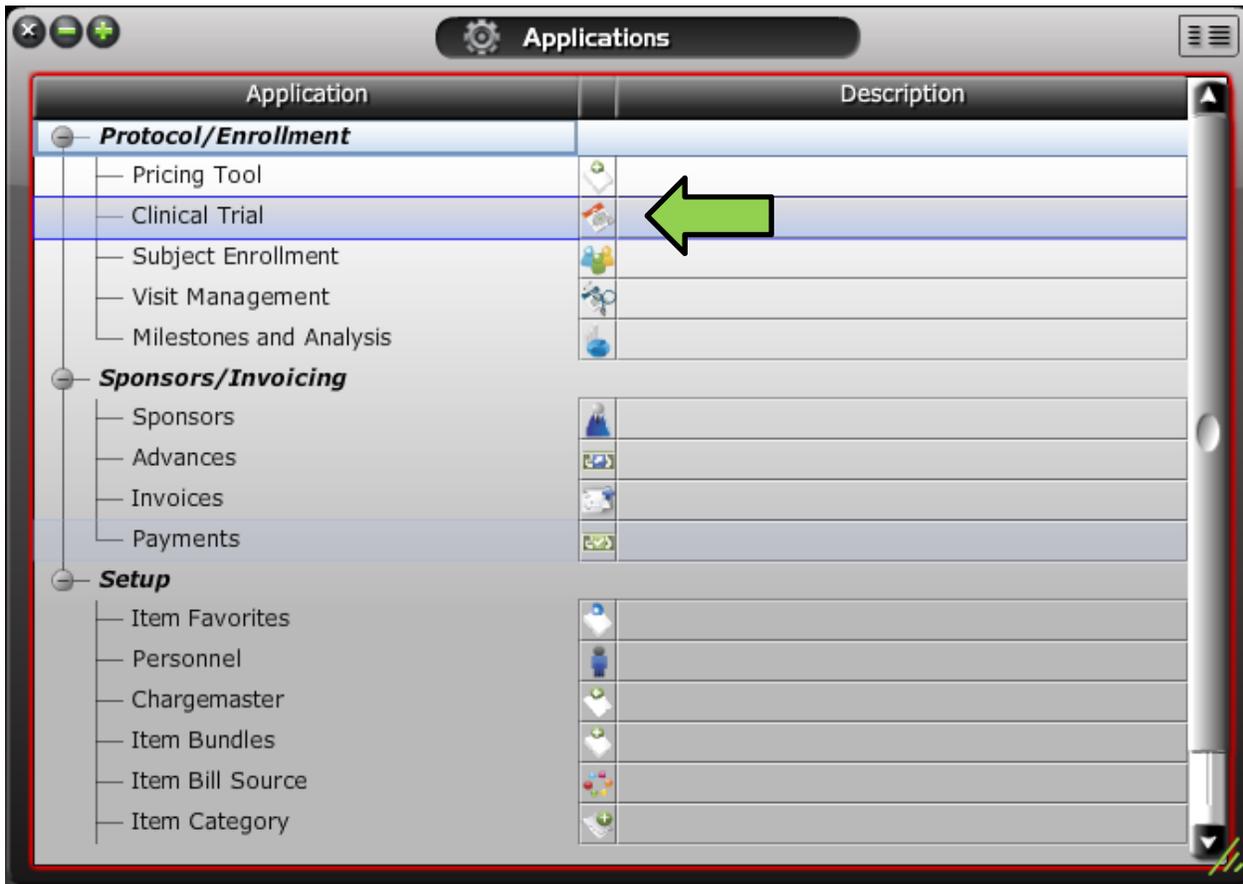


Steps to Create an Exempt Billing Calendar for Enrollment in MBECT

Why does my study need to enter enrollment in MBECT?

- Updates to the Clinical Research Billing and Enrollment Policy require this effective **January 1, 2014**.
- All trials that have a billing calendar and/or meet the definition of a UM Clinical Trial are required to enroll in MBECT, **including Clinical trials exempt** from completing a billing calendar.
- **A UM Clinical Trial is defined as:** a prospective, biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, biologics, treatments, devices, procedural interventions, or new ways of using known drugs, biologics, treatments, or devices); behavioral interventions are intended to prevent or treat an acute or chronic disease or condition.
- **Enrollment must be entered in MBECT no later than the same day the informed consent is signed.** The timely submission of enrollment information, in conjunction with the final approved billing calendar, is essential for compliant routing of charges and insurance claim submissions.
- For the complete updated policy please visit:
<http://www.med.umich.edu/i/policies/umh/01-04-701.htm>

Double click on the name “Clinical Trial” or single click on the icon in the Applications menu.



Click on the “Add” button in the new Clinical Trials window that opens.



Complete the required fields, which are indicated by the asterisks (*).

From this screen you can complete the Title and HUM.

To add your investigator, click on the ellipsis (...) box next to the field.

