

UW ICTR Clinical Research Unit (CRU)

CHARGE GUIDANCE

CRU is a service supported by the UW-Madison Institute for Clinical and Translational Research (ICTR).

This guide is intended to provide direction for study teams during budget development.

Please contact the CRU Protocol Team (CRUProtocolTeam@uwhealth.org) or Protocol Manager (Danielle Gale, 262-3005 or dgale@uwhealth.org) if further assistance or clarification is needed.

Note: If the study is an industry-funded study, please remember to account for a CRU Proposal Review and Implementation Fee (and potential amendment review fees).

- When applying these charges in the OnCore system, choose the appropriate service(s); then select the CRU Cost Center.
- Overnight (OSS) Visit Charges
 - Participant must stay overnight if anticipated discharge time is after 9:00 pm OR visit duration is greater than 12 hours.
 - The status of either an overnight stay/OSS or outpatient visit will be determined by the CRU at the time of budget review.
 - Changes/amendments to the protocol or procedures done by the CRU nursing staff may result in the need to make budget revisions.

OVERNIGHT STAYS	CHARGE CODE	Definition/Notes
OUTPATIENT SHORT STAY (OSS)	OSS RECOVERY 1ST HOUR (HBX0018) OSS RECOVERY EACH ADDITIONAL HOUR (HBX0019)	<ul style="list-style-type: none"> • For overnight stays (formerly “Inpatient Admissions”) • Charged an initial “1ST HOUR” charge, followed by an hourly charge for the duration of the stay <ul style="list-style-type: none"> – Study Team is responsible for estimating the length of stay for each study visit – Study Team is responsible for determining if any Professional Fees will apply • “OSS RECOVERY” includes CRU research-related nursing services, such as blood draws, sample processing and vital signs. <ul style="list-style-type: none"> – Current exceptions include: <ul style="list-style-type: none"> ▪ Drug administration (infusions, pushes, injections; no charge for oral) ▪ ECGs that are performed by CRU staff on study provided equipment (HB93005A) ▪ Holter Monitor set-up by CRU staff on sponsor-provided equipment (HB93225)

*** NOTE: Services provided by CRU nursing staff do not generate UW Medical Foundation (UWMF) professional fees.**

Some examples of services provided by UWMF and UW SMPH departments that could generate professional or other fees include physicals performed by the admitting MD or APP, ECG interpretation, and some Respiratory Therapy procedures. These fees are applicable to both OSS and outpatient services. Please contact the provider for details.

➤ Outpatient Visit Charges

- **All outpatient visits will be charged one visit level or room use charges.**

Note: Visit charges are bundled to include vital signs, pulse oximetry (single timepoints only; continuous pulse oximetry not included – see additional procedure charge on pg. 7), blood draws, and sample processing.

- **“Visit duration”** is determined by the CRU staff using the following as a guide, based on what is expected for the visit:
 - UWH Labs (if planned to be drawn on CRU) = 1hr
 - If only UWH upreg = 20min
 - ECG = 15min + wait time between ECGs if duplicate/triplicate
 - VS = 5min + wait time for repeat measures
 - Ht/Wt = 5min
 - Waist/Hip = 5min
 - Physical exam (PE) = 30min
 - RN assess / obtain ok to treat = 30min (included for all medication administration visits)
 - Blood draw = 15min (single timepoint only; not counted for serial blood draws)
 - Lumbar puncture (LP) = 1.5hr (includes PE through 20min post-LP monitoring)
 - Add additional time if the participant needs to lay flat or be monitored for more than 20min post-LP.
 - Pre-meds = 30min (add more time if study protocol requires pre-meds to be administered more than 30min in advance)
 - Medication administration = 2h drug prep + medication administration time + wait time between drugs
 - Add length of post-dose or post-procedure monitoring and/or timepoint (e.g., monitor 60min post-dose or 4h post-end of infusion PK).
 - Note: Timed pre-dose activities require additional time to be added because the activity will not be performed until drug arrives (e.g., ECG within 30min of dose-start).
- Procedures are billed separately in addition to the Visit Level charge – see pages 5-7.
- Sample processing “Grades” are defined on page 4.

