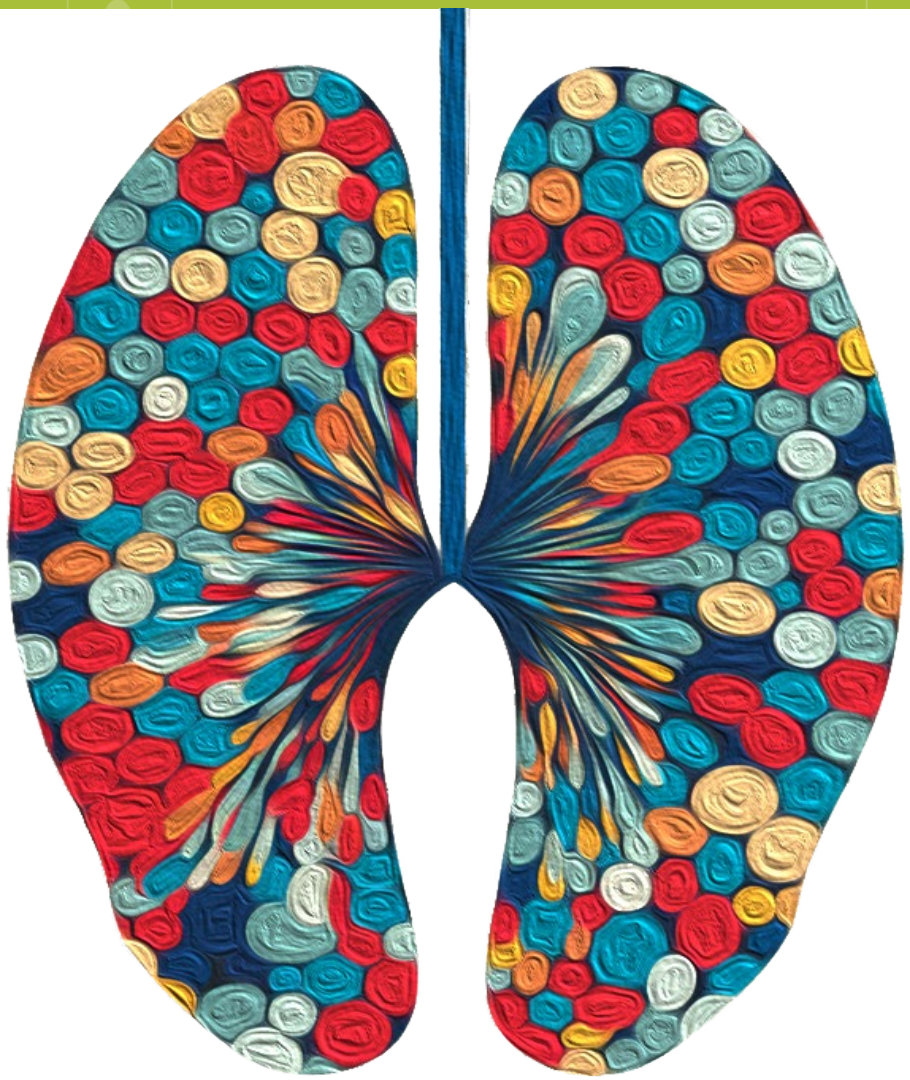
TB Research Guidelines and Protocol



September 2023

USAID
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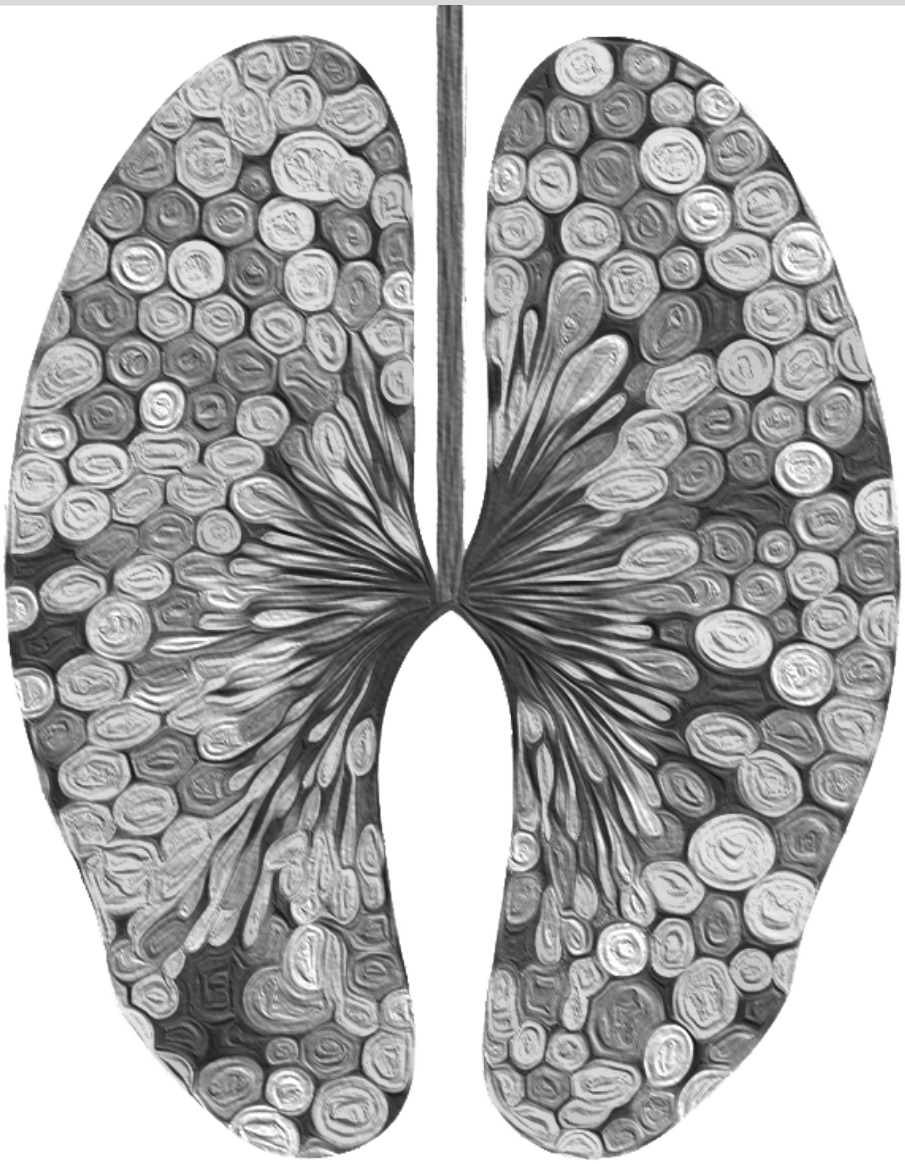
TB DIAH
Tuberculosis Data, Impact Assessment and Communications Hub

TB Research Guidelines and Protocol



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Foreword

The first United Nations General Assembly (UNGA) High-Level Meeting on Tuberculosis (UNGA-HLM-TB) resulted in the adoption of a Political Declaration on Tuberculosis on October 10, 2018. This declaration reaffirmed commitment to ending the tuberculosis epidemic globally by 2030 and included ambitious and bold targets for scale-up of TB care and prevention services. It also included commitments on research for new tools, principles of equity and patient rights, and resource needs. Cambodia is committed to contributing to the realization of these global goals, and the country's National Strategic Plan to End Tuberculosis in Cambodia 2021–2030 (NSP) targets reflect this commitment by being derived from UN recommendations.

This NSP addresses the requirements for attaining the national End TB objectives and is guided by the "FIND–TREAT–PREVENT–BUILD, STRENGTHEN, AND SUSTAIN" strategy, with an emphasis on addressing program priorities and specific needs. The focus is on early diagnosis of all TB patients using more sensitive diagnostic instruments, reducing transmission, and treating those at first contact with the most effective drugs, regimens, and patient support systems. It is supplemented by infection control and management of latent TB infection in populations at risk. All of these are supported by establishing a conducive environment with sufficient funds and resources, as well as robust programmatic surveillance, monitoring, evaluation, and research systems.

The absence of TB research guidelines in Cambodia necessitated development of the TB Research Guidelines and Protocol, under the supervision of the National Centre for Tuberculosis and Leprosy (CENAT), to ensure the scientific and ethical validity of TB research in the country. The TB Research Guidelines and Protocol also included the TB research agenda developed by the Cambodia Committee for TB Research (CCTBR).

CENAT acknowledges the contributions of all stakeholders, particularly the long-term partners of the national TB Program: the TB Data, Impact Assessment and Communications Hub (TB DIAH) project, USAID, the National Institute of Public Health, CCTBR members, and the NGO partners of the national TB program. This multisectoral and collaborative strategy ensured that the TB Research Guidelines and Protocol reflect the finest collective thinking of a wide variety of stakeholders.

CENAT is grateful to USAID, through TB DIAH, for the financial support that facilitated the development and printing of these research guidelines.

