Date:	Study Title	PI NAME:	
OVERALL STUDY FEASIBILITY			
Questions for Discussion	**Additional Considerations/Risks**	**Budget considerations**	**Responses based on your study protocol**
What are the timelines for grant submission?	Will you have sufficient time to meet with departments to discuss logistics and determine how much funding will be needed to include in budget and obtain estimates? Will you miss the deadline? High Risk: Under budget if not enough time to obtain estimates.		
Is the IRB approval required prior to the grant submission? Prior to funds allocation?	Does the agency require a full protocol/consent for grant submission?	Analyst time to prepare IRB submission, IRB initial fee. IRB Fee calculator: https://ucdavis.co1.qualtrics.com/jfe/form/SV_eQIFUVPsVXdG9Dw	
When will the study open and Close? Total Duration.	To start a study here at UCD can take average of 6 months, will you meet the study timelines? High Risk: unable to start the study within the required timelines.		
Will it require multi-site or single site to achieve enrollment goal?	High Risk: multicenter requires contract agreement with other centers, IRB reliance, and establishment of the coordinating center.	FTEs to staff the coordinating center, costs for administering budgets and invoices to other centers, FTE to maintain regulatory and compliance, data collection and management, audits/monitoring, IRB reliance fees	
Is the study already open at other sites?	If so, how many subjects have been enrolled? How many sites are activated? Will you meet study timelines? High Risk: unable to start the study within the required timelines.		
If the study is already open, are there hurdles other sites are experiencing?	How will these hurdles affect your site? What have other sites done to resolve the hurdles, should we implement these resolutions? Can we find out the experience of other sites?	Additional permissions may be required (i.e. IT, purchasing equipment, or contracts). Allow for time to establish logistics of the study considering these hurdles. More time may be required.	
Are there any competing studies that will affect enrollment for this study?	What will you do to achieve enrollment goal for each study? Are the enrollment timelines the same? High Risk: small patient population already engaged in other competing studies	More time for recruitment may be required. Might have to advertise outside of the UC Davis.	
What is the funding source?	Industry, Federal grant (NIH, DOD), Other grant (Foundation), Department funded. High risk: study will not cover all of the costs.	Might need to find additional funding or request CTO support for reduced or subsidized staffing.	X

STUDY TEAM

Questions for Discussion	Additional Considerations/Risks	Budget Considerations	Responses based on your study protocol
Research Personnel List- CO-PI, Sub-investigators, other research personnel	Who will be consenting, does any team member have conflict of interest, what is the team members role on the study. High risk: COI disclosures done on time, insufficient staffing, lack of expertise, etc.	Percent effort for PI and co-I's.	
How will the primary and secondary endpoints be collected?	Do you have the necessary technology or equipment to collect the end point data, do you have qualified staff to collect and evaluate the end point data. High risk: end point assessment is very complicated, requires a lot of technology.	Training of qualified personnel, obtaining necessary equipment and technology, data access for statistical analysis. Effort for training subject on app.	
Are there any procedures the PI/study team is not able to do?	Outsourcing, Outside Investigators/specialist, other departments - i.e. other department, outside specialty that UCDH does not have, or CCRC. Will a Cardiologist need to read the EKG? Are there any potential referrals to/consults in other departments required for eligibility, etc.? High risk: UCD doesn't have access to a specialty that is needed.	CCRC costs or other specialties to be involved. Analyst to request an estimate from CCRC Finance based on these activities. If Inpatient, ask CCRC to create a flowsheet as part of collaboration.	
What is the level of outsourcing? Which activities are being outsourced? How many vendors are involved in the same activity?	What specialty departments are being utilized? Consider internal/external specialists. Implications on Regulatory for any external research staff, and listed for contractual agreements. When can Contracts Office allow 3rd party agreements with external specialists or vendor? High risk: time needed to negotiate with outside vendors.	Cost of contractual agreements	
Time and availability of study team (including external departments)	Does PI/Sub-I have adequate time and scheduling availability to devote to the protocol and keep up with training requirements? How many hours per week does PI have to dedicate to research activities such as protocol-related procedures, training, reviewing documents, signing forms etc. Consider budget or grant. High risk: If PI doesn't have the time who will perform the exams and other protocol related activities.	Adequate budgeting of PI & CRC time, or contractors.	
Does the Department have coordinators that may be available for this study?	Are they experienced and meet the needs of the study (skill set, qualifications, certifications)? Do they need training, who will train them, do they need a mentor? Do they have the bandwidth to manage this study? Do they work on more than one study?	Adequate budgeting of PI & CRC time, or contractors.	
What do you expect CRCs to do?	Identify and screen patients; obtain informed consent; complete screening evaluations; conduct assessments, provide instructions on use of the technology; randomize eligible patients; dispense medication or devices; IP accountability; data collection forms and surveys; EMR data transcription into eCRF; periodic checking with participants; conduct allowed procedures (i.e. blood draw, see Policy 1505); submit data ot the central; IRB documentation; training; calls and other communication; maintain study records; conduct monitoring visits; report AEs	Adequate budgeting of PI & CRC time, or contractors.	