The screenshot shows a software interface with the following fields and elements:

- * Title:** Study Title (indicated by a green arrow pointing to the asterisk)
- Protocol #:** (empty field)
- * Investigator:** Rocky And Bullwinkle (indicated by a green arrow pointing to the ellipsis button next to the field)
- * Start:** 07/01/2012 (calendar icon)
- * End:** 06/30/2013 (calendar icon)
- HUM:** 00099999 (indicated by a green arrow pointing to the asterisk)
- Custom Fields:** (button)
- Header:** (tab)
- Financial:** (tab)
- Startup:** (tab)
- Coordinator:** (empty field with ellipsis button)
- * Sponsor:** (empty field with ellipsis button)
- Full Title:** (empty field)

A dialogue box will appear. Highlight the name of your investigator(s) and use the “Add” button or double click to select them.

Note: if you have multiple investigators, you will need to scroll to the right and select the check box to indicate which investigator is primary.

After your selections click “OK”.



NOTE: If you do not see the investigator you need, please refer to our Personnel Input module.

Use the ellipsis (...) next to Sponsor to complete that field.

The screenshot shows a software interface with a form. The form has several fields: * Title: Study Title; Protocol #: ; * Investigator: Rocky And Bullwinkle; * Start: 07/01/2012; * End: 06/30/2013; HUM 00099999; and a blue button labeled 'Custom Fields'. Below the form is a sidebar with buttons for 'Header', 'Financial', and 'Startup'. To the right of the sidebar are fields for Coordinator, * Sponsor: my sponsor, and Full Title. A green arrow points to the 'Custom Fields' button, and another green arrow points to the ellipsis (...) next to the Sponsor field.

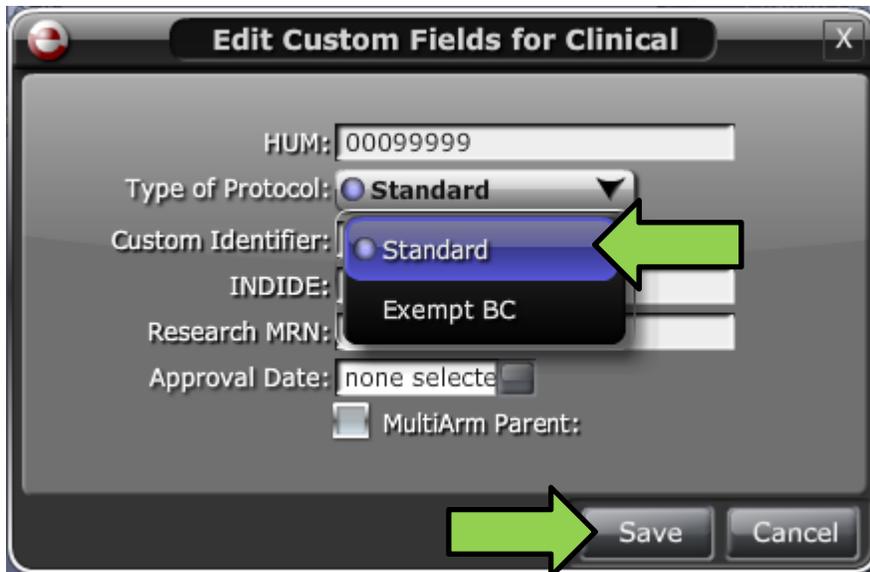
Once finished, click “Custom Fields”.

From the dialogue box, select your Type of Protocol from the drop down menu. Studies that require a billing calendar will be “Standard”, those that do not will be “Exempt BC”.

Note: if you aren't certain, check with your CRAO Analyst.

If your study involves investigational drugs or devices you may have an IND or IDE number. If you do, please complete the INDIDE field.

Once you have finished click “Save”.



Back on the main page click “Save”.



The screenshot shows a software interface for setting up a study. At the top, there is a toolbar with buttons for 'Print', 'Filter', a help icon, a settings icon, and a 'Save' button. A green arrow points to the 'Save' button. Below the toolbar, the form contains several input fields: 'Title' with the text 'Study Title', 'Protocol #' (empty), 'Investigator' with 'Rocky And Bullwinkle', 'Start' with '07/01/2012' and 'End' with '06/30/2013', and 'HUM' with '00099999'. There is a 'Custom Fields' button and a 'Global' checkbox. At the bottom, there are tabs for 'Header' and 'Financial'. The 'Header' tab is active, showing 'Coordinator' with 'Rocky And Bullwinkle' and 'Sponsor' with 'my sponsor'. There are also checkboxes for 'Deemed & Qualified' and 'Inactive'.

These are the only mandatory fields to set up a study for the purposes of enrollment. Additional fields are available for a user building a billing calendar. Those fields are explored in our other Billing Calendar modules.

For further information on entering enrollment, please refer to our Subject Enrollment module.