

INSTRUCTIONS FOR COMPLETING STUDY GRID

A Study Grid is required for any Clinical Human Subjects Study involving billable patient care costs. The Study Grid is important as it captures the charges that are billable to third party payers versus another source of funding and other pertinent information related to the Study.

Definitions:

Standard Therapy (Standard of Care): Medically necessary therapy that a patient would receive regardless of participation in a research study.

Non-Standard Therapy: Care that a patient receives *only* because patient is participating in a human subjects study. Care can be categorized as follows:

- a) Item or service is for purposes of screening a prospective subject to determine enrollment eligibility;
- b) Item or service is to establish a baseline that will be compared to subsequent values to analyze the effect of the study treatment;
- c) Item is investigational or not conventional care;
- d) Item or service required by study is not generally used with non-study patients (i.e. repeat H & P, repeat CBCs, etc.).

Rate Policy: Regulations require that no sponsor may be charged less than that charged to a federally-sponsored award.

Federal Sponsor:	Medicare or 50%, whichever is less
Industry Sponsor:	Full rates. May be negotiated to Foundation/Non-Profit Sponsor Rate by Research Administration
Foundation/Non-Profit Sponsor:	Medicare or 50%, whichever is more

Steps to Complete Study Grid (Use Legend to properly complete fields):

1. Principal Investigator must designate a responsible person (study coordinator, fellow, resident, or other staff person) as the key contact for the coordination of the study including study subject billing.
2. Designated responsible person develops budget with PreAward Specialist (x3018) in Research Administration, utilizing appropriate rate charts. Any reduction or waiving of fees or rates that deviate from the Study Subject Rate Policy (below) must be approved *before* submission of budget and/or negotiation with sponsor.
3. Study Grid is forwarded electronically for signature in the following order:
 1. Principal Investigator
 2. Research Administration
 3. Fiscal (2 signatures)
 4. Research Administration
 5. To Responsible Person
4. Final signed form is sent electronically to the PreAward Specialist (#4 above), who will forward to Responsible Person (#5 above). PreAward Specialist uploads form to InfoEd record and forwards complete file (including signed contract and Sponsor documents) to Grant Accountant for account setup. Assistant Grant Accountant sets up research cost center and notifies PI and Study Personnel of account number. *Study cannot begin until HSC Approval is received, Study Grid is approved and received by Research Administration, and cost center is activated.*

Please Note: If there are changes to the protocol that affect the Study Grid, then an amended Study Grid must be completed and routed as above.