



**Office of Clinical Research
Lunch & Learn**



**The Budgeting Process for Industry Sponsored
Clinical Trials:
Overview and Updates
Thursday, September 16th, 2021**

Office of Clinical Research

New CDA and CTA Submission Process

All new clinical trial contracts are being processed by the Sponsored Research Services (SRS) Contract Management team at the University of Cincinnati.

Important: An executed CDA between UC and the study sponsor **MUST** be executed before a CTA can be negotiated by UC.

A new online submission process has been developed to support the new contracting process:

<https://redcap.research.cchmc.org/surveys/?s=CLDDCECC84>

Existing agreements executed through UC Health will continue to be managed at UC Health until their conclusion.

As always, feel free to reach out to the Office of Clinical Research for any questions

September 2021 Studies of the Month

Systemic Lupus With Hair Loss or Skin Involvement Study for Adults 18 to 45 Years Old

What

A study to evaluate the safety, tolerability and effectiveness of an investigational drug, tofacitinib, to see if it helps young adults who have skin lesions associated with lupus, also known as systemic lupus erythematosus-cutaneous lesions (SLE-CL)

Who

Adults 18 to 45 years old who have systemic lupus with hair loss or skin involvement

Pay

Up to \$730 for their time and effort to complete the study

Contact

Angela Merritt | angela.merritt@cchmc.org | 513-603-2118



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Best photo ever made!

September 2021 Studies of the Month

Binge Eating Disorder Study

For Participants with Obesity

What

The purpose of this research study is to learn more about binge eating disorder (BED). Participants will be asked to come in for 8 visits over 8 weeks. Participants will be asked to wear an activity monitoring watch and provide saliva samples. They will also be randomly assigned to an individualized intervention (morning light and/or nightly melatonin or placebo) in the final four weeks of the study.

Who

Adults age 18-50, currently with obesity and experiencing binge eating disorder symptoms.

Pay

Eligible participants will be paid up to \$440.

Details

For more information, contact Brian or George at (513) 536-0707 or visit www.LCOH.info and fill out a pre-screen questionnaire. Located at the Lindner Center of HOPE in Mason, Ohio.



13-21 IRB # 2020-0245





**Office of Clinical Research
First Friday**

Friday, October 1st, 2021

Biobanking for Clinical Research

Kelsey Dillehay Mckillip, PhD

Director, University of Cincinnati Biorepository

University of Cincinnati College of Medicine

Today's Presentation:

The Budgeting Process for Industry Sponsored Clinical Trials: Overview and Updates

A review of the budgeting process for industry sponsored clinical trials, with updates to the process, and best practices and tips regarding setting up budgeting for your studies.

