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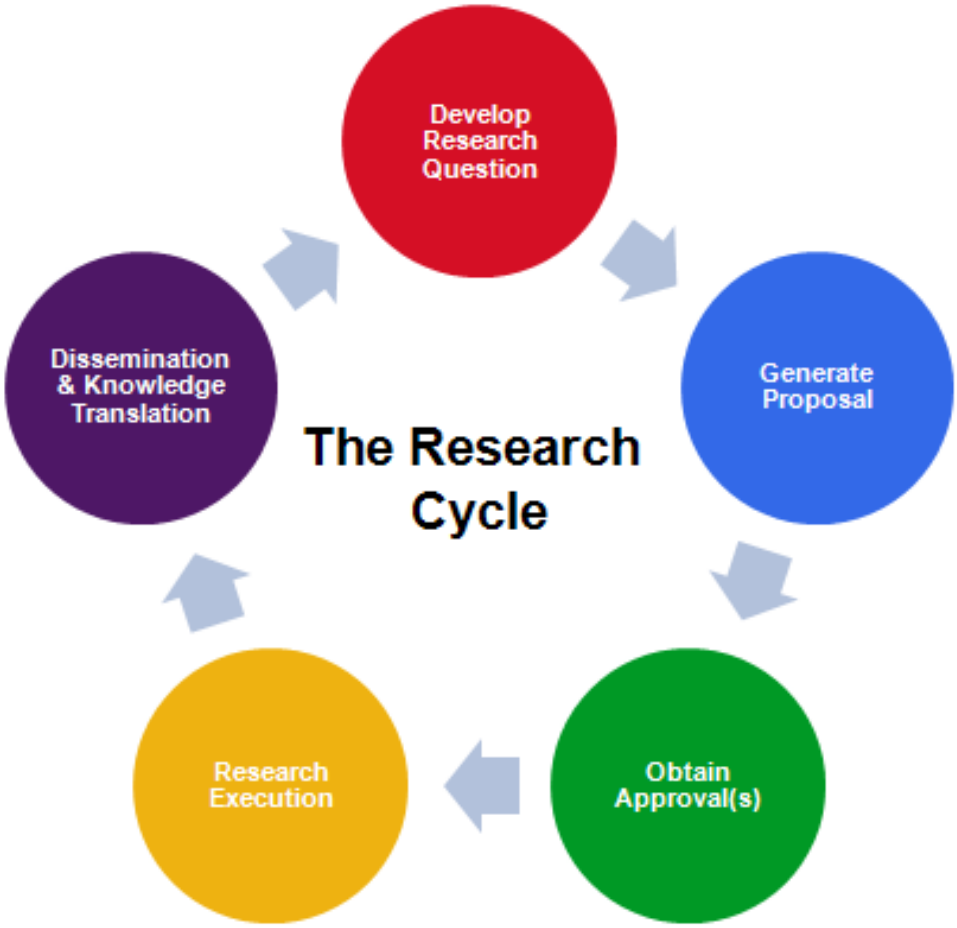


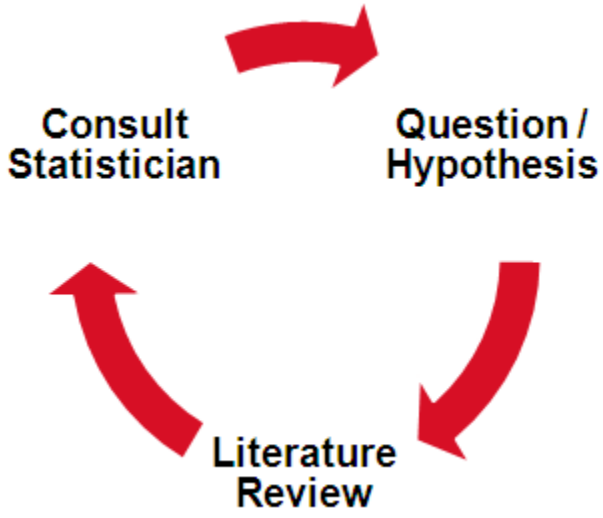
1. Develop Research Question

Careful planning is the key to successful research. The Research Office is happy to help you with all of your planning needs. If you have any questions about any available resources please contact the Research Manager.

Identify your question

One of the most difficult part of research is refining and framing your research question. You may have an idea of the question that you would like to answer already from your practice, or you may need to talk with a potential mentor to help you identify a research question.

Residents who are interested in identifying a research mentor are encouraged to contact the Postgraduate Education Office to obtain a list of available mentors. PI's who are interested in mentoring residents/fellows or graduate students are encouraged to contact the Research Manager.



When considering your research question ensure it is good practice to evaluate your idea to ensure your proposed study is:

- Achievable - given the available time, funding and patient population
- Novel - ensure that the study has not already been done
- Relevant - other individuals in your field would benefit from the knowledge or findings
- Ethical - does the work you are proposing ensure

Individuals without previous research experience are encouraged to begin with a common convention for framing a research questions, the PICOT approach (1-2).

- **P**opulation/**P**roblem
- **I**ntervention
- **C**ontrol
- **O**utcome
- **T**ime frame

Literature review

A thorough literature review will help ensure that your question is novel and has not been answered already. If you have never performed a detailed lit search before please visit the UBC Library Research Help site to see the excellent resources available for faculty, staff and students.

UBC Library has links to 50+ Indexes and Databases for Medicine including:

- MEDLINE (PubMed interface) - primary biomedical database
- BIOSIS - biomedical life sciences research database
- Cochrane Library - systematic reviews in healthcare
- Embase - international biomedical database

Note that C2E2, the Centre for Epidemiology and Evaluation, offers periodic courses in systematic review. Individuals interested in conducting systematic reviews are encouraged to look for training opportunities.

Consult with a Statistician or Methodologist

Careful planning and purposeful collection of data is key to the successful outcome of a research project. Consulting with a biostatistician or methodologist at the beginning of your project can assist with the following:

- Help you ensure that you are collecting all the information you need to answer your question
- Develop a plan for how to deal with missing data/ incomplete data sets
- Assist with sample size estimates for budgeting and planning your study

Department of Medicine researchers may have access to a variety of Statistical and Methodological support services, ranging from drop-in support, collaboration, rounds and group/panel discussions. For assistance in determining the best option for your project please contact the Research Manager.

