

Fee Schedule

Effective for Studies Submitted between
01/01/2019 and 12/31/2020

Clinical Research Unit (CRU) – Sprague and Aston & Investigational Drug Service (IDS) – Aston

The Clinical Research Unit (CRU) and the Investigational Drug Service (IDS) are made possible by UT Southwestern Medical Center, the Clinical and Translational Science Award (CTSA), and the implementation of a cost-recovery program. All revenue collected is invested back into the CRU and IDS in order to maintain service levels and to extend resources and investigator support. Inpatient stays at Zale-Lipshy Hospital are made possible by University Hospitals and UT Southwestern Medical Center.

This fee schedule should be used as a guideline for developing research budgets. Because several fees may vary depending on the complexity of the protocol, study teams **must** submit a *Request for Research Services*, and a meeting with the CRU and/or IDS **must** be scheduled in order to obtain a formal written quote. This should take place prior to the submission of budgets included as part of any grant application or funding request. Failure by a study team to obtain a formal written quote or a coverage analysis will not obligate the CRU and IDS to honor any prior fee schedules that may have been in place at the time any funding requests were submitted by the study team.

Fees are structured on a per hour, per diem, or per service basis and are based on the actual cost incurred by the CRU for providing the service, which includes personnel costs, basic supplies, and any administrative costs related to scheduling and billing. Items which are noted as being charged at “cost” include the actual cost of the item, including overhead.

Important (Please Read Carefully)

CRU and IDS services are only available to investigators who have UTSW IRB-approved protocols (excluding CRU research coordinator services used in conjunction with IRB submissions) and valid Letters of Agreement. Participant scheduling or other services may not occur until the following actions have been completed:

- 1) CRU Inpatient/Outpatient or Zale Lipshy, as applicable, are listed in Velos and eIRB as performance sites;
 - 2) A fully approved Letter of Agreement is in place;
 - 3) The study team has provided all necessary protocol training to the CRU or Zale staff prior to any research visits;
- AND**
- 4) The PI has created an account in **iLab** and:
 - a. Linked at least one valid Chart of Accounts (CoA) for use when scheduling research services (if the PI does not yet have a study CoA, then a departmental CoA **must** be linked to the PI’s iLab account for usage until such time as a study CoA is provided); and
 - b. Study members who will request services or review invoices on behalf of the PI have registered for iLab accounts and been added to the PI’s iLab “lab.”

UNDER NO CIRCUMSTANCES will services be scheduled if there is not a valid CoA linked to the PI’s iLab account. Instructions on how to do this are available upon request.

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OUTPATIENT SERVICES

INVESTIGATIONAL DRUG SERVICE

Administrative Services

Service	Cost
Study Initiation and Closure Fees (one-time fee) – Industry <ul style="list-style-type: none"> • Initial receipt and inventory of investigational agents, • Preparation and maintenance of drug accountability records, • Meetings with investigators and study monitors, • Preparation of protocol synopsis and drug information for pharmacy and nursing, • Randomization chart, • Study termination, reconciliation of drug accountability records, drug returns, • Maintaining record of dispensations – up to 5 years per state law, and • Maintenance of discontinued study file. 	\$2,750.00
Study Initiation and Closure Fees (one-time fee) – Non-Industry	\$2,000.00
Auditing/Monitor Visit (excluding site selection and site initial visit) <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Site selection and site initial visits (SIVs) are not subject to this fee.</i>	\$120.00/hour
Auditing/Monitor Visit (excluding site selection and site initial visit) – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Site selection and site initial visits (SIVs) are not subject to this fee.</i>	\$110.00/hour
Drug Transfer Fee <i>Per transfer. For transfer of study drugs to a different location.</i>	\$75.00
Study Maintenance Fee (monthly)	\$100.00
Study Maintenance Fee (monthly) – NIH-Funded Studies	\$90.00
Storage of Returned Study Drug (monthly)	\$65.00
Storage of Returned Study Drug (monthly) – NIH-Funded Studies	\$55.00
Destruction, per each occurrence	\$75.00
Destruction, per each occurrence – NIH-Funded Studies	\$65.00
Destruction container, per container	\$65.00