Heather Roberson

Macy Michael

Clinical Research Budgets Specialists

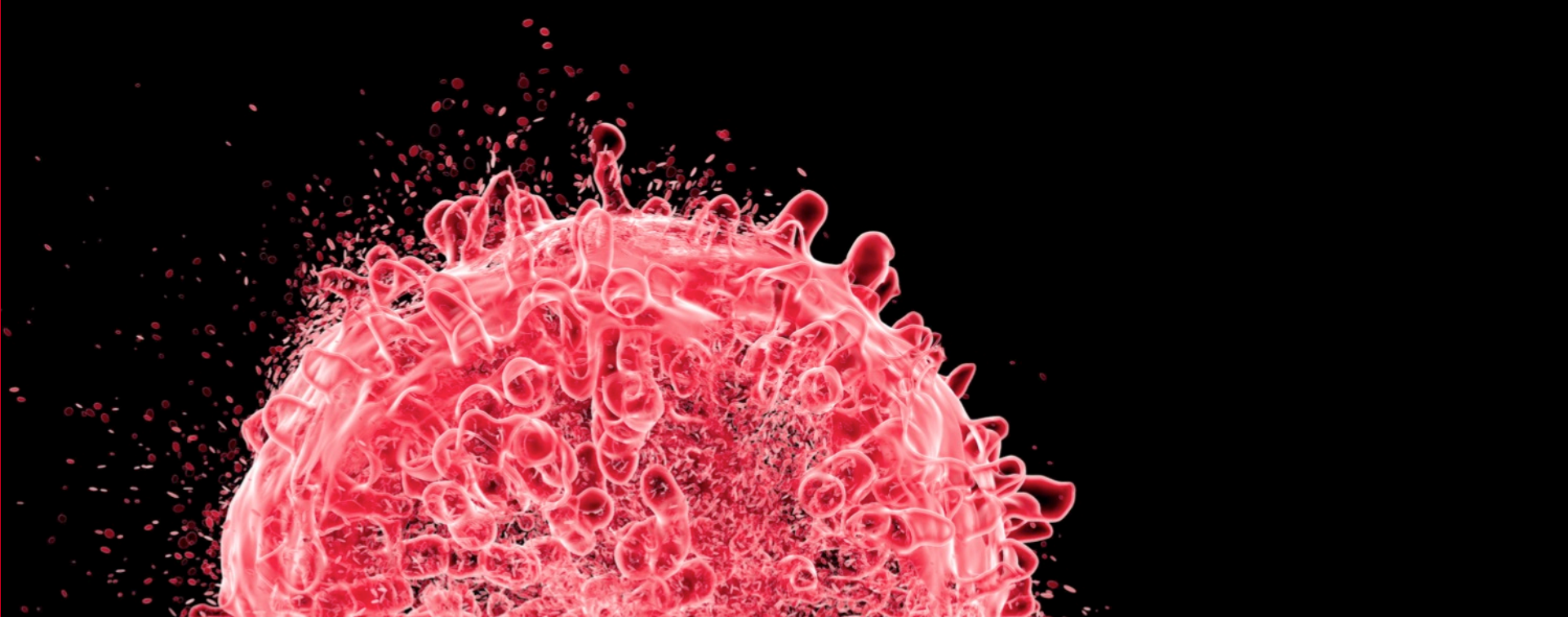
UC Office of Clinical Research





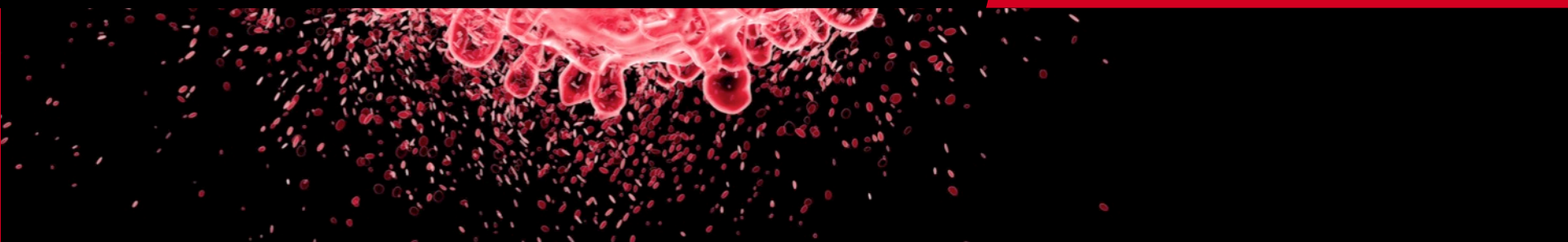
LC Health[™]

The Budgeting Process for
Industry Sponsored Clinical
Trials: Overview and Updates



LEC Health[™]

**Overview of the
Clinical Trial
Budgeting Process**




Overview of Clinical Trial Budget Process



REDCap Submission

Link: <https://redcap.research.cchmc.org/surveys/?s=CLDDCECC84>



Resize font:

[Returning?](#)

Clinical Trial Contract Intake

As of July 1, 2021, all new clinical trial contracts will begin being processed by UC rather than UC Health. Existing contracts will continue with UC Health until their conclusion unless assigned to UC.

Please complete the form below to submit a clinical trial agreement or amendment. All fields are required except for optional document uploads and submission comments.

Please define your request

New Agreement
 Amendment

[reset](#)

Contacts

Primary Submission Contact Information

Name

Email Phone

Sponsor Contact Information

Name Company

Email Phone

Investigator Contact Information

Name

Email

Information

Study Short Name

Department

REDCap Submission

The screenshot shows a REDCap form with two questions. The first question, 'How is the study budget to be handled?', has a dropdown menu open. The second question, 'Will this study utilize Investigational Drug Service (IDS)?', is partially visible below. A large grey oval highlights the dropdown menu area.