Phnom Penh, 29 September 2023

Director, CENAT

Acknowledgments

This TB Research Guidelines and Protocol was developed by the Tuberculosis Data, Impact Assessment and Communication Hub (TB DIAH) in collaboration with the National Center for Tuberculosis and Leprosy Control (CENAT), the United States Agency for International Development (USAID) Sustaining Technical and Analytical Resources (STAR), the National Institute of Public Health (NIPH), and the Cambodia Committee for TB Research (CCTBR) members in Cambodia. We would like to express our gratitude to Dr. Hout Chan Yuda, Director of CENAT and Dr. Song Ngak, TB Management Specialist of USAID Cambodia mission, for their support in this research document.

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Abbreviations

APA	American Psychological Association
CCTBR	Cambodia Committee for TB Research
CENAT	National Center for Tuberculosis and Leprosy Control
CHAI	Clinton Health Access Initiative
COMMIT	Community Mobilization Initiatives to End Tuberculosis
FGD	focus group discussion
GF	The Global Fund to Fight Aids, Tuberculosis and Malaria
HR	hazard ratio
IDI	in-depth interview
IPC	Institute Pasteur of Cambodia
KHANA	Khmer HIV/AIDS NGO Alliance
LHSS	Local Health System Sustainability (Project)
MOH	Ministry of Health
NCHADS	National Center for HIV/AIDS, Dermatology, and STD
NECHR	National Ethics Committee for Health Research
NIPH	National Institute of Public Health
NTP	National Tuberculosis Program (Cambodia)
PH	proportional hazards
PI	principal investigator
PLHIV	People Living with HIV
SAP	statistical analysis plan
SDG	Sustainable Development Goals
STAR	Sustaining Technical and Analytical Resources
TB	tuberculosis
TB DIAH	Tuberculosis Data, Impact Assessment and Communication Hub
TPT	tuberculosis preventive treatment
USAID	United States Agency for International Development
WHO	World Health Organization

1. Introduction

Cambodia has dropped out of the list of the world's top thirty high-burden countries for tuberculosis (TB) but is still on the global TB watch list. Based on the 2021 World Health Organization (WHO) Global TB report, the TB incidence was 274 per 100,000 population, while the mortality rate was 20 per 100,000 population in 2020. The treatment success rate of TB has been maintained at over 90 percent during the last 23 years. The National Tuberculosis Program (NTP) in Cambodia achieved a success rate of 95.6 percent in 2021, exceeding the 90 percent national target. The report also showed that in 2021, 493 TB patients died (1.8%) during treatment, 52 patients (0.2%) failed, and 433 patients (1.6%) were lost to follow-up.

In 2019, the joint program review acknowledged that Cambodia was on track to meet the national commitments towards the "End TB Strategy," the TB-related targets of the Sustainable Development Goals, and the actions agreed in the first United Nations High Level Meeting on TB. The Ministry of Health's (MOH) NTP has already achieved the 1990–2015 Millennium Development Goals targets in reversing incidence and reducing the prevalence and mortality of TB by 50 percent since 2011, which was four years ahead of schedule. Recently, NTP has also reached the 2020 milestone target of reducing the TB incidence by 20 percent.

For the UNLHM, Sustainable Development Goals, and End TB targets for Cambodia, the "Find-Treat-Prevent-Build, Strengthen, and Sustain" approach has been applied with a particular focus on addressing program priorities and specific needs. All the TB treatment and prevention strategies are supported by an enabling environment with adequate finances and resources, as well as a robust programmatic surveillance, monitoring and evaluation system, and research activities.

Nevertheless, to reach these ambitious TB targets, new revolutionary technology including rapid, simple, point-of-care diagnostics for infection and disease, shorter regimens for infection and disease, and eventually an effective vaccine, are needed. This requires invigorated efforts in research, along with a continuum that links upstream fundamental research to discovery and new tool development and ultimately to operational and implementation research allowing innovative strategic approaches to be adapted to specific country needs.

In addition to Pillar One (integrated patient-centered TB care and prevention) and Pillar Two (bold policies and supportive system), "intensified research and innovation" was listed as Pillar Three in the End TB Strategy by the WHO. In Cambodia, TB has been included as one of five strategic pillars in the National Center for Tuberculosis and Leprosy Control's (CENAT) National Strategic Plan to end TB, 2021–2030. Therefore, TB research and innovation have become one of the essential efforts to end TB in Cambodia.

The WHO has identified several TB research issues that are challenging to the development of TB policy guidance worldwide. These are identified as follows: a shortage of good-quality evidence; inaccessible data on program experiences of the benefits and safety of interventions; and insufficient evidence on acceptability, feasibility, equitable resource distribution, and health.

The NTP of Cambodia has committed to strengthen TB research in the country through different approaches such as aligning with the WHO's global direction to end TB by 2035 through "intensified research and innovation;" the National Strategic Plan to End TB in Cambodia 2021–2030 by strengthening

“surveillance, monitoring, evaluation and research;” and the recommendations by the joint program review in 2019 to “pursue innovation and research.”

In general, guidelines are a type of document containing recommendations about health issues, including clinical, public health, or policy recommendations. As WHO suggests, these guidelines should be prepared after consultation on the scope of the guidelines and the issues to be covered. Currently there is no TB research guideline in Cambodia; therefore, it is essential to develop the TB Research Guidelines and Protocol, supervised by the CENAT, for the scientific and ethical soundness of TB research activities in Cambodia. The research agenda developed by the Cambodia Committee for TB Research (CCTBR) in 2021 was also included in the TB Research Guidelines and Protocol.

The TB Research Guidelines and Protocol include the following components: (1) CCTBR, (2) TB Research Agenda, (3) Research Proposal Development, (4) Research Ethics and Review, (5) Research Data Management, (6) Research Data Analysis, and (7) Research Publications and Disseminations. This TB Research Guidelines and Protocol would be subjected to review and approval by CCTBR members and should be endorsed by CENAT and the MOH. Several research stakeholders would assist CENAT to review and implement the TB research guidelines on a regular basis.

The objectives of the TB Research Guidelines and Protocol are intended to:

1. Ensure the integrity of TB research;
2. Provide standard procedure and format for TB research activities;
3. Establish and update TB research agenda; and
4. Improve the quality of TB research publication and dissemination.

2. Cambodia Committee for TB Research (CCTBR)

In 2020, the CCTBR was established to map available resources for research, as well as to identify and address domestic TB research to support programmatic efforts in achieving the End TB strategy. Specific objectives of CCTBR are to assist NTP in the following activities:

1. To establish a platform for knowledge sharing and collaboration among TB control and research stakeholders at the national level;
2. To develop a country-specific TB research plan based on the characteristics of the TB epidemic and an inventory of resources and activities;
3. To monitor the implementation of the research plan;
4. To develop a plan for funding TB research and capacity building;
5. To advocate for TB research and funding.

The CCTBR is chaired by the Director of National Center for Tuberculosis and Leprosy Control (CENAT), co-chaired by the Deputy Director of CENAT and a National Institute of Public Health (NIPH) representative, with a secretariat of representatives from the CENAT and the United States Agency for International Development (USAID) Sustaining Technical and Analytical Resources (STAR) project. The members of this research committee include the NIPH, the University of Health Sciences, the National Center for HIV/AIDS, Dermatology, and STD (NCHADS), WHO, the United States Center for Disease Control and Prevention, USAID, the Institute Pasteur of Cambodia (IPC), the National University of Singapore, and other national and international organizations.

After its establishment in late 2020, the CCTBR has organized different meetings with the purpose of updating the current status of TB research in Cambodia, presenting research findings in the country, identifying the TB research agenda for the country, and providing technical inputs on proposed TB research from partners. The CCTBR should have active quarterly meeting schedules; however, the most recent meeting was convened after nine months since the meeting took place in December 2021. It is planned that meetings of the CCTBR will take place on a quarterly basis.

3. TB Research Agenda

Under the leadership of the NTP, in December 2021, a CCTBR meeting was conducted to identify TB research priorities for the upcoming years. These TB research priorities will serve as a roadmap for the NTP in TB research. Thirty TB research priorities under five themes were proposed by the CCTBR's members in the December 2021 meeting: twelve in TB case detection, four in TB treatment, nine in TB prevention, five in TB comorbidity with HIV and diabetes, and other topics such as prevalence, digital health, and data quality. The TB research agenda includes the expectations on TB research from the NTP and CCTBR research partners.

The TB research agenda is a work in progress that will evolve over time and continue to be revised by CENAT and CCTBR. The action plan (including data sources, study design and leading agencies) should be discussed and updated at the regular CCTBR meetings to develop the timely and comprehensive TB research agenda. The research agenda is a living document and requires regular updates to reflect developing needs. The CCTBR members have compiled research priorities outlined in Table 1 below.

