Navigating the Clinical Research Process: From ideation to completion

CHÉOS
Centre for Health Evaluation & Outcome Sciences

Introduction

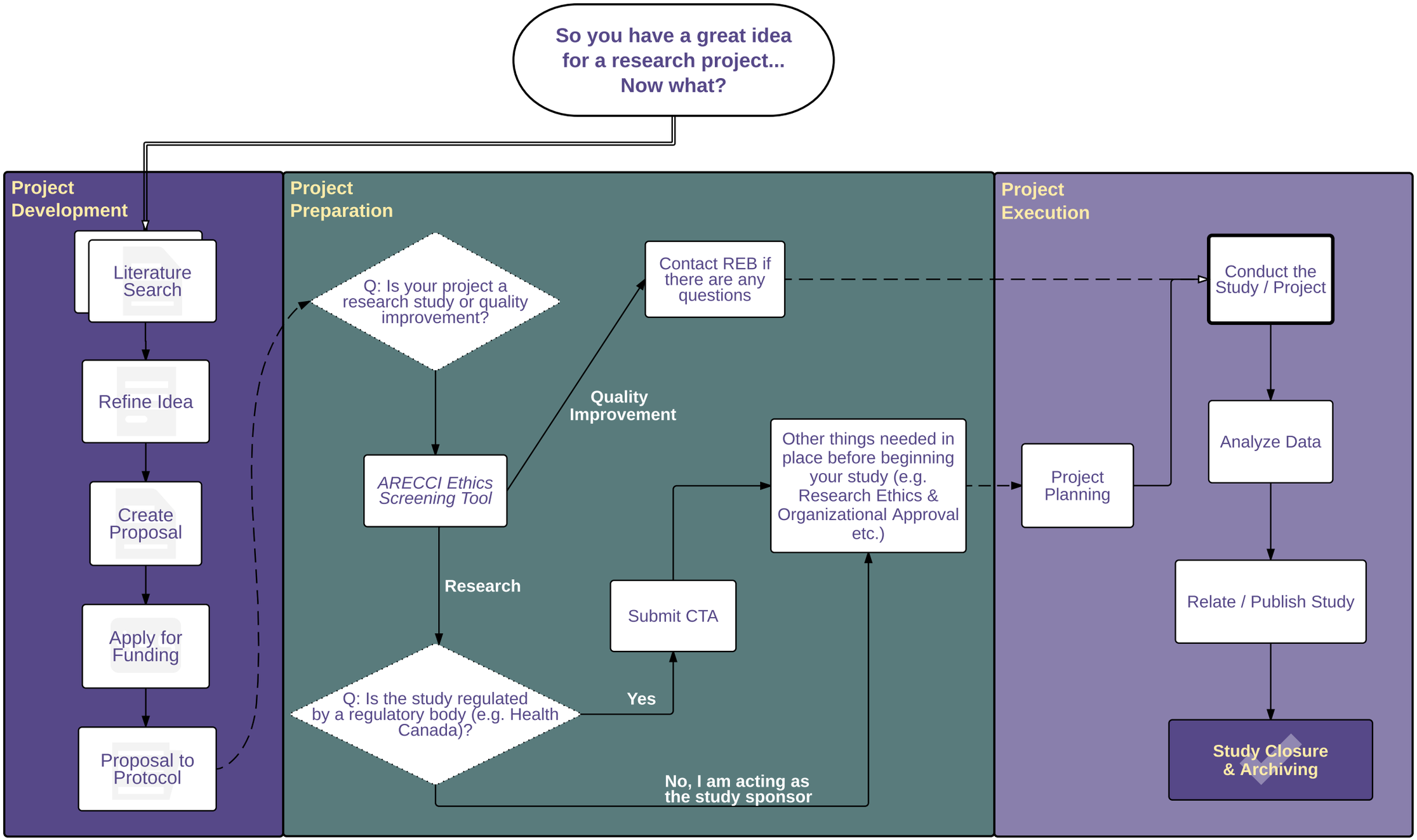
You have a great idea for a research project … now what?

It is important to plan all aspects of your clinical research study as early as possible, and prior to beginning your project, to prevent data collection, human resource, budget, regulatory compliance, or timeline challenges. Dedicate significant time to designing your study: clearly articulate your objectives, hypothesis, and how you will meet these objectives. If necessary, be sure to obtain professional advice on protocol design, data collection, and analyses. CHÉOS provides support for clinical researchers in the form of:

- Project and data management
- Methodology and statistics
- Program evaluation
- Regulatory affairs
- Trial monitoring, and
- Health economics

CHÉOS also provides one hour of free consultation: http://www.cheos.ubc.ca/services/request-services/. We recommend that you conduct a literature review and prepare specific questions prior to your consultation to ensure that you maximize the potential of your consultation. To help you prepare for the consultation, our staff have prepared questions that they routinely ask during the consultation process. (H:\Research Education\Research process Map\Study Document Templates\To post).

