

# Why Write a Study Protocol?

#### Introduction:

Creating a study protocol is like writing the blueprint for your research. It tells everyone what you are doing, why you are doing it, and how you'll do it. A good protocol keeps your team organized, your study ethical, and your findings trustworthy. Whether you are running a simple survey or a complex clinical trial, this document is your go-to plan. Let us break down what a protocol needs and how to make it work for you.

#### **Relevant documents**

WHRI Standard Operating Procedure (SOP): Research Question Development

WHRI guidelines for research question development

#### The study id card (the title)

Start with the basics. Your study needs a name—something short, descriptive, and memorable. If you have a fun acronym, even better. A good acronym makes it easier to refer to your study in everyday conversations, emails, team meetings, or presentations. It is like giving your project a nickname everyone can remember and use.

- Provide a concise and descriptive title that reflects the primary objective of the study. You may also wish to create a study nickname (such as an acronym) for quick reference.
- Protocol Version: Include the version number and date.
- Principal Investigator(s): Name, qualifications, and affiliation.
- Co-Investigator(s): Name, qualifications, and affiliation.
- Sponsor/Funding: Specify funding agency or sponsor if applicable.
- Contact Information: Provide details for the Primary Contact of the study.
- Study site location\s if applicable
- For approved studies include Ethics number



#### Why are you doing this (Background and rational)

This is your chance to explain the "why" behind your study. What problem are you tackling? What is missing in current research or practice that needs attention? You already did a great job by developing the research question. What left is to describe the bigger picture using your findings from the literature review—it is about improving public health, addressing a care gap, or exploring something that has not been studied enough.

Your background section should briefly show what we already know, what is uncertain, and where your study fits in. This ties directly back to your research question: in fact, the process of developing your question—identifying a broad topic, reviewing the literature, and mapping gaps—is what brings you here. If you have followed the steps outlined in your Research Question Development guide, you should already have a clear rationale in mind. Now is the time to connect those dots and tell that story in your protocol.

You do not need to list everything that has been done before—but you should show that you've done your homework and that your study builds on (or challenges) what's already known. This helps others understand why your study is important and why now is the right time to do it.

## What Do You Want to Achieve? (Objectives)

Once you have explained the why of your study, it is time to define the what. What exactly are you hoping to learn, change, or improve through your research?

To keep things clear and manageable, it is best to write your objectives using the SMART framework. SMART stands for Specific, Measurable, Achievable, Relevant, and Time-bound. Each of these elements helps make your objectives stronger and more focused.

More information about how to write SMART objectives can be find here:

How to write SMART goals (with examples) How+to+write+SMART+Goals+v2.pdf

Let us walk through each one, with examples from the field of women's health: **Specific:** Your objective should be defined clearly and unambiguous—no vague or general statements. Be as precise as possible about what you are studying.

• An objective must be clear, focused, and precise to avoid ambiguity. Study Protocol Development April 23, 2025



- Why: Specific objectives help researchers stay focused on the purpose of the study.
- How to achieve specificity: Use precise terms instead of vague language.
- Clearly define what is being measured or investigated.
- Answer the "Who, What, Where, and Why" questions.

#### Example:

"Study mental health in postpartum women."

"Evaluate the impact of sleep quality on symptoms of postpartum depression in first-time mothers within the first six weeks after birth."

*Measurable:* You need to be able to track your progress and know when the goal is met. This usually means including some kind of data, scale, or indicator.

- Objectives must include criteria for measuring progress and success.
- Why: Measurability ensures that the outcomes can be quantified or assessed objectively.
- How to make objectives measurable:
  - Define the metrics, indicators, or tools that will be used to evaluate success.
  - Specify the desired change or outcome.

## Example:

"Measure changes in EPDS (Edinburgh Postnatal Depression Scale) scores before and after a sixweek mindfulness intervention in postpartum women."

This is measurable because the EPDS is a validated tool with a clear scoring system.

**Achievable:** Be realistic. Your objective should be something you can do with the resources, timeline, and participants you have. Think about your budget, team, time, and data access.

Objectives should be realistic given the study's resources, constraints, and timeframe. Consult
with field experts including (where relevant), people with lived experience, clinicians, healthcare
decision makers, and other potential knowledge users of your research, to ensure the objectives
are achievable and make sense.