COMPLEXITY OF THE STUDY SETTING

Questions for Discussion	Additional Considerations/Risks	Budget Considerations	Responses based on your study protocol
Are all procedures done at UC Davis in the clinic visits, or are there at-home requirements for the subjects	Examples for at home requirements include: diary, home urine collection, phone/iPad assessments, etc.? Will a nurse or CRC be sent to homes? High risk: At home requirements are quite involved and require trainings, reminders, procedures can be difficult/complex, calibration of equipment.	Cost for kits or equipment to collect data at home. Cost for CRC to oversee home visits, cost for data output from the devices to the central system. Cost for training of study staff and participants.	
Does the protocol require any complex or uncommon procedures beyond the usual standard of care?	Consider potential enrollment and retention impact for both study sites and study subjects; are the subjects willing to undergo the procedures repeatedly. Consider whether there is strict timing for certain procedures in the protocol. Do you have trained personnel and equipment for the complex procedures? High risk: challenges with recruitment and retention, difficulty accessing equipment needed,	Cost of procedure if not SOC, cost for training, cost to retain participants (higher stipend).	
What UCD Health services will need to obtained?	Pathology (CROC intake form), Radiology (RSR-Radiology for Use Request & RUC-Radiology Use Committee), Echo, IDS request, Stem Cell Oversight Committee, MIND (Grant proposal submission form, IDDRC research project application, MICRO application), Biological Use Authorization (BUA), Cancer Center (SRC-Scientific Review Committee, IRB, Clinical Engineering, IT Evaluation, FDA, California Research Advisory	Quotes for ancillary services	
Is the risk greater than or less than the Standard of Care(SOC)	Will IRB grant approval based on these ethical considerations for these procedures	Procedures that are non SOC must be charged to the grant.	
Will the study occur during business hours, or will there be any after-hours requirements?	Will any visits in the outpatient clinic last longer than 4 hours? If so what location will be utilized for long visits? Can your department clinic space accommodate this? Are there any overnight stays? Would a different location make more sense? High risk: the procedures take place outside of normal business hours, or inpatient setting.	Cost for CCRC to accommodate long study visits.	
Are there expected SAEs, AEs, TEAEs, AESIs,etc.?	Consider PI and CRC time to assess, entering data, reporting to sponsor/coordinating center and IRB. High risk: patient safety and frequency of occurrence.	Adequate budgeting of PI & CRC time.	
Will the sponsor or grantee be paying for all research procedures, or, are some procedures standard of care?	Medicare Coverage Analysis needs to be completed for every study at UCD that falls under policy 2317. High risk: clear understanding of SOC vs. research procedures.	Procedures that are non SOC must be charged to the grant.	
Will the sponsor be using central IRB? If yes, who is the IRB of record?	Does the study team have experience utilizing Central IRBs, Submitting to Central IRBs?	Cost of IRB reliance fees and analyst time to submit application.	
What research devices will be provided for use in the study? (tablets for assessments, EKG machine, BP machine, ePRO, eDiary, etc.)	If devices are being provided it needs to go to clinical engineering. All software will need an IT evaluation. If your site is using their own equipment devices, you may need to provide calibration records. High risk: time required for IT evaluation. Acquiring device if not provided, ongoing maintenance.	Cost of device and acquisition, maintenance.	

