

DHHS Information

Research Patient Care Costs

General

This section provides NIH policy on the determination and reimbursement of research patient care costs under grants. This general policy is intended to be applied in conjunction with the requirements of 45 CFR 74, Appendix E, Cost Principles for Determining Costs Applicable to Research and Development under Grants and Contracts to Hospitals. In addition, specific NIH programs may have additional or alternative requirements with which an applicant/grantee must comply. This includes the General Clinical Research Center Guidelines as specified in this section.

Definitions

Research Patient Care Costs are the costs of routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter “rates”). Research patient care costs do not include: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or in an affiliated medical school/university based on an institutional fee schedule, or (3) the data management or statistical analysis of clinical research results.

Hospital includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.

Research Patients refers to inpatient and outpatient subjects, volunteers, or donors participating in a research protocol.

Routine Services are the regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customarily made.

Ancillary Services are those special services for which charges are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.

Outpatient Services are services rendered to subjects/volunteers who are not hospitalized.

Usual Patient Care refers to items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible health professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services. These expenses are for care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance usually will provide for reimbursement of charges for “usual patient care” as opposed to non-reimbursement for those charges generated solely because of participation in a research protocol.

Discrete Centers are groups of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an

ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

Scatter Beds are beds assigned to research patients based on availability. These beds are not physically separate from non-research beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

Cost-Finding Process is the technique of apportioning or allocating the costs of the non-revenue-producing cost centers to each other and to the revenue-producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.

Allowability of Costs

The determining factors for allowing research patient care costs as charges to NIH grants depend on the patient and the type of services received. If the patient is receiving service or care that neither differs from usual patient care nor results in expenses greater than those that would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the grant will not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the grant may pay the additional costs. The grantee must decide whether, in fact, the hospitalization period, the tests, or the services have been extended beyond or added to what would ordinarily have been expected, and to what extent. Patient care costs for individuals who are receiving accepted treatment according to standard regimens would not ordinarily be acceptable charges to an NIH grant. Similarly, in certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs generally may be charged to a grant only insofar as they are measurements or services above and beyond those that constitute usual patient care and are specified by the study protocol.

NIH funds may be used to pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for individuals who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the grantee's records. These individuals may include:

- ◆ Persons to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be normal controls for metabolic or other studies; persons with genetic or certain abnormalities of interest to the investigator; and sick persons brought to the hospital solely for studies when they otherwise would not require hospitalization.
- ◆ Sick persons of research importance to the investigator but without funds of their own or without funds available to them through a responsible third party to pay hospitalization expenses. This includes patients for whom some third-party payer, such as city, county, or State government, might pay hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.
- ◆ Sick persons with limited personal funds or health insurance but who are not willing to spend their own money or use their hospital plan coverage at that particular time. (Fear of more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special

responsibility in making the decision to include patients in this group with full charges to the grant. Ordinarily, NIH expects the patient and/or third party to pay the total costs of the usual care portions of the hospitalization. However, in exceptional circumstances, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the grant if this is required to secure timely cooperation of a valuable study patient not otherwise available.

Computation of Research Patient Care Costs

Patient care costs, whether expressed as a rate or an amount, shall be computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs. Under this policy, separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the discrete unit.

When provisional rates are used as the basis for award of research patient care costs, the amount awarded shall constitute the maximum amount that the IC is obligated to reimburse the grantee for such costs. Provisional rates must be adjusted if a lower final rate is negotiated.

Facilities and Administrative Costs

F&A costs should not be paid on any cost component representing the cost of research patient care activities. Patient care rates (routine and ancillary) include F&A costs related to “hospital-type” employees (nurses, medical technicians, etc.) supported as a direct cost under a grant.

Therefore, to preclude over-recoveries of costs similar to these F&A costs, salaries and wages (S&W) of all “hospital-type” employees working on the grant must be excluded from the S&W base used to claim F&A costs. Related fringe benefits also should be excluded if such costs are part of the S&W base. If a “total direct costs” base is used to compute and claim F&A costs, the above-mentioned “hospital-type” salaries also must be excluded from the base as well as any other base costs chargeable to the grant through the application of a research patient care rate.

If the grant or a consortium agreement/contract under a grant provides funding exclusively for research patient care activities, no F&A costs will normally be allowed as a separate cost element since all allocable F&A costs will be accounted for in the routine or ancillary activity costs contained in research patient care rates.