Why: Unrealistic objectives can lead to frustration, poor data quality, or incomplete studies.
 Study Protocol Development
 Page 3 of 20
 April 23, 2025



- How to ensure achievability:
  - Consider the availability of time, funding, and expertise.
  - Ensure the scope of the study aligns with logistical and technical capabilities.

#### Example:

"Explore perceived barriers to accessing long-acting reversible contraception (LARC) among women aged 18–35 receiving care at two urban clinics over a three-month recruitment period." Why this works:

- It narrows the population by age and location.
- The timeframe (three months) is defined.
- The focus (perceived barriers to LARC) is concrete.
- The setting (two clinics) is manageable for a small study team.

**Relevant:** The objective should address a meaningful issue with implications for improved health outcomes, scientific understanding, clinical practice, or health policy. It must align with the overarching goals of the study and contribute constructively to the existing body of evidence—whether by filling a knowledge gap, informing interventions, or guiding decision-making in the field.

- Objectives must align with the overall purpose and goals of the study.
- Why: Irrelevant objectives waste time and resources, and they detract from the primary research aim.
- How to ensure relevance:
  - Align objectives with the study hypothesis or research question.
  - Focus on outcomes that have practical or theoretical significance.

#### Example:

"Assess the barriers to cervical cancer screening among immigrant women in urban Canada." This objective is relevant because it addresses a known disparity and has implications for public health interventions.



*Time-bound:* A well-defined objective should include a specific timeframe for completion. Establishing a clear time boundary not only enhances the feasibility of the study but also ensures that progress can be systematically monitored. It helps maintain focus, facilitates efficient resource allocation, and ensures the research remains aligned with its intended milestones and deliverables.

- Objectives must have a defined timeline for completion.
- Why: Time constraints encourage efficient use of resources and help track progress.
- How to set time-bound objectives:
  - Specify deadlines for each phase of the study (e.g., regulatory approval, data collection, analysis, reporting).
  - Be realistic about the time required to achieve the objective.

## Example:

# "Track physical activity levels using a wearable device over 12 weeks during pregnancy to examine their effect on gestational weight gain."

The timeline (12 weeks) helps define the study window and keeps data collection focused.

Incorporating the SMART framework into research objective development enhances the overall clarity, focus, and effectiveness of a study. By ensuring that objectives are specific, measurable, achievable, relevant, and time-bound, researchers create a shared understanding among team members, funders, and stakeholders about the study's purpose. SMART objectives also provide a practical structure for monitoring progress, promoting accountability, and guiding the efficient use of resources—all of which contribute to a more organized and successful research process.

## Type of objectives:

In studies with multiple aims, it is essential to distinguish between **primary** and **secondary** objectives to maintain clarity and focus. <u>The primary objective</u> represents the central purpose of the study—the main research questions the design is intended to answer. In contrast, <u>secondary</u> <u>objectives</u> explore additional outcomes that may provide valuable context or insight but are not Study Protocol Development Page **5** of **20** April 23, 2025



the primary focus. Clearly stating both types of objectives strengthens the protocol by guiding the study design, informing sample size calculations, and aligning data collection with analytical plans.

<u>Example:</u> In a study evaluating interventions for postpartum well-being, the <u>primary objective</u> might be: *"To evaluate the effect of a structured six-week postpartum exercise program on depressive symptoms among first-time mothers, as measured by changes in EPDS scores."* <u>Secondary objectives</u> could include: *"To assess participant adherence to the exercise program and levels of satisfaction with its delivery,"* and *"To explore whether participation in the program is associated with improvements in sleep quality over the same period."* 

Clearly distinguishing between primary and secondary objectives is essential for maintaining methodological rigor and ensuring the study remains focused on its core aim. While the primary objective drives the overall design and analysis, secondary objectives provide valuable complementary insights important for real-world implementation and intervention fidelity. This structured approach enhances the clarity, relevance, and interpretability of research findings.