CHEOS RESEARCH PROCESS MAP



Literature Review

A proper literature search is integral to defining your research question and designing your study. Here are a few examples of available resources that can help in conducting an in-depth review:

- http://guides.library.ubc.ca/c.php?g=307302&p=2049908
- http://www.cochranelibrary.com/
- http://research.fraserhealth.ca/research-support/research-development/planning-your-research/researching-the-literature/

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Refine Idea

- If your research question is too broad, you will have difficulty designing a focused study and collecting data to answer your hypothesis. If it's too narrow, you will have difficulty finding the appropriate participants.
- Engaging patients in research is a relatively new aspect of clinical research, but has recently shown to improve participant experience and outcomes in clinical trials.*

The BC SUPPORT (Support for People and Patient-Oriented Research and Trials) Unit is a "multi-partner organization created to support, streamline, and increase patient-oriented research throughout BC. Patient-oriented research is research that engages patients as partners and focuses on patient-identified priorities with the goals of improving patient experiences, health outcomes, and the health system".

The BC Unit is one of ten SUPPORT Units established across the country by the Canadian Institutes of Health Research (CIHR) as part of Canada's Strategy for Patient-Oriented Research (SPOR).

Three CHÉOS Scientists currently serve as Methods Cluster Leads. Under the Methods Cluster structure, experts in specific methodological approaches to patient-oriented research are connected to foster innovation and collaboration. http://bcsupportunit.ca/methods-clusters/

See: http://bcsupportunit.ca/about/ for more information.

SPOR BC SUPPORT Unit helps researchers develop patient engagement plans: http://bcsupportunit.ca/services/

* *Baker, R. G. (2014). Evidence boost: a review of research highlighting how patient engagement contributes to improved care. Ottawa, ON: Canadian Foundation for Health Improvement*

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Create Proposal

- If you need to create a proposal to apply for funding, and the funding agency does not have their own template, you can use the CHÉOS template here: H:\Research Education\Research process Map\Study Document Templates\To post

- Planning Methodology
  - Need help understanding the basics of statistics? See: http://www.graphpad.com/support/faqid/1790/
  - Contact Biostatistician: http://www.cheos.ubc.ca/services/request-services/

- Preparing a Budget:
  - CHÉOS provides a budget template with a list of possible set up costs, procedures, incidental costs and suggested hourly rates for the primary study team members. Don't forget that funding can be subject to overhead costs which range from 10% to 40% (pharmaceutical or device company-funded studies). See: Link to CHEOS budget template H:\Research Education\Research process Map\Study Document Templates\To post
  - Providence Health Care (PHC) does not have a list of fees for common research procedures or tests associated with research projects (e.g. lab tests), but attached is a list of the departmental contacts, who may be able to help you with your budget. H:\Research Education\Research process Map\Study Document Templates\To post

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Apply for Funding

CHEOS does grant facilitation

CIHR is the primary source of federal funds for health research in Canada:
http://www.cihr-irsc.gc.ca/e/37788.html

Other suggestions for funding are:

- Disease-related foundations (e.g. Heart and Stroke Foundation, Cystic Fibrosis Foundation) Industry partners. A pharmaceutical or medical device company may not provide direct funding for a project, but they may consider donating the study intervention (e.g. drug or device).
- St. Paul's Hospital Foundation
- The Providence Health Care Research Institute (PHCRI) website lists some awards and funding opportunities: http://www.providenceresearch.ca/news-events/awards-and-funding
- PHCRI and CHÉOS have weekly or bi-weekly e-newsletters that include funding opportunities. Subscribe at:
  PHCRI: research@providencehealth.bc.ca
  CHÉOS: http://www.cheos.ubc.ca/ *Scroll to the bottom of the page and enter your email address.*

For UBC Researchers: The UBC Office of Research Services (ORS) also maintains a list of upcoming funding opportunities for UBC researchers:
https://ors.ubc.ca/funding-opportunities/upcoming-funding-opportunities.

SPARC (Support Programs to Advance Research Capacity) offers services and resources to UBC faculty members to make the most of their funding proposals. They will also provide examples of sample grant proposals. See: https://sparc.ubc.ca/

Funding agencies usually require departmental approval for your proposal. This includes your department head and the ORS at UBC. UBC provides an excellent graphic of the steps required and the timelines for developing and submitting a proposal for funding:
http://medicine.med.ubc.ca/research/guide/proposal/#7

For further information on signature requirements and timelines, see:
https://ors.ubc.ca/proposal-submission

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Turn Your Proposal Into a Protocol

While you can use your proposal as a template for your protocol, a proposal is written to only obtain support for your study. A study protocol contains detailed instructions on how the study will be conducted, and includes information to meet regulatory requirements (if applicable). CHÉOS provides protocol templates for use in interventional and non-interventional clinical studies.

- Link to CHÉOS protocol templates: H:\Research Education\Research process Map\Study Document Templates\To post
- Statistics and Statistical Analysis Plan: What is the purpose of the analysis and how will the results be used? (See CHEOS consultation document in the introductory section.)
- Note that UBC requires that any protocol that is more than minimal risk*, must undergo a peer review. See UBC Research Ethics, General Guidance Notes, Article 8.2 for more information (https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes). Peer review should come from a colleague not involved in the research, or a supervisor or mentor for trainees. In rare circumstances, it may come from the funding agency or sponsor.
- ** The BC Ethics Harmonization Initiative (2013) defines minimal risk research as "research in which the probability and magnitude of possible harms implied by participation is not greater than those encountered in the aspects of everyday life that relate to the research".* *http://www.msfhr.org/sites/default/files/BCEHI_minimal_risk_common_criteria_guideline.pdf*

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