

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

Policy No.: 115
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Previous Date: None
Revised Date: None

Participant Categories

Purpose: To provide a structure for adherence to the National Center for Research Resources (NCRR's) Participant Category definitions for evaluation of the research services provided within the GCRC setting. This structure is also used for payment rate determination of research interventions.

Procedure:

The Participant Categories are defined as follows:

1. **Category A.- Research Patients:** These are research patient days or outpatient visits utilized solely for research purposes. All hospitalization costs associated with Category A research days or visits are the financial responsibility of the grant or an investigator's research funds. Patients hospitalized for research purposes only, whose care is partly supported by non-GCRC funds, (e.g. Other grants, industry) may also be classified as Category A. This category includes normal volunteers or controls. Patients may participate in research projects which include normal volunteers or controls. These individuals may include persons to whom no health advantage may be expected to accrue as the result of hospitalization. Patients may participate in research projects which include unproved forms of therapy or diagnostic techniques that may become future standards of care. Even though the patient may have a third party insurance carrier and have an underlying disease, the GCRC assumes all research costs.
2. **Category B- Research Service Patients:** This category includes patients who require hospitalization or outpatient studies for diagnosis or treatment according to established standards of care. Category B patients may also participate in GCRC-based research studies. The cost of established medical care is not charged to the grant. The patient or third party carrier is responsible for costs related to non-research charges. The cost of ancillary services performed solely for research on Category B patients and not related to their routine medical care may be charged to the grant, and shall not appear on the patient's bill which is submitted by the hospital to the patient or the insurance carrier. Patients appropriate for Category B may not be classified as Category A simply because they lack applicable hospitalization insurance.
3. **Category C - Non-Research Patients:** Patients who are not participating in a research project may be admitted to the GCRC solely for the purpose of diagnosis and treatment according to established procedures when GCRC space and staffing is available. The purpose of Category C patients is to decrease the cost of the GCRC operation. No charges for this category can be applied to the grant. Category C patients should not require an extraordinary level of care (e.g. Dialysis patients, post-operative patients, intensive care patients) that could compromise the research studies.
4. **Category D -Industry Initiated Projects:** This category includes patient days or outpatient visits utilized for an industry-initiated study. All charges are paid directly by industry through the responsible investigator. The charge for each project is developed by the GCRC Advisory Committee.

5. Scatter-bed Inpatient Days:
- a. Scatter-bed Inpatient Category A: The cost of occasional, unexpected, temporary use of special facilities, such as intensive care unit or other off-site area uniquely required to accommodate a research patient, may be charged to the GCRC grant provided that the care is required by the nature of the clinical research or by an illness resulting from the research. The GAC must review and approve this activity.
 - b. Scatter-bed Inpatient Category B: These patients require hospitalization for diagnosis or treatment according to established standards of care and are also research participants. These off-site inpatients may require ancillary services solely for research purposes that may be charged to the grant. Nursing hours related to this activity are tracked as “scatter-bed Research Nurse Hours”.

Originator: GCRC Clinical Nurse Specialist

References: General Guidelines for the General Clinical Research Centers Program of the National Center for Research Resources National Institutes of Health, 2000.

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