## Study Design: Choosing the Right Approach

What type of study are you doing? Is it a survey, an experiment, or a follow-up study over time? Choose the design that best fits your research question and objectives. Briefly describe the timeline—how long the study will run and the major phases (planning, data collection, analysis, etc.). A clear description of the study design is fundamental to ensuring that the research methodology is appropriate for addressing the primary objective. The chosen design should align with the research question and the type of data needed to answer it. Common designs include:

 Randomized Controlled Trials (RCTs): Used to assess the effectiveness of an intervention by randomly assigning participants to intervention or control groups. This design minimizes bias and is considered the gold standard for establishing causality.



- Cohort Studies: Suitable for evaluating exposures over time, particularly in longitudinal research. Participants are followed prospectively to observe outcomes, making this design ideal for studying incidence and temporal relationships.
- Case-Control Studies: Used primarily in retrospective research to examine associations between exposures and outcomes by comparing individuals with a condition (cases) to those without (controls).
- Cross-Sectional Surveys: Capture data at a single point in time and are useful for estimating prevalence or exploring associations, though they do not support causal inference.

<u>Example:</u> In a study evaluating postpartum mental health, a longitudinal cohort design may be selected to follow women from late pregnancy through six months postpartum to assess changes in depression symptoms over time in relation to sleep quality and support systems.

Justifying the study design involves explaining how it best fits the research objectives, the feasibility of implementation, and the nature of the data being collected.

More information about different study designs can be found here:

<u>Study designs — Centre for Evidence-Based Medicine (CEBM), University of Oxford</u> <u>Understanding Research Study Designs - PMC</u>

In addition, an overview of the study timeline is crucial for planning, resource allocation, and ensuring that each phase of the study is executed within a reasonable timeframe. Including a visual aid such as a Gantt chart or timeline table can further support transparency and planning, making it easier for reviewers and team members to understand the study flow. The timeline should outline the key stages of the research, including:

- Start-up phase (e.g., ethics approval, staff training, and pilot testing)
- Recruitment and enrollment period
- Data collection intervals (especially for longitudinal designs)
- Follow-up schedule, if applicable



- Data analysis and reporting phase
- Dissemination activities (e.g., publication, presentations)

#### Who's In and Who's Out? (Study Population)

Clearly defining the study population is a critical step to ensure the validity and applicability of research findings. This section outlines how to articulate who is eligible to participate, number of participants that are required, and how they will be identified and retained throughout the study.

<u>Inclusion criteria</u> specify the characteristics that participants must possess to be eligible for enrollment, such as age range, sex, health status, diagnosis, or geographic location. These criteria ensure that the study sample reflects the target population for which the research question is relevant. Conversely, <u>exclusion criteria</u> identify characteristics or conditions that disqualify individuals from participating—for example, comorbidities that may interfere with the study intervention or outcomes, or language barriers that would hinder informed consent or participation.

The sample size determination should be justified using appropriate statistical methods, considering the study design, expected effect sizes, power, and significance levels. This ensures that the study is adequately powered to detect meaningful differences or associations.

Recruitment strategies should describe how eligible participants will be identified, approached, and invited to participate. Incorporating patient partners is a critical enabler to feasible recruitment methods and research procedures. The Strategy for Patient Oriented Research (https://www.cihr-irsc.gc.ca/e/45851.html) offers a variety of tutorials to incorporate practices into your research project. Recruitment methods may also include outreach through clinical settings, community organizations, or digital platforms. For longitudinal studies, it is equally important to outline retention strategies, often enabled by integrated Knowledge Translation



practices which encourages regular contact and study updates, appointment reminders, or incentives—to minimize loss to follow-up and maintain data completeness.

In sum, a well-defined population, supported by thoughtful recruitment and retention plans, enhances the study's internal validity, and ensures that results are both interpretable and generalizable to the intended population.

## Intervention:

If your study includes an <u>intervention</u>—like a new drug, therapy, or training—describe it in detail. What are you doing? How often? For how long? Who or what is it being compared to (e.g., standard care or no treatment)? Make sure it is clear and replicable. In studies involving an active intervention, it is essential to provide a detailed and transparent description of what is being evaluated. This enables accurate interpretation, replication, and assessment of the intervention's feasibility and effectiveness in real-world settings. The intervention should be described clearly, including its type (e.g., behavioral, pharmacological, educational), content, mode of delivery (e.g., clinician, trained facilitator). If there is a comparator group, such as standard care, a placebo, or an alternative intervention, this should also be explicitly described to allow for meaningful comparison and interpretation of outcomes.

