|  |  |
| --- | --- |
| **Phase** | **Process** | **Purpose** | **Resources** |
| 1. Research Study Development & Refinement (2 - 6 months) | 1.1 Literature review; scoping review; systematic review | * Identify knowledge gaps
* Define and refine research question
* Identify potential collaborators
* Explore types of study designs
* Focus research plan to ensure feasibility and appropriateness of your research question
 | * [Your research mentor](https://experts.news.ubc.ca/fields/)
* Your Departmental Research Manager
* [VCHRI Researcher Directory](https://www.vchri.ca/researcher-directory)
* VCHRI Research Facilitator
* [VCH Library Services](http://www.vch.ca/for-health-professionals/library)
* [UBC Library](https://www.library.ubc.ca/)
* [VCH CRU](https://www.vchri.ca/services/clinical-research-unit)
* [UBC DoM](https://medicine.med.ubc.ca/research/guide/)
* [C2E2](http://www.c2e2.ca/)
* [CHEOS](http://www.cheos.ubc.ca)
* [BC AHSN](https://bcahsn.ca/)
* [N2](http://n2canada.ca/)
 |
|  | 1.2 Identify Patient Partners | * Engage patients and community as partners
* Consider the knowledge users of your research and engage with them early to develop a Knowledge Translation (KT) plan for your research
* Consider appropriate Indigenous health research guidance
 | * [VCH CEAN](http://cean.vch.ca/)
* [VCH Aboriginal Health](http://www.vch.ca/your-care/aboriginal-health)
* [Indigenous Research Support Initiative (UBC)](https://research.ubc.ca/about-vpri/indigenous-research-support-initiative)
* [PVN](https://patientvoicesbc.ca/) (PHC)
* [GOV BC Patients/Partners](https://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/partners/patients)
* [CIHR SPOR](http://www.cihr-irsc.gc.ca/e/41204.html)
* [KT Pathways](https://ktpathways.ca/)
* [VCH Community Engagement](http://cean.vch.ca/wp-content/uploads/sites/26/2017/07/How-to-Engage-Patient-and-Public-Advisors-A-Guide-for-Staff-FINAL2.pdf)
* [CIHR Guidelines for Health Research Involving Aboriginal People](http://www.cihr-irsc.gc.ca/e/29134.html)
 |
|  | 1.3 Identify Study Framework | * General designs: Qualitative or Quantitative
* Health Services
* Program Evaluation
* Clinical Trials
 | * [C2E2](http://www.c2e2.ca/)
* [CHEOS](http://www.cheos.ubc.ca/services/)
 |
|   | 1.4 Refine Methodology | * Confirm your study design is appropriate for your research question
* Consult with statistician or methodologist to ensure you plan to collect the data you need to answer your research question
* Develop a plan for how to deal with missing data/incomplete data sets
* Calculate the sample size you need (if applicable)
* Is it Research or QI?