Table 1. Research priorities in TB research agenda by CCTBR (as of May 2023)

Research Topics	Status in 2023	Implementing Partner
I. TB Screening, Diagnosis and, Case Detection		
1. To understand the factors associated with the detection of bacteriologically confirmed TB from the perspectives that include but are not limited to: ● The quality of sputum, lab procedures and performance, availability of diagnostics, healthcare workers' capacity, and other individuals/community-level predictors. ● Provincial-level comparisons and disaggregation by age group, sex, and membership of key populations.	Ongoing: Community Mobilization Initiatives to End Tuberculosis (COMMIT) and STAR plan to conduct the documentation of qualitative of sputum collection (COMMIT allocates some small budget)	Khmer HIV/AIDS NGO Alliance (KHANA) and COMMIT
2. To evaluate the effectiveness and accuracy of different screening and diagnostic algorithms using WHO TB screening strategies (e.g., four symptoms screening strategy) and other modalities such as chest radiography, C-reactive protein, molecular diagnostic platforms, sputum pooling, and non-symptoms-based approach on TB case detection.	In the third TB prevalence survey all participants will systematically undergo TB symptom screening and chest X-ray. We can use data from the current third national TB prevalence survey. Needs further discussion in small groups	CENAT

Research Topics	Status in 2023	Implementing Partner
3. The effect of these algorithms on TB case detection at secondary and tertiary health facilities, mass screening campaigns in the community, opportunistic infection/antiretroviral therapy sites (people living with HIV), facilities managing persons with other comorbidities (diabetes, older persons, and other chronic diseases), and among specific populations such as children, pregnant women, prisoners, smokers, alcohol and drug users, migrants, mentally ill, the homeless, and those suffering from malnutrition.	The project is completed (in the process of writing manuscript).	KHANA/COMMIT
4. To evaluate the feasibility and cost implications of these algorithms and approaches	The project is completed (in the process of writing manuscripts).	KHANA/National University of Singapore
5. To evaluate the impact of integrating contact tracing for TB preventive therapy with TB case finding activities conducted in the health facilities and communities in Cambodia	Protocol development	COMMIT
6. To assess the impact of the COVID-19 pandemic on TB service delivery and TB epidemiology	Documentation of challenges and lessons learned from the COMMIT and Global Fund programs during COVID-19 through desk review and rapid assessment.	COMMIT/GF
7. To assess the effectiveness of TB screening on the yield of TB diagnosis using different modalities of chest radiography—upfront digital chest radiograph, analog chest radiograph, and utilization of computer aids in TB detection (e.g., CAD4TB)	Explore funding source with University of Singapore: 5% initiative grant? Other sources?	
8. To understand the role of the private sector in TB case detection and assess the operating procedures, referral, and reporting processes from the private sector to the public sector.	KHANA in discussion with Sydney University to plan for proposal	KHANA/Sydney
9. To evaluate the effectiveness of case finding and referral by the private sector for TB diagnosis, treatment, and care.	GF will conduct pilot study to expand the role of public-private mixed system to make diagnosis for TB (KHANA will discuss with NTP on that for technical support)	GF

Research Topics	Status in 2023	Implementing Partner
10. Multi-drug resistant TB (MDR) prevalence survey (proposed by USAID and agreed by the director)	This will be tentatively implemented in 2024. Further discussion with CENAT.	CENAT
II. TB Treatment		
1. To assess the acceptability and feasibility of the 4-month regimen for drug-susceptible TB in Cambodia		
2. To understand the resistance profile of fluoroquinolones in Cambodia, one of the antibiotics used in the 4-month regimen		
3. To assess the pharmacokinetics of the drugs used in the regimen in Cambodian adults, children, and people with comorbidities		
4. To assess the acceptability and feasibility of the shorter and more effective treatment regimen for drug-resistant TB, once recommended by the WHO, in Cambodia	Completed	CENAT/WHO/COMMIT
5. To evaluate the effectiveness of TB treatment support mechanisms such as video and community Directly Observed Therapy Short Course.		
6. To evaluate the financial mechanism for TB care in the current decentralized system and the consequences of the system on patients' pathway, including diagnosis and care	Completed https://gh.bmj.com/content/bmjgh/8/3/e010994.full.pdf	CENAT/WHO/KHANA
III. TB Preventive Treatment		
1. To evaluate the long-term efficacy of tuberculosis preventive treatment (TPT) in preventing TB among the key populations for TPT, people living with HIV (PLHIV), close contacts of bacteriologically confirmed TB)		

Research Topics	Status in 2023	Implementing Partner
2. To optimize the delivery of TPT services through better understanding of the supply and demand projections (e.g., size estimations of PLHIV population and the projected TPT coverage)	Data analysis. The results will be available in Aug./Sept. 2023	Optimizing Latent Tuberculosis Treatment Initiation in Cambodia Among People Living with HIV (OPTICAM) study by CENAT, NCHADS, IPC, Clinton Health Access Initiative (CHAI)
3. To evaluate potential interactions between antiretrovirals and TPT and their long-term effectiveness in TB prevention among children living with HIV		
4. To operationalize and evaluate the acceptability, feasibility, and effectiveness of TPT implementation among close contact of people living with drug-resistant TB		
5. To understand barriers and facilitators of TPT uptake among key populations for TPT (close contacts of bacteriologically confirmed TB, and PLHIV) and healthcare workers.	Ongoing data collection (Complete in July 2023)	KHANA/COMMIT
6. To understand challenges in TPT service delivery from the perspectives of the healthcare workers.	Completed https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-023-02379-7	CENAT
7. To conduct TB infection prevalence survey among populations at risk of TB and evaluate the accuracy, acceptability, and feasibility of the different TB infection testing modalities such as tuberculin skin test and interferon gamma release assay.	Proposal development	KHANA/COMMIT/ Sydney
8. To evaluate the effectiveness of TPT among pregnant women and infants who are eligible for TPT		

Research Topics	Status in 2023	Implementing Partner
IV. Others: TB Prevalence, Digital Health, Post-TB Health and Well-Being, and Data Quality		
1. To estimate TB prevalence among key populations (e.g., prisoners, homeless person, elderly, close contact, people who use drugs/people who inject drugs for TB, their risk perception, and factors affecting their care seeking behaviors.)		
2. To assess the feasibility and effectiveness of incorporating mobile technology in improving TB knowledge, care-seeking behavior, and treatment support.		
3. To evaluate the post-TB health and wellbeing of people with TB	Preliminary results	KHANA/COMMIT
4. To assess the acceptability, user experience, and feasibility of incorporating health information technology to improve the quality of TB data at the health center and community levels.		
V. TB Financing and Sustainability		
1. National TB patient costs survey (to be conducted in 2023)	NECHR-approved; data collection in July to August 2023	Local Health System Sustainability (LHSS) Project
2. Documentation of implementation of community-based TB model with focused engagement of communes/sangkats (in 2–4 provinces)	Completed planning for 1 operational district (OD) (Kang Meas)	LHSS
3. TB fund mapping and gap analysis in Kampong Cham and Svay Rieng provinces (2022)	Completed	LHSS
4. Financial analysis for required costs for including TB service in the National Social Security Fund package (no timeline yet)		

4. Research Protocol Development

The development of a research protocol is the essential step for researchers to:

- Clarify study objectives;
- Establish a plausible research hypothesis;
- Develop study design;
- Explain the theoretical and practical aspects of the methodology;
- Set up an accurate and effective data analysis plan;
- Describe the expected results; and
- Deliver a well-organized plan of research ethics in the protection of human subjects.

The standard format of research protocol should include the following components and information:

4.1. Project Title

Research project titles should be concise, specific, and informative. The length of titles should be limited to 150 characters for a research project. The researchers should not use overly general titles, declarative titles, titles including the direction of study results, or questions as titles. For clinical trials, meta-analyses, and systematic reviews, the project may include the type of study as a subtitle, such as "A Randomized Clinical Trial," "A Meta-analysis," or "A Systematic Review." For other types of research, researchers should not include study type or design in the title or subtitle.

4.2. List of Researchers

Principal investigators (PIs) and Co-PIs should have at least an advanced research or medical degree (e.g., Ph.D. or MD) or a master's degree with extensive research experience. They should make substantial contributions to the research conception, design of the study, data acquisition, data analysis, or substantial interpretation of data for the research project. Each PI or Co-PI should be listed with their academic degrees and affiliations. Additional investigators can be listed if they provide critical collaborations to the project. The curriculum vitae (CV) for PIs, Co-PIs, and investigators should be included in the annex.

4.3. Research Summary/Abstract

Researchers should use the following headings in the study summary: background, study objectives, methods, expected results, and research ethics. For brevity, parts of the study summary may be written as phrases rather than complete sentences. The usual word count for a study summary or abstract would be about 250–300 words.

The summary should begin with a sentence or two explaining the epidemiological or clinical importance of the proposed study question. State the precise objective or study question addressed in the report (e.g., "To determine whether...").

The methodology includes the basic sampling design and the specific study type, for example, randomized clinical trial, cohort, cross-sectional, case-control, case series, survey, or meta-analysis. The time period of the proposed study should be included.

Expected results and relevance should be summarized to provide a statement of relevance indicating implications for clinical practice or health policy.

4.4. Background/Introduction

The background section is about 150–250 words. The first two to three sentences of the background or introduction should establish the importance of this proposed study. The first paragraph should provide a general summary of the clinical or epidemiological issue (e.g., TB). The next paragraph should focus on the specific aspect of the public health or clinical issue the study will explore (e.g., diagnosis for TB). The epidemiology of the disease or condition should be briefly summarized and generally should include disease prevalence and incidence. The third paragraph should discuss exactly what material would be explored in this study (e.g., methods and accessibility in TB diagnosis).

The literature search should be as current as possible, except for distinguished research publications. A search of the primary literature should be conducted, including multiple bibliographic databases (e.g., PubMed/MEDLINE, Embase, CINAHL, PsycINFO). The highest-quality evidence (e.g., randomized clinical trials, meta-analyses, systematic reviews, and high-quality prospective cohort studies) should receive the greatest emphasis. Clinical practice guidelines ordinarily should not be used as a primary component of the evidence base for the literature review.