RECRUITMENT			
Questions for Discussion	**Additional Considerations/Risks**	**Budget Considerations**	**Responses based on your study protocol**
What is the site enrollment goal? How many subjects are needed for statistical significance?	Can you meet this goal? Are there multiple cohorts? What is enrollment goal for each cohort? What is the PIs patient population? How many subjects total are needed for entire study? High risk: not enough potential participants, or PI doesn't have sufficient time to recruit. Unable to obtain enough participants to achieve statistical significance to derive the study endpoints.	CTSC free services: 1. Biostatistical consult. 2. SlicerDicer cohort based on the Incl/Excl criteria. If the statistician is retained for the duration of the study, they will need to e included in the percent effort.	
Have you done the analysis of your study cohort via Slicer Dicer?	Slicer Dicer is a self-service reporting tool within EPIC that provides research teams and other users intuitive and customizable data explorations. Slicer dicer can assist in identifying a cohort for research. During the slicer dicer session, the PI and our EMR specialist utilize the protocol and inclusion/exclusion criteria to narrow their search in identifying the patient population in EPIC database that may qualify for the trial. High risk: If the PI's enrollment goal is 10 and there are only 5 patients in the database, the PI may want to reconsider taking on the trial as it may cause a financial loss.	CTSC free services: SlicerDicer cohort based on the Incl/Excl criteria.	
What are the recruitment methods to be use for this study? What are the PI's recruitment plan/strategy?	Advertising, Medical Record Review, registries of participants who have given permission to be contacts for research studies, Personal contact, Referrals, Clinical Trials Website (Study Pages, CT.gov), Internet, Social Media (FB, Instagram, Reddit), MyChart, Epic BPAs, Slicer Dicer. Is the Sponsor willing to pay for recruitment expenses? High risk: Barriers to advertisement, or advertisement is insufficient.	CTSC free services: 1) StudyPages and 2) SlicerDicer cohort based on the Incl/Excl criteria. Budget may be needed for external advertising campaigns through public affairs. Printing or flyers, graphic design, letters, mail costs, TV/radio spots.	
What is the type of the patient population?	Vulnerable population is defined as: Patients who are racial or ethnic minorities, children, elderly, socioeconomically disadvantaged, underinsured or those with certain medical conditions. High Risk: defined "vulnerable population"	Allocate more funding to recruitment and retention, additional time for consents. Covering costs for travel, stipends, meals. May be considerable attrition and loss to follow up. Increase time for retention activities	
What is the disease/condition studied?	Consider pts disease/ condition; has potential for SAEs or subject risk, co-morbidities, complexity of disease state. High risk: high disease/condition burden.	Time and funding for procedures to detect SAE. Time for data entry may increase.	
Is the study an extension, roll over, related study, sub-study? Is there a sister study?	If yes, are the patients rolling over from any other study? Or can patients enter into the study with participating in a prior study? If there is a sub study, is it optional or required? High risk: Will be complicated to enroll patients into these study designs.	Time for recruitment can decrease if you rollover from another study. However, you need to also consider that your study may be delayed if you are waiting for the precedent study to complete.	
How specific are the eligibility criteria?	Consider ability to document requirements/verify inclusion/exclusion criteria. Consider stratification based on subject population. What is required in terms of documentation for diagnosis? Consider clarity on central vs. local lab results being acceptable for inclusion/exclusion ranges. High risk: additional procedures needed to establish eligibility.	Allocate time to determine your cohort based on inclusion exclusion criteria. CRC may spend significant time going over the charts of the criteria cannot easily be pulled out. You may need to establish periodic data pull for newly identified patients. Cost for additional procedures if needed to establish eligibility.	
Who will primarily be spending time on recruitment? What is the current workflow for the team that initially sees these patients?	Will you need to outsource for assistance with recruitment? Will the workflow be feasible for the study? Will new workflow need to be created with additional staff? High risk: complicated recruitment workflows.	Time needs to be added to the budget for CRC or study team involved on recruitment and recruitment workflows. Or budget clinical care team for recruitment. CTSC free service to develop EMR based workflows to assist with participant recruitment.	

When will enrollment start and stop?	Will you be able to enroll participants? Will you be able to complete your enrollment goal? Risk: are you able to complete the study within your grant period?	No cost extension request may need to be submitted to sponsor for additional time.	
What is the expected screen failure ratio for the study?	Is there a plan in place to cover the costs of the screen failures? Will coordinating center or sponsor pay for unlimited screen failures? High risk: Poor estimate of screen failure ratio.	Continue to prescreen without enrolling is added cost in time or cost of procedures.	
Will there be subject compensation/stipend for their participation and/or travel expenses?	What is the total compensation participants may receive? Who will provide compensations amounts (Sponsors, third party vendor, dept)? When and how (form of payment - check, gift card, debit card, etc.) will participants be compensated? Will transportation/parking/lodging/meals/airfare be reimbursed? If no to above, will dept be willing to provide reimbursement? what will be the reimbursement process? Risk: compensation is inadequate to retain participants. Compensation is not processed timely or is not in a format the participant wants. Social security number needs to be provided for payments issued via check and some may not want to provide or have a SSN.	Cost of stipend, travel, meals, parking, etc.	
Informed consent; Will the study enroll participants unable to speak or read English? What languages are needed (based on your pt population? Will the waiver of informed consent be required to accomplish your recruitment goal?	Who prepares the informed consent form? Assent form for children? Translation: If so will the consent form be translated into a language the participant can understand? Will translated documents be provided? Will they have translation certificate? Risk: Not anticipating the patient population and which translation will be needed.	Time for preparing consent form and other regulatory materials. Cost for translation.	
Will subjects be allowed to be rescreened if they do not pass all eligibility criteria?	Consider situations to allow rescreening. Consider ways to track subjects that are rescreened.	Time to maintain screening log. Costs associated with additional rescreening.	