OUTPATIENT VISIT	CHARGE CODE	FREQUENCY CHARGED	DEFINITIONS / NOTES
Level-0	HBCRUL0	Once per outpatient visit	<p><u>Must meet ALL criteria:</u></p> <ul style="list-style-type: none"> - Visit duration of ≤ 30 minutes - A maximum of one blood draw - No sample processing by CRU
Level-1	HBCRUL1	Once per outpatient visit	<p><u>Visit does not meet Level-0 criteria AND meets one or more of the following criteria:</u></p> <ul style="list-style-type: none"> - Visit duration ≤ 2 hours - ≤ 2 blood draw timepoints - Sample processing by CRU (Grade-1 only)
Level-2	HBCRUL2	Once per outpatient visit	<p><u>Meets one or more of the following criteria:</u></p> <ul style="list-style-type: none"> - Visit duration ≤ 4 hours - ≤ 5 blood draw timepoints - Sample processing by CRU (Grade-2)
Level-3	HBCRUL3	Once per outpatient visit	<p><u>Meets one or more of the following criteria:</u></p> <ul style="list-style-type: none"> - Visit duration < 8 hours - Study requires dedicated blinded/unblinded RNs separate from assigned nurse - < 10 blood draw timepoints - Sample processing by CRU (Grade-3)
Level-4	HBCRUL4	Once per outpatient visit	<p><u>Meets one or more of the following criteria:</u></p> <ul style="list-style-type: none"> - Visit duration ≥ 8 hours but < 12 hours and discharged prior to 9pm* - Visits that include dosing with a theranostic agent (requiring additional room time for isolation set-up/take-down and clearance by Radiation Safety) - Cardiac monitoring required during visit (i.e., Telemetry) - ≥ 10 blood draw timepoints <p>*Participant must be admitted overnight for OSS if visit duration expected to run greater than 12 hours or discharge planned after 9pm.</p>
ROOM USAGE FEE PER HR	HBCRURU	Charged per hour of room use. After 15 minutes, charge is rounded up to the next hour (i.e., If room use is 1hr + 10min, charge applied is 1hr. If room use is 3h + 20min, charge applied is 4hs).	<p><u>Visit does NOT involve CRU nursing services (use of CRU room only).</u></p> <ul style="list-style-type: none"> - If room use only is planned and nursing care becomes necessary, a visit and other applicable charges will apply. - CRU application must clearly outline the procedures that will be conducted by study staff; these services will need to be reviewed and approved by CRU PIR.

➤ (CRU LAB) SAMPLE PROCESSING GRADES

- Highest applicable processing grade will apply to entire visit; even if only applicable to one timepoint.
- Timepoint refers to the different collection times (e.g., pre-dose, 1 hour post).
- Blood processing, Urine, and Lumbar Puncture (LP) processing count as 3 separate timepoints.

<p>Processing Grade-1</p>	<ul style="list-style-type: none"> ▪ Simple processing, which includes one or more of the following criteria: <ul style="list-style-type: none"> - No more than 2 different sets of centrifuge instructions (temp/speed/time) per timepoint; (i.e., can batch all samples into 2 centrifuge spins) - No centrifuge needed, but refrigerate, freeze, or freeze after a certain time - Sample transfer next day (e.g., -20° to -80°)
<p>Processing Grade-2</p>	<ul style="list-style-type: none"> ▪ Mid-level processing, which includes one or more of the following criteria: <ul style="list-style-type: none"> - No more than 3 different sets of centrifuge instructions (temp/speed/time) per timepoint; (i.e., can batch all samples into 3 centrifuge spins) - Buffy coat or slides - Priority processing (e.g., centrifuge immediately or within ≤ 30min) - Documentation of processing – no more than 2 types of documentation (e.g., centrifuge time, transfer time, freeze time, # of aliquots, volume of aliquots) - No brake for any processing step (i.e., centrifuge required to stop on its own, decel set to 0, adds ~ 20 min extra spin time)
<p>Processing Grade-3</p>	<ul style="list-style-type: none"> ▪ Increased complexity than defined in level 1 or 2, which includes one or more of the following criteria: <ul style="list-style-type: none"> - More than 3 different sets of centrifuge instructions (temp/speed/time) per timepoint; (i.e., need to batch all samples into > 3 centrifuge spins) - Documentation of processing – more than 2 types of documentation (e.g., centrifuge time, transfer time, freeze time, # of aliquots, volume of aliquots) - Samples requiring a double spin - More than 30 cryovials in a single timepoint