1. SCARL – This is the UBC department of Statistics consulting group. They have general consultancy terms which are clearly set out and available to all UBC members here. They are happy to get involved with studies right from the grant writing stage, helping to be sure that the objectives set out in grants are statistically feasible with the described methodology. Their consulting costs approximately $80-$200/hour, depending on the length of the project and qualifications of the consultant.
2. C2E2 – The Centre for Clinical Epidemiology and Evaluation is part of VCHRI. VCHA members can sign up for free one hour consultations with the statisticians, after which arrangements for continuing support must be made.
3. CHEOS – The Centre for Health Evaluation and Outcome Sciences at St. Paul's Hospital offers consultations on data management, grant facilitation, health economics, mentoring, methodology, and statistics. They also maintain a list of research-related seminars and workshops. CHEOS offers an initial free consultation,

after which the fees will depend on the extent of the project and the expertise required. Internal PHC researchers get a discounted fee.

4. DASI – The statistical consulting unit in the Faculty of Pharmaceutical Sciences at UBC provides Data Analytics, Statistics and Informatics support for researchers and investigators.

2. Generate Proposal / Protocol

I. Introduction

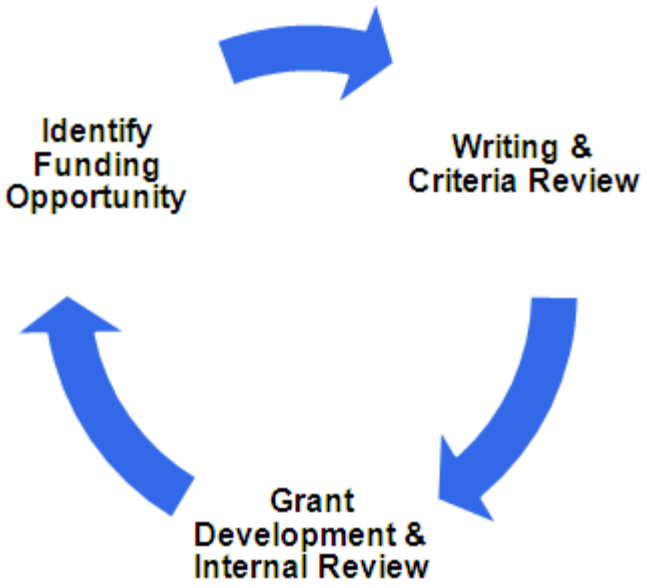
A **grant proposal** and a **research protocol** are not equivalent documents. Grant proposals aim to convey the necessary information to inform a panel of peers why a study should be funded, and that the individual/team has the skills to execute the research. A research protocol is a master document on how to operationalize the research idea. The protocol should contain sufficient information so that the study could be repeated successfully, by another site, group or individual. A variety of sample grants are available through both the Research Office and the SPARC office for individuals who wish to view successful grant applications. Sample protocols are available through the Research Office for individuals who would like to look at different examples. In this section we will focus on steps required to generate research grant/award proposals. For assistance with protocols please refer to the next section. Obtaining funding for your research involves two phases which are referred to by UBC as pre- and post- award management.

- Pre-award management
  - generate a grant proposal
  - obtain signatures
- Post-award management
  - award acceptance
  - PG accounts
  - contracts
  - reporting requirements

II. Generate a Grant proposal

External funding typically falls into one of the following general grant types: operating grants, salary awards, infrastructure/equipment grants, industry sponsored research, and postdoctoral fellowship/trainee grants. Here we outline the general steps for the submission of a grant or award application.

1. Identify Funding Opportunity
2. Review Edibility and Assessment Criteria
3. Prepare proposal draft
4. Have your draft reviewed by Grant Development or Internal Review
5. Finalize your draft
6. Obtain all necessary signatures
7. Submit your application



1. Identify Funding Opportunities

It is not always easy to know where to look to find open funding competitions. Most investigators are aware of the major competitions run by CIHR, and NIH but may not be aware of some of the other opportunities they could explore. Consider disease specific funding agencies in your area as well as National Centres of Excellence (NCE's). There are a few resources available to help you identify open funding competitions:

- Department of Medicine Research Office
- Faculty of Medicine
- Canadian Institute of Health Research (CIHR)
- National Institutes of Health (NIH)
- Vancouver Coastal Health Research Institute
- UBC Office of Research Services

2. Review eligibility and assessment criteria (both UBC and sponsor)

Who is eligible to apply for funding at UBC?

1. Individuals who hold full time UBC clinical or academic appointments are eligible to apply for funding to conduct research.
2. Only tenure track assistant, associate and professors are eligible to apply for external salary support such as the CIHR New Investigator Award. See Faculty of Medicine website for more information.
3. Research trainees including post-doctoral fellows are eligible to apply for funding providing they are supervised by an eligible researcher.

**Note: ensure that your appointment covers the duration of the award funding or that you have discussed with your Division Head your interest in applying for major awards.*

Review the eligibility of the sponsor and check for any of the following:

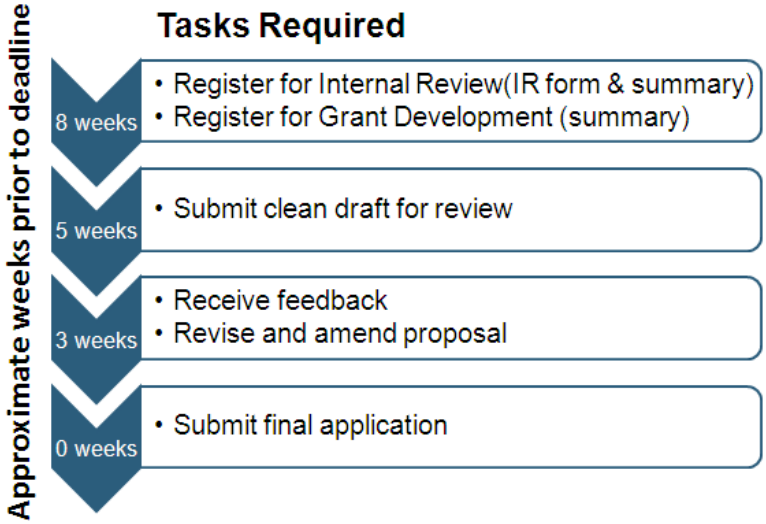
- Education requirements (i.e. MD, PhD)
- Career stage requirements (i.e. within first 5 years of first academic appointment)
- Carefully read the evaluation criteria and make sure you address the key criteria in your proposal. If headings are provided ensure your proposal uses the same headings. Make it easy for the reviewer to understand how your proposal meets both the objectives of the funding agency and the evaluation criteria.

