

Enrollment Policy Frequently Asked Questions

1) The policy is in effect as of 1/1/14. View the policy here:
<http://www.med.umich.edu/i/policies/umh/01-04-701.htm>

2) Does this impact me? Do I have to do something different?

- a. The only studies that have to do something different are studies that are:
 - i. Not required to have a billing calendar **and**
 - ii. Are considered a U of M clinical trial.
- b. Nothing changes for anyone else.

Required to have a billing calendar?	Considered a U of M clinical trial?	Does this change my process?
Yes	Yes or No	No
No	Yes	Yes
No	No	No

3) That is me! What do I do?

- a. There are **three** essential activities:
 - i. Create an exempt billing calendar in MBECT in less than ten steps.
 - 1. <http://tinyurl.com/MBECTexempt>
 - ii. Request an RSH (defined starting at Question 13).
 - 1. http://www.med.umich.edu/i/mcit/cust_srvc_ctr/rm/rm_TSn.htm
 - 2. For assistance, contact the MiChart Research Application Coordinators (RACs) at MiChart-Research@med.umich.edu
 - iii. Enter subject enrollment in even fewer steps.
 - 1. <http://tinyurl.com/MBECTExemptEnroll>

4) What does it mean that my study is “billing calendar exempt”?

- a. These studies are not required to have a billing calendar. To understand if you meet this requirement:
 - i. Refer to our website:
 - 1. <http://medicine.umich.edu/medschool/assets/research/exemption-determination-form>
 - ii. Contact your CRAO analyst:
 - 1. <http://medicine.umich.edu/medschool/assets/research/rescraodepartmentlist>

5) My study is exempt and this is a lot of work for my team. Why do I need to do this? What value does this add to research?

- a. Research is one of our key missions at the University of Michigan and a goal was set to double patient participation in research over the next five years.

- b. With our old enrollment policy, we could not quantify patient participation in research because it was fragmented in multiple systems and incomplete. This made it impossible to measure whether we had achieved our goal and inhibited our ability to effectively plan for the future of Research at our institution.
- c. MBECT was chosen as the place for enrollment data entry. Now we will be able to successfully measure our progress and the health of our Research infrastructure.

6) I'm not sure if I am a U of M clinical trial. Who can I ask?

- a. A U of M 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."
- b. Study teams that feel comfortable making this distinction for themselves are empowered to do so. This is recorded in section 1-2.7 of the IRB application in eResearch.
- c. For study teams that would like more guidance as to their clinical trial status, please contact Regulatory Affairs.

7) Why are we using the U of M definition of a clinical trial?

- a. Research at the University of Michigan is diverse and a broader definition was chosen to be more inclusive for teams that do things like behavioral intervention that may not fit the National Institute of Health (NIH) or clinicaltrials.gov scope. This definition was chosen to represent more accurately the wide range of research we do here.
- b. Research leadership asked a number of study teams to help write a definition that gave them the power to decide for themselves whether or not they are a clinical trial.

8) How do I know if I need to enter enrollment in MBECT?

- a. If you are **required to have a billing calendar** then you must enter enrollment in MBECT. This policy was already in effect before 1/1/14.
- b. If you are **not required to have a billing calendar, but are considered a U of M clinical trial**, then you must enter enrollment in MBECT. This is a new policy effective 1/1/14.
- c. If you are **not required to have a billing calendar, and are not considered a U of M clinical trial** you do not have to enter enrollment in MBECT.