 | * [C2E2](http://www.c2e2.ca/)
* [UBC Applied Statistics and Data Science Group](https://asda.stat.ubc.ca/)
* [CHEOS](http://www.cheos.ubc.ca/)
* [PopDataBC](https://www.popdata.bc.ca/)
* [SFU Big Data Hub](https://www.sfu.ca/big-data/services)
* [ARECCI](https://albertainnovates.ca/our-health-innovation-focus/a-project-ethics-community-consensus-initiative/arecci-ethics-guideline-and-screening-tools/) Evaluation Framework
* [Qualitative Designs & Methods](http://web.b.ebscohost.com/ehost/detail/detail?vid=0&sid=9687f1ac-f9f9-49b8-95b0-6068c03ac729%40pdc-v-sessmgr06&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#AN=1286427&db=nlebk)
 |
|   | 1.5 Develop study protocol | * For clinical research, the protocol details how the study will be conducted
* General components include: project title, summary, research proposal, ethical considerations, roles and expertise of team members, study timeline, strengths and limitations, results and implications, anticipated results and implications and references
* Must be aligned with regulatory requirements
* Consider appropriate Indigenous health research context
 | * [VCHRI Quality](https://www.vchri.ca/services/clinical-trials-administration/clinical-research-quality)
* [SPIRIT](https://www.spirit-statement.org/title/)
* [WHO](https://www.who.int/rpc/research_ethics/format_rp/en/)
* [UBC DoM](https://med-fom-medicine.sites.olt.ubc.ca/files/2014/02/Research-protocol-outline_Version4.doc)
* Writing a Research Protocol
 |
|   | 1.6 Develop budget | * Consider set up costs, staffing, participant enrollment costs, supplies, incidentals over the time frame of your research study
* Consider the time it takes to operationalize a study (regulatory and compliance steps); travel, overhead and administrative support required; costs for trainees
 | * Departmental Research Manager
* VCHRI budget negotiation tips and calculator
* CHEOS [budget checklist](http://www.cheos.ubc.ca/wp-content/uploads/2017/05/4-Research-Project-Expense-ChecklistMay2017.pdf) and [template](http://www.cheos.ubc.ca/wp-content/uploads/2017/05/4a-CRRC-Schedule-of-Standard-Costs-Template26May2017-FINAL.xls)
* [UBC FOM Indirect Costs of Research Policy](https://mednet.med.ubc.ca/AboutUs/PoliciesAndGuidelines/Policies%20Guidelines/Faculty%20of%20Medicine%20Indirect%20Costs%20of%20Research%20Policy.pdf)
* [UBC Salary Scales](http://www.hr.ubc.ca/compensation/salary-administration/salary-scales/)
* [UBC HR](https://www.hr.ubc.ca/careers-postings/staff-s.php)
 |
|   | 1.7 Identify appropriate funding source | * Depending on size and scope of your project, you can determine whether to focus on internal, local, national or international funding sources
* Consider Tri-Council (CIHR, NSERC, SSHRC) operating grants and priority announcements; charities and foundations; local research institutes and internal divisional or centre funding may be available
* Subscribe to newsletters, which often circulate funding opportunity announcements (VCHRI, VCH Department of Family Practice, CIHR, MSFHR, UBC, Faculty of Medicine, your Faculty/Department, UBC SPARC, CHEOS, iCORD, etc)
 | * [VCHRI Internal Awards](https://www.vchri.ca/services/funding-opportunities)
* [UBC ORS](https://ors.ubc.ca/funding-opportunities/upcoming-major-funding-opportunities) (includes all major funding opportunities)
* [UBC SPARC](https://sparc.ubc.ca/resources-sample-grants)
* [CIHR ResearchNet](https://www.researchnet-recherchenet.ca/rnr16/srch.do?all=1&search=true&org=CIHR&sort=program&masterList=true&view=currentOpps)
* [MSFHR](https://www.msfhr.org/funding/current-funding-opportunities)
* [US grants (NIH, DOD, etc)](https://www.grants.gov/web/grants/search-grants.html)
* UBC & Hospital Foundations
* Area-specific Charitable Foundations
 |
|   | 1.8 Confirm eligibility to apply for funding and review evaluation criteria; confirm application deadlines | * Before developing your grant application, ensure you are eligible to apply. Each funding opportunity will specify eligibility criteria, which may include:
* Education requirements (MD, PhD, etc)
* Career stage requirements
* Appointment type, protected time for research, requirements for funding commitments
* Familiarize yourself with the evaluation criteria for the funding opportunity to ensure you fully address it in your grant
* Confirm application deadlines early in the process
* Check for internal requirements or additional documents needed by your Department, Faculty and/or VCH
 | * [VCHRI ORS](https://www.vchri.ca/services/grant-signing)
* VCHRI Research Facilitator
* [UBC FOM MedNet](https://mednet.med.ubc.ca)
 |