Research Services

Service	Cost
Dispensing Fee <i>Per patient, per dispensation. Price varies depending on complexity of dispensation method. Contact IDS prior to budget submission.</i>	\$80.00 - \$400.00
Dispensing Fee – NIH-Funded Studies <i>Per patient, per dispensation. Price varies depending on complexity of dispensation method. Contact IDS prior to budget submission.</i>	\$70.00 - \$380.00
Pharmacist Support <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Includes study meetings, etc.</i>	\$150.00/hour
Pharmacist Support – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Includes study meetings, etc.</i>	\$140.00/hour
Drug Randomization <i>Per hour, billed in 15-minute increments (rounded to the next highest increment).</i>	\$80.00/hour
Non-Sponsor-Provided Drug	Actual Cost + \$10.00 Administrative Fee

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Service	Cost
Supplies: Special-Order Diluent	Actual Cost + \$10.00 Administrative Fee
Supplies: IDS Special-Order Supplies	Actual Cost + \$10.00 Administrative Fee



CLINICAL RESEARCH UNIT

Administrative Services

Service	Cost
Study Initiation and Closure Fee (one-time fee) - Industry <i>Includes:</i> <ul style="list-style-type: none"> • Protocol review, • Formal protocol meetings with study staff to review consents, timelines, requested services, contingencies, etc., • Preparation and circulation of Letter of Agreement, • iLab set-up and study team in-service, • Staff in-service to review protocol requirements (non-complex), • Development of nursing flow sheets, • On-going meetings with investigators and study monitors, and • Preparation and maintenance of patient study files. 	\$750.00
Study Initiation and Closure Fee (one-time fee) – Non-Industry	\$500.00
Study Initiation and Closure Fee (one-time fee) – NIH-Funded Studies	\$300.00
Study Initiation and Closure Fees (one-time fee) – Research Coordinator Services Only <i>If study implementation services are requested at a later date (e.g. room usage, nursing, etc.), the balance of the Initiation and Closure Fee (to total the amount equal to either the Industry or Non-Industry rate, as applicable) will be charged in conjunction with a new Letter of Agreement (LOA) adding additional services.</i>	\$250.00
CRU Study Initiation and Closure Fees (one-time fee) – Metabolic Meal Services Only <i>If study implementation services are requested at a later date (e.g. room usage, nursing, etc.), the balance of the Initiation and Closure Fee (to total the amount equal to either the Industry or Non-Industry rate, as applicable) will be charged in conjunction with a new Letter of Agreement (LOA) adding additional services.</i>	\$250.00
CRU Study Initiation and Closure Fees (one-time fee) – Limited Services <i>Application of this rate will be determined on a case-by-case basis and is at the sole discretion of the CRU. If additional services are requested at a later date, the balance of the Initiation and Closure Fee (to total the amount equal to either the Industry or Non-Industry rate, as applicable) will be charged in conjunction with a new Letter of Agreement (LOA) adding those additional services.</i>	\$250.00
Staff Protocol Training <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Includes attendance at required sponsor training via on-line, phone, or in person, etc.</i>	\$50.00/hour
Record Storage Fee <i>All data collected by CRU staff during research visits shall be the property of the PI, and the PI will be advised, upon CRU closure of a study (CRU services no longer required/requested) or expiration of a Letter of Agreement, when records are available for pick-up. This fee will be charged at the beginning of each month after the expiration of 10 business after notice of availability for pick-up if the study team fails to retrieve the records from the CRU.</i>	\$100.00/month/file box