Rather than a mere summary of what research has been published before, the background section should display a broad understanding of how the literature fits together and led to the current research. The background or introduction should include relevant quantitative and/or qualitative literature on research topics. Sometimes it is appropriate to adopt a critical stance towards existing research and highlight any gaps or methodological limitations, while at other times stressing the importance of previous research in informing your own study design.

4.5. Research Objectives

Research objectives must be clearly defined at the beginning of the project (the topic ideation and proposal stage). The research objectives and questions define the focus and scope of your research project. They aid in restricting the scope of your research so that you may thoroughly explore a particular issue or opportunity in depth. Research objectives also help keep you on track since they act as a test for relevance. In other words, if you're ever unsure whether to include something in your research, simply ask yourself the question "does this contribute to my research objectives?"

Researchers should state the precise objective or study question addressed in the study (e.g., "To determine whether..."). If more than one objective is addressed, the main objective should be indicated and only key secondary objectives stated. If an a priori hypothesis was tested, it should be stated.

Research objectives describe what you intend your research project to accomplish. They serve to focus your study by providing an overview of the project's methodology and goals. The objectives should follow the problem statement at the beginning of your research protocol.

Objectives can be broad or narrow. The general objective of your study describes what you hope to accomplish in broad strokes. Specific objectives subdivide the overall objective into smaller, logically interconnected parts that meticulously address the various facets of the problem. Your specific objectives should detail precisely what you will do during each phase of your study, as well as when, where, why, and how.

Research objectives should be developed with "**SMART**" criteria:

Specific: Who is involved? What do you want to accomplish?
Measurable: Is it quantifiable and can you measure it?
Achievable: Can you get it done in the proposed time frame with the available resources and support that you have?
Relevant: Will this objective influence the desired goal or strategy?
Time bound: When will this objective be accomplished?

4.6. Methods

To plan and conduct TB research, researchers should have extensive knowledge of or have received in-depth training in the research methodology. In the methods section of a research protocol, researchers should present their research designs based on the following research methodologies:

4.6.1. Quantitative Methods

Quantitative research is the process of collecting and analyzing numerical data. It may be used to discover patterns and averages, to make predictions, to verify causal linkages, and to generalize results to larger populations. It is essential to describe the basic design of the study, and include the specific study type:

1. **Cross-sectional study:**
    - Observational in nature, cross-sectional studies provide a snapshot of the characteristics of subjects at a singular point in time.
    - Cross-sectional studies, unlike cohort studies, lack a follow-up period and are therefore relatively easy to conduct.
    - As the exposure status/outcome of interest information is collected at a single point in time, typically through surveys, the cross-sectional study design is the weakest of the observational designs because it cannot establish a cause-effect relationship.
    - This study design is typically applied to determine the disease prevalence in a population.
2. **Cohort study:**
    - Initial patient classification in cohort studies is based on their exposure status.
    - Over time, cohorts are monitored to determine who in the exposed and non-exposed groups develops the disease.
    - Both retrospective and prospective cohort analyses are possible.
    - The incidence can be directly computed from a cohort study because it begins with exposed and unexposed patients, whereas a case-control study begins with diseased and healthy individuals.
    - In a cohort study, the measure of effect is relative risk.
    - Recall bias is extremely low in cohort studies, and multiple outcomes can be investigated simultaneously.
    - A drawback of cohort studies is that they are more susceptible to selection bias.
    - Using cohort studies to investigate rare diseases and outcomes with lengthy follow-up periods can be costly and time-consuming.

3. **Case-control study:**
    - It is applied to assess the strength of associations between risk factors and outcomes. Exposures are the factors that influence the risk of a disease.
    - Case-control studies can help determine whether an exposure is beneficial or detrimental.
    - There are two categories of patients: cases and controls. Patients with a specific disease, condition, or disability are cases. Patients who do not have the disease are referred to as controls.
    - Researchers identify adequate representative controls from the general population for the cases they are studying. Then, they investigate the potential exposures these patients may have had to risk factors in the past.
    - The selection of patients for the control group is an essential aspect of case-control research.
    - Case-control studies are susceptible to recall bias due to the retrospective nature of their design.
    - Case-control studies are economical, efficient, and frequently quicker to conduct. This study design is particularly appropriate for uncommon diseases with lengthy latency periods.
4. **Randomized clinical trial:**
    - Research subjects are randomly assigned to a control group and an experimental group.
    - Randomization in randomized controlled trials prevents confounding and minimizes selection bias. This allows the researcher to have comparable experimental and control groups, allowing them to determine the effect of an intervention.
    - The experimental group receives the exposure/treatment, which may be a disease-causing, disease-preventing, or disease-treating agent.
    - Depending on the study's objective, the control group receives no treatment, a placebo, or another standard of care treatment.
    - Two groups are then observed prospectively to determine who develops the desired outcome.
    - The randomization integrity is frequently compromised by refusals, dropouts, crossovers, and noncompliance.
    - This study design is costly, and researchers employing this study design frequently encounter issues with refusals, dropouts, crossovers, and noncompliance.
5. **Quasi experiment:**
    - It encompasses a diverse assortment of nonrandomized intervention studies. When it is impractical or unethical to conduct a randomized controlled trial, these designs are frequently employed.
    - It is also known as the pre-post intervention design and is frequently utilized in the field of health research for the purpose of determining the efficacy of a variety of interventions.
    - Even though the randomized controlled trial is generally thought to be the most reliable way to determine cause and effect, researchers often choose not to randomize the intervention for one or more of the following reasons: ethical concerns, the difficulty of randomly assigning subjects, the difficulty of randomly assigning places, and the small number of available samples.

6. **Case report:**
    - Case reports, case series, and case study research are descriptive methods for presenting patients in their natural clinical environment.
    - Case reports, which typically involve three or fewer patients, are written to illustrate aspects of medical practice and to generate novel research questions that may contribute to the expansion of the body of literature.
    - Multiple patients are involved in case studies, a qualitative research method that includes in-depth analyses or experiential inquiries of an individual or group in their natural environment.
    - Case study research emphasizes the contextual analysis of multiple events or conditions and their interrelationships.
    - In addition to their teaching value for students and graduate medical education programs, case reports provide a starting point for neophyte investigators, which may prepare and encourage them to seek out additional contextual writing experiences in the future.
    - It may also provide senior clinicians with information about emerging epidemics or previously unknown syndromes.
    - Extrinsic to the learning paradigm are the lack of generalizability and implications for clinical practice, which are the primary limitations.
7. **Meta-analysis:**
    - Meta-analysis is a formal, quantitative, and epidemiological study design used to systematically evaluate previous research studies and draw conclusions about the corpus of research.
    - The results of a meta-analysis may provide a more precise estimate of the effect of a treatment or disease risk factor, or other outcomes, than any individual study that contributed to the aggregated analysis.
    - Examining the variability or heterogeneity of the study's results is another crucial outcome.
    - Benefits of meta-analysis include a quantitative review of a large, frequently complex, and sometimes seemingly contradictory body of literature.
    - A sensitive literature search is essential to the conduct of meta-analyses, as is the specification of the outcome and the hypotheses to be tested.
    - A failure to identify the majority of existing studies can lead to erroneous conclusions; however, there are techniques for scrutinizing data to identify the possibility of missing studies, such as funnel plots.
    - In evidence-based medicine, meta-analyses conducted with rigor are useful instruments.
    - The need to incorporate findings from multiple studies makes meta-analytic research desirable, and the large amount of research that is now being produced makes its conduct possible.

For quantitative research design, the sampling frame, sample size, and statistical power should be calculated and justified in the methods section. For sampling procedures, these terms should be used, if appropriate: random sample (where random refers to a formal, randomized selection in which all eligible individuals have a fixed and usually equal chance of selection), population-based sample, referred sample, consecutive sample, volunteer sample, and convenience sample. If matching is used for comparison groups, characteristics that are matched should be specified.

4.6.2. Qualitative Methods

Qualitative research is applied to find out “why” and “how” factors in your research questions. It is exploratory and not about producing numerical data. Instead, qualitative research focuses on reasons, motivations, behaviors, and opinions in your research questions. It is best for gaining insight and exploring problems beyond the surface level. This type of data typically comes from conversations, interviews, and responses to open questions. The aim of qualitative research is to collect and analyze non-numerical data (e.g., text, video, or audio) to understand concepts, opinions, or experiences. It can be used to gather in-depth insights into a problem or generate new ideas for research.

