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

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International Exchange Rates	☐ If participating in an international study/sites	
Monitoring Requirements	☐ Site initiation visits ☐ Ongoing monitoring ☐ Close out	
Audits and Inspections	☐ Sponsor Audit (consider the number of days and personnel cost) ☐ Health Canada Inspections – usually five days (consider the number of days and staff costs) ☐ Other international agencies (e.g. FDA, NIH)	
Participant Amounts	☐ Screen failures ☐ Lost to follow up ☐ Early termination ☐ Site start-up amount ☐ Per participant amount (compensation for each participant enrolled into the study) ☐ Serious Adverse Events ☐ Advertising ☐ Parking and transportation costs ☐ Remuneration (if applicable) ☐ Providing research results to participants (e.g. by mail, by email, by website) in lay language at the end of the study	
Privacy Requirements	☐ Privacy Impact Assessment cost ☐ Additional considerations for cohort or registry studies	
Archiving/Long term storage requirements	☐ 15 years storage for regulated clinical trials ☐ 5-7 years of storage for non-clinical trials (based on institutional requirements)	
Regulatory (if applicable)	☐ Clinical Trial Application to Health Canada ☐ Clinical Trial Amendments ☐ Pharmacovigilance Reporting (will the study have a lot of events that will need to be reported to Health Canada?)	
Training Needs	☐ Staff training requirements for proof of competency (licensing fees/insurance, GCP trainings, TDG training, etc) ☐ Protocol-specific training (at each participating centre) ☐ Investigator meetings ☐ If sponsoring a multi-centre study – possible travel to train other sites, conduct site initiation visits, train monitors, etc	
Additional considerations	☐ Chart retrieval/medical records ☐ Electronic health/administrative data retrieval ☐ IT purchases (laptops or servers) ☐ Communications: telephones (landline and cell phone), conference call requirements, webinar needs, if multi-national compensating personnel for conducting meetings outside regular working hours ☐ Online survey development ☐ Translation services ☐ Transcription services	

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	☐ Courier requirements (shipping specimens, documents, etc)	
Common Services (Note for multi-centre studies, the sponsor must provide funds for each participating site)		
Expense	**Projected Expense**	**Estimated Cost & Notes**
Radiology	☐ Administration fee ☐ CT costs ☐ Test scan & transfer / submission ☐ Single area CT ☐ Double area CT (each additional area) ☐ Post scan reconstructions ☐ IV contrast (up to 150 cc's) ☐ Radiologists consultation (for each exam) ☐ Head scan w/o contrast ☐ Head scan with contrast ☐ Double head scan 2 planes ☐ Body scan w/o contrast ☐ Body scan with contrast ☐ Double body scan 2 planes ☐ CD/ROM with patient ID removed ☐ CD packaging / form completion/ Fed-Ex ☐ MRI – variable based on test ☐ Data processing – reporting ☐ Contrast for MRI ☐ General Radiography ☐ Ultrasound	
Cardiology	☐ ECG ☐ Ultrasound	
Medical and Allied Health Professional Services	☐ Nursing ☐ Physical / Occupational therapists ☐ Fitness / exercise instructors ☐ Dietician	
Laboratory Costs	☐ Protocol review fee ☐ Administration fee ☐ Protocol revisions ☐ Individual laboratory test costs ☐ Urine standard ☐ Urine 24 hour ☐ Phlebotomy (up to 4 tubes) ☐ Shipping between labs ☐ Inter-hospital shipping ☐ Ambient packaging ☐ Frozen packaging ☐ TDG container, forms & materials ☐ Storage of serum/urine	
Pathology	☐ Administration ☐ Procedures ☐ Electron Microscopy ☐ Light Microscopy	
Pharmacy Costs	☐ Set-up fees & Assessment ☐ Clinical dispensing ☐ Maintenance ☐ Product costs ☐ Courier costs	

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Service Contracts / Maintenance	☐ Freezer maintenance ☐ Annual software licences ☐ Computational cluster fees	
Materials & Expendables for the Study		
Expense	**Projected Expense**	**Estimated Cost & Notes**
Study Intervention	☐ Drug/Device/Biologic Cost per participant ☐ Shipping costs ☐ Central pharmacy, packaging and licensing fees ☐ Specialized study equipment (e.g. equipment not already at the site or not accessible for research purposes) ☐ Medical Monitor review	
Printing & copy costs	☐ Flyers / brochures / posters for recruitment ☐ Consent documents ☐ Questionnaires ☐ Patient information ☐ Toner ☐ Paper ☐ Trial Master File (clinical study) ☐ Other:	
Sample collection / analysis & disposables	☐ Salivettes / swabs / collection vials ☐ Syringes ☐ Slides ☐ Gloves ☐ Butterfly tubes ☐ Alcohol pads ☐ Cell culture materials ☐ Antibodies ☐ Synthesis / preparation of reagents ☐ Pathology supplies ☐ Other: ☐ Other:	
Specialized materials	☐ Cameras / recording devices ☐ Exercise equipment ☐ Other:	
Miscellaneous	☐ Calibration of equipment (scales etc) ☐ Gas (NO, CO_2, O_2) ☐ Dry ice ☐ 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	☐ Airfare ☐ Conference fees ☐ Transportation	
Publication & Dissemination Costs	☐ Immediate release fees ☐ Publication fees ☐ Manuscript preparation ☐ Collaborator meetings ☐ Costs for distributed materials	

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	☐ If integrated KT is required – funds for patient/advocacy group meetings, public meetings.	

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 (e.g. 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 Advancing Health Outcomes 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?

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