➤ PROCEDURE CODES FOR SERVICES PERFORMED ON SPONSOR-PROVIDED EQUIPMENT

– These procedures are billed in addition to Overnight/OSS and Outpatient Visit charges.

PROCEDURE	CHARGE CODE	FREQUENCY CHARGED	Definition/Notes
EKG <u>SINGLE</u> TRACING W/ STUDY EQUIP (RESEARCH ONLY) *	HB93005C	Per ECG timepoint	
EKG <u>DUPLICATE</u> TRACING W/ STUDY EQUIP (RESEARCH ONLY) *	HB93005D	Per ECG timepoint	
EKG <u>TRIPLICATE</u> TRACING W/ STUDY EQUIP (RESEARCH ONLY) *	HB93005E	Per ECG timepoint	
HOLTER MONITOR (Performed on sponsor-provided equipment by CRU nursing staff)*	HB93225	Single charge - includes both connection and disconnection of sponsor-provided Holter monitor	NOTE: If Holter is used for ECG collection, collection must occur automatically, and data extracted from the device by the sponsor/study team. If specific timepoints require collection by CRU staff, ECG charges apply.

* NOTE: A baseline UW Health ECG (within the last 30 days) is required for comparison.

➤ **CHARGES FOR DRUG ADMINISTRATION**

- These charges are used throughout UW Health based on Medicare guidelines.
- **These procedures are billed in addition to Overnight/OSS and Outpatient visit level charges.**
- Items of note:
 - There is no administration charge for oral medications.
 - If drug is a biological response modifier (immunotherapy, such as cytokines, cancer treatment vaccines, and some antibodies, and some targeted therapies), or a monoclonal antibody (usually end in a “-mab” suffix), “Chemo” codes apply.
 - Note: “Primary” represents the primary reason for the encounter/most significant service provided for the patient and is reported irrespective of the order in which the services occur. (On CRU, the research drug would be considered “Primary” if given by IV or injection.)
 - See [UWHC’s IV Infusion Mini Manual](#) for guidance.
 - There is also a Hierarchy that is not defined in UW Health document: See <https://www.hopkinsmedicine.org/-/media/compliance/documents/infusion-guideline-092020.pdf>