IDS Pharmacy

Questions for Discussion	Additional Considerations/Risks	Budget Considerations	Responses based on your study protocol
Does your study require an investigational new drug (IND) application?	Consider these IND exemptions: • The drug product is lawfully marketed in the United States. • The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug. • In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug. • The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)). • The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50). • The investigation is conducted in compliance with the requirements of § 312.7 (i.e., the investigation is not intended to promote or commercialize the drug product). If there is a device associated with the delivery it could be a combination product or drug product and that needs to be evaluated by the FDA.	CTSC Free Services: IND consultations and preparation. Cost for analyst to prepare IRB submission.	
Which pharmacy will be dispensing the drug? Main IDS or Cancer Center.	Must be familiar with IDS SOPs, and understand the costs.	Consider costs for currier delivery if required. IDS rough estimate of fees: https://confluence.ucdmc.ucdavis.edu/confluence/display/UDCRG/Investigational+Drug+Services. Submit to IDS for approval and obtain quote for services.	
What is the route of administration?	What are the logistics of delivering the drug to the patients? Tablet, IV, sub-cutaneous, radioactively labeled compounds, placebo. Storage temps, timing of administration vs. dispensing. Storage containers, filters, and infusion bags. Consider how diluents will be provided? High risk: complicated logistics of dispensing.	Pharmacy costs for dispensing, CRC time, cost for compounding.	
Is there any risk related to availability of investigational product?	Drug overage, manufacturing time, expiry dates, etc. Which vendor/s will be supplying the drug/s? who will provide the IP? Is UCD expected to procure drug for patients? Risk: logistical challenges in obtaining and maintaining investigational product.	Cost of procurement, replacement of expired, destruction.	
Is there dose titration or is the preparation of the dose to be calculated/modified based on measured parameters (e.g.. weight, renal function, age)?	Consider the algorithm for dose titration or dose adjustments; is it clear, what is the potential for error?	Submit to IDS for approval and obtain quote for services.	
Is "rescue" therapy permitted?	Who will supply it, will sponsor or coordinating center provide it? Will site have to pay? Will Medicare/insurance cover it? Is it SOC? Where will it be stored? Risk: site will bear the cost for rescue therapy.	Cost for rescue therapy, procurement, maintenance, dispensing, administration.	
Are interruptions/restarts permitted?	Maintain enough supply on hand for restart.	Cost for procurement, maintenance, dispensing, administration.	
Is this compound/class known to have any serious side effects/toxicity? Have events of special interest been identified?	Consider detection methodologies and tests of any toxicities. Consider any protocol-specific reporting requirements for (S)AEs and data collection for SAEs. Risk: high probability of AEs and toxicities.	Costs for additional procedures to mitigate toxicities, data collection, and AE review.	

Is the compound known to have any significant interactions with other medications?	Consider the list of prohibited meds and cautionary therapies.	CTSC Free Services: Contraindicated medication warnings	
What is the randomization process like?	Are there multiple titrations? Any special requirements for randomizing (lead-ins with other drugs, holding other medications, etc.)?	Consider costs for randomization if done by IDS pharmacy.	
Is blinding needed for the Investigational Product (IP)?	How will this be set up? How are the blinding assignments administered/created? e.g. IVRS//IWRS?	Costs for additional personnel if blinded and unblinded individuals are needed. (pharmacist, unblinded monitor, unblinded CRC, unblinded sub-I)	
Are there potential ways to unblind a subject other than through study medication as described above?	Are there lab results that could unblind study medication. Are there procedures in place to ensure labs are not performed that have the potential to unblind; consider whether single or multiple results have the potential for unblinding; Consider also AEs that might potentially unblind. what's the risk of unblinding?	CTSC Free Services: EMR workflows to maintain blinding.	
Is this a Device Trial?	Who will supply it, will sponsor or coordinating center provide it? Will site have to pay? Will Medicare/insurance cover it? Is it SOC? Where will it be stored? Clinical engineering may need to review device. If device has software it will need to go through IT review.	Submit to Medicare for approval of device. Will a UCD purchase agreement be needed.	