Budget

Variable: budget Branching logic: [request] = '1' or [amend(2)] = '1'

How is the study budget to be handled?
* must provide value

- To be negotiated by department
- Requesting secondary budget review
- Requesting aid to develop and negotiate the budget
- Approved - final budget attached
- Not Applicable

Variable: ids Branching logic: [request] = '1'

Will this study utilize Investigational Drug Service (IDS)?
* must provide value

Required Documents

New CTA

- Protocol
- Draft Informed Consent
- Draft Budget
- Budget terms (often found in Clinical Trial Agreement)
- Pharmacy Manual (if IDS pricing is needed)

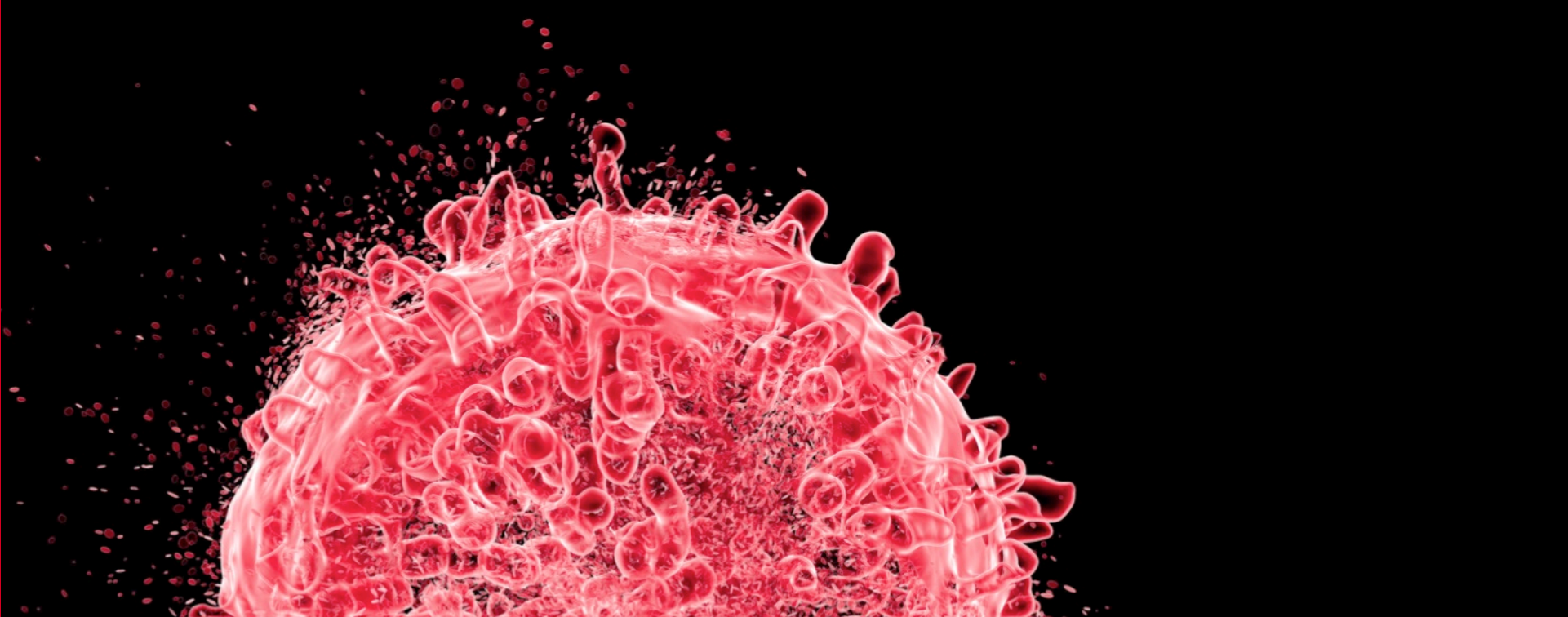
Budget Amendment

- Amended Protocol (if budget is being changed due to a protocol amendment)
- Amended Informed Consent (if applicable)
- Amended Budget
- Contract Amendment
- Pharmacy Manual (if updated)