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Research Services

Services	Cost
Nursing and Coordinator Services <i>Includes basic phlebotomy and nursing supplies only.</i>	
Research Nursing Services <i>Per hour, billed in 15-minute increments (rounded to the next highest increment). Includes nursing admission, infusions, blood draws, and urine collections. Does not include ECGs or supplies.</i>	\$70.00/hour
Research Nursing Services – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment). Includes nursing admission, infusions, blood draws, and urine collections. Does not include ECGs or supplies.</i>	\$65.00/hour
Research Coordinator Services <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Includes standard coordinator services, blood draws, specimen collections, lab processing, etc. Does not include CRU equipment usage or supplies.</i>	\$65.00/hour
Research Coordinator Services – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Includes standard coordinator services, blood draws, specimen collections, lab processing, etc. Does not include CRU equipment usage or supplies.</i>	\$60.00/hour
Add-on to Nursing Visit: ECG Equipment Charge <i>Charged when ECGs are performed as part of nursing visit for use of CRU-owned equipment. Include supplies.</i>	\$25.00/ECG
Add-on to Nursing Visit: ECG (Study-owned equipment) <i>Includes nursing. Does not include interpretation.</i>	Included in nursing charge
Nursing: Glucose Finger Stick (includes supplies)	\$5.00 each
Mobile Nursing Services <i>Does not include supplies.</i>	
Mobile Research Nursing Services (UT Southwestern Campus Only) <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Does not include supplies</i>	\$70.00/hour
Mobile Research Nursing Services (UT Southwestern Campus Only) – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Does not include supplies</i>	\$65.00/hour
Facility Usage Only <i>Nursing services and supplies added on to a facility-usage-only visit will incur additional charges listed below.</i>	
Facility Fee – Room Usage <i>Per hour, billed in 15-minute increments (rounded to the next highest increment). Study teams must provide all supplies related to the visit. Does not include nursing.</i>	\$50.00/hour
Facility Fee – Room Usage – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment). Study teams must provide all supplies related to the visit. Does not include nursing.</i>	\$40.00/hour
Add-on to Facility-Only Visit: ECG by CRU Nurse <i>Includes nursing and supplies. Does not include interpretation.</i>	\$50.00 each
Add-on to Facility-Only Visit: ECG by CRU Nurse (Study-owned equipment) <i>Includes nursing. Does not include interpretation.</i>	\$25.00 each
Add-on to Facility-Only Visit: Phlebotomy <i>Includes nursing and basic phlebotomy supplies.</i>	\$15.00/time point
Add-on to Facility-Only Visit: Phlebotomy – NIH-Funded Studies <i>Includes nursing and basic phlebotomy supplies.</i>	\$10.00/time point
Add-on to Facility-Only Visit: Administer Drug Screening Test <i>Does not include supplies.</i>	\$10.00

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Services	Cost
Facility Fee – Phlebotomy Chair Usage <i>Will be incurred for phlebotomies performed by a study team member not in conjunction with a room-usage visit. Include supplies for one draw.</i>	\$15.00
Facility Fee – Phlebotomy Chair Usage – NIH-Funded Studies <i>Will be incurred for phlebotomies performed by a study team member not in conjunction with a room-usage visit. Include supplies for one draw.</i>	\$10.00
After-Hours Lab and/or Metabolic Meal Storage Access <i>For access to and use of the facilities listed below after regular business hours.</i>	\$125.00/request
Supplies and Equipment-Usage	
ECG Equipment-Usage-Only <i>Charged when ECGs are performed by study team using CRU-owned equipment. Include supplies.</i>	\$25.00/ECG
IV Pump Equipment-Usage-Only <i>Per patient, per visit. Charged when infusions are performed by study team using CRU-owned equipment. Does not include supplies.</i>	\$15.00
Vein-Finder (Doppler) <i>Per patient, per visit.</i>	\$10.00
Supplies: IV Infusion <i>Includes syringe, vacutainer, extension tubing, primary tubing, and 2 saline flushes</i>	\$30.00/infusion
Supplies: Micron Filter	\$10.00 each
Supplies: Glucose Finger Stick	\$5.00 each
Supplies: Urine Pregnancy hCG Test	\$15.00 each
Supplies: Drug Screening (iCup)	\$15.00 each
Supplies: Other supplies <i>Refers to general CRU floor stock. The CRU will not order or store specialized supplies. The study team is responsible for the provision and storage of specialized supplies.</i>	Actual cost + 10% admin fee

