

## Project Expense Considerations

These are items to consider when developing a budget for a clinical research study (includes site costs and cost to sponsor a study). The true estimates should be based upon the role (participating site of sponsor), actual clinical research protocol and study design/intervention. Note that some of these sections may not apply.

Study Budgeting Considerations		
Research Staff and Trainees		
Expense	Projected Expense	Estimated Cost & Notes
Study Coordinator/ Technician/Assistant/ Nurse/On-call Nursing	<input type="checkbox"/> Salary/Benefits for each <input type="checkbox"/> On-call fees for nurses and coordinators required outside of regular working hours	
Research Trainees	<input type="checkbox"/> Masters Student stipend <input type="checkbox"/> Doctoral Student stipend <input type="checkbox"/> Post-Doctoral Fellow stipend	
Grant & Protocol Development		
Expense	Projected Expense/considerations	Estimated Cost & Notes
Protocol Development	<input type="checkbox"/> Statistician/Methodologist <input type="checkbox"/> Database (development, IT platform, data manager) <input type="checkbox"/> Project Manager <input type="checkbox"/> Regulatory Affairs/Serious Adverse Event Reporting <input type="checkbox"/> Patient Engagement (including funds to cover their time, provide for expenses) <input type="checkbox"/> Health Economics <input type="checkbox"/> Health Technologist (e.g. radiologist) <input type="checkbox"/> Integrated Knowledge Translation advice	
Grant Development	<input type="checkbox"/> Grant writer <input type="checkbox"/> Literature searches <input type="checkbox"/> Knowledge Translation Plan <input type="checkbox"/> Patient engagement	
Informed Consent Development	<input type="checkbox"/> Lay language summary of study <input type="checkbox"/> Translation/back-translation requirements <input type="checkbox"/> If providing to non-English speakers, do you require an on-site translator?	
Other documents	<input type="checkbox"/> Manual of Operations <input type="checkbox"/> Protocol-specific training (investigator's meetings, technical training) <input type="checkbox"/> Marketing materials (pamphlets/posters/online) <input type="checkbox"/> Drug accountability logs <input type="checkbox"/> Shipping logs <input type="checkbox"/> Sharing study documentation (e.g. use of WorkSpace, other document storage services) for multi-centre studies, including trial master file and/or regulatory documentation	
Contracts & Budget Negotiation	<input type="checkbox"/> Research Manager/coordinator time	
Ethics	<input type="checkbox"/> Initial fee, amendments annual renewals	
Overhead	<input type="checkbox"/> Amount of overhead (varies if funded by industry or investigator-initiated). <input type="checkbox"/> If sponsoring a multi-centre study– overhead at other participating sites	
International Exchange	<input type="checkbox"/> If participating in an international study/sites	

## Project Expense Considerations

Rates		
Monitoring Requirements	<input type="checkbox"/> Site initiation visits <input type="checkbox"/> Ongoing monitoring <input type="checkbox"/> Close out	
Audits and Inspections	<input type="checkbox"/> Sponsor Audit (consider the number of days and personnel cost) <input type="checkbox"/> Health Canada Inspections – usually five days (consider the number of days and staff costs) <input type="checkbox"/> Other international agencies (e.g. FDA, NIH)	
Participant Amounts	<input type="checkbox"/> Screen failures <input type="checkbox"/> Lost to follow up <input type="checkbox"/> Early termination <input type="checkbox"/> Site start-up amount <input type="checkbox"/> Per participant amount (compensation for each participant enrolled into the study) <input type="checkbox"/> Serious Adverse Events <input type="checkbox"/> Advertising <input type="checkbox"/> Parking and transportation costs <input type="checkbox"/> Remuneration (if applicable) <input type="checkbox"/> Providing research results to participants (e.g. by mail, by email, by website) in lay language at the end of the study	
Privacy Requirements	<input type="checkbox"/> Privacy Impact Assessment cost <input type="checkbox"/> Additional considerations for cohort or registry studies	
Archiving/Long term storage requirements	<input type="checkbox"/> 25 years storage for clinical trials <input type="checkbox"/> 5-7 years of storage for non-clinical trials	
Regulatory (if applicable)	<input type="checkbox"/> Clinical Trial Application to Health Canada <input type="checkbox"/> Clinical Trial Amendments <input type="checkbox"/> Pharmacovigilance Reporting (will the study have a lot of events that will need to be reported to Health Canada?)	
Training Needs	<input type="checkbox"/> Staff training requirements for proof of competency (licensing fees/insurance, GCP trainings, TDG training, etc) <input type="checkbox"/> Protocol-specific training (at each participating centre) <input type="checkbox"/> Investigator meetings <input type="checkbox"/> If sponsoring a multi-centre study – travel to train other sites, conduct site initiation visits, train monitors, etc	
Additional considerations	<input type="checkbox"/> Chart retrieval/medical records <input type="checkbox"/> Electronic health/administrative data retrieval <input type="checkbox"/> IT purchases (laptops or servers) <input type="checkbox"/> Communications: telephones (landline and cell phone), conference call requirements, webinar needs, if multi-national compensating personnel for conducting meetings outside regular working hours <input type="checkbox"/> Online survey development <input type="checkbox"/> Translation services <input type="checkbox"/> Transcription services <input type="checkbox"/> Courier requirements (shipping specimen, documents, etc)	