Coverage Analysis

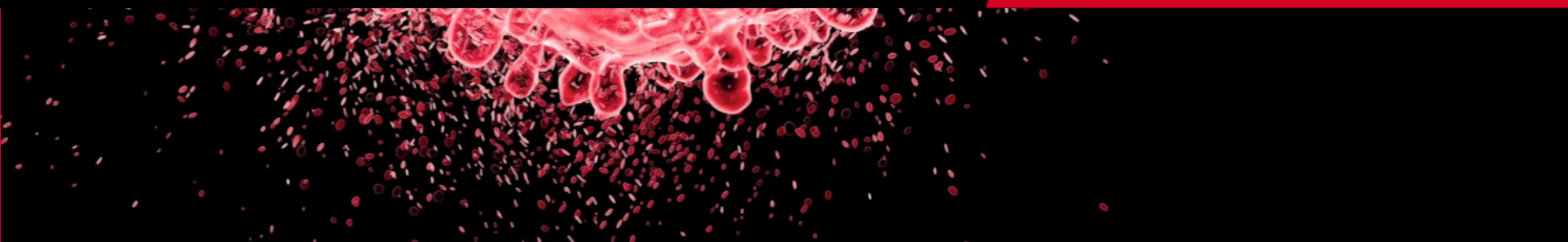
vaughthr@ucmail.uc.edu

Protocol Related Items and Services	CPT / HCPCS (Sample codes)	Screening	Double-Blind Placebo-Controlled Treatment Period																WS2/ET/EOS	Comments
			Baseline	W2	W4	W8	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48/EOT				
Procedures / Evaluation Management																				
Physical Exam / Vital Signs (height, weight, BMI, temp) / Facility Fee	99202-99205, 99211-99215, G0463	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	* Paid by sponsor per sponsor budget	
Vital Signs / Facility Fee	99211-99212 G0463																		* Paid by sponsor per sponsor budget	
EKG	93000-93010	S	S			S		S		S								S	* Paid by sponsor per sponsor budget	
Imaging																				
Drug(s) / Therapy																				
Investigational Drug	IND: 117288		S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	* Supplied by sponsor	
subcutaneous or intramuscular (if study staff)	96372		S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	* Administration	
Laboratory																				
QuantIFERON TB Gold Plus or T-SPOT (locally performed - if applicable)	86480 / 86481	S																	* Per protocol, Testing to be performed at the central laboratory or locally * Paid by sponsor per sponsor budget	
Covid testing (local - if applicable)	86769	S																	* Per protocol, Testing to be performed at the central laboratory or locally * Paid by sponsor per sponsor budget	
ESR (local - if applicable)	85651		S			S		S		S		S						S	* Per protocol, Testing to be performed at the central laboratory or locally * Paid by sponsor per sponsor budget	
Specimens (Centrally Processed)																				
Collection, Shipping, Handling - Blood - Clinical labs samples (hematology, blood chemistry, coagulation, virology, CD19, Total, IgG, IgA, IgM, Complement C3 / C4, CRP, ESR, Serum Preg, Covid, etc.)	36415, 99000-99001	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	* Per protocol, A central laboratory has been selected by the Sponsor to analyze all hematology, blood chemistry, coagulation, urine samples, urine protein-creatinine ratio, urine drug screen, FSH, serum pregnancy tests, serum virology, CD19 B cell counts, direct Coombs test, anticardiolipin, lupus anticoagulant, haptoglobin, immunoglobulin, vaccine-related immunoglobulin titers in serum, hydroxychloroquine levels where applicable, complement C3 and C4, SLE-related autoantibodies (ANA, anti-dsDNA, anti-Smith, anti-SSA/SSB, anti-RNP, rheumatoid factor), and CRP collected for this study	
Collection, Shipping, Handling - Blood - Vaccine-Related Immunoglobulin Titers in Serum (Tetanus, Diphtheria, and Pneumococcus)	36415, 99000-99001		C															C	* Central lab sample	
Collection, Shipping, Handling - Blood - Serum Biomarker Sample	36415, 99000-99001		C	C				C		C								C	* Central lab sample	
Collection, Shipping, Handling - Blood - DNA Sample	36415, 99000-99001		C																* Central lab sample	
Collection, Shipping, Handling - Blood - Blood RNA Sample	36415, 99000-99001		C	C	C			C		C								C	* Central lab sample	
Collection, Shipping, Handling - Blood - Anti-dsDNA	36415, 99000-99001	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	* Central lab sample	
Staff Activities																				
Informed Consent	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Genetic Research ICF (Optional)	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Future Scientific Research ICF (Optional)	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Additional Use of Study Photography ICF (Optional)	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Indusion/Exclusion Criteria	Not Applicable	F	F																* Effort based / data collection activity. Performed for research purposes.	
Randomization	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Demographic Data	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Medical History	Not Applicable	F																	* Effort based / data collection activity. Performed for research purposes.	
Prior Corticosteroid and Lupus SOC Therapy Use	Not Applicable	F	F																* Effort based / data collection activity. Performed for research purposes.	
Concomitant medications	Not Applicable	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	* Effort based / data collection activity. Performed for research purposes.	
Adverse events (SAE / TEAEs)	Not Applicable	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	* Effort based / data collection activity. Performed for research purposes.	
C-SSRS (Columbia Suicide Severity Rating Scale)	Not Applicable	F	F					F		F								F	* Effort based / data collection activity. Performed for research purposes.	
Diagnostic 2019 EULAR/ACR Classification Criteria for SLE	Not Applicable	F	F																* Effort based / data collection activity. Performed for research purposes.	
Skin Photography	Not Applicable	F	F					F		F								F	* Effort based / data collection activity. Performed for research purposes.	