Nutrition and Metabolic Services

Service	Cost
Metabolic Meal Consultation/Design <i>Per hour, billed in 15-minute increments (rounded to the next highest increment).</i>	\$80.00/hour
Nutritional Counseling <i>Per hour, billed in 15-minute increments (rounded to the next highest increment).</i>	\$80.00/hour
Analysis of Diet Records	\$20.00/record
Metabolic Meal <i>Actual cost depends on ingredients and complexity of meal preparation.</i>	\$12.00 - \$22.00 each
Regular Meal <i>(for research participant only)</i>	\$10.00 each

Body Composition and Exercise Testing

Service	Cost
DXA Scan – Industry <i>Includes report but does not include interpretation. Study team will be responsible for pre-scan pregnancy tests, if necessary.</i>	\$300.00
DXA Scan – Non-Industry <i>Includes report but does not include interpretation. Study team will be responsible for pre-scan pregnancy tests, if necessary.</i>	\$150.00
Exercise: Blood Glucose Measurement	\$50.00
Exercise: Blood Lactate Measurement	\$50.00
Exercise: Graded exercise stress test (GXT) with 12-lead ECG	\$125.00
Exercise: Graded exercise test (GXT) to assess VO ₂ max (treadmill) or VO ₂ peak (cycle)	\$50.00
Exercise: Maximal graded exercise test (GXT) with 12-lead ECG and respiration kinetics (VO ₂ , VCO ₂ , RER, V _E , etc.)	\$150.00

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Service	Cost
Exercise: Resting Metabolic Rate (RMR) Measured by Indirect Calorimetry <i>For measurement of the metabolic rate by the determination of oxygen consumption (O₂).</i>	\$100.00
Exercise: Submaximal, steady state exercise test (walking, stair climbing, or cycling) with respiration kinetics to assess exercise metabolism	\$50.00

Lab Processing and Specimen Shipping

Service	Cost
Lab Processing, Packaging, and Shipping (if by CRU staff) <i>Staff time to process billed in 15-minute increments (rounded to the next highest increment).</i>	\$30.00 equipment fee + \$65.00/hour
Lab Usage Only <i>Per patient, per visit. For usage of CRU lab and equipment (centrifuges, etc.) by study team personnel as part of a research participant visit held in the CRU. Does not include supplies.</i>	\$30.00
Cold Storage <i>Annual fee.</i>	\$100.00
Shipping Costs	Study team must provide pre-printed, pre-paid shipping labels

INPATIENT SERVICES

ZALE-LIPSHY HOSPITAL

Service	Cost
Zale-Lipshy Inpatient Stay – Industry <i>Up to 24 consecutive hours. Includes nursing services by Zale-Lipshy staff and non-chargeable supplies such as linens, gauze, etc. Zale-Lipshy Pharmacy services and drug will incur additional costs. Includes telemetry. If CRU nurses specifically requested to perform study, additional nursing charges will apply.</i>	\$1,500.00
Zale-Lipshy Inpatient Stay – Non-Industry <i>Up to 24 consecutive hours. Includes nursing services and non-chargeable supplies such as linens, gauze, etc. Zale-Lipshy Pharmacy services and drug will incur additional costs. Includes telemetry.</i>	\$750.00

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CLINICAL RESEARCH UNIT

Service	Cost
Zale-Lipshy Inpatient Admission Facilitation	\$75.00/admission
Mobile CRU Research Nursing Services (UT Southwestern Campus Only and Zale-Lipshy Requests) <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Does not include supplies</i>	\$70.00/hour
Mobile CRU Research Nursing Services (UT Southwestern Campus Only and Zale-Lipshy Requests) – NIH-Funded Studies <i>Per hour, billed in 15-minute increments (rounded to the next highest increment), including travel time. Does not include supplies</i>	\$65.00/hour
Inpatient Refrigerator Usage (Metabolic Meals) <i>Per day, per refrigerator. For usage of CRU refrigerators (to be relocated to Zale for each visit) during inpatient stays. Sample storage refrigerator or food storage refrigerator.</i>	\$10.00
Inpatient Refrigerator Usage (Specimen Storage) <i>Per day, per refrigerator. For usage of CRU refrigerators (to be relocated to Zale for each visit) during inpatient stays. Sample storage refrigerator or food storage refrigerator.</i>	\$10.00