<u>Example:</u> "In a study evaluating mental health support during pregnancy, the intervention might consist of an eight-week mindfulness-based stress reduction (MBSR) program delivered in weekly 90-minute group sessions, facilitated by a certified instructor. Participants in the control group may receive standard prenatal education materials without the mindfulness component."

Clear and thorough documentation of the intervention and comparator ensures transparency, supports reproducibility, and enhances the overall scientific rigor of the study.

#### Study settings:



Explain where the study takes place—one clinic or multiple sites? If it is a multi-site study, highlight why that is useful and whether anything changes from place to place. Identify your lead site. The setting in which a study is conducted plays a crucial role in shaping its feasibility, generalizability, and relevance. Describing the study setting provides important context for understanding how and where participants will be recruited, how interventions will be delivered, and how data will be collected.

Clearly state whether the study will be conducted at a single site—such as a hospital, clinic, community center, or academic institution—or across multiple sites. For multi-site studies, provide the rationale for selecting multiple locations. This may include increasing sample size, enhancing diversity and representativeness of the study population, or evaluating the intervention across varied real-world environments. For example, conducting a maternal health intervention at both an urban teaching hospital and a rural health center may allow for comparisons across different healthcare access contexts.

It is also important to note mitigation strategies to maximize adherence to the protocol and also, whether there will be any site-specific adaptations to the protocol. These might include differences in the way the intervention is delivered, minor modifications to accommodate site infrastructure, or variation in the characteristics of the study population. While consistency across sites is ideal, acknowledging and accounting for necessary variations ensures transparency.

Be sure to identify the lead site—typically the institution responsible for coordinating the study, managing data, and serving as the primary liaison for regulatory oversight and communication. The lead site often hosts the Principal Investigator and may provide central training, monitoring, and quality control.

Providing a clear and detailed description of the study setting ensures transparency, supports reproducibility, and helps reviewers and readers assess the relevance and applicability of the study findings to other contexts. Study Protocol Development Page **10** of **20** April 23, 2025



## What Are You Measuring? (Methodology)

The methodology section outlines what will be measured in the study and how those measurements will be conducted. A clear and structured plan for data collection ensures consistency, reliability, and validity of the findings and directly aligns with the study's objectives. Begin by defining the primary outcome, which represents the main effect or result the study is designed to evaluate. This outcome should directly reflect the primary objective and serve as the basis for determining the study's success. For example, in a postpartum mental health study, the primary outcome may be the change in depressive symptom scores using the Edinburgh Postnatal Depression Scale (EPDS) at eight weeks post-intervention.

Next, describe the secondary outcomes, which are additional effects that provide complementary information. These might include variables such as anxiety levels, sleep quality, program satisfaction, or physiological markers, depending on the study context. While not the central focus, secondary outcomes can offer valuable insight into broader impacts or mechanisms of action.

In addition to outcomes, identify and justify the covariates—such as age, parity, education level, or baseline mental health status—that will be measured to control for potential confounding or effect modification. These variables should be selected based on theoretical relevance or evidence from previous studies.

Finally, specify the measurement tools that will be used. These may include validated questionnaires, structured interviews, clinical assessments, electronic health record data, or laboratory tests. Wherever possible, reference tools that are widely accepted and previously validated in similar populations.

A detailed and thoughtfully designed methodology ensures that the data collected are both relevant and robust, providing a solid foundation for meaningful analysis and interpretation.

# Data Management (what to include): Study Protocol Development



A robust data management plan is essential to ensure the accuracy, consistency, and security of research data throughout the study lifecycle. This section outlines how data will be collected, stored, processed, and monitored to uphold data integrity and comply with ethical and legal standards.

Great recourse on how to develop a robust data management plan: Data Management Plans | rdm.ubc.ca

## Data Collection

Describe the procedures for collecting data, including what will be collected, when, and by whom. Specify the time points for data collection—such as baseline, post-intervention, and follow-up—and indicate whether data will be gathered through in-person assessments, electronic surveys, medical records, or other sources. Identify the personnel responsible for data collection (e.g., trained research assistants, nurses, or clinicians), and outline any protocols or scripts they will use to ensure standardization across participants and sites.