L&C Health™

**Getting to Know
Your Study
Budget**



Per Patient Grid

Procedure Name	Fee	Freq	Baseline	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
			RG001	RG002	RG003	RG004	RG005	RG006	RG007	RG008	RG009	RG010	RG011
Informed consent	200	1	200										
Prescreening ICF for RET Testing	150												
Inclusion/exclusion criteria review	150	1	150										
Randomization via IWRS	50	1	50										
Molecular pathology report(s) describing RET alterations (germline or tumor); includes prep and ship to Central Lab	723	1	723										
Complete physical exam; includes Medical history, Height, Weight, and Vital Signs	300	1	300										
Symptom-directed physical exam; includes Vital Signs	300	26		600	300	300	300	300	300	300	300	300	300
Vital signs collected independent of Physical exam	71												
Concomitant medications	65	38	65	195	130	130	130	65	130	65	65	130	65
Adverse events	75	38	75	225	150	150	150	75	150	75	75	150	75
CTCAE	50	38	50	150	100	100	100	50	100	50	50	100	50
ECOG performance status	50	26	50	50	50	50	50	50	50	50	50	50	50
ECG (Local, Triplicate)	483	10	483	966	483	483	483	483	483	483	483		
Port Fee	129	37	129	129	129	129	129	129	129	129	129	129	129
Blood draw	75	37	75	225	150	150	150	75	150	75	75	150	75
Hematology (Local Lab)	67	27	67	134	67	67	67	67	67	67	67	67	67
Coagulation (Local Lab)	33	1	33										
Thyroid Panel (Local Lab)	126	1	126										
Clinical Chemistry (Local Lab); includes Direct Bili, Cholesterol, LDH, Magnesium, and Phosphorus	90												
Specimen processing for central labs; includes prep and ship to Central Lab	75	64	150	675	375	150	300	75	300	75	75	300	75
Urinalysis (Local Lab)	22												
Urine pregnancy test (Local Lab)	57	26	57	57	57	57	57	57	57	57	57	57	57
RECIST	135	10	135		135		135		135			135	
Patient Diary includes Dispense and Review	50	35		150	100	100	180	50	100	50	50	100	50
Survival and PFS2 assessment	50	2											
Investigator Fee	150		150	150	150	150	150	150	150	150	150	150	150
Study Coordinator Fee	225		225	225	225	225	225	225	225	225	225	225	225
Facility Fee	30		30	30	30	30	30	30	30	30	30	30	30
Data Manager Fee	75		75	75	75	75	75	75	75	75	75	75	75
Pharmacy Fee for LOXO-292 or Cabozantinib or Vandetanib	40		40	40	40	40	40	40	40	40	40	40	40
Per Patient Cost Before OH	54,152		3,398	4,076	2,746	2,386	2,751	1,996	2,671	1,996	1,996	2,188	1,513
Overhead (35%)	0.35		1,189	1,427	961	835	963	699	935	699	699	766	530
Cost Per Patient with Overhead for Baseline and Cycles 1-V802-8XX	73,105		4,587	5,503	3,707	3,221	3,714	2,695	3,606	2,695	2,695	2,954	2,043

Patient Stipend/Payment v. Reimbursement

- **Stipend/Payment: money awarded to a study participant for time and participation in a human subject research study.**
 - Taxable income
 - Fixed sum
 - Payment triggers by completion of an activity/visit
- **Reimbursement: money repaid to the participant of a human subject research study to cover expenses or money already spent on travel, meals, etc.**
 - Refund for out-of-pocket expenses
 - Requires documentation, such as receipts
 - Reimbursable items include mileage, transportation, parking, lodging and meals

Invoiceable Fees

- Protocol Amendment
- SAE Reports
- IND Safety Reports
- Study Monitoring
- Dry Ice
- Re-Consenting
- Not-for-cause FDA Audits
- Invoiceable Procedures

Invoiceable Procedures are specific to each study.