PROCEDURE	CHARGE CODE	FREQUENCY CHARGED AND NOTES (TPD = Therapeutic Drug; SQ = Subcutaneous; IM = Intramuscular)
IV INFUSION, HYDRATION 1ST HR	HB96360	For infusions of fluid and electrolytes (e.g., Normal Saline); “1st hour” is 31 min-90 min Primary is used only when no other infusions are occurring at visit; otherwise use HB96360
IV INFUS HYDR EA ADD'L HR	HB96361	For each additional hour over 90 min
PRIMARY IV INFUSION TPD 1ST HR	HB96365	For non-chemo infusion; 1st hour is 16 min-90 min
IV INFUS TPD EA ADD'L HR	HB96366	For each additional hour over 1hr 30 min
SEQUENTL IV INFUSN TPD 1ST HR	HB96367	“1st hour” is 16 min-90 min; use HB96366 for each additional hour
CONCURRENT IV INFUSION GIVEN	HB96368	– Applies to TPD infusions only; 1 occurrence regardless of the length of concurrent infusion – Charge cannot be used for concurrent chemo infusions; use HB96417 (sequential) and HB96415 (additional hour) as applicable
INJECTION SQ/IM	HB96372	For TPD SQ or im injection (not given by peripheral IV)
PRIMARY INJECTION IV PUSH	HB96374	For TPD given by peripheral IV and TPD IV infusions of ≤ 15 min
SEQUENTIAL INJ IV PUSH EACH	HB96375	For TPD given by peripheral IV and IV infusions of ≤ 15 min
SEQNTL INJ IV PUSH EA, SAME DRUG	HB96376	For multiple IV push administrations of the same drug when injections are each 31 min apart
INJ SQ/IM CHEMO NON-HORMONAL	HB96401	Per SQ or IM injection
INJ SQ/IM CHEMO HORMONAL	HB96402	Per SQ or IM injection
PRIMARY INJ CHEMO IV PUSH	HB96409	For chemo drugs given by IV push and IV infusions of ≤ 15 min
SEQUENTL INJ CHEMO IV PUSH EA	HB96411	For chemo drugs given by IV push and IV infusions of ≤ 15 min
PRIMARY IV INFUSN CHEMO 1ST HR	HB96413	“1st hour” is 16 min-90 min; use HB96415 for each additional hour
IV INFUSN CHEMO EA ADDL HR	HB96415	For each additional hour over 90 min
SEQUENTL IV INFUSN CHEMO 1STHR	HB96417	“1st hour” is 16 min-90 min; use HB96415 for each additional hour
IMMUNIZATION ADMIN 1ST	HB90471	For a single or first IM vaccination, use HB90472 for each additional vaccination
IMMUNIZATION ADMIN EA ADDL	HB90472	Used when additional IM vaccinations are administered at a visit

➤ **LESS FREQUENTLY USED PROCEDURES AVAILABLE TO STUDIES ON THE CRU**

- These procedures are billed in addition to Overnight/OSS and Outpatient visit level charges.

PROCEDURE	CHARGE CODE	FREQUENCY CHARGED	Definition/Notes
NEBULIZER TREATMENT/BAGGED	HB94640B	Per occurrence.	The treatment is administered several times a day at short intervals (e.g., 10 min) and is less than 60 min, for treatment for acute airways obstruction (e.g., with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device) – see HB94640D for sputum induction for diagnostic purposes.
OXIMETRY MONITORING	HB94761	Per hour.	Continuous monitoring on machine where no specific timepoints checks are needed.
PUNCTURE SPINAL LUMBAR DX	HB62270	Per procedure.	The LP itself must be performed by a staff member (physician or APP) identified by the study team and credentialed by UW Health to perform an LP. CRU nursing staff assists during the procedure.
SPUTUM INDUCTION	HB94640D	Per occurrence.	Inhalation treatment for sputum induction (e.g., with an aerosol generator, nebulizer, or metered dose inhaler)
INITIATE CHEMO INFUS W/PUMP > 8 HRS	HB96416	Per initiation, using a sponsor-provided pump.	Definition is “Initiation of prolonged chemotherapy infusion [more than 8 hours] requiring use of portable or implantable pump.” This service is usually provided by Home Health, but exceptions are possible. Use of a sponsor-provided pump must be discussed with Home Health and CRU. This is only charged by the CRU if a CRU RN does the pump connect/initiation; otherwise, this is charged by Home Health.
REFILL AND MAINTENANCE OF PORTABLE PUMP	HB96521	Per occurrence.	See HB96416. As noted above, this service is usually provided by Home Health; charge will only be applied if done by a CRU RN.
IRRIGATE IMPLNTD VENOUS ACCESS DEVICE	HB96523	Per occurrence.	Can bill only if this is the only service provided; for example, this charge is allowable if a flush is done for a pump disconnect and pump connect/initiation was not done by a CRU RN (e.g., done by Home Health).
BIOPSY MUSCLE PERCUTANEOUS NEEDLE	HB20206	Per procedure.	The Muscle Biopsy itself must be performed by staff member (e.g., physician, APP) identified by the study team and credentialed by UW Health to perform a Muscle Biopsy. CRU nursing staff assists during the procedure.