
 - c. Standard pricing from the Charge Description Master
 - d. Any special pricing agreements that apply to items and services needed
2. The RAL develops a budget by populating the study grid with charges for all items and services to be supplied by the HF facility. These items and services typically include
 - a. Everything identified in the Coverage Analysis as being having a cost and not being paid by a third party payer for routine care
 - b. Everything specifically identified as being paid by the Sponsor
3. The RAL adds any additional charges that were not identified in the Coverage Analysis. These may include:
 - a. All nonrefundable startup fees typically associated with a study
 - b. Any unusual costs that are specific to the study
4. The RAL transmits the budget to the investigator for review/approval.
5. The investigator returns the budget to the RAL.
6. If the budget is returned unchanged and approved, it is attached to the Contract.
 - a. If a Master Service Agreement (MSA) is in place, the budget is incorporated into the Clinical Research Services Request Form (CRSRF)
 - b. If no MSA is in place, the budget is attached to the Clinical Trial Agreement
 - c. All Agreements are subject to HF legal review, according to HF Policy governing contracts and agreements
7. If the budget is returned with requests for revision, the RAL may revise the budget and present it for attachment to the Clinical Trial Agreement or CRSRF if
 - a. Items and services were added or omitted mistakenly, deviating from the Coverage Analysis, or if
 - b. Erroneous charges were used to develop the budget, or if
 - c. The CEO, COO, or CFO of the an HF facility agrees to discount research rates further below the standard research discount.

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Attachments:

- Attachment 1: Clinical Research Budgeting Procedures

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