



ICTR Clinical Research Unit Fees for Industry-Funded Studies (updated July 2019)

Change/Amendment Fees:

- 1) Changes to an already-approved industry protocol impacting CRU flow sheets, changes in charge codes, or other documents and/or procedures will incur the following fee:

- \$250 fee for each occurrence

Examples:

- *Original protocol approved Visit X for inpatient status, and research group wishes to change Visit X to outpatient status for subject Z.*
- *Additional study days are added (e.g., study is approved for outpatient visits on Days 1 and 3, and a request is submitted to add Days 2 and 4).*
- *Change affects procedures being done during the standard CRU admission/visit (e.g., additional labs being drawn, additional medications being given).*

Clarifications/comments:

- Any change from Inpatient to Outpatient status must continue to meet CRU guidelines (outpatient visit lasts no longer than 10 hours AND subjects are discharged prior to 9pm) AND be allowable per the sponsor protocol.
- In the case of a change from Inpatient to Outpatient status (or vice versa), it is the responsibility of the study team to determine whether a change of protocol needs to be submitted to the IRB.
- Changing or creating new flow sheets and orders requires considerable time, and the ability of the CRU to accommodate this request is dependent on available resources.
- There is no change fee when a subject originally scheduled for an outpatient visit arrives and his/her condition requires admission as an inpatient (or vice versa).

- 2) Requests for “RUSH” implementation will incur the following fee:

- \$250 fee for each request

Example: Research group indicates a subject is identified to start, but the CRU processes have not been finalized and/or reservations have not been released for subject enrollment.

Instructions:

- Email requests for the “Rush” service should be sent to the CRU Protocol Team email (cruprotocolteam@uwhealth.org). CRU protocol team staff will forward to other CRU staff as needed.

Clarifications/comments:

- A Rush request requires the CRU to give priority to the protocol (including, but not limited to, special meetings, development and release of reservations, completion of orders, changes in flow sheets, etc).
- The Rush request requires moving a nurse off another protocol for quick turnaround to meet the special timeline, and often necessitates calling in a nurse to help complete the process to satisfy the request for an early start to the protocol.
- The CRU will do everything possible to enable a subject to begin a research study under a Rush scenario and request, but there may be times when the timeline is not doable and the request impossible to meet.
- If a Rush request is sent and implementation begins, the \$250 charge will be billed even if the study team decides not to complete the early visit (or the subject cancels).
- Rush fees can apply to initial study start-up or to amendments.

UW ICTR Partners

Protocol Review and Implementation Fee

1) Industry-sponsored protocols will be assessed one of the following Protocol Review and Implementation fees, regardless of number of subjects requested in the initial CRU application:

- \$1250 for protocols that do NOT require the option of scheduling Inpatient or Outpatient status within ONE subject visit

Example: Visit X always Inpatient and Visit Y always Outpatient

- \$1500 for protocols that DO require the option of scheduling subjects as Inpatients or Outpatients within ONE subject visit

Example: Visit X to allow Inpatient or Outpatient status based on subject needs

Clarifications/comments:

- Outpatient visit option must meet CRU guidelines (outpatient visit lasts no longer than 10 hours AND subjects are discharged prior to 9pm) AND be allowable per the sponsor protocol.
- If a study's status later changes where the option of scheduling a study visit as either an inpatient day or outpatient visit is needed, an additional \$250 fee will be billed.

All Change/Amendment, Rush, and Protocol Review and Implementation fees will be billed against the study's research account.

Please direct any questions to the CRU Protocol Manager Danielle Gale (dgale@uwhealth.org).

(Ver 7/15/19) (new letterhead, removed MJW as contact)