3. Prepare Proposal Draft

Writing from scratch can be a daunting task, it is often helpful to look at sample successful proposals. Both the Research Office and the SPARC office have a collection of sample grants which may be viewed on-line or in person. To access the SPARC resources you will need to use your Campus Wide Login (CWL). If you do not remember your CWL please contact the Research Office. The Departmental Grant Library is located on a special SharePoint site. To access the Departmental Grant Library please contact the Research Manager for a password.

4. Have your draft reviewed by Grant Development or Internal Review

Both the SPARC Internal Review and Faculty of Medicine Grant Development resources are offered for major competitions, including CIHR, NSERC, and SSHRC. The two resources have very differ and complimentary aims. Both of these valuable resources require a registration to ensure that there are sufficient resources to accommodate the need. The dates and deadlines will be specific for each competition, a general schedule is provided here for planning purposes only. Please check with the Research Office to determine current deadlines and availability of review for other competitions.



To get the most out of these services investigators are encouraged to submit close to final drafts for review. If you submit your first draft the comments and reviews will not be as useful, as they would reflect changes you would likely make yourself.

5. Finalize your draft

When finalizing your application it is a good idea to review the criteria again to ensure that you have addressed all the requirements and have all of the necessary documents, including collaborators/co-investigator CCVs, letters of support, quotes etc.

6. Obtain necessary signatures

All grants submitted require the following signatures:

- PI/applicant(s)
- UBC Department Head
- UBC Faculty Dean- Application form (please view this link for the documents that may be required for your application)
- Direct, UBC Research Services (or site designate)

Instituional Signatures are required for all of the following

- Full grant applications
- LOIs (when specified by granting agency)
- Requests for renewal
- Post Doctoral Fellowships
- Graduate and Undergraduate scholarships and fellowships
- Faculty awards, fellowships even when funds not administered through UBC
- *Note: the Department of Medicine has a 48 turnaround policy for signatures. We will do our best to provide a timely service but all researchers are encouraged to begin collecting signatures 5 – 7 working days in advance of any ORS deadline.*

The Research Office will be happy to pass on your complete signature package to the next level for signature. If you would like assistance collecting signatures please contact the Research Manager. When submitting grants for signature please ensure the following are complete and provided.

1. UBC Research Project Information Form (RPIF) with PI signature
2. Title Page or grant cover page
3. Signature Page and routing slip
4. Abstract, or summary of the proposed research
5. Budget and justification
6. Letters of Support & Collaboration (if applicable)
7. Matching funds documents (if applicable)

All requests for signatures for industry sponsored applications are required to be submitted in full and complete form. Applications for salary awards have more stringent

signature guidelines, and will require more time, please plan accordingly. For salary awards please keep the following in mind.

- Your application must be signed by the Dean, not one of the site designates.
- If your appointment is at one of the Senate-approved research centres you must have your RPIF form signed by the Centre Director.

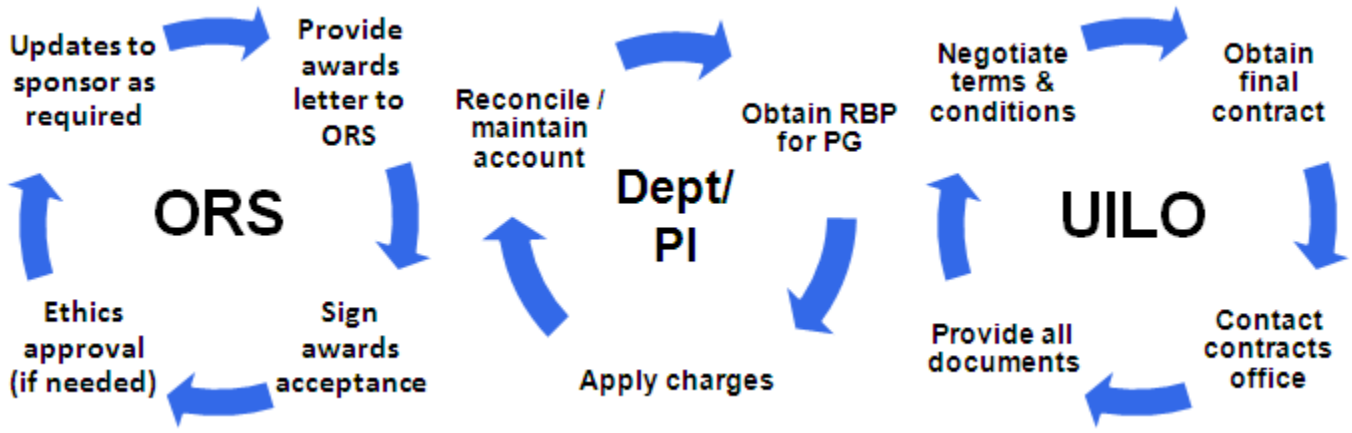
Some rare cases require the signature of the President, and specify that no delegated signatures will be accepted. Please allow at least 3 days to obtain this signature, contact the Vice-President, Research & International Office to obtain this signature.

7. Submit your application

It is the responsibility of the investigator to ensure that they meet any internal (ORS) and external (agency) deadlines. If the investigator is responsible for submitting the grant to the agency you will receive a wet signature from UBC ORS, signatory which you will need to upload/send with your grant. Some grants participate in an e-Submit process. In this case you will need to adhere to ORS internal deadline to be sure there is enough time for ORS to process your grant and submit on your behalf.

III. Post Award Management

You have received a grant! Now what? Most people are surprised to find out that there are a few more important steps required before they can access their grant/awards funds. The term post award management refers all of the processes which occur after a grant has been awarded. The exact activities required will depend on the type of award, sponsor requirements, and whether any contracts are required. Unlike the pre-award phase the post award management may involve the interaction of multiple UBC units such as Research Trust Accounting (RTA), Office of Research Services (ORS), University-Industry Liasion Office (UILO) and the Department.



We will look at each of these cycles here:

1. Opening a R PG (ORS)
2. Applying charges & managing research finances (Dept & PI)
3. Execution of Contracts (UILO) (if needed)

1. Opening a Research PG Account

Grants and awards are always held in trust by UBC, not given directly to individual PI's. Funds for research are kept in R PGs which are set up by ORS, managed by the Department and overseen by RTA. The following rules apply to R PG's at UBC.