## Data Storage

Data storage procedures should prioritize confidentiality, security, and regulatory compliance. Describe where and how data will be stored—such as encrypted files, secure servers, or secure cloud platforms – and who has access to it. If personal identifiers are collected, explain how data will be de-identified with identifying information stored separately and access restricted to authorized personnel, or completely anonymized, . Outline regular backup procedures to prevent data loss and describe contingency plans in the event of system failure or breach.

## Data Cleaning

Effective data cleaning is necessary to prepare high-quality datasets for analysis. Describe the planned procedures for checking completeness, identifying missing or inconsistent data, and correcting errors. Specify how outliers or invalid responses will be reviewed and managed, and



whether any imputation or correction methods will be applied. Documenting these processes ensures reproducibility and transparency in the analysis phase.

#### Data Quality Assurance

Maintaining data quality requires proactive measures throughout the study. Describe any training provided to data collection staff, including protocols for handling sensitive information, or administering standardized tools. Mention use of double-entry systems for critical variables, periodic data audits, or automated checks built into electronic data capture platforms to minimize errors and flag inconsistencies.

## Data Collection Timeline

Provide a timeline for all phases of data collection, aligned with the study design and objectives. This should include the expected duration of recruitment, timing of each data collection point (e.g., baseline, mid-intervention, follow-up), and the estimated date of data completion. Timelines help guide study coordination, resource planning, and stakeholder expectations.

In summary, a well-documented data management plan enhances the credibility of the study, facilitates accurate and efficient analysis, and safeguards participant information. It is a cornerstone of ethical and high-quality research practice.

## Statistical analysis plan (what to include):

This section outlines the statistical methods, tests, and models that will be used to address the study objectives. The analysis plan is organized in three stages—preliminary, descriptive, and inferential analysis—each serving a specific purpose in understanding and interpreting the data.

## Preliminary Analysis

Preliminary analysis involves an initial exploration of the dataset to assess data quality, identify potential issues, and prepare the data for more advanced analysis. This early step is critical to



avoid errors or misinterpretations later in the research process. Data cleaning procedures will be implemented to check for and address missing values, duplicate entries, and inconsistencies. Any apparent errors, such as outliers, typographical mistakes, or invalid entries, will be reviewed and resolved systematically. Exploratory Data Analysis (EDA) will also be conducted to provide an initial summary of key variables. This will include the calculation of summary statistics such as means, medians, standard deviations, and ranges. Visual tools like histograms and box plots will be used to help identify patterns, anomalies, or distributional irregularities in the data.

## **Descriptive Analysis**

Descriptive analysis aims to summarize and present the main characteristics of the dataset in a clear and interpretable format. This step is essential for understanding the sample and context before conducting more complex modeling. For continuous variables, statistics such as means, medians, standard deviations, ranges, or interquartile ranges will be reported. For categorical variables, frequencies, proportions, and percentages will be provided. Data visualization will support these summaries using appropriate and relevant data visualization. Cross-tabulations and contingency tables will be used to explore relationships between categorical variables. Where applicable, subgroup analyses will be conducted to highlight demographic or clinical differences, such as by age, gender, or income level. For longitudinal studies, this section will also describe how data will be analyzed over time, including strategies for visualizing time trends or patterns.

## Inferential Analysis

Inferential analysis is designed to draw data-driven conclusions that can be generalized beyond the study sample. This phase focuses on testing specific hypotheses and evaluating relationships, associations, or potential causal effects. The type of statistical test will depend on the study design and data type. Examples include t-tests for comparing group means, chi-square tests for categorical variables, and ANOVA or non-parametric alternatives for more complex comparisons. Regression modeling will be used to assess relationships between variables and to Study Protocol Development Page **14** of **20** April 23, 2025



control for potential confounding. Depending on the outcome and exposure, linear, logistic, or Cox proportional hazards models may be applied. Multivariable models will be used to adjust for covariates and assess independent effects. If needed, more advanced techniques such as mixed-effects models, or machine learning algorithms may be considered, depending on data richness and the complexity of the research questions. Assumptions underlying all statistical models—such as normality, homoscedasticity, and independence—will be assessed. If assumptions are violated, data transformation or alternative analytic methods will be employed and documented.