DATA

Questions for Discussion	Additional Considerations/Risks	Budget Considerations	Responses based on your study protocol
Is there a new tool/device being implemented to capture data by participants?	Consider ePRO , iPad, vital signs collection devices, other devices for this assessment. Consider how difficult the device is to use and how much training will be required. Is the new device being used to capture a primary/secondary endpoint? Consider what the diary is being used to collect (e.g. study medication) or data being collected to support a primary or secondary endpoint. Consider reconciliation of the paper diary information against the AE page. Risk: patient noncompliance with data capture. Errors in data entry, technology not working.	Time for training of the CRC and participant. Cost for technology itself, cost for data collection, cost of replacement technology, and cost of handling. Time for troubleshooting technology with participants.	
What is your initial gauge of how burdensome the data collection will be? Will it be complex? High volume?	How many different databases are required for the study? What type of data validation and monitoring is required? Are there unique complexities associated with the collection of data in this trial that pose risks to data integrity? Are there study-specific edit checks that can be introduced to reduce transcription errors? Is the data collected manually or electronically? Are there any data collected using eSource (direct data entry)? Are CRF data collected using EDC/Redcap? Consider readiness of the technology for the data collection (eCRF, ePRO, Central Reading Center/Imaging/Diagnostic data ,etc.) Risk: Large amount of data needs to be collected and there is a lot of manual data conversion.	Cost for CRC data entry.	
Do source documents need to be created? If so, please list what source documents will be created at a minimum.	Who will create these? Will it be via EPIC, Redcap or paper? Risk: Source documents are complex and/or multiple.	Cost for CRC to create source documents.	
What questionnaires or assessments are required per visit? Please include who can perform assessments/administer questionnaires per protocol/sponsor/coordinating center	Some assessments require MD, certificates, with experience administering assessment/questionnaire. If so do you have the bandwidth or staff to perform? Who will train? How long do they take to complete? Who is providing? How will they be administered. Risk: Complicated assessments that need specialized training.	Cost for CRC to be trained and certified on performing various assessments.	
What is the monitoring plan for the study? Remote? Risk Based or 100% data source verification (in person)?	Consider the granting agency monitoring plan.	Cost for UCD internal monitoring.	
What are your anticipated data export and reporting requirements?	Export data to SAAS, creating data analyses and reports	CTSC Free Services for EMR functionalities	
Have you created data sharing plan?	https://health.ucdavis.edu/ctsc/area/informatics/nih-data-management-data-sharing-policy.html		