1. In order to hold a UBC research Project Grant (PGs) the researcher must hold a permanent appointment at the rank of either assistant/clinical assistant professor or higher. Post doctoral fellows, research fellows, students or visitors cannot hold PGs in their name. Instead the PG will be opened under either the name of the supervisor or department head
2. For lecturers and research associates, upon confirmation of the appointment covering the term of the grant special permission may be granted by the Dean to open a PG account.
3. In order to open a R PG account the following must be in place:
    1. RPIF form
    2. notice of award
    3. copy of application (if available)
    4. budget plan for funds
    5. ethics certificate (if applicable)

In most cases, with the exception of the ethical approval, these items will be provided to ORS at the time of submission and will be kept on file in the event the application is successful.

1a. Notify the Department/ORS

For all grant/awards the investigator will be given an Awards Notice. This notice outlines the key terms of the award including the duration and any limitations on the use of the funds. ORS will use the information in this letter to open a Research PG account in the investigators name. For major competitions (CIHR/NSERC/SSHRC), ORS will receive a copy of this letter directly. However, it is always recommended that the investigator send a copy of this letter to the Department Research Office. We will forward this to ORS directly, and determine if there are any additional outstanding

items required. If you have receive funds for which there was no application submitted (i.e start-up funds) you will need to submit your letter along with an Research Project Info Form (RPIF), project budget, and brief summary. The Departmental Research Office will collect these and obtain the necessary signatures.

1b. Reply to the Sponsor (if needed)

Some sponsors require that you return a signed copy of a Notice of Awards Acceptance. In some cases they also require an institutional signature. If you require a UBC signature, please contact the Research Office and provide us with a copy of the Awards Notification Letter. If you have already signed a RPIF form the information required will be on file.

1c. Ensure Ethics Approval is in place (if needed)

If your study requires ethical approval, the approval must be in place before the funds are released. Be aware that in some cases there is a restriction on how long an investigator has to get these approvals once they have accepted the award.

1d. Obtain the RPB for your PG

Once all of the required documentation is in place, ORS will upload this documentation and a PG account in the investigator's name will be opened. The investigator will be sent a Research Project Budget (RPB) in their email with the details about this account including, who to contact from Office of Finance Services (OFS), or Research Trust Accounting (RTA). The RPB contains important information needed to apply charges to this account including your PG #, speed chart and signing authority for the account.

1e. Sponsor reporting requirements

Some sponsors require yearly updates or progress reports. It is the investigators responsibility to ensure that they meet these requirements to continue receiving funds.

2. Applying Charges & Managing Research Finances

Researchers are responsible for the responsible management of their research funds. Any charges applied to their accounts are subject to restrictions and limitations of the funding agency, and it is the responsibility of the PI and any individual who manages research funds on behalf of the PI to understand which expenses are eligible/ineligible.

2a. Applying charges to your PG account

To reimburse funds or to pay an invoice under $3500.00 please submit a Q req to the Department FinanceCluster.

3. Draft any required contracts

For larger studies we will often have a situation where UBC is the institution paid, but the work will be shared by a number of different institutions/centres or research groups. If money is to be provided to another group outside the home institution in exchange for work, services or to support research you will need to work with the UILO to establish and execute any required investigator initiated contracts. These include the following:

- Service agreements
- Material transfer agreements
- Non-disclosure agreements
- Sub-site agreements

To expedite the process please ensure that you have the required information before contacting UILO:

- study protocol
- REB application number
- duration of the study
- names and contact information for each site investigator
- site budgets and payment schedules (see UILO templates)
- site investigator responsibilities (if not in protocol)
- UBC account(s) from which the funds will be paid to other sites
- information about any investigational products/devices (if applicable)
- a copy of a Health Canada No Objection Letter (if applicable)
- notice of award (if applicable)
- case report forms (if applicable)
- reporting requirements SAE's at sites (if applicable)

Note that UILO does not handle budget-related questions. It is the responsibility of the PI and sub-site investigators to agree on budget, payment terms and any other remuneration.

IV. Generate a Protocol

Preparing a Research Protocol

Preparing research protocols is often a daunting task, particularly if you have not prepared one in the past. Preparing a detailed and complete research protocol can help you clarify your research question, clearly identify variables, establish endpoints and operationalize your research. Importantly, a well constructed protocol will be a key reference for your study that will convey to all members of the team how to carry out study criteria, methodology, and data evaluation. A proper research protocol is necessary for **all** UBC REB applications, as outlined here by UBC CREB Guidance Note #7, Article 8.1. The complexity of the protocol will depend largely on the study design. Randomized control trials will have very lengthy and detailed protocols while retrospective chart reviews will have much shorter protocols will less emphasis placed on areas such as sample size justification and study methods. However, it is important to realize that even simple studies can benefit from having a complete protocol.

Basic Protocol Requirements

All protocols should follow the same basic structure including the following elements:

- Title page
- Background information and study motivation
- Study hypothesis, objectives and aims
- Study procedures & methodology
- Data & statistical analysis plan (if applicable)
- References

Sample Protocol Templates

To help researchers we have created protocol templates for use by Department of Medicine researchers. The simplified template is suitable for chart reviews and minimal risk projects involving no interventions. A more detailed template is also available for general research projects. We are currently working on developing a template for randomized control trials, and hope to have this available for researchers in the near future.

- Simplified Research Protocol Template
- Research Protocol Template

You may adapt these protocols to your study include the relevant sections and omit those which are not applicable. **Note that you will have to enable editing to use these Word document templates*

Requirements for Peer Review of Protocols

As per UBC REB Guidance Note #7 article 8.2, protocols which are deemed more than minimal risk must undergo some form of peer review. Additionally, projects undertaken by residents and fellows must undergo some form of peer review, regardless of the determined risk level. In all cases it is up to the PI submitting the application to demonstrate to the REB that sufficient review of the scientific content of the study has occurred.

Peer review may include review by an agency or sponsor (for grant funded studies), a supervisor or mentor, or an individual at arm's length to the research with the scholarly expertise to judge the merit of the proposed work. For resident and fellow researchers, protocols should be reviewed first by your supervisor and then by at least one other individual.

