Instructions for Completing a Clinical Research Billing Calendar

- Fill out all sections at the top of the Billing Calendar
  - Include the full study name. You can include the local identifier (e.g. UMCC #) at the end of the full study name.
  - Include a "shortcut" name you will use to refer to the study among the study team.

- To complete the Billing Calendar, use the study calendar/schedule of events from the protocol (if included) as the starting point.
  - If included, the schedule of events typically is a summary of the items or services for the protocol.
  - You will need to check the protocol narrative for information or testing that may have been left off the schedule of events.
  - If a service or item (e.g., test or procedure) may (but not always) occur, you should include this item or service on the Billing Calendar.

- As the protocol is reviewed, enter the name of any tests, procedures, devices or research specific requirements in the rows under the appropriate headings (shaded grey areas).
  - When describing the service or item, please be as specific as possible in order to assist with appropriate designation of billing codes.
  - A good way to think about the calendar is that the item/service listed on the billing calendar should be specific enough to be matched up with a billing code. All billable items/service should be listed on the calendar. The only exception is for planned inpatient stays provided within the context of the research. Please see page 2 for additional information regarding inpatient stays.
  - The Misc. heading should be used for items that do not fit under any of the other headings or for items that would not be considered billable but the study team wants reflected on the billing calendar (e.g., study questionnaire).
  - Change the “Day/Week/Month” cells at the top to the specific timeframes that align with the study protocol.
  - Delete any unused rows or columns.

- Complete a separate calendar for each arm of the study as per protocol.
  - Assign a logical name for the study arm(s) and enter it into the light yellow cell found at the upper left of the spreadsheet, Column A, Row 1.

- Determine who is to pay for the item or service. Reference the informed consent, study budget, standard protocols and Medicare LCDs (Local Coverage Decisions) and NCDs (National Coverage Decisions). See http://www.cms.hhs.gov/mcd/search.asp
  - Using the Clinical Research Billing Key found in the upper right of the Billing Calendar, enter the appropriate abbreviation in the cell corresponding to the specified time frame. Please shade any unused cells to signify that they were intentionally not used.

- Any item or service designated on the billing calendar as “routine” must be supported with appropriate documentation. Such documentation should be readily available in the event of an internal audit conducted by your department, the UMHS Compliance Department, health plans or government programs such as Medicare or Medicaid. For additional guidance, see the CRBU FAQ on routine care at: http://www.med.umich.edu/u/medschool/research/crbu/crbfaqs.htm

- Check to be sure that your Billing Calendar is consistent with your Informed Consent, Budget (if any) and Contract (if any).
  - For example, the Informed Consent cannot promise no charges to the subject if anything on the Billing Calendar is Routine Care, and therefore billable to his/her insurance.
  - We understand that you may not have final budgets or contracts and can work with draft versions of these documents.
  - We are only concerned with the parts of the contract related to billing and charges.

- You do not need to submit the billing calendar with the CPT/CDM codes filled in. The CRBU will work with the respective billing units to obtain the proper billing codes for the listed items/services. Billing staff may contact you with questions in order to select the appropriate billing code.

- After billing codes have been added to the billing calendar, a new version will be sent back for PI signature. The principal investigator is required to sign the bottom certifying to the accuracy of the Billing Calendar. A pdf version of the signed billing calendar must be returned to the CRBU and is required for the completion of the review process. If a pdf version cannot be sent electronically, the signed Billing Calendar can be faxed to 8-6634.
Additional information for research involving inpatient stays:

- For inpatient stays, every item/service to be paid for with research or sponsor funds must be listed on the billing calendar with enough detail that billing codes can be assigned.

- Items/services to be provided within the context of the research that are considered routine costs and will be billed to the subject and/or insurance provider should be listed in general terms, but not every billable item/service needs to be listed. For example, just list the name of the procedure for a surgery (i.e. appendectomy). You do not need to identify all of the medications and supplies to be used during the surgery.

- For known inpatient days/visits, please include “Inpatient” in your description when you change the “Day/Week/Month” cells at the top to the specific timeframes that align with the study protocol.