|   | 1.9 Grant development | * Identify requirements for the funding opportunity (partners, letters of support) and elements that will improve the competitiveness of your proposal
* Review previous successful grants (SPARC maintains a library of grants)
* Participate in internal grant review process
* Engage your Department’s grant writer to strengthen your proposal
 | * [VCHRI Internal Awards](https://www.vchri.ca/services/funding-opportunities)
* [UBC SPARC](https://research.ubc.ca/support-resources/research-funding-support/funding-opportunities/project-development-sparc)
* [Grant Development Office in your Department](https://ors.ubc.ca/funding-opportunities/grant-facilitators)
 |
|   | 1.10 Obtain signatures and submit funding application | * Each funding application requires a completed and signed Research Project Information Form (RPIF), which is reviewed by your Department Head, Centre Director (if applicable), and Dean
* Depending on the funding opportunity, there may be multiple signature requirements at the Divisional, Departmental, Faculty and Institutional levels – allow adequate time for obtaining all the necessary signatures well before application deadline
* If you do not have a UBC affiliation, contact VCHRI ORS
 | * [VCHRI ORS](https://www.vchri.ca/services/grant-signing)
* [Research Project Information Form](https://research.ubc.ca/support-resources/forms-tools-resources/research-project-information-form)
* [UBC Policy 87](https://universitycounsel.ubc.ca/files/2016/04/policy87.pdf)
* [FoM signature process](https://mednet.med.ubc.ca/Research/SubmitApplications/SignatureProcess/Pages/default.aspx) (for Faculty Salary Awards)
 |
| 2.0 Research Study Setup (4-9 months) | 2.1 Tracking your project | * UBC uses RISe, an online system to manage and track funding applications
* You can access RISe using your CWL
* CWL is used for all Ethics applications
 | * [UBC RISe](https://www.rise.ubc.ca/)
* [UBC Campus-Wide Login](https://activate.id.ubc.ca/iamweb/)
 |
|   | 2.2 Setting up a research account | * Once you receive funding, ORS will create a Project Grant (PG) research account for your study
* You will need to provide your RPIF (if you haven’t already), award letter including payment schedule, and complete any required compliance steps
* For Sponsor clinical trials, contact VCHRI Clinical Trials Administration
* For Investigator-led clinical trials, contact UILO
 | * [VCHRI ORS](https://www.vchri.ca/services/grant-signing)
* [VCHRI CT Administration](https://www.vchri.ca/services/clinical-trials-administration/contract-facilitation)
* [UILO](https://uilo.ubc.ca/)
* [RPIF](https://research.ubc.ca/sites/research.ubc.ca/files/vpri/Research_Project_Information_Form.pdf)
* Department Manager – PI Dashboard
 |
|   | 2.3 Research Approvals | * Before you begin your study, you may need multiple approvals, and this may be time-consuming to complete
* You can often complete all these requirements simultaneously, and you can do many of them while you are applying for funding.
* ORS can advise on which requirements will apply to your study:
	+ Human Research Ethics
	+ Biosafety
	+ UBC Conflict of Interest
	+ UBC Financial Conflict of Interest
 | * [VCHRI ORS](https://www.vchri.ca/services/grant-signing)
* [UBC ORS](https://ors.ubc.ca)
* [UBC Risk Management Services](https://rms.ubc.ca/)
* [UBC Conflict of Interest](https://ors.ubc.ca/compliance-reporting/compliance-requirements/conflict-interest)
 |
|   | 2.4 Human Research Ethics | * All research involving human participants must have Ethics approval, and are centrally processed through UBC REB
* Ethics applications, templates and other resources are available on the RISe website
* Regular workshops to guide and support researchers through the application process are held by CREB
* Consider the ethics of research involving Indigenous people, as applicable to your study
 | * [UBC RISe](https://www.rise.ubc.ca/)
* [CREB Guidance Notes](https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes)
* [UBC Office of Research Ethics Policies & SOPs](https://ethics.research.ubc.ca/policies-sops)
* [TCPS2](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)
* [Indigenous Peoples’ Health Research Centre](http://iphrc.ca/pub/documents/ethics_review_iphrc.pdf)
* [Considerations & Templates for Ethics Research Practices](https://fnim.sehc.com/getmedia/209c3242-9e05-4ae3-877d-ff0912534ff7/Considerations_Templates_Ethical_Research_2007.pdf.aspx?ext=.pdf)
 |
|   | **2.5 VCHRI Operational Approval**  | * Any research conducted on any Vancouver Coastal Health site requires VCH Operational Approval.