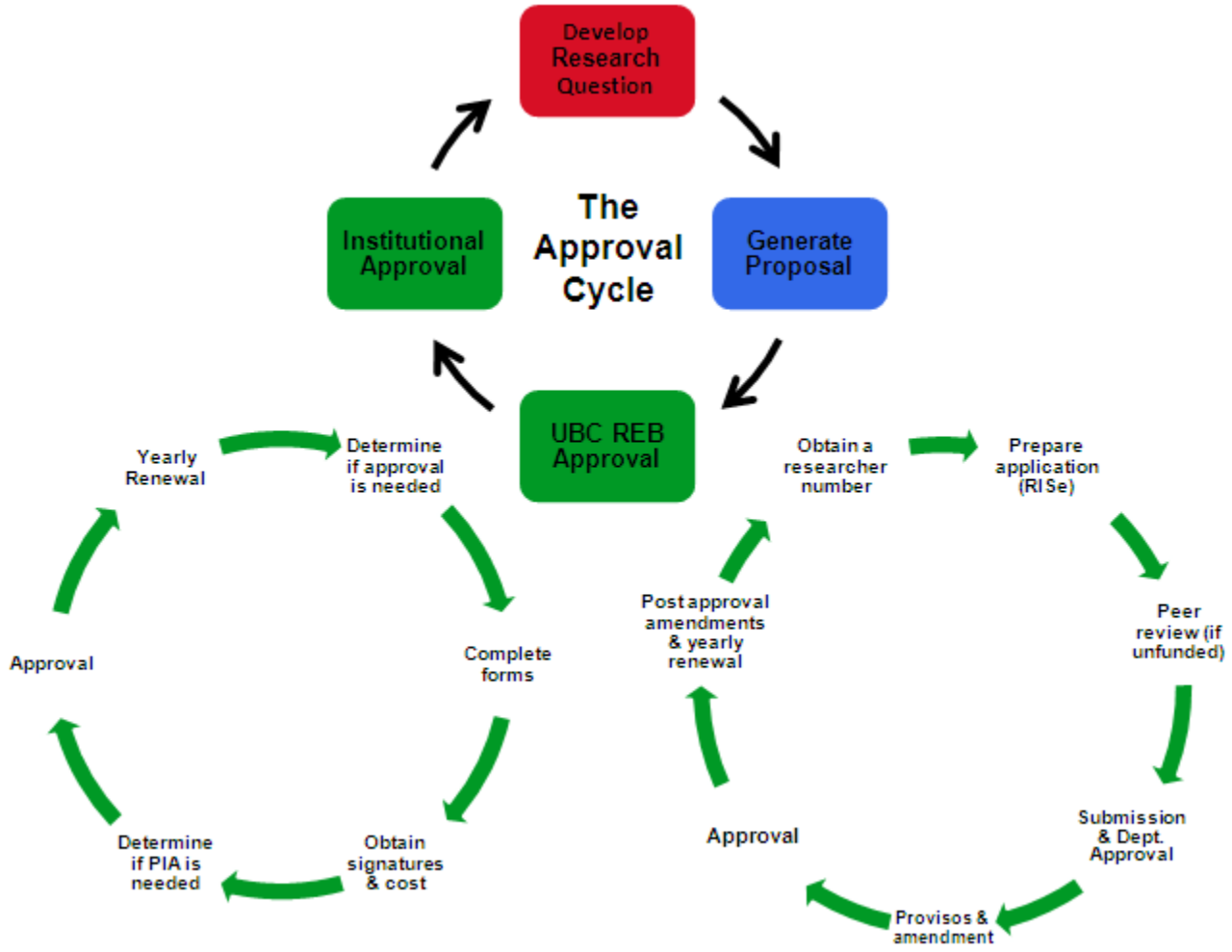
For UBC REB applications please attach documentation of this review to the application in section 9.8. You may attach copies of emails or you may use the following Protocol Peer Review Form.

If you are unable to find someone to review your protocol please contact the Research Office. We will be happy to help you identify individuals who may be willing to review your study.

Resources

Harvey BJ, Lang ES, JR Frank, editors. *The research guide: a primer for residents, other health care trainees, and practitioners*. Ottawa: Royal College of Physicians and Surgeons of Canada; 2011

3. Obtain Approval(s)



General Approval Information:

At the beginning any research study it is the responsibility of the investigator to determine if their study requires ethical approval and ensure they have all the necessary approvals in place before collecting any data. All research studies require both ethical and operational approval, but the process may look different depending on which hospital site or location you are working at. Please ensure that you read and understand the approval requirements for your site. If you have any questions please contact the Research Office.

Use the links provided in the following table to connect directly to site specific instructions for completing necessary forms. For assistance or signatures please contact the Department of Medicine Research Manager.

Site	REB Approval	Operational Approval	PIA Required	Notes
Vancouver Coast Health	CREB, BREB	Yes	If requested	Operational approval must be renewed with yearly ethics renewal
Providence Health	PHC REB	Yes	If requested	
Fraser Health	FH REB	Yes	Yes	Investigators will be given an Letter of Authorization when all of the approvals are in place, no research can occur before this letter is received

Who Needs to Apply for Ethical Review?

According to the TCPS 2 (article 2.1) any research which involves human participants or live biological material which is executed through a disciplined inquiry using scientific methods requires review.

Not every project requires ethical review. The following is a list of projects which do not require ethical review:

- Quality assurance / quality improvement
- Program evaluation
- Research which relies exclusively on publicly available information
- Observational research carried out in public where there is no expectation of privacy
- Research relying exclusively on secondary use of anonymous biological materials
- Case reports which include one or two individuals

If you feel that your project qualifies as exempt from review it is strongly encouraged that you consult with a member from your local UBC REB to ensure.

For more information about ethics please consult the UBC Research Ethics Guidance Notes.

The UBC REB Approval Process

All UBC affiliated researchers are required to apply to a UBC affiliated REB for their research studies. Both human and animal research applications are completed through the online RISe system. If you are not familiar with the RISe system please see the RISe tutorials for assistance.

- Information on Animal Care Applications & Procedures
- Information on Human Research Ethics Applications & Procedures

I. Human Research Ethics Applications & Procedures

1. Determine which of UBC's Research Ethics Boards your research falls under

The University of British Columbia REBs include:

- Behavioural Research Ethics Board (Behavioural Research)
- BCCA Research Ethics Board (Behavioural and Clinical Cancer Research)
- Clinical Research Ethics Board (Clinical Research)
- UBC/Providence Research Ethics Board (Behavioural and Clinical Research at a Providence Health Care site)
- UBC Okanagan Research Ethics Board (Behavioural Research conducted at the UBC Okanagan campus)
- UBC Children's and Women's Health Centre Research Ethics Board (Behavioural and Clinical Research conducted at the Oak street campus)

2. Complete a REB application and update your COI declaration using the RISe system

Each new research project requires its own REB application and associated protocol. For detailed guidelines on filling out an application, see the REB Guidance Notes, the RISe tutorials, and the Guidance Note regarding the research protocol itself.

