Rate Change Work Group - Business Rules/FAQ

These questions and answers address the change of cost-sharing rates at MCRU. Please note that this is an iterative process that will be completed over two years, ending in June 2017. As such, all information is subject to change, as we gain experience that informs our future approach.

Have a comment or experience to share? Send it to MCRU Administration.

How do I know which rate structure (Industry Sponsored, Investigator Initiated) applies?

The different hourly rate is determined by the funding mechanism(s) chosen in the initial MCRU eResearch application for the protocol.

Industry sponsored studies are generally requested and funded by an industry partner. Investigator initiated studies are driven by PI and may be funded by a variety of means, including federal, foundation, department, pilot, or discretionary funds.

How do I know if my protocol will be billed at the old rate or the new rate?

For Industry Sponsored studies, those with contracts signed AFTER July 1, 2015 will be billed at the new rate. MCRU will determine this by checking the PAF.

For Investigator Initiated studies with department or discretionary funding, those with IRB approval AFTER July 1, 2015 will be billed at the new rate.

AFTER June 1, 2017, ALL STUDIES will be billed at the new rates.

What does the Administrative Life Cycle Fee include?

The Administrative Life Cycle Fee includes all costs related to the personnel responsible for protocol initiation, protocol specific staff education, protocol amendments, scheduling, and other administrative activities surrounding protocol execution at MCRU.

When is the Administrative Life Cycle Fee billed?

The Administrative Life Cycle Fee is billed once at the beginning of each protocol. This will usually be at time of the Protocol Initiation Meeting.

Can the Administrative Life Cycle Fee be billed in installments over the course of the protocol?

No. The Administrative Life Cycle Fee must be billed, in its entirety, at one time.

What if I do not have a short code when I try to schedule an initiation meeting?

You will still be allowed to schedule an initiation meeting. However, your protocol will not be approved without a short code.

How are billable hours determined for Lab Only?
Lab Only services are billed for a minimum of an hour per visit and may be billed for more time depending on the complexity and number of samples. This will be determined at the Protocol Initiation Meeting and included in the budget from the beginning.

How is MCRU2U billed?

MCRU2U can be billed two ways depending on the location of service:

On campus, MCRU2U is billed in half hour increments, with a minimum service of one half (1/2) hour. It is billed at the All Inclusive Bundled rate. This is applicable for prescheduled, just-in-time, or drop-in visits.

In the community, MCRU2U is billed in one hour increments, with a minimum service time of one hour. This is billed at the MCRU2U specific rate.

What constitutes “on campus” versus “in the community” for MCRU2U?

“On campus” constitutes the major sites within the U-M Medical or Central Campuses, which have included the Hospital, the Taubman Center, Mott Children’s Hospital, and the Cancer Center, as well as the School of Public Health and the School of Dentistry. Domino’s Farms and all of its lobbies are also considered to be “on campus,” as MCRU has a clinic on site.

“In the community” covers any site to which driving is required, such as patient homes, off site clinics, and off site locations within the U-M Health System, including the East Ann Arbor and Briarwood locations.

Is a MBECT billing calendar required?

No. MCRU does not require a billing calendar (institutional requirements still apply). MCRU does require a Time and Events Table, however, which can be generated through MBECT. For studies that are not required to have a billing calendar, some templates have been provided.

How are the billable hours determined from a patient visit?

Billable hours include only the time the participant is present in MCRU and are determined from participant check-in to check-out.

Can I use Space Only time after regular MCRU hours?

No. Space Only appointments will only be booked during regular business hours. At Domino’s Farms, this includes all rooms 8:00 am - 4:30 pm, Monday through Friday. At the CVC location, one room is dedicated to Space Only appointments 8:00 am to 8:00 pm Monday through Saturday, while all other rooms are available 2:00 pm – 8:00 pm Monday through Friday and 2:00 pm – 4:30 pm Saturday.

All appointments are booked on a first-come, first-served basis.
I have an industry sponsored study currently being billed at the old rate. Can I request an adjustment to the new rate?

Yes. Any industry sponsored study can request an adjustment to the new rate ($125/hour) without any additional initiation fees if done so before January 1, 2016.

All industry sponsored studies will be switched to the new rate automatically on June 1, 2017.

What do each of the a la carte options include? (What does Space Only include? What does Lab Only include?)

Space Only includes:

- Participant check-in,
- Participant roomed,
- Supplies within the room (linens, equipment, gloves),
- Snacks for the participant if required, and meals for those who stay longer than 4 hours (CVC location only).

**Space Only option is available only to investigator initiated studies.**

Lab Only includes:

- Services of the skilled laboratory staff to process protocol specific samples,
- Supplies for processing samples, with the exception of unique or protocol-specific reagents,
- Well maintained equipment for processing samples,
- Shipping.

**Laboratory Only is available to both investigator initiated and industry sponsored studies.**

MCRU2U includes:

- Services of the appropriate scope to perform a protocol specific blood draw, skin biopsy, or EKG, and document the encounter in MiChart,
- Supplies for collecting samples,
- All items within Lab Only services.

**MCRU2U is available to both investigator initiated and industry sponsored studies.**

All Inclusive Bundled Rate:

- Space in MCRU to perform protocol specific clinical research activities,
- Services of the appropriate skilled laboratory technicians to perform protocols specific sample processing and the necessary equipment and supplies to do so,
- Services of the appropriate skilled nursing staff able to perform protocol specific clinical research functions and document those activities in MiChart,
- All supplies necessary for clinical and laboratory procedures with the exception of unique or protocol-specific items.

**Can Space Only be combined with other services?**

For each visit, you will only be allowed to select one service type: Space Only, Lab Only, MCRU2U, or All Inclusive. These service types cannot be combined within one appointment request.

Multiple, consecutive appointments for the same participant on the same study will be converted to a single appointment at the All Inclusive service level.

The exception is the Nursing Fee, as it is an ad hoc charge (56/incident) for a single service from a nurse, such as a blood draw or IV insertion. This service can be requested as needed during a Space Only visit. These services are already included as part of any MCRU2U or All Inclusive appointment. This service cannot be requested as part of a Lab Only visit.

**What about Bionutrition or DEXA?**

Services of the Nutrition and Obesity Research Center, including bionutrition, specialized research meals, and DEXA are always billed separately.

**Can MCRU2U be used to pick up blood samples that the study team has drawn?**

No. MCRU2U cannot be used as a courier service to pick up or drop off specimens or supplies. MCRU2U personnel are only available to perform research related blood draws, skin biopsies, and EKGs. They can only transport specimens they have obtained from these procedures to the MCRU Specimen Processing lab.

**How will I be billed for extended stay visits?**

Extended stay visits will be billed at the All Inclusive rate for each hour the participant is in MCRU. This includes both regular hours and overnight.

**What if my team unexpectedly needs a nurse during a Space Only visit?**

In a true emergency, study teams should always follow appropriate clinic procedure and contact an emergency response team. Participant safety should never be put in danger.

If the study team unexpectedly requires the assistance of the MCRU clinical staff for research related tasks such as a blood draw, a request can be made at the nursing station. A one-time Nursing Fee will be assessed to the visit, in addition to the Space Only cost.