* This process allows for the review and approval of research projects that impact or affect VCH services and resources
* There are two main components:
	+ Proof of Ethical Approval
	+ VCH Department/Unit/Clinic Impact Review
* Submit completed application form to the Coordinator, Research Approvals
 | * [VCHRI Operational Approval Process](https://www.vchri.ca/services/operational-research-approval) and [Application Form](https://www.vchri.ca/sites/default/files/form_-_vch_application_for_operational_approval_sept2018.doc)
* VCHRI Coordinator, Research Approvals
 |
|   | 2.6 Contracts | * VCHRI contract support (Sponsor clinical trials)
* UILO contract support (Investigator-led studies)
 | * [VCHRI contract facilitation](https://www.vchri.ca/services/clinical-trials-administration/contract-facilitation)
* [UBC UILO](https://uilo.ubc.ca/)
 |
|   | 2.7 Clinical Trials | * All VCH Clinical Trials must adhere to Good Clinical Practice (GCP) standards, and all Investigators and research personnel at VCH are required to complete GCP training.
* Free, online access to GCP training is available on the CITI website through VCHRI’s agreement with N2
* VCHRI CRU offers services to Investigators
* Clinical Trials regulated by Health Canada require maintenance of Essential Documents
* Clinical Trials must be registered on clinicaltrials.gov
 | * [VCHRI Quality Assurance](https://www.vchri.ca/services/clinical-trials-administration/clinical-research-quality)
* [VCHRI CRU](https://www.vchri.ca/services/clinical-research-unit)
* [CITI link](https://about.citiprogram.org)
* [ORS Clinical Trials Registration](https://ors.ubc.ca/compliance-reporting/clinical-trials-registration)
* [Clinical Trials BC](https://www.clinicaltrialsbc.ca)
 |
|   | 2.8 Assemble your research team | * Conduct a needs assessment to determine:
	+ How much work there will be
	+ What the specific duties are
	+ What qualifications are required to complete the duties
	+ Which existing resources can be committed to the position
	+ What training is needed for research personnel
* Before you can hire research personnel, your funding must be in place
* The hiring process includes developing a job description, appropriately classifying it, posting, interviewing and hiring steps
* Connect with HR early to develop appropriate timelines for your research project
 | * [UBC HR](http://www.hr.ubc.ca/)
* [UBC Student Research Volunteer](https://www.uroubc.com)
 |
|   | 2.9 Engage trainees | * If you are interested in mentoring residents, graduate or undergraduate trainees, you will need to meet eligibility criteria to become a member of the UBC Faculty of Graduate and Postdoctoral Studies
 | * [Faculty of Graduate and Postdoctoral Studies](https://www.grad.ubc.ca/contact-us)
* Your departmental graduate program
 |
|   | 2.10 Data collection and management | * Consider:
	+ What kind of data management tool and IT infrastructure is needed for your research project?
	+ How will your data be collected and securely stored?
	+ How will the system be validated?