PDF reference versions of the application can be found on the RISe website BUT all applications are done online through the RISe system, these PDFs are for reference only.

You will need to have the following information to fill out an application (this is a guideline only, other information may be required):

- PI, contact person, co-investigators and study team names (all must already have been added to the RISe system to be added to the application)
- Study name and nickname
- Start and end date of the study
- Funding source details
- Conflict of interest information
- Peer review details (if applicable)
- Lay summary of study and research proposal summary
- Recruitment information (including inclusion and exclusion criteria, recruitment methods for both case and control subjects, and a summary of research procedures)
- Subject involvement information, including numbers of subjects, risks, benefits, time commitment, and reimbursements
- Consent form information
- Details on experimental drugs, devices, or products use (if applicable)
- Details on subject confidentiality, including subject data
- Research or Clinical Trial protocol and/or proposal (see guidelines)*
- Any documents given to the subjects (consent forms, questionnaires, recruitment information, etc)

Note: A fee of $3,000 applies for some industry-funded reviews. This will be assessed during the application process when you declare your source of funding. In a few cases (generally when the study is only partially industry-funded), an exception can be made. Contact the specific REB itself for more information.

If you are performing research at UBC, you should also have a valid Conflict of Interest declaration on file, also through the RISe system. All full-time and part-time members of faculty and staff of the University and any person (including students & visiting professors) who teaches, conducts research or works under the auspices of the

University need to have an up-to-date Conflict of Interest/Conflict of Commitment declaration on file.

3. Submit your application for Department approval

When you submit your application, it will go first to the Department for approval. Please be advised that the Department can not guarantee same day approval for applications. If your application is urgent and you are aiming to get it submitted for a specific Council meeting, be sure to submit it on RISe early enough that Departmental approval can be acquired before the meeting deadline.

Departmental deadlines for approval are Thursdays at 4:00 pm.

4. Modify the application as required by the Department/REB (if required)

Once you have submitted you application, any changes or amendments are submitted the same way. You should receive an email from the Department or REB when any changes, amendments, or provisos to your application are requested. Any changes in the status of your application will be marked in the Inbox section of your RISe homepage.

Note: It is *very important* to document the changes you make to your submission when you are responding to provisos. Highlight the altered text so that it can be clearly identified. You will also need to respond to the provisos when re-submitting. The best way to do this is to copy the (usually numbered) requests into a document, and write a short description of what you did to address the request after each one.

Example:

- Statistical analysis mentioned in research protocol not listed in summary section 5.1.B. Please add.

Statistical analysis has been carried out as requested

- Specifics about study methodologies not included in protocol. Please add this information

See revised protocol version 2.0 attached.

- Recruitment poster #3 deemed inappropriate. Please replace or remove this poster.

See revised recruitment poster #3, version 2.0 attached.

This response will be included with your re-submission to detail the areas where the REB will look for changes.

You only have to change the attachments associated with revisions. If there were no comments on a particular attachment, you are able to leave it as is.

5. Once approved, print a copy of your Certificate of Approval

Approval is good for 1 year. Any deviations from the approved protocols or methods must be submitted promptly to the approving REB through the RISe system. Any changes (including annual renewal, amendments to the study, completion of the study, and Request for Acknowledgement notifications to the REB which include accidental protocol deviations, closing of studies to enrollment, new information acquired, and Serious Adverse Event reports) should be filed using the Post Approval Activity process. Each type of PAA has a specific time limit that should be followed (for example, annual renewals must be completed by a given date (usually 2 weeks before the anniversary of the original approval), SAE reports should be filed within 7 days of the event).

Assistance with Ethics Applications

If you are having trouble with your ethics application we encourage you to ask for help. There are a number of local resources which you can access:

1. The REB staff are very friendly and accommodating and knowledgeable. If you have a specific question you may contact them by phone or by email. Details on how to contact the CREB and PHC REB are listed on their respective websites.
2. CREB offers hands-on monthly workshops for people who are filling out their first ethics application, or would like to go through the application in detail. Workshops are listed on the Research Office website.
3. If you are having general issues with your application, you may contact the Research Office and book a time to go over your application with the Research Manager.
4. VCHRI currently offers ethics facilitation for VCH researchers, through the Clinical Research Unit in the Diamond Health Care Centre. Researchers should contact them directly to schedule an appointment.

Ethics Harmonization

Researchers who are carrying out studies under the jurisdiction of multiple UBC REBs need to only apply to one REB for approval.

In addition UBC REBs have a written agreement with the following: Simon Fraser University, University of Alberta, University of Northern British Columbia, University of Saskatchewan and the University of Victoria, to reduce duplication of review efforts.

A detailed description of the current harmonization practices, policies and procedures is provided by UBC REB.

REB Contact Information:

If you have questions about your application you may contact the REB.

- Pia Ganz, CREB Manager, (604) 875-4149
- Shirley Thompson, BREB Manager, (604) 827-5112
- Bonnie Shields, BCCA Research Ethics Coordinator, (604) 877-6284
- Jennie Prasad, UBC C&W REB Manager, (604) 875-2441
- Lisa Shearer, UBC Okanagan REB Chair, (250) 807-8736
- Michelle Storms, PHC REB Ethical Review Manager, (604) 684-2344 ext 63496

II. Animal Care Applications & Procedures

The UBC Animal Care Committee is the interface between you, UBC, the Canadian Council on Animal Care and the public. The Committee has a very comprehensive website containing all the information you will need to complete your application. This is an outline of the procedure for your reference.

1. Complete the apropriate training course(s).

This can be done at any time after your arrival at UBC but before your begin working with animals. The Canadian Council on Animal Care (CCAC) has made training in animal research a requirement. UBC has training courses that meet this requirement. Investigators and all members of their research team who will be using animals must be able to demonstrate knowledge of techniques and ethics of using animals in research by completing and passing at minimum the Biology and Husbandry of the Laboratory Rodent course, and any others deemed required for your specific experiments.

Upon successful review of test results by the UBC Animal Care Committee, an Animal Care Certificate will be issued, and the certificate number will be associated with each researcher on the RISe system.