PATHOLOGY

Questions for Discussion	Additional Considerations/Risks	Budget Considerations	Responses based on your study protocol
Is a central lab or local labs being used?	If a central lab is being used, are tests performed centrally or locally and then harmonized? How will local labs be harmonized? Have there been any previous issues with the lab being able to deliver the test? Risk: results vary significantly between labs.	Submit to CROC for a quote for services.	
Lab draw site?	Comprehensive Cancer Center, Midtown, Cypress Building/CCRC, ACC Building, MIND, Other□	Costs associated with using the draw site.	
Who can draw the lab?	Phlebotomist, Bedside Nurse, Infusion Center (for port/PICC/CVC draws), CRC, MA	Submit protocol to CCRC for cost quote of blood draws by nurse. If CRC needs to draw blood they will need to attend the limited skills training course. ($400	
What is the complexity of the data type/biomarker?	Consider collection, sample storage, visits, logistics, testing methods by labs related to these samples. Is there any tissue banking or hazardous research materials being collected/used for this study? Consider risk of loss of samples during transportation and storage.	Unique costs for unusual blood collection or specimen procedures. Cost of biobanking and storage.	
Will the study collect PK samples?	If yes, consider number of time points. If investigator initiated study consider supplies, if peds - will you need an exam room for IV placement for multiple draws. Risk: prolonged or complicated PK collection.	Submit protocol to CCRC for cost quote of blood draws by nurse. Cost for specimen processing.	
What are the shipping requirements?	Who will store, where will they be stored, storage supplies, ambient temperature shipping, batch-shipped, and Dry ice. Risk: Unable to ship on-time or delays in shipping.	Cost of shipping.	
Anatomic Pathology (e.g., tissue histology, cytopathology, etc.)	Who will be performing these procedures, where will it be performed, do you have supplies.	Submit to CROC for a quote for services.	
Using your best judgment, do you think the lab processing will be simple or time consuming?	multiple draws, multiple vials, processing, packing/shipping, CRC/staff time, Any labs that need to be ordered stat (e.g., results needed quickly to make decisions regarding study drug dosage, screening inclusion/exclusion, etc.)? Risk: Errors in specimen processing if complex.	Cost for CRC time for specimen processing.	
What equipment is required for lab processing and freezer storage?	Ambient centrifuge, refrigerated centrifuge, -20 or -70 Freezer, Refrigerator, etc. Does the equipment need to be returned to the sponsor at the end of the study. Risk: Need specialized equipment that we don't have or it is not accessible.	Cost for storage unit (i.e. freezer). Cost for annual maintenance of equipment. Cost for shipping equipment to and/or from sponsor.	
Are there any time windows that need to be met for certain procedures?	Blood draw windows (e.g., +/- 10 minutes of study drug administration)? Risk: unable to meet windows.	Cost for CRC to be available to meet time window.	
Are there other samples that need to be collected, Are there specific instructions?	urine, urine pregnancy test, stool, etc.?	Cost of collection device, storage, and shipping.	
Is biorepository access needed?	How to access historically saved biological smaples. How to add samples to the pathology biorepository.		

RADIOLOGY			
Questions for Discussion	**Additional Considerations/Risks**	**Budget Considerations**	**Responses based on your study protocol**
Are there any imaging procedures/Radiology services needed? Has the Imaging Manual been provided?	Need codes and costs for CT, interventional Radiology, MRI, PET, Vascular lab, DEXA, Mammography, Nuclear, Ultrasound, and X-ray. Radiology services requests are submitted through the PPMS system and a For additional information and questions, contact Research Supervisor Dana Little at (916) 734-7749 or dalittle@ucdavis.edu new user account might need to be created:https://ppms.us/ucdavis/login/?pf=1 Another approval needs to be obtained from the Radiation Use Committee. Submit for review and approval of study prior to IRB Review and approval. https://confluence.ucdmc.ucdavis.edu/confluence/display/UDCRG/Radiation+Use+Committee	Once a Radiological Services Request has been submitted in PPMS, the imaging team determines if the imaging requirements of the study are outside of standard imaging protocols, and thus requires an estimate and invoicing.	
Where will the imaging be performed?	Radiology - hospital, ACC, Imaging Research Center	IRC Quote for services. Email "Protocol Initiation Form" (PIF) to Michele Ono available through the following webpage: https://health.ucdavis.edu/irc/content/start/setup.html	
Are the following needed? UCDH Radiologist interpretation, Special data transfer request?	Is the sponsor providing, CDs or Flash drives to send images or test, where are images being sent, who is sending.	Cost of CD's, flash drive, and/or external hard drive. Cost of time to download imaging reports.	
Is tracer supplied by study/sponsor? Are there supplies, equipment being provided by study/sponsor?	Radioactive tracer studies require approval of Nuclear Medicine.	Supply or equipment costs. Nuclear Medicine costs from radiology request.	
Is an echocardiogram required for this study?	If yes, submit request to ECHO lab using Echo Lab Services Request Form once as a preparatory request for an estimate for internal budget then again as a procedure request after IRB approval. hs-echoresearch@ucdavis.edu	Incorporate estimate into budget	

Add items that have impact on the budget and provide estimate for each line item

Start Up

PI Time	
CRC Time	
IDS Fees	
CCRC Fees	
Pathology Fees	
Radiology Fees	
Clinical Engineering Fees	
	0

Subject Visits

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Total
Procedure 1									
Procedure 2									
Procedure 3									
Procedure 4									
Procedure 5									
PI Time									
CRC Time									
	0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
								Multiplied by # of Subjects	**0**

Annual Costs

IDS Annual Fee	0
IRB Regulatory Continuing Review (if app	0
Financal Maintenance	0
PI Time for oversight	0
CRC Time for study maintenance & regul	0
	0

Closeout

IDS Closeout	
Document Storage (if applicable)	
PI Time	
CRC Time	
	0

Total Direct Costs	0
Indirect Costs	0
Grand Total	0