Qualitative methods might include:

1. **In-Depth Interview (IDI):**
    - An unstructured interview, with open-ended questions.
    - Flexible to enable respondents to discuss their opinions.
    - Key Informant Interview (KII) to explore the insights from selected stakeholders.
    - The interviewing and relationship facilitation skills of researchers are critical to collect good qualitative data.
2. **Focus Group Discussion (FGD):**
    - A semi-structured group discussion and interaction on exchange of ideas and opinions among participants.
    - A type of group interview which explores a topic concern.
    - The group leader (moderator) will explore a particular topic with the group by asking questions, actively listening to the responses, and asking probing questions to follow-up on the responses.
    - A note taker keeps records and identify specific reactions and interactions among participants.
    - There should be about 8–10 participants recruited in an FGD. Each session should not last more than one and half hours.
3. **Direct Observation:**
    - It is also known as observational study, collecting evaluative information while the evaluator watches the subject in his or her usual environment without altering that environment.
    - Direct observation is used when other data collections (such as surveys or questionnaires) are not effective.
    - The goal is to evaluate an ongoing behavior process, event, or situation when there are physical outcomes that can be readily seen.
    - Structured direct observations are most appropriate when standardized information needs to be gathered and might result in quantitative data.
    - Unstructured direct observation looks at natural occurrences and provides qualitative data.
    - One critical problem of direct observation is the “Hawthorne effect,” meaning that people usually perform better when they are being observed.
    - Another problem is the “observer bias” caused by personal or objective factors to affect the evaluation results.

4. **Case Study/Life History:**
    - It is an in-depth study of a health issue explored through one or more cases within a setting or a context.
    - It is also an in-depth description of the experience of a single person, a family, a group, a community, or an organization.
    - An example of a qualitative case study is a life history, which is the story of one specific person who could be representative of a research topic.
    - A case study may be done to highlight a specific issue by telling a story of one person or one group.
    - Multiple sources of information to provide comprehensive case stories.
    - Data are collected through observations, interview, oral history, and documents.

Although qualitative studies may ask broad, exploratory, and inter-connected questions that are not always pre-specifiable as conventional hypotheses, it is necessary to offer a cogent and well-reasoned justification or rationale for research. These might be construed as broad research issues to be investigated, rather than pre-determined hypotheses. Transparency about the conceptual framework(s) and theoretical perspectives applied is important for quantitative and qualitative research.

Researchers should describe the study setting to determine the applicability of the report to other circumstances, for example, population-based or primary care or referral center(s). A concise description of the setting(s) where the research took place is essential. A common weakness in research, especially in qualitative studies, has been a tendency to offer only a national or regional overview of notified cases and estimated prevalence, while neglecting the social, cultural, gender, economic, or political context in which TB control is embedded.

4.6.3. Mixed Methods

To answer complex research questions, mixed methods research incorporates elements of quantitative research and qualitative research. Incorporating the benefits of both quantitative and qualitative research methods, mixed methods enable researchers to obtain a more complete picture than quantitative or qualitative research alone. When formulating the research question, researchers should attempt to directly address how qualitative and quantitative methods will be integrated.

Mixed methods research does not simply entail collecting both types of data; rather, researchers must closely consider the relationship between these two methods and integrate their findings in a coherent manner. Based on the chronology of qualitative and quantitative research, mixed research comprises three distinct research purposes:

1. Using qualitative findings to develop a new quantitative research instrument: qualitative research is conducted first, followed by quantitative research.
2. Determining which quantitative discoveries require additional explanations; quantitative research precedes qualitative research.
3. Comparing the similarities and differences between qualitative and quantitative findings: both research methods were conducted concurrently for comparisons.

Researchers of mixed-method research must make a very concise, yet compelling, case for how both methods mutually inform the study. Mixed-method research often requires lengthy descriptions of study

procedures, offering little space for discussion and conclusions. A common weakness in mixed-method research is that one methodology is described comprehensively and the other is superficially developed. If both methods are used, it is essential to describe the relationship between the two types of data collected.

4.7. Research Sampling Methods

Sampling is a technique for choosing certain individuals or a small portion of the population to draw conclusions about the population as a whole and estimate its characteristics. Applying various sampling techniques in research, researchers do not have to study the full community to gather useful information. It is also a time-convenient and cost-effective method as the basis of any research design. Research designs may use probability or non-probability sampling techniques depending on the selection probability being considered.

4.7.1. Probability Sampling Methods

Four probability sampling methods have been widely applied in research:

1. **Simple random sampling:**
    - Every person in the population has an equal probability of getting chosen in a simple random sampling.
    - The entire population should be included in your sampling frame.
    - You might utilize instruments like random number generators or other methods that just rely on chance to carry out this kind of sampling.

2. **Cluster sampling:**
    - Cluster sampling also involves dividing the population into subgroups, but each subgroup should have similar characteristics to the whole sample.
    - Instead of sampling individuals from each subgroup, you randomly select entire subgroups.
    - If it is feasible, you can include every individual from each sampled cluster.
    - If the clusters are large, you can sample individuals from within each cluster using one of the techniques described above. This is known as multistage sampling.
    - Although this strategy is effective for handling big and dispersed populations, there is a higher chance of error in the sample due to the possibility of significant differences between clusters. It is challenging to ensure that the sampled clusters accurately reflect the entire population.
3. **Systematic sampling:**
    - Every person in the population is assigned a number, but instead of assigning numbers at random, people are picked at predetermined intervals.
    - Simple random sample and systematic sampling are comparable, but systematic sampling is typically simpler to carry out.

4. **Stratified sampling:**
    - Stratified sampling is used to divide the population into subpopulations that may differ significantly.
    - It enables you to draw more precise conclusions by ensuring that all subgroups are adequately represented in the sample.
    - When using this sampling method, you divide the population into subgroups (called strata) based on the relevant characteristic (e.g., gender identity, age range, income bracket, or job role).
    - You calculate how many people should be sampled from each subgroup based on the overall population proportions.
    - Then, you select a sample from each subgroup using either random or systematic sampling.

4.7.2. Non-Probability Sampling Methods

Four probability sampling methods have been widely applied in research:

1. **Convenient sampling:**
    - A convenience sample consists of people who are most easily accessible to the researcher.
    - This is a simple and inexpensive way to collect preliminary data, but there is no way to know if the sample is representative of the population, so the results are not generalizable.
    - Convenience samples are vulnerable to both sampling and selection bias.
    - A voluntary response sample, like a convenience sample, is primarily motivated by ease of access.
    - People volunteer themselves rather than the researcher selecting and contacting them (e.g., by responding to a public online survey).
2. **Purposive sampling:**
    - This type of sampling, also known as judgment sampling, entails the researcher using their expertise to select a sample that is most useful to the research objectives.
    - It is frequently used in qualitative research, where the researcher prefers to gain detailed knowledge about a specific phenomenon rather than making statistical inferences, or when the population is very small and specific.
    - An effective purposive sample must have clear inclusion criteria and rationale.
    - Always describe your inclusion and exclusion criteria and be mindful of observer bias in your arguments.
3. **Snowball sampling:**
    - Snowball sampling can be used to recruit participants through other participants if the population is difficult to reach.
    - The number of people you can contact “snowballs” as you make more contacts.
    - The disadvantage is that you have no way of knowing how representative your sample is due to the reliance on participants recruiting others.
    - This can result in sampling bias.

4. **Quota sampling:**
    - Quota sampling divides a population into subgroups based on characteristics such as age or location and establishes targets for the number of respondents needed from each subgroup.
    - The main difference between quota sampling and stratified random sampling is that a random sampling technique is not used in quota sampling.

4.8. Data Collection Tools

4.8.1. Quantitative Data Collection Tools

Before using a data collection tool, researchers should contemplate the following study design characteristics:

- Variable type: Think about the type of information you want to gather, your research specialty, and the overall goals of the study.
- Study design: Choose the method you'll use to collect this data.
- Data collection methods: Decide techniques and tools you prefer to collect data.
- Sampling frame: First, decide the location you want to collect data. Next, identify the population to be sampled. Also, figure out which part of the population will be included in your investigation.
- Sample size: Consider how many subjects you want to include in your study.
- Sampling method: Consider how you will select the samples.

Any data collection tool is required to be validated prior to the data collection. The first steps are providing extensive training for your data collection crew and performing a thorough pilot. These are vital components in every effective survey; however, they will not entirely eliminate data inaccuracies. Data validations might help decrease mistakes. Digital data collection solutions offer a wide range of question types and technical tactics to assist you in effectively incorporating validations into your survey and collecting error-free data.

Several validation measures could improve the data collection tools through piloting interviews:

- Make your most important questions mandatory.
- Test the multiple-choice questions: dynamic or static limits on the number of choices someone can select, randomized options, and logical checks on special options like "All of the above."
- Set maximum and minimum values for numerical questions.
- Add logic to "None of the above" and "All of the above."
- Limit the number of digits or characters in questions.
- Customize the survey for different types of respondents using "skip logic."

Research questions or questionnaires, along with the informed consent form, should be enclosed in the annex section.

4.8.2. Qualitative Data Collection Tools

Qualitative data collection tools should be presented with the interview guides first to:

- Identify interview topics and questions.
- Decide on the level of detail.
- Draft the questions.
- Order the questions.
- List probes and prompts.
- Pilot the guide.

Probing is a technique used to encourage a respondent to produce more information without injecting yourself into the interaction. Examples of probing are listed as follows:

- Would you explain that point a little further?
- Would you give me an example of what you mean?
- Would you say more?
- Please describe what you mean.
- What experiences have you had that make you feel that way?

During the qualitative data collection, several formats of records are carefully stored, including:

- Semi-structured questionnaires in IDI
- Note taking in IDI, FGD, and case study
- Observation checklist and inventory list in direct observation
- Keeping a diary in case study
- Digital voice recording in IDI, FGD, and case study
- Video recording in FGD, direct observation, and case study

Research questions and interview guides, along with the informed consent form, should be enclosed in the annex section.