2. Complete and submit your application

PDF reference versions of the application can be found online, BUT all applications are done online through the RISe system, these PDFs are for reference only.

You will need to have the following information to fill out an application:

- PI, contact person, co-investigators and study team names (all must already have been added to the RISe system to be added to the application)
- Start and end date of the study
- Funding source information
- Emergency contact name
- CCAC animal type and use information
- Research Objectives (lay summary of purpose and value of study)
- Animal use details, including;
- Details of procedures, including drug dosages, monitoring, endpoints
- alternatives considered
- specific animal strains used with justification
- total number of animal used with justification

A few notes on filling out the application: This application is extremely detailed, and many of the questions are required by the Canadian Council on Animal Care. These are intended to ensure ethical and humane treatment of animals used in experiments. If you are interested in how the reviews are conducted, you can ask to sit on a review (the last Monday morning of every month) or, even better, put your name forward to become a member. The administrative staff of the Committee are very open and willing to answer questions. The best people to contact are Lynn McDonald and Roger Chow.

- When you fill out the application, keep in mind that the Committee is composed of individuals from various backgrounds, including students, animal technicians and lay persons. They may not necessarily belong to your area of research or perfectly understand it. They need to be assured that you know what you are doing with animals. So, write the protocol and answer the questions in simple but detailed and accurate terms. For example, don't just say you will do a 3-hour long open heart surgery, place a stent, close up and go home. Explain why you need to do it, describe the main surgical procedures, e.g. what a stent is, drugs used, volume of injections (if any) etc., and how the animal will be cared for post-surgery and by whom.

- Please note that applications funded by a for-profit agency (Industry) that require ethical review by the UBC Animal Care Committee will be charged a fee of $500. Send a cheque or a journal voucher to ORS. Check the web site for more information or contact Roger Chow at or (604) 827-5115.

- When you submit your application, it will go first to the Department for approval. If your application is urgent and you are aiming to get it submitted for a specific Council meeting, be sure to submit it on RISe early enough that Departmental approval can be acquired before the meeting deadline.

3. Complete any modifications to the protocol recommended by the committee (if required)

Once you have submitted your application, any changes or amendments are submitted the same way. Your Inbox on the RISe system will inform you when any changes, amendments, or provisos to your application are requested and how to deal with them.

It is *very important* to document the changes you make according to the requests. The best way to do this is to copy the (usually numbered) requests into a document, and write a short description of what you did to address the request after each one.

Example:

- 1. Transgenic mouse strain mentioned under breeding protocol SOP not listed in section on Animal Information. Please add.

The requested information has been added.

- 2. Specifics about study methodologies not included in protocol. Please add this information

A revised protocol has been attached as requested.

This response will be included with your re-submission to detail the areas where the ACC will look for changes.

You only have to change the attachments associated with revisions. If there were no comments on a particular attachment, you are able to leave it as is.

4. When your protocol is approved, print a copy of your Certificate of Approval

Once you have received approval, you are ready to begin your research. Once every year, a renewal, which does not require full Committee approval, will have to be completed. Every three years, you will have to resubmit an updated protocol for full Committee review.

4.Research Execution

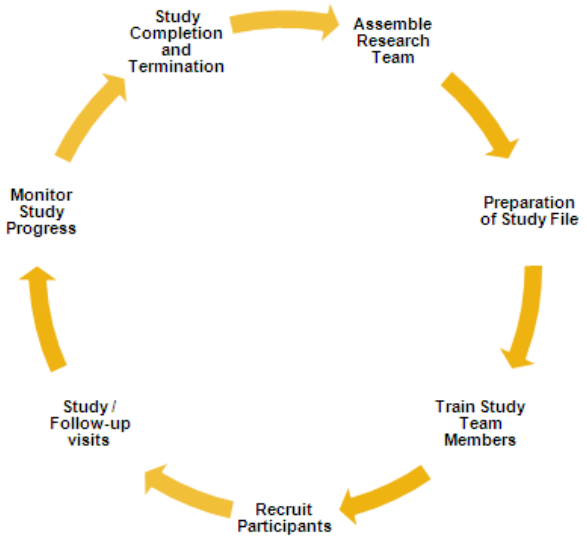
1. Assemble your research team

Once you have obtained funding for your study it is a good idea to complete a needs assessment to determine:

- how much work will there be
- what are the specific duties
- what qualifications are needed to perform the duties and work
- what available resource can be committed to this position

After you have determined the needs for your study you may realize that you have to hire a new employee. Before making any verbal or written commitments to any individuals it is a good idea to get in touch with your divisional administrator or HR representative to address any questions you may have, and ensure that you are following the necessary UBC guidelines. If you are thinking of hiring an individual who is already a UBC employee please speak with your HR representative to determine the individuals seniority level.

If you have not already done a full budget forecast it is a good idea to determine what the full projected costs for your hire will be for the duration of the project. A full forecast would include an estimate of full benefits, cost of living increases, mid-point progression increases, merit increases, and tuition waivers.



If you decide to hire a new employee through UBC or post a new position through UBC you will need to complete the following steps:

- Create the job description
- Post/advertise the position
- Establish the interview/selection committee
- Shortlist candidates
- Develop interview questions, including behavioral based interview questions
- Contact candidates
- Conduct interviews
- In-basket test (recommended but not required)
- Reference checking, including the current supervisor
- Analysis of candidates against the assessment criteria
- Make the job offer
- First day orientation

Links & Contact Information

- To determine who your divisional HR representative is please consult the DoM HR website.
- HR Resources
- For a sample employee forecast for the most common employee types please contact the Research Manager.

2. Prepare study file documentation

Every research study should have it's own study file which contains all the key documents for the study. The number and type of documents required will depend on the type of study being done. When conducting a clinical trial your monitor or sponsor will typically assist in the preparation of all required documents. When conducting an investigator initiated trial it is the responsibility of the investigator to ensure that all of the documentation is in place.

The Research Office has prepared a checklist for all essential documents that should be in the study master file for every study which is conducted in the Department of Medicine.

Essential Documents for a Research Study V1.0

The study master file should be kept in a secure location and maintained for both the duration of the study, and the required storage time period following the completion of the study.