For descriptive and inferential analysis include significance levels, and handling of confounding factors.

Decide which type of analysis would be used: exploratory, confounding, or predicting modeling:

**Explanatory modeling** is used to explore why something occurs, particularly when limited information is available. It is grounded in the examination of potential causal relationships and is often considered a form of causal research. These models investigate patterns or trends in existing data that may not have been previously studied, aiming to provide insight into underlying mechanisms or contributing factors.

Backward, forward, and stepwise selection methods can be used in exploratory modeling, particularly when the goal is to identify potential predictors or patterns in the data where limited prior knowledge exists. These variable selection techniques are data-driven and help build models by systematically including or excluding variables based on statistical criteria (usually p-values, AIC, or BIC). If you decide to use one of those techniques it is important to include the full model in your publication.

**Confounding modeling** is a causal framework focused on identifying and accounting for confounding variables—those that influence both the independent (exposure) and dependent (outcome) variables, potentially distorting the observed relationship. Confounding cannot be



addressed through correlation alone; instead, it requires conceptual and statistical adjustment to avoid spurious associations and ensure valid causal inference.

*Predictive modeling* is a statistical approach used to forecast future outcomes based on historical data. It typically relies on data mining techniques to identify trends and patterns, which are then used to build models that can predict behaviors or results in new or unseen data. Unlike explanatory models, predictive models prioritize accuracy over causal interpretation.

! Note: there is a multitude of analyses to chose from. If you need help to define modeling type for your study protocol or grant proposal, please contact us at: <a href="mailto:sabina.dobrer@cw.bc.ca">sabina.dobrer@cw.bc.ca</a>.

By selecting the most appropriate modeling approach for the research objective—whether exploratory, confounding, or predictive—the analysis remains purposeful and methodologically sound, while clearly communicating the intended scope, assumptions, and interpretation of findings.

In summary, why description of diverse types of the analysis will enhance your study protocol and guide your analysis. Preliminary analysis ensures that the dataset is well-prepared and free of critical errors. Descriptive analysis provides the necessary context for understanding the study sample and key variables. Inferential analysis builds on these findings to answer the primary and secondary research questions, allowing for interpretation and potential generalization of the results. This structured approach ensures data are analyzed in a logical and methodologically sound manner, leading to valid and reliable conclusions.

To learn more about specific types of statistical analysis, you can use those sources:

Exploratory Research | Definition, Guide, & Examples Confounding Variables | Definition, Examples & Controls Definition of Predictive Modeling - Gartner Information Technology Glossary



Assessing the performance of prediction models: a framework for some traditional and novel measures - PMC

#### Statistical software:

Do not forget to specify statistical software and packages to be used for the analysis. Software websites give an example of appropriate citations to be used.

#### Sensitivity Analyses:

Where applicable, sensitivity analyses can be conducted to evaluate the robustness of the results. These may involve re-running analyses with alternative definitions of exposures or outcomes, using different model specifications, or excluding outliers to assess their influence on findings.

#### **Ethical Considerations:**

A detailed informed consent process should be in place to ensure that all participants are adequately informed about the study's purpose, procedures, risks, and benefits before agreeing to take part. Describe how participants will receive a written information sheet and consent form, both presented in clear, accessible language. State how the research staff will be trained to facilitate consent discussions, respond to participant questions, and ensure that participation is entirely voluntary and free from coercion.

Great resource and templates for the development of the consent form: <u>CREB Forms + Templates | Office of Research Ethics</u>

Explain how confidentiality and data privacy are maintained through secure data handling protocols. How participant data will be anonymized or pseudonymized, and identifying information stored separately from research data, with access restricted to authorized personnel. For example, electronic data are stored in encrypted files on secure servers, and physical records are de-identified and kept in locked, limited access locations.



The protocol should outline anticipated risks to participants—such as emotional discomfort, data security concerns, or potential physical side effects—and describes measures to minimize or manage these risks, including monitoring protocols, referral procedures, and participant support resources.

Finally, the benefits of the study are clearly articulated. It may include direct advantages to participants, such as increased awareness or access to supportive interventions, as well as broader societal impacts like informing policy, improving clinical practice, or addressing gaps in current research.