4.9. Data Collection Plan

Researchers should define the data collection plan, including setting, recruitment and training of data collection team(s), data collection time, eligibility of participants, informed consent, incentives for participants, study tools (e.g., questionnaire), and project time frame.

The eligibility criteria and key socio-demographic features of patients (or other study participants) should be described in detail (e.g., the numbers of eligible participants, how they were selected, and the number approached but who refused or were excluded). The recruitment, background/experiences, and training plan for data collectors should be determined in this section of research protocol.

Researchers should establish a standardized data collection procedure to adhere to the requirements in research ethics. A study time frame should be clearly shown at the end of this section.

4.10. Data Management Plan

One of the key components of conducting research responsibly is data management. All health researchers are impacted by this significant, multidimensional topic, which warrants special consideration and effort. Researchers should be aware of the fundamentals of data administration to provide full and accurate supervision. They should also make sure that every member of the research project team participates in the development, implementation, and upkeep of data management policies and procedures. Thus, a detailed data management plan should be drafted in the research protocol.

A comprehensive system for data management should include a continuous system for rigorously evaluating effective or deficient elements in the project protocol or the research team's data collection process. When research data is collected, all records should fairly depict the status of a project and address issues including what, how, and why data were obtained or changed. Records must be enduring, accessible, and secure against manipulation or fabrication. A plan for thorough record keeping is necessary to guarantee the accuracy of data. The maintenance of both paper and electronic records should be well planned and protected.

It is important to outline a procedure to safeguard all information in a project. A project must save all the raw data that were collected, but it must also store any significant statistics and analyses from this data as well as any notes or observations. Additionally, while using biological samples for study, a detailed procedure should be made to keep them until their quality deteriorates. Project data should be protected from physical harm as well as manipulation, loss, or theft to retain the integrity of stored data. Finally, the project's data storage strategy should include data protection. More details in data management are also listed in Section 6. Research Data Management.

4.11. Data Analysis Plan

The data analysis plan should provide a detailed description of the association or causal effect to be estimated and the rationale for this choice. It should describe the pre-specified methods of analysis to draw inference about treatment, exposure effect, or association and plan to control for multiplicity of inferences as discussed earlier in these guidelines.

4.11.1. Quantitative Data Analysis Plan

Researchers should briefly describe the statistical tests that would be used for the analysis. State any a priori levels of significance and whether hypothesis tests were one- or two-sided. Also include the statistical software used to perform the analysis, including the version and manufacturer, along with any extension packages (such as SPSS, STATA, or R).

It is not necessary to provide a detailed description of the methods used to generate summary statistics, but the tests should be briefly noted in this section (e.g., Chi-square, ANOVA or Fisher exact test). In regression analysis, it should be clear to identify regression models with more than one "independent" variable as multivariable, but regression models with more than one "dependent" variable as multivariate.

4.11.2. Qualitative Data Analysis Plan

As qualitative research is subjective, qualitative analysis is also interpretive and subjective. The researcher contributes their own interpretation and meaning to the analysis.

The conceptual framework should be presented at the outset of the qualitative data analysis plan. A conceptual framework comprises (in part or in whole) one or more formal theories, as well as other concepts and empirical findings from the literature. It serves to illustrate the connections between these concepts and their relevance to the research study.

It is imperative for researchers to provide a thorough description of their approach to processing qualitative data:

- The methodology of cutting and sorting to extract relevant quotes for a particular theme. Additionally, it explores the technique of pile sorting, which involves pawing and shuffling to identify sub-themes within the extracted quotes.
- The utilization of word lists and keywords-in-context as a means of summarizing text by condensing it into words or organizing specific words within their respective contexts.

4.12. Expected Results

Researchers should include the expected study results. Give positive and negative findings of equal scientific merit equal weight in the expected research findings. In addition, researchers should provide a statement of significance outlining the implications for clinical practice or health policy, avoiding speculation and overgeneralization. Additionally, the relevance statement may indicate whether additional research might be necessary before the information can be implemented in health settings.

4.13. Research Ethics

Details of ethics approval (or a statement as to why it was not required) should be provided in this section. All studies involving human subjects should include details of informed consent. Researchers should describe their safeguarding steps to protect human subjects, assure the confidentiality of personal identity, guarantee data security, and provide documents for informed consent. More details in Research Ethics are reviewed in Section 5. Research Ethics and Review.

4.14. References

Citations and bibliographies are essential components of any research paper. Referencing is a scientific method for defining a data source through the provision of a standard set of information that facilitates identification, searchability, and retrieval. While referencing includes only the sources of information cited in the research paper, the bibliography provides a list of all relevant sources, whether or not they were cited. In-text citations are used to validate authors' claims and establish the relationship between multiple studies, allowing readers to compare and contrast their findings. Medical literature most frequently applies the Vancouver American Psychological Association (APA), and Harvard styles among the numerous scholarly citation formats. Author-date format (APA and Harvard styles) or numbered format (Vancouver style) are utilized.

When using the appropriate format, a wide variety of materials such as: journal articles, entire books, book sections, conference proceedings and papers, dissertations and theses, patents, newspaper articles, legal documents, letters and other personal communications, unpublished manuscripts, electronic articles, e-books, software, blogs, and website pages are all considered to be valid sources of citable references. However, researchers are responsible for the accuracy and completeness of their references and for correct text citation.

To address these issues, several web-based and non-web-based referencing applications have been developed. These tools identify and store the component data fields of a reference so that varying formatting rules can be applied to each component in accordance with different referencing styles. EndNote and Thomson Reuters' Reference Manager are the two most established pieces of reference software. These desktop-based reference programs have seen the greatest amount of use because their layout may be modified. They save all references and associated files in offline libraries on the computer itself. The introduction of referencing tools has resulted in a reduction in the manual labor and complexity involved in reference management.

Several important styles in references are as follows:

- Number references in the order they appear in the text.
- Identify references in text, tables, and legends with superscript Arabic numerals.
- When listing references, follow AMA style and abbreviate names of journals according to the journal list in PubMed.
- List all authors and/or editors up to six names; if more than six authors, list the first three authors followed by "et al."
- Journal references sometimes include the issue number in parentheses after the volume number.
- References to an article should include the names of the authors followed by their initials. List all authors when there are three or fewer:

  Gordon JB, Bennett AM. Tuberculosis in reindeer. Scand Rev Respir Dis. 1978; 96 (Suppl): 217-219.
- References to a piece of work: (book/monograph) should include the names of the authors, the title of the piece of work, the ISSN number of the publication, the name of the editor, the place and year of publication, the number of the volume and the first and last page numbers:

  McPhee SJ, Winker MA, Rabow MW, Pantilat SZ, Markowitz AJ, eds. Care at the Close of Life: Evidence and Experience. New York, NY: McGraw Hill Medical; 2011.
- References to a chapter in a book should include the names of the authors, the title of the chapter with the word "In" preceding the reference of the work:

  Girling DJ. The chemotherapy of tuberculosis. In: Ratledge C, Stanford J, Grange JM, eds. Biology of the mycobacteria. London, UK: Academic Press, 1989: pp 285-323.
- Electronic references should be given only when an original citation is unavailable; please provide as much information as possible, including an html address:

  Centers for Medicare & Medicaid Services. CMS proposals to implement certain disclosure provisions of the Affordable Care Act. http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4221. Accessed January 30, 2012.
- References to an article yet to be published should give the name of the journal as (In Press)' and include the article DOI:

  Murray CJL. Maximizing antiretroviral therapy in developing countries: the dual challenge of efficiency and quality [In Press]. JAMA. doi:10.1001/jama.2014.16376
- Personal communications should be given in the text with the name of the individual cited and with his/her consent.

4.15. Annex

The annex in a research protocol might include: (1) CVs of PI, Co-PIs, and investigators; (2) Questionnaires (English & Khmer); (3) Informed consent form (English & Khmer); and (4) other documents (such as supportive letters, funding sources, conflict of interests).

5. Research Ethics and Review

5.1. Importance of Research Ethics

To adhere to ethical norms in TB research is essential to researchers. Ethical norms promote the aims of research, such as knowledge and avoidance of errors. For example, prohibitions against fabricating, falsifying, or misrepresenting research data promote the scientific evidence and minimize errors. Thus, policies on research misconduct, conflicts of interest, human subject protections, and animal care and use are necessary to make sure that researchers can be held accountable to the public. Ethical norms in research also help build public support for research. People are more likely to fund a research project if they can trust the quality and integrity of research.

Since research often involves intensive cooperation and coordination among many different disciplines and institutions, ethical standards promote the values that are essential to collaborative work, such as trust, accountability, respect, and fairness. To safeguard intellectual property rights and promote cooperation, several ethical standards in research (such as authorship criteria, copyright and patenting regulations, data sharing policies, and confidentiality rules in peer review) have been established. Most researchers want to receive credit for their contributions but do not want to have their ideas stolen or disclosed prematurely.

Additionally, the ethical norms in research could promote several important moral and social values, such as social responsibility, human rights, animal welfare, compliance with the law, and public health and safety. Ethical conflicts in research can significantly harm human and animal subjects, researchers, and the public.