3. Train all individuals involved in the study

Training and documentation of the training is another essential building block of a high quality research. Investigator initiated studies are not exempt from training

- Every individual who participates in research involving human subjects must complete the TCPS2 Course On Research Ethics (CORE) training.
  - CORE training
- Clinical investigators and other essential study team members should have up-to-date ICH – GCP training certificates on file. These certificates are valid for 2 – 3 years and are proof that you understand your responsibilities and obligations.
- All study team members including the PI should be trained on relevant SOPs and the study protocol.
- All training should be documented in a training log, signed and dated by all trained individuals, in accordance with training SOPs.

Training may be done through the Network of Networks (N2) and the Collaborative Institutional Training Initiative (CITI). Through CITI investigators and research staff may access any of the following training modules:

- Good Clinical Practice (GCP) **must have this training**
- Health Canada Division 5 Course
- Human Subjects Research – Biomedical
- Human Subjects Research – Social & Behavioral
- Transportation of Dangerous Goods/International Air Transport Association
- Responsible Conduct of Research

UBC, VCHRI and PHCRI are members of N2 and thus as employees you have access to this very important resource.

- Education & Training Resources through N2
- CITI website

Setting up an account and completing the courses:

- You may create a CITI account and select either VCHRI, PHCRI or UBC as your institution or organization. You may add multiple organizations, but will only have one account. Each institution receives confirmation that you have completed the course
- You can work at your own pace, at home, over lunch or during a designated training time frame
- You must achieve a mark of > 80% to pass the modules. Once you complete the course you will receive a printable certificate. Print off the certificate and include this in your training file

Troubleshooting:

If you are having trouble accessing these resources please contact the Research Office

4. Recruit participants

Recruitment of participants is often the most challenging of the research execution steps. Remember that all recruitment materials must be approved by the REB before use.

VCHRI can assist VCH investigators with the recruitment process by listing your study on their Active Clinical Trials Registry, or sending an "E-blast" out notices to all VCH staff about studies which are currently enrolling participants.

5. Study & follow-up visits

For all participant study and follow-up visits it is the responsibility of the research team to ensure proper documentation. Remember that if it is not written down, it did not happen.

6. Monitor study progress, quality systems & update accordingly

It is very important that throughout your study you take time to ensure that your quality systems are in place. Are there deviations from the protocol or SOPs, are these deviations documented, and what corrective and preventative actions have been implemented to address the deviations? In a quality or systems audit you will be measured against what you say you will do in your protocol and SOPs, so it is important to ensure that these match with your actual working practice.

Remember that if you need to update or revise your protocol or add a study team member that you must complete a Post Approval Amendment (PAA) of your ethics application in a timely manner.The UBC CREB website has a number of helpful guidance documents for how to deal with protocol deviations, unanticipated problems and how to report adverse events.

7. Study Completion and Termination Procedures

At the completion of a study the PI is responsible for notifying the UBC REB of record, and the institution (if required), and completing a Study Completion PAA. Studies at a VCH site must also complete a Notification of Study Completion or Termination form.

Please refer to the CREB Guidance for Study Completion to determine when a study may be considered complete, and requirements for data retention.

Audit and Inspection Preparedness

All registered studies, whether investigator or sponsor initiated may be subject to audit or inspection, by a sponsor, Health Canada, or a foreign agency. While this not a frequently occurring process it is important to carry out your research practices as though it may occur.

The BC Clinical Research Infrastructure Network (BCCRIN), and VCHRI have collaborated to create an Audit and Inspection Preparedness Program (AIPP). In addition to workshops, the program provides researchers with resources needed to prepare for an audit or inspection including, checklists, educational materials, SOPs and a very detailed manual. Individuals who wish to access these resources may contact the Research Manager.

If a research group is expecting an audit/inspection they should inform the following individuals (if applicable):

- Sponsor
- Institution Representative (VCHRI) Stephania Manusha or (PHCRI) Esther Wu
- Hospital Management
- Medical Records
- IT Department / Security
- Pharmacy
- Storage (if records are in storage facility external to site)
- Department Research Manager

5. Dissemination

Assemble Data, Deal with Missing Data & Analyze Study Results

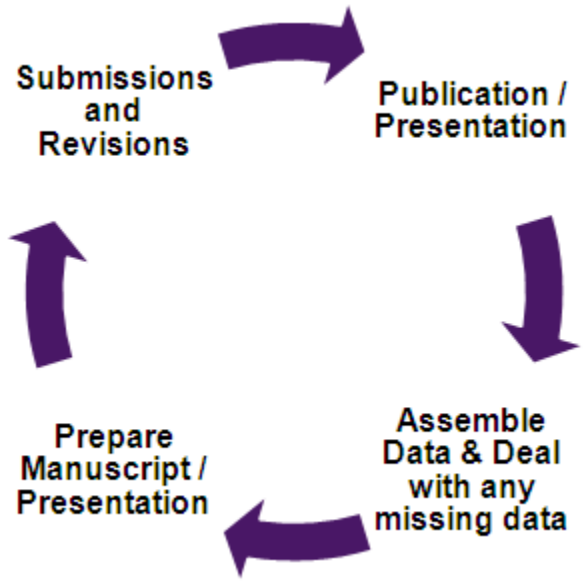
Once you have collected your data you will likely need to go back and work with a bio-statistician to evaluate the results of your study.

If you need to schedule an appointment with a statistician contact the Research Manager.

Preparing Manuscripts

Remember that each journal will have their own guidelines and format, but there are a number of general resources that may be useful when preparing manuscripts for publication:

The EQUATOR (Enhancing the Quality and Transparency of health Research) Network website maintains a list of standardized guidelines, checklists and flow diagrams for evidence-based studies including the following:



Acronym	Group Name	Focus

CONSORT	Consolidated Standards of Reporting Trials	Parallel Groups & Randomized Trials
STROBE	Strengthening the Reporting of Observational studies in Epidemiology	Observational/Epidemiology studies
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses	Systematic reviews and meta-analyses
STARD	Standards for Reporting of Diagnostic accuracy	Studies of diagnostic accuracy
COREQ	Consolidated criteria for Reporting Qualitative research	Qualitative research interviews and focus groups
ENTREQ	Enhancing Transparency in Reporting the synthesis of Qualitative research	Synthesis of qualitative research
SQUIRE	Publication guidelines for quality improvement in health care	Quality Improvement in healthcare
CARE	Consensus-based Clinical Case Reporting Guideline Development	Case reports and data from point of care

SAMPL	The Statistical Analyses and Methods in the Published Literature	Basic statistical reporting for articles published in biomedical journals
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials	Standard protocol items in clinical trials

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