

STUDY CALENDAR (INSTRUCTIONS ONLY)

The Study Calendar will be used to outline study related versus routine clinical services within a study protocol. This document should guide preparation of the Research Budget and patient Informed Consent Form. **This form is required for all clinical research projects.**

1. This form should be completed by the coordinator or PI of the study and submitted with JHS Clinical Trials Application to the JHS Clinical Trials Office 1500 NW 12 Ave JMT suite 1112.

2. Please complete the Calendar based on the requirements of the protocol in the following manner:

Column A: Please list ALL the services and procedures required by the protocol. Also list device or supply items provided by the study.

Column B: Please list the 5 digit CPT, ICD-9, or DRG codes if known. If there is not a code for the service or procedure, please list N/A (not applicable).

Column C: Please list the research price for each lab, test, procedure, etc. as indicated in Column A.

Column D: Please list the visits in column C based on the protocol.

Indicate S if the service or procedure is to be billed to the Sponsor. Indicate M if the service or procedure reflects standard of care and should be billable to Medicare.

EXAMPLE: PROTOCOL BILLING GRID

Column A	Column B	Column C	Column D								Notes
Procedures*	CPT Code	Research Price	Screen	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6 or EW	FU	
Patient Care Procedures*											Services that potentially generate a bill. Example: blood draws, radiology, clinic visits
Initial Office Visit (MD)	99201		M								These patients are already regular clinic patients. Drawn w/ SOC labs, but processed by coordinator and shipped out centrally.
FU Office Visit (M.D.)	99213				M		M		M		
ECG	93010		S			S			S		
PK sampling											
Hematology	85025		M			S		M	M		
Serum Preg. Test	84702		S		S		S		S		
Administrative Costs											Example: Consenting, Patient Stipend, Survey, Research Questionnaire
Informed Consent	NA		S								Done after clinic visit.
Coordinator Fee	NA		S	S	S	S	S	S	S	S	
PI Fee	NA		S	S	S	S	S	S	S	S	
Pt reimbursement for travel	NA		S	S	S	S	S	S	S	S	

1. To add additional "visits," right click on last "visit" column, choose "insert," and choose "entire column."

2. Save the study calendar.

If you have questions regarding this form, please contact JHS Clinical Trials Office at: clinicaltrialsoffice@jhsmiami.org