5.2. Protection of Human Subjects

When conducting research on human subjects, researchers should strike to:

- Minimize harms and risks and maximize benefits;
- Respect human dignity, privacy, and autonomy;
- Take special precautions with vulnerable populations;
- Distribute the benefits and burdens of research fairly; and
- Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

Researchers should be explicit about steps taken to shield participants from social and physical risks. When research involves hidden, stigmatized or marginalized populations, it is crucial to be explicit and unambiguous about the steps taken to ensure privacy and confidentiality, avoid coercion, and respect the ethical principles of justice and beneficence. Similarly, it is important to relate the responsibilities of the researchers to the relevant ethical guidelines. Medical ethics should not be used to override the safety concerns in qualitative research, which may frequently differ from those in quantitative research. The final document may need to reflect on the reasoning behind what was done and how it was influenced by certain ethical standards (rather than just a statement saying that relevant clearance has been achieved).

5.3. Confidentiality

The protection of research participants' personal information is one of the most important parts of protecting research subjects. This includes preserving participant anonymity, maintaining information's confidentiality, and/or protecting participants' privacy.

Researchers must carefully evaluate how to approach an individual, the proper circumstances and setting in which participants may be reached, and where participant information will be collected when addressing privacy concerns. In a public setting, for example, a participant should not be implored for personal or sensitive information. Instead, information should be gathered in a quiet setting where others cannot witness or overhear the conversation. Researchers should also limit the information acquired to that which is necessary for study objectives and only after the participant has given informed consent.

Confidentiality refers to the protection of the participant's personally identifiable information. Confidentiality also represents an agreement between the researcher and the participant through the informed consent procedure that ensures the participant's identity, personal information, and responses will not be disclosed to anyone other than the research team unless otherwise agreed upon. Participants should be warned that confidentiality cannot be guaranteed when identifying information is collected, and they should also be informed about how their information will be stored during and after the study. Breach of confidentiality is a potential risk of participating in research. To protect participants' confidentiality, researchers should encrypt computer-based files and store documents (including signed consent forms) in a locked file cabinet and remove personal identifiers from study documents.

Anonymity is maintained in research by ensuring that no members of the research team acquire any personal identifiers, either direct or indirect, that would link responses to a specific individual. If a study is undertaken with a population in which a combination of indirect identifiers (e.g., gender, ethnicity, age, or class) is recorded and may be used to identify a specific individual, then the study is not anonymous. Researchers should make every effort to prevent linking study data to personally identifiable information.

5.4. Informed Consent and Compensation

The guiding principles of the informed consent process are taken from historical documents that focus on respecting the people who participate in research. These principles include:

- Participants have the choice to agree to participate or not ("voluntary consent").
- Participants have the option to withdraw at any time (that is, they are free to stop at any time).
- People are autonomous and should be treated with respect.
- Protected groups like participants who are unable to consent for themselves require additional protection (the consent in these cases may be provided by a caregiver or legal guardian).

An informed consent form includes the following components:

- The purpose of the research
- A description of each activity they will need to do and how long each should take to complete
- What data will be collected, who will have access to the data, how the data will be used, and how we will make sure the data stays safe
- Potential risks and benefits of participating in the study

- A statement that participation is voluntary and that participants can withdraw at any time during the study
- If and how they will be compensated for participating in the study (for example, gift card, travel vouchers, small gifts, etc.)

Compensation could be given to research participants as an incentive at the end of the interview. Researchers should avoid paying direct money as an interview incentive. Compensation amounts and types should be reported for research ethical approval.

5.5. Transparency & Accountability

For transparency in research, researchers should disclose methods, materials, assumptions, analyses, and other information needed to evaluate their research. Researchers should be open to the possibility of sharing data, results, ideas, tools, and resources. It is important to be open to criticism and new ideas as well.

Researchers should be accountable for their contributions to the research process and be ready to explain or defend their actions and decisions. Researchers should avoid discrimination against all human subjects involved in the study based on sex, race, ethnicity, or other factors not related to scientific competence and integrity. It is also important to promote social good and prevent or mitigate social harm through research, public education, and advocacy.

5.6. Plagiarism and Intellectual Property

To avoid the plagiarism and to protect intellectual property of research findings, researchers should take the following actions:

- Strive for honesty in all scientific communications;
- Report data, results, methods and procedures, and publication status honestly;
- Do not fabricate, falsify, or misrepresent data;
- Do not deceive colleagues, research sponsors, or the public;
- Honor patents, copyrights, and other forms of intellectual property;
- Do not use unpublished data, methods, or results without permission; and
- Give proper acknowledgement or credit for all contributions to research.

5.7. Safeguard Steps in Research Ethics

Researchers should develop the safeguard steps throughout the research process:

- **Study design:** Aim to protect the safety and confidentiality of participants in developing the effective questionnaires and interventions.
- **Field work:** Provide a reasonable incentive and an informed consent for participant to have their rights to refuse, stop or withdraw in the study.
- **Data protection:** Conduct the strict protection of any personal identification information with limited and encrypted access.
- **Data analysis:** Pay attention to small numbers in stratified tables to prevent intentional speculation or deduction to reveal any personal identification information.
- **Research report/manuscript:** Disclosing any conflict of interests or potential ethical concerns.

5.8. NECHR Review

All health research projects in Cambodia are subject to an internal evaluation of research ethics overseen by the National Ethics Committee for Health Research (NECHR) at the MOH, located within the NIPH. The top administrators or technical directors from various centers and departments within the MOH and academic institutions are the NECHR members. Applications are typically accepted and reviewed by NECHR every two months.

The application submission process is listed as follows:

- All proposals are to be submitted in the prescribed application form, the details of which are given in the Annex.
- All relevant documents should include the application form.
- Twenty copies of the proposal must be submitted along with the application in prescribed format.
- Electronic copies of the submitted proposal and related documents are required.
  The date of the meeting will be communicated to the researcher to be present, if necessary to offer clarifications.
- The decision will be communicated in writing. If revisions will be made, then 20 copies of the revised document must be included for submission.

For a thorough and complete review, all research proposals are to be submitted with the following documents:

- Name of the applicant with designation
- Name of the Institute/hospital /field area where research will be conducted
- Approval from the director of the institution where the researcher works
- Summary of the protocol in Khmer and English
- Full protocol of the proposed research
- Ethical issues in the study and plans to address these issues including statements describing compensation for study subjects for participation and/or study related injuries
- Study tools: Questionnaires, follow up card, etc. in Khmer
- Patient information sheet and informed consent form in Khmer
- For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other countries, if applicable
- Curriculum vitae of all the investigators with relevant publications from the last five years
- Any other relevant regulatory clearances and support
- Source of funding and financial requirements for the report
- An agreement to report any serious side effects or adverse drug reactions to NECHR if applicable
- Statement of conflicts of interest if any
- Any other information relevant to the study
- The review fee of an equivalent amount of $400 USD for research proposals except research conducted by students (without sponsors) for education/academic purposes. In case the proposal needs to be revised, the next review will not be charged.

With the approval from the Chairperson of NECHR, the secretariat determines what type of review is required for each protocol received. Two types of ethical review are as follows:

1. Expedited Review:

Eligibility criteria

- Non-significant risk protocols
- Protocols that are non-confidential
- Not likely to harm/offend
- Involve non-invasive/routine procedures (finger stick collection of blood samples but not use of x-rays or microwaves)
- Protocols that use previously collected data/specimens
- Minor revision of previously approved protocol

Expedited Review Procedures

- The chairperson nominates two or more NECHR members or secretariat team members to review the protocol (previous reviewers if resubmission).
- The reviewers review the complete protocol.
- Circulate protocol for comments, telephone discussion, or meeting to arrive at a consensus.
- In the absence of consensus or if NECHR member expresses concern, protocol is referred for full review.
- The reviewers forward the decision to the secretariat that notifies the chair.
- Communicate the decision to the investigators.

2. Full Review Procedures:

- Chairperson assigns two or three primary reviewers (committee members or secretariat team members) with appropriate expertise to review the protocol.
- The primary reviewers use the assessment form to review the protocol.
- All proposals for review will be sent to all members at least two weeks in advance.
- The primary reviewers report their assessment during the meeting.
- Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
- Researchers will be invited to offer clarifications if needed.
- Decisions will be taken by majority vote.
- The decisions will be recorded and the chairperson’s approval taken in writing.

6. Research Data Management

Data management is one of the core principles of responsibly conducted research. This important, multifaceted issue affects all health researchers and deserves extra attention and diligence. Data management represents a significant investment of time and effort not only for the PI but also for other researchers in a research project. For oversight to be thorough and correct, researchers should understand the basic concepts of data management and ensure that every member of the research project team is involved in the planning, implementation, and maintenance of data management policies and procedures. Several issues in data management are addressed as follows:

6.1. Data Ownership

Data ownership refers to the control and rights over the data as well as data management and use. For most research projects, ownership of data involves at least three different entities:

1. **Sponsoring Institution**: As long as the PI works at the sponsoring institution, ownership of the project's data is typically retained by that organization. The institution frequently oversees all financing or the distribution of government funds; as a result, it is also in charge of making sure that financed research is carried out in a morally and ethically appropriate manner.
2. **Funding Agency:** Many research projects are funded by government agencies, philanthropic organizations, or private industries. These funding agencies frequently have detailed rules governing the storage and dissemination of data. Instead of the supporting organizations or the principal investigator, they may choose whether to publicize the project's findings or commercialize a product that is created.
3. **PI(s):** Some ownership of the data may remain with PI. In small enterprises, unless otherwise stated, it is presumed that ownership and rights to data will always remain with the company itself or the financing source. However, PIs are occasionally permitted in academic institutions to take their study and its data with them if they shift research institutions.