## Project Expense Considerations

<b>Common Services</b>		
<b>(Note for multi-centre studies, the sponsor must provide funds for each participating site)</b>		
Expense	Projected Expense	Estimated Cost & Notes
Radiology	<input type="checkbox"/> Administration fee <input type="checkbox"/> CT costs <ul style="list-style-type: none"> <li><input type="checkbox"/> Test scan &amp; transfer / submission</li> <li><input type="checkbox"/> Single area CT</li> <li><input type="checkbox"/> Double area CT (each additional area)</li> <li><input type="checkbox"/> Post scan reconstructions</li> <li><input type="checkbox"/> IV contrast (up to 150 cc's)</li> </ul> <input type="checkbox"/> Radiologists consultation (for each exam) <ul style="list-style-type: none"> <li><input type="checkbox"/> Head scan w/o contrast</li> <li><input type="checkbox"/> Head scan with contrast</li> <li><input type="checkbox"/> Double head scan 2 planes</li> <li><input type="checkbox"/> Body scan w/o contrast</li> <li><input type="checkbox"/> Body scan with contrast</li> <li><input type="checkbox"/> Double body scan 2 planes</li> </ul> <input type="checkbox"/> CD-ROM with patient ID removed <input type="checkbox"/> CD packaging / form completion/ Fed-Ex <input type="checkbox"/> MRI – variable based on test <ul style="list-style-type: none"> <li><input type="checkbox"/> Data processing – reporting</li> </ul> <input type="checkbox"/> Contrast for MRI <input type="checkbox"/> General Radiography <input type="checkbox"/> Ultrasound	
Cardiology	<input type="checkbox"/> ECG <input type="checkbox"/> Ultrasound	
Medical and Allied Health Professional Services	<input type="checkbox"/> Nursing <input type="checkbox"/> Physical / Occupational therapists <input type="checkbox"/> Fitness / exercise instructors <input type="checkbox"/> Dietician	
Laboratory Costs	<input type="checkbox"/> Protocol review fee <input type="checkbox"/> Administration fee <input type="checkbox"/> Protocol revisions <input type="checkbox"/> Individual laboratory test costs <input type="checkbox"/> Urine standard <input type="checkbox"/> Urine 24 hour <input type="checkbox"/> Phlebotomy (up to 4 tubes) <input type="checkbox"/> Shipping between labs <input type="checkbox"/> Inter-hospital shipping <input type="checkbox"/> Ambient packaging <input type="checkbox"/> Frozen packaging <input type="checkbox"/> TDG container, forms & materials <input type="checkbox"/> Storage of serum/urine	
Pathology	<input type="checkbox"/> Administration <input type="checkbox"/> Procedures <input type="checkbox"/> Electron Microscopy <input type="checkbox"/> Light Microscopy	
Pharmacy Costs	<input type="checkbox"/> Set-up fees & Assessment <input type="checkbox"/> Clinical dispensing <input type="checkbox"/> Maintenance <input type="checkbox"/> Product costs <input type="checkbox"/> Courier costs	
Service Contracts / Maintenance	<input type="checkbox"/> Freezer maintenance <input type="checkbox"/> Annual software licences	