If you need help with the protocol development, please contact our research managers: Veenstra Jesse <u>jesse.veenstra@bccdc.ca</u>, Muñoz Carola <u>Carola.Munoz@cw.bc.ca</u>, Gordon Shanlea shanlea.gordon@bcchr.ca, Derkivand Sara sara.derikvand@cw.bc.ca

Here is example of appropriate <u>data transfer</u> techniques available within PHSA and UBC: PHSA has a legal duty to ensure that data in its custody and control is adequately safeguarded. Appropriate transportation and data transmission methods must be selected to ensure that data is protected. PHSA has guidelines, requirements, expectations, and even policies on how and when to transport and transmit data using certain method. PHSA affiliated employees can share files using Secure File Transfer Protocol (FTP) <u>https://sftp.phsa.ca/</u>

All files containing private/confidential information must be sent with appropriate security measures using passwords or encryption based on the sensitivity of the information. Passwords should be provided in a different manner (e.g. by phone, text). Please also ensure that recipients secure the information appropriately

PHSA affiliated employees that have access to CWBC network folder can provide the location of the data in the folder without transferring the data using FTP

UBC affiliated employees can share files using UBC Microsoft OneDrive that allows users to securely store, share, and synchronize files and folders from anywhere at anytime Microsoft Study Protocol Development Page 18 of 20 April 23, 2025



OneDrive | UBC Information Technology All files containing private/confidential information must be sent with appropriate security measures using passwords or encryption based on the sensitivity of the information. Passwords should be provided in a different manner (e.g. by phone, text). Please also ensure that recipients secure the information appropriately.

## Implementation and Monitoring:

Effective study implementation requires clear planning, staff preparation, and ongoing oversight. A detailed timeline or Gantt chart (or other appropriate tools) should outline key milestones, including participant recruitment, data collection, analysis, and dissemination activities. To ensure consistency and data quality, all study personnel will undergo training specific to their roles, including instruction on study procedures, ethical conduct, and use of data collection tools. Describe quality control measures that will be used to promote adherence to the protocol, including standardized operating procedures, regular team check-ins, and routine data checks. Additionally, add how what monitoring procedures—either internal or external will be used to track progress, ensure compliance with ethical and regulatory standards, and safeguard the integrity of collected data throughout the study period.

#### **Dissemination plan:**

The dissemination of study findings is an integral part of the research process and ensures that results contribute meaningfully to scientific knowledge, policy, practice, and improved health outcomes. Findings are shared with relevant stakeholders through multiple channels, including peer-reviewed publications, conference presentations, and community engagement activities. Depending on the nature of the study, tailored summaries or infographics may be developed for non-academic audiences such as participants, patient advocacy groups, or health service providers. This approach promotes transparency, encourages knowledge translation, and maximizes the impact of the research beyond the academic setting.



! Note: please contact our KT WHRI team if you need help with developing of the detailed KT plan for your research at <u>Nicole.Prestley@cw.bc.ca</u>.

#### **Budget and Funding:**

A comprehensive budget is developed to outline all anticipated study costs, including personnel salaries, materials and supplies, data collection tools, participant reimbursements, and institutional overhead. Budget planning is aligned with the scope and timeline of the study to ensure efficient allocation of resources. Funding sources are identified, and where applicable, grant applications are submitted to secure financial support from external agencies, institutions, or partners. Any in-kind contributions or internal support are also documented to demonstrate sustainability and resource availability.

#### Limitations:

The study should acknowledge potential limitations and sources of bias that may affect the validity or generalizability of the findings. These may include sampling constraints, reliance on self-reported data, loss to follow-up, or unmeasured confounding variables. Wherever possible, strategies to mitigate these limitations—for example, by using validated instruments, conducting sensitivity analyses, and incorporating multiple data sources. Transparent reporting of limitations strengthens the credibility of the research and provides important context for interpreting results.

#### **Appendices:**

Supporting documents essential to study implementation are included in the appendices. These materials comprise recruitment tools such as invitation letters and posters, informed consent forms, case report forms, and data collection templates. Additional documentation may include validated survey instruments, interview guides, or detailed descriptions of intervention components. These resources ensure consistency across research sites and facilitate reproducibility and oversight. Study Protocol Development Page 20 of 20 April 23, 2025