	+ Privacy requirements
	+ Ethics requirements
	+ Quality Data Management System
	+ Data requests are part of Operational Approval
	+ Indigenous data principles
 | * [C2E2](http://www.c2e2.ca/)
* [CHEOS](http://www.cheos.ubc.ca/services/navigating-the-clinical-research-process/)
* [UBC IT resources and Data management](https://medicine.med.ubc.ca/research/additional-resources/it-resources/)
* [VCHRI Privacy](https://www.vchri.ca/services/research-privacy)
* [Redcap](https://arc.ubc.ca/redcap)
* [OCAP](https://fnigc.ca/ocap)
 |
| 3.0 Research Study Execution | 3.1 Managing your finances and financial reporting  | * Your UBC account is viewable on FMS
* Each UBC department has their own Finance contact and should be your first point of contact
* Contact ORS for budget increases or award changes
* Many funding agencies require ongoing reporting to ensure that project expenditures and activities continue to meet their requirements
* The PI is responsible for the oversight of a number of financial reporting and monitoring activities once a research grant has been awarded
 | * Department Finance Contact
* [VCHRI ORS](https://www.vchri.ca/services/grant-signing)
* [UBC ORS](https://ors.ubc.ca/)
* [UBC Research Finance](https://finance.ubc.ca/research-finance)
 |
|   | 3.2 Analyze data | * Statistical support for data analysis can be accessed for underfunded projects by contacting DOM Research office, but accessing other UBC resources or services from affiliated centers
 | * [C2E2](http://www.c2e2.ca/)
* [CHEOS](http://www.cheos.ubc.ca/)
* [UBC Applied Statistics and Data Science Group](https://asda.stat.ubc.ca/)
 |
|   | 3.3 Disseminate findings | * Knowledge Translation is an important part of research. Specific activates will depend on the end users of your research and can include publishing papers, presenting locally or at national/international conferences, creating toolkits, websites, movies, presenting at patient forums, contributing to guidelines or working with the Ministry of Health
 | * [KT Pathways](https://ktpathways.ca/)
* [MSFHR KT Resources](https://www.msfhr.org/our-work/activities/knowledge-translation/kt-resources)
* [VCHRI KT Challenge](https://www.vchri.ca/ktchallenge)
* [VCHRI Communications](https://www.vchri.ca/services/communications-and-media)
 |
|   | 3.4 Intellectual Property; Commercialization | * If your research involves partnerships with industry, non-profits or government, you have a research discover you wish to commercialize, a technology you want to patent, or a spin-off you want to create, you will need to work with UILO.
* UBC has a venture accelerator that can help provide seed funding, support your setup, and connect you with other entrepreneurs
 | * [VCH Intellectual Property](https://www.vchri.ca/services/clinical-trials-administration/intellectual-property)
* [UBC UILO](https://uilo.ubc.ca/)
* [entrepreneurship@UBC](http://entrepreneurship.ubc.ca/)
 |
| 4.0 Terminating Study |  | * Terminate ethics application on UBC RISE
* Submit completion of study to VCHRI Operational Approval
* For regulated clinical trials, inform Health Canada/FDA
 | * [UBC RISE](https://www.rise.ubc.ca/)
* [VCHRI Operational Approval](https://www.vchri.ca/services/operational-research-approval)
* [VCHRI QA](https://www.vchri.ca/services/clinical-trials-administration/clinical-research-quality) (for clinical trials)
 |

Additional clinical research training and education resources:

* [CITI training](https://about.citiprogram.org/en/homepage/) – free and online training, including Good Clinical Practice (GCP) and Health Canada Division 5
1. go to: [www.citiprogram.ca](http://..www.citiprogram.ca)
2. Click on ‘Register’
3. Select “Vancouver Coastal Health Research Institute” in the ‘Canadian Institutions’ dropdown menu
4. Submit requested information
* [VCHRI SOPs and Tools](https://www.vchri.ca/services/clinical-trials-administration/clinical-research-quality) – log into vchri.ca to view SOPs and Tools
	+ To request access to the VCHRI internal website contact marc.saunders@vch.ca
* [VCHRI Richmond Research Support](https://www.vchri.ca/richmond-research-support)
* VCHRI Coastal Research Support
* VCHRI Community Research Support
* [VCHRI Events Calendar](https://www.vchri.ca/researchers/education-events/calendar) – free events and workshops offered through VCHRI
* [ACRP e-learning library](http://learning.acrpnet.org/ext/avectra/login/index.php) (co-hosted by VCHRI and Clinical Trials BC)
	+ To request access to the Learning Portal contact marc.saunders@vch.ca
* [TCPS-2](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) Course of Research Ethics (CORE)