Required to have a billing calendar?	Considered a U of M clinical trial?	Required to Enroll in MBECT?	Effective date
Yes	Yes or No	Yes	Prior to 1/1/14
No	Yes	Yes	1/1/14
No	No	No	Prior to 1/1/14

- 9) **My study was enrolling subjects before 1/1/14. I was not required to have a billing calendar but it is a U of M clinical trial. Do I need to enter subjects if _____?**
- This policy only affects enrollment from 1/1/14 forward.** Study teams do not need to enter subjects who were enrolled prior to 1/1/14, even if they are still considered active on the study.
 - Here are some common scenarios for subjects enrolled **prior to 1/1/14** that study teams have asked about. **Do I need to enter this subject if.....**

My study is closed to accrual.	No, this policy only affects enrollment from 1/1/14 forward.
My subject is in follow-up.	No, this policy only affects enrollment from 1/1/14 forward.
My subject enrolled prior to 1/1/14 and is still active on the study.	No, this policy only affects enrollment from 1/1/14 forward.
My study is closed to enrollment and subject participation but open for data entry/verification/analysis and preparation of publications.	No, this policy only affects enrollment from 1/1/14 forward.
My subject enrolled after 1/1/14 but failed the screening.	Yes. Screen failures after 1/1/14 should be counted for enrollment.
Another scenario not represented here.	Contact CR2-AO@med.umich.edu for assistance.

10) **I'm in a multi-site study. Do I need to enroll subjects from other sites?**

- If the other sites have a site PI, you do not need to enter enrollment for those sites.
- If a U of M PI is serving patients at other institutions as part of the study and serving as the PI at those sites, those patients need to be enrolled, even if they are not U of M patients.
- EXAMPLE:** A study is occurring with U of M and Henry Ford. Henry Ford **does not** have a site PI so a U of M PI goes to Henry Ford and works on the study. The U of M PI must enroll those Henry Ford patients in MBECT.
- EXAMPLE:** A study is occurring with U of M and Henry Ford. Henry Ford **does** have a site PI and a U of M PI goes to Henry Ford and works on the study. The U of M PI does not need to enroll those Henry Ford patients in MBECT.

11) **How do I enroll non-U of M patients if MBECT requires them to have a Medical Record Number (MRN)?**

- For subjects that are not U of M patients, enter "99999999", or nine "9"s, in the MRN field.

The image shows a close-up of a form with two input fields. The first field is labeled '*Med Rec Num:' and contains the text '99999999'. A green arrow points from the right towards this field. Below it is another field labeled '*First Name:' which is currently empty.

12) I already enter my subjects in Velos. Do I need to enter them in MBECT, too?

- a. **No.** Enrollment from Velos is imported into MBECT automatically. If your study does not require a billing calendar, you will still need to build an exempt billing calendar in MBECT and request an RSH. Refer to questions 3 and 15 for additional details.

13) What is an RSH or an NB RSH?

- a. The **RSH** is the name for the research study record in MiChart. It contains information like the study name, PI, HUM, and if there are any procedures associated with the study for billing.
- b. An **NB RSH** is a Non-Billable RSH, where there are no procedures associated with the study for billing.

14) Why do I need an RSH?

- a. The RSH is the component that lets MBECT talk to MiChart about studies and enrollment. Even for studies that have no research billing components the RSH has important functions.
 - i. An RSH is necessary to prevent errors from triggering in the MiChart enrollment work queue.
 - ii. Best Practice Alerts (BPAs) can only be triggered from studies with an RSH.

15) Do I need to do something to get an RSH?

- a. **Studies with billing calendars** are created differently. As you complete your billing calendar and application, your RSH is created for you. If you are required to have a billing calendar then you do not need to take additional steps to get an RSH.
- b. **Studies that don't require a billing calendar but are a U of M clinical trial** need to enter enrollment, and therefore need an RSH. Those studies need to complete a form to have one created. To request an RSH, complete a form here:
 - 1. http://www.med.umich.edu/i/mcit/cust_srvc_ctr/rm/rm_TSn.htm
 - 2. For assistance, contact the MiChart Research Application Coordinators (RACs) at MiChart-Research@med.umich.edu
- c. **Studies that don't require a billing calendar and are not a U of M clinical trial** do not have to enter enrollment and do not need an RSH.

Required to have a billing calendar?	Considered a U of M clinical trial?	Need an RSH?	Required study team action?
Yes	Yes or No	Yes	No
No	Yes	Yes	Yes
No	No	No	No

16) I have a different question than anything I see here.

- a. Please feel free to contact us at CR2-AO@med.umich.edu.