Tip: If an invoiceable item is in your budget, make sure you are invoicing when the activity occurs!!

Startup and Site Fees

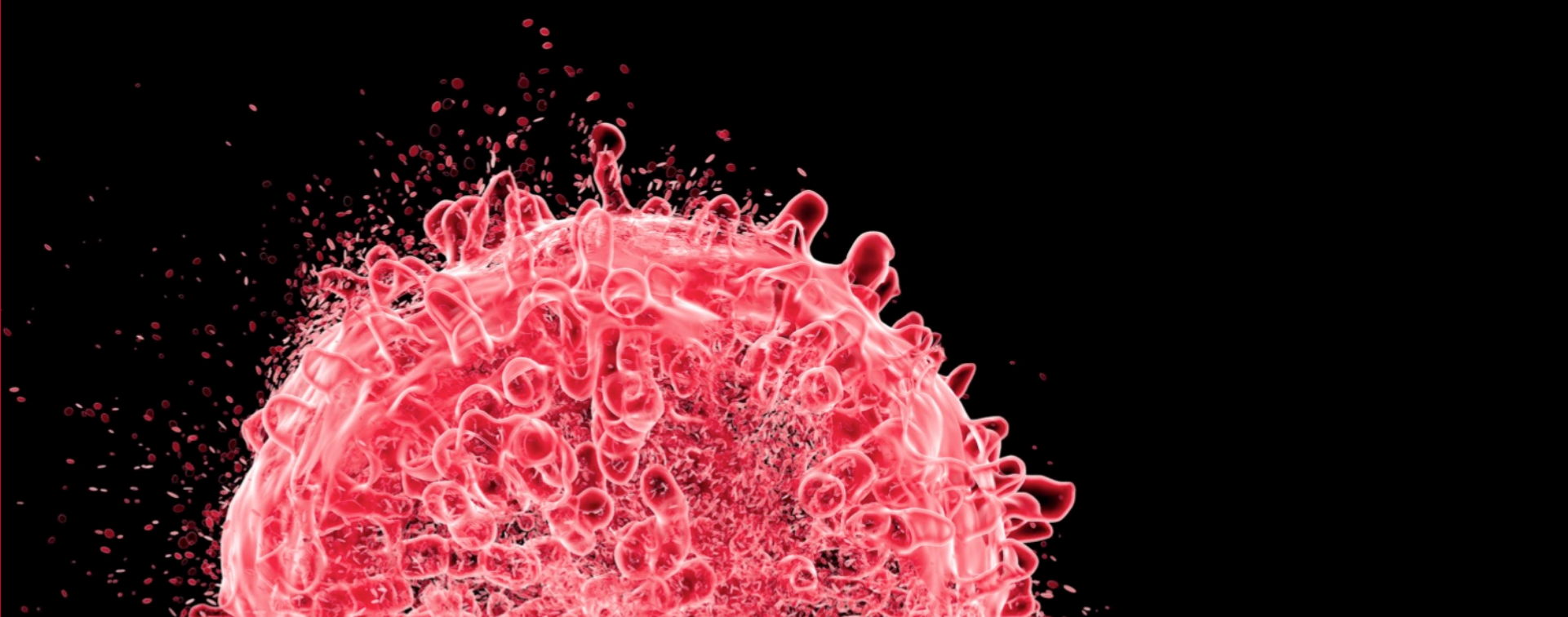
- Startup Fees
- IRB Fees
- Coverage Analysis
- Complion
- Recruitment (High Enroll)
- Annual Regulatory Maintenance
- Study Closeout
- Archiving

Pharmacy Fees

- Pharmacy Startup
- Pharmacy EPIC Build Fee (for infusions only)
- Pharmacy Annual
- Pharmacy Closeout