## Project Expense Considerations

	<input type="checkbox"/> Computational cluster fees	
Materials & Expendables for the Study		
Expense	Projected Expense	Estimated Cost & Notes
Study Intervention	<input type="checkbox"/> Drug/Device/Biologic Cost per participant <input type="checkbox"/> Shipping costs <input type="checkbox"/> Central pharmacy, packaging and licensing fees <input type="checkbox"/> Specialized study equipment (e.g. equipment not already at the site or not accessible for research purposes) <input type="checkbox"/> Medical Monitor review	
Printing & copy costs	<input type="checkbox"/> Flyers / brochures / posters for recruitment <input type="checkbox"/> Consent documents <input type="checkbox"/> Questionnaires <input type="checkbox"/> Patient information <input type="checkbox"/> Toner <input type="checkbox"/> Paper <input type="checkbox"/> Trial Master File (clinical study) <input type="checkbox"/> Other:	
Sample collection / analysis & disposables	<input type="checkbox"/> Salivettes / swabs / collection vials <input type="checkbox"/> Syringes <input type="checkbox"/> Slides <input type="checkbox"/> Gloves <input type="checkbox"/> Butterfly tubes <input type="checkbox"/> Alcohol pads <input type="checkbox"/> Cell culture materials <input type="checkbox"/> Antibodies <input type="checkbox"/> Synthesis / preparation of reagents <input type="checkbox"/> Pathology supplies <input type="checkbox"/> Other: <input type="checkbox"/> Other:	
Specialized materials	<input type="checkbox"/> Cameras / recording devices <input type="checkbox"/> Exercise equipment <input type="checkbox"/> Other:	
Miscellaneous	<input type="checkbox"/> Calibration of equipment (scales etc) <input type="checkbox"/> Gas (NO, CO <sub>2</sub> , O <sub>2</sub> ) <input type="checkbox"/> Dry ice <input type="checkbox"/> Use of clinic space/research space outside of regular working hours (if required, e.g. evenings and weekends)	
Travel & Dissemination		
Expense Category	Eligible	Estimated Costs & Notes
Travel	<input type="checkbox"/> Airfare <input type="checkbox"/> Conference fees <input type="checkbox"/> Transportation	
Publication & Dissemination Costs	<input type="checkbox"/> Immediate release fees <input type="checkbox"/> Publication fees <input type="checkbox"/> Manuscript preparation <input type="checkbox"/> Collaborator meetings <input type="checkbox"/> Costs for distributed materials <input type="checkbox"/> If integrated KT is required – funds for patient/advocacy group meetings, public meetings.	



## Project Expense Considerations

---

### Final Item to Consider: TIME

Time is the forgotten variable in most research plans/protocols and budgets. There are specific regulations, procedures and requirements which must be met when engaging in clinical research, all of which require “time”. Some departments do have specific costs associated with the time required for a particular procedure/task, others account for this time in their administration fees. Even if you have research staff (i.e. coordinator) it is important to consider how much time each activity will take, and who will undertake each of the activities in the protocol and budget accordingly. If you do not have research staff who can dedicate their time to the necessary activities, you may need to work with CHEOS in a fee-for-service model to cover the costs.

For example:

1. How much time is required to screen and consent each patient?
2. Will we require any additional time for translation or interpretation during consent?
3. How much time is required to complete a case report form (CRF) for each clinic visit?
4. How much time is required to assemble a trial master file/study master file?
5. Is there any required patient follow up, telephone interviews or time to schedule patient visits?
6. How much time is required to compile documents for clinical trial agreement?
7. How much time is required to complete REB application?
8. How much time is required to train staff on protocol?
9. How much time is required to analyze the data?
10. How much time is required for study closeout?
11. How much time is required to create a study questionnaire?
12. How much time is required to collect, compile and analyze questionnaire data?