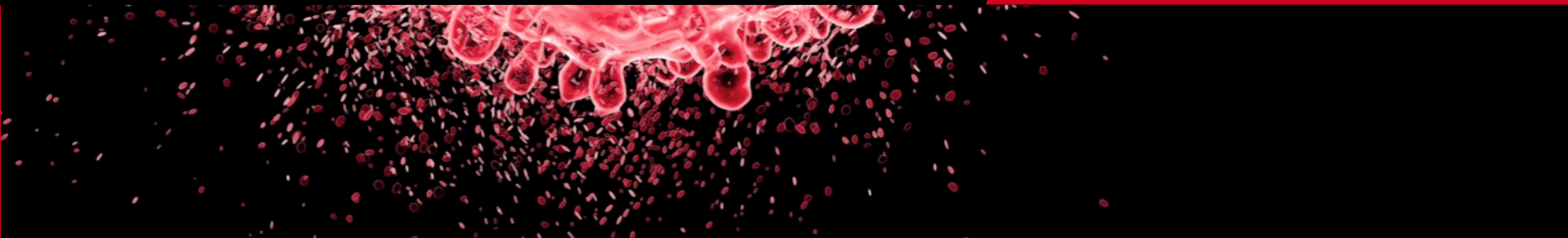
Radiology Fees

- Radiology Startup
- Radiology Protocol Amendment



LCC Health™

Chargemaster



Chargemaster

228	30000062	82784	HC IGG CSF S/O						9.30				Units
229	30000063	82785	HC IGE, TOTAL						16.46				Units
230	30000064	82985	HC FRUCTOSEMINE						16.76				Units
231	30000065	83003	HC GROWTH HORMONE						16.67				Units
232	30000066	83010	HC HAPTOGLOBIN						12.58				Units
233	30000067	83020	HC HEMOGLOBIN ELECTROPHORESIS TEST						12.87				Units
234	30000068	83090	HC HOMOCYSTEINE						17.92				Units
235	30000069	83497	HC 5-HIAA RANDOM URINE						12.90				Units
236	30000070	83498	HC 17 HYDROXYPROGESTERONE						27.17				Units
237	30000071	83516	HC TRANSGLUTAMINASE IGA AUTOAB						11.53				Units
238	30000072	83516	HC GLIADIN AB IGA						11.53				Units
239	30000073	83516	HC GLIADIN AB IGG						11.53				Units
240	30000074	83516	HC TISSUE TRANSGLUTAMINASE,IGG						11.53				Units
241	30000075	83516	HC HISTONE ANTIBODY						11.53				Units
242	30000076	83516	HC MPO (ANCA) AB						11.53				Units
243	30000077	83516	HC GASTRIC PARIETAL CELL ANT						11.53				Units
244	30000078	83516	HC FECAL PANCREATIC ELASTASE 1						11.53				Units
245	30000079	83519	HC PANCREATIC POLYPEPTIDE						18.40				Units
246	30000080	83519	HC IGF BINDING PROTEIN-3						18.40				Units
247	30000081	83519	HC TRYPSIN-LIKE IMMUNOREACTIVITY						18.40				Units
248	30000082	83520	HC ANDIPONECTIN						17.27				Units
249	30000083	83520	HC THYROID STIMULATING HORMONE RECEPT						17.27				Units
250	30000084	83520	HC MPO (ANTIMYELOPEROXIDASE ANTIBODIES)						17.27				Units
251	30000085	83520	HC GLUTAMIC ACID DECARBOXYL AB						17.27				Units
252	30000086	83520	HC IMMUNOASSAY BY RIA-COM						17.27				Units
253	30000087	83520	HC COTININE						17.27				Units
254	30000088	83520	HC NEURON SPECIFIC ENOLASE						17.27				Units
255	30000089	83520	HC MYLELIN ASSOCIATED GLYCOPROTEIN						17.27				Units
256	30000090	83520	HC RIBSOMAL P ANTIBODY						17.27				Units
257	30000091	83520	HC GLIADIN ANTIBODY-IGA						17.27				Units
258	30000092	83520	HC GLIADIN ANTIBODY-IGG						17.27				Units
259	30000093	83520	HC C-1 ESTERASE INHIB,FUNCTIONAL						17.27				Units
260	30000094	83520	HC TRYPTASE						17.27				Units
261	30000095	83655	HC LEAD - URINE						12.11				Units
262	30000096	83700	HC LIPOPROTEIN ELECTROPHORESIS						11.26				Units
263	30000097	83701	HC VAP CHOLESTEROL TEST						33.86				Units
264	30000098	83721	HC LDL CHOL						10.50				Units

Questions?

Contact Information

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