The PI and the funding agency frequently have "rights" to access and use the project data, even though the institution/organization typically owns the data. Physical custody of the data is often exercised by the PI on behalf of the organization. These ownerships, however, change based on the institution and the funding sources.

6.2. Data Collection and Storage

Data collection provides the information necessary to develop and justify research. A successful project collects reliable and valid data. Data collection is reliable when it is employed in a consistent and comprehensive manner throughout the course of a project. Thorough data collection enables research team members to answer any question about a project.

When data are collected, the records should accurately represent the progress of a project and answer such questions as what, how, and why data were collected or amended. Records must be enduring, accessible, and secure against manipulation or fabrication. Thorough data collection should include a continuous system for rigorously evaluating effective or deficient elements in the project protocol or the research team's techniques. Diligent record keeping is essential to ensure the validity of data. Many research projects keep both written and electronic records to balance the benefits of each.

Storing data safeguards your research and your research investment. Storage enables access to the data in the future so that it may be used to replicate the results, support more study, or set a precedent. It is important to save enough information to make it simple to rebuild a project and its results. A project must save all the raw data that were collected, but it also has to store any significant statistics and analysis from this data, as well as any notes or observations. Additionally, while using biological samples for study, care should be made to keep them until their quality deteriorates.

6.3. Data Protection and Retention

To maintain the integrity of stored data, project data should be protected from physical damage as well as from tampering, loss, or theft. Every project's data storage strategy should include data protection. Limiting access to data is one of the good methods to secure project data, whether it is in printed or electronic form. PIs should decide which project members are authorized to access and manage the stored data.

Field notebooks or questionnaires should be kept together in a safe, secure location away from public access, e.g., a locked file cabinet. By substituting names and other details with encoded identifiers and keeping the encryption key in a separate, safe place, privacy and anonymity may be guaranteed. Ultimately, the best way to protect data may be to fully educate all members of the research team about data protection procedures.

Electronic data storage offers many benefits but requires additional consideration and safeguards, including:

1. Protecting access to data, such as unique user ID and password, access to data files through a centralized process, and limitation in administration access rights.
2. Protecting data systems, such as anti-virus protection, network firewall protection, and monitoring access logs.
3. Protecting data integrity, such as using encryption or electronic signatures to monitor changes of data files, and routine data backups.

There is no obligatory amount of time for which data should be stored. In some cases, the time period is at the discretion of the PIs; however, many sponsor institutions require that data be retained for a minimum number of years after the last expenditure report. Most research project teams would retain the original paper study records for three years following the publication of the final report or research manuscripts. Digital data retention periods are typically not set.

Once the minimum storage period has been met, the PI must decide whether to continue storing the data. When the decision has been made to end data storage, data should be thoroughly and completely destroyed. Effective data destruction ensures that information cannot be extracted or reconstructed.

6.4. Data Sharing

The accurate representation of research to the scientific community and the general public depends on data exchange. Sharing of data typically happens after a study is finished. In the context of a certain scientific discipline, data reporting involves explanation of the data, data analysis, and project authorship. In order to share data and discuss findings, results are often published in a scientific publication or a

product is granted a patent. Sharing information while a project is still in development should be done with caution as the data's potential effects could not yet be fully understood.

When and how much of a research study should be released depends on the guidelines set forth by the funding organizations and sponsoring institutions in some cases. There is frequently no requirement to share any preliminary data before publishing. However, in some cases preliminary data should be shared immediately with the public and/or other researchers since it would be of immediate benefit (e.g., if a research project found that a new drug placed subjects at grave risk or greater benefit). Additionally, many researchers believe that it is beneficial to share early results with peers before the study is finished in a conference setting.

Any data associated with a project should be treated as open data once the research has been published or patented. To confirm the results that have been published or to advance their own research projects, other researchers may ask for raw data or other project-related material. However, each project should assess how well it can exchange raw data in terms of specific needs and budget constraints.

A crucial component of the research infrastructure should be the sustainable availability of publicly funded research data. This entails accepting administrative accountability for ensuring the long-term availability of data that has been found to necessitate long-term storage for further research. Given that most research projects, along with the public financing they receive, have short lifespans while providing access to the data produced is a long-term endeavor, this may be a challenge. Therefore, before starting a new project, research funding organizations and academic institutions should consider the long-term preservation of data and choose the most appropriate archival facilities for the data.

7. Research Data Analysis

7.1. Quantitative Data Analysis

The scientific integrity of the data analysis is of primary importance with a comprehensive statistical process. The statistical editors at the *New England Journal of Medicine* advise using the following best practices for putting together papers for both designing research studies and reporting research findings. For the following recommendations on the analysis and interpretation of quantitative data, we have modified these specifications to fit in current TB research in Cambodia.

7.1.1. Requirements in Statistical Analysis

- A protocol document and a statistical analysis plan (SAP) could be needed with each publication for some scientific journals. The SAP should include enough information to let other researchers perform the analysis on a comparable set of data. Documents should be dated, and any modifications to the research plans should be explained together with their supporting rationales. Formal protocol adjustments and accompanying changes to the SAP will normally be available for clinical studies and should be submitted with the article.
- The methods section of the manuscript should contain a brief description of the methods for primary, secondary, and exploratory analyses, as well as a brief description of sample size considerations for the study, including statistical power computations when applicable.
- To prevent confusion, researchers should draw a clear distinction between statistical significance and clinical (or other non-statistical) significance. This can be achieved by reserving the adjective "significant" to mean "statistically significant."
- Significance tests should be accompanied by effect estimates with standard errors or 95% confidence intervals.
- Confidence intervals for ratio quantities, such as relative risks, odds ratios, and hazard ratios, should be computed in the analysis.
- Unless one-sided tests are required by the study design, all reported P values should be two-sided.
- In general, P values larger than 0.01 should be reported to two decimal places, and those between 0.01 and 0.001 to three decimal places; P values smaller than 0.001 should be reported as P<0.001.
- Results should be presented with precision in scientific value, given the available sample size. For example, measures of association, such as odds ratios, should ordinarily be reported to two decimal places. Results derived from models should be limited to the appropriate number of significant digits.

7.1.2. Missing data

- Researchers should report the number of participants with missing data for baseline variables and for all variables used in analyses, including response and predictor variables.
- In the abstract and results sections of the manuscript, researchers should report analyses that address missing data using appropriate methods and assumptions about missing data, such as missing at random.
- The methods section of the manuscript should include a description of the approach used to address missing data, including a statement of assumptions being made about the missing data or the missing data mechanism. Because these assumptions cannot be tested with data, they should be accompanied by contextual justification.

7.1.3. Observational Studies

- The validity of findings from observational studies depends on several important assumptions, including those relating to sample selection, measured and unmeasured confounding, and the adequacy of methods used to control for confounding. The methods section of observational studies should describe how these and other relevant issues were addressed in study design and analysis.
- In any case, a SAP document must be submitted, even if it was not prepared during the conduct of the study. The SAP should include the aims of the study, identify primary and secondary end points, and describe the eligibility criteria for the selection of cases and method of sampling from the data, with a diagram as appropriate.
- The SAP should also provide a detailed description of the association or causal effect to be estimated and the rationale for this choice and describe the pre-specified methods of analysis to draw inference about treatment, exposure effect, or association and plans to control for multiplicity of inferences, as discussed earlier in these guidelines. The SAP should be dated and should make clear whether it was written before or after preliminary data analyses.
- Causal language (e.g., exposure X leads to outcome Y, or changes in exposure X produce changes in outcome Y) should not be used in observational studies where only associations can be estimated.
- In studies in which estimating a causal effect is the goal, the analysis should use methods specifically designed for causal inference and should be accompanied by a description of the assumptions required supporting a causal interpretation. These methods generally attempt to mimic the benefits of randomization using techniques such as matching, instrumental variables, inverse probability weights, or standardization techniques. The choice of method should be justified and accompanied by diagnostics.
- Studies reporting the association of a treatment or exposure with an outcome should show the distribution of potential confounders and other variables stratified by exposure or intervention group. When the analysis depends on the confounders being balanced by exposure group, standardized mean differences between groups calculated after matching, weighting, or other adjustment techniques should be reported.
- Complex models and their diagnostics can often be best described in a supplementary appendix. Researchers are encouraged to conduct an analysis that quantifies potential sensitivity to bias from unmeasured confounding; researchers must provide a discussion of potential biases induced by unmeasured confounders.
- Researchers are encouraged to retest findings in a similar but independent study or studies to assess the robustness of their findings.

7.1.4. Regression Modeling

- For regression models fit to dependent data (such as clustered or longitudinal data), the models should account for the correlations that arise from clustering and/or repeated measures.
- Failure to account for such correlation will result in incorrect estimates of uncertainty (e.g., confidence intervals). Describe how the model accounted for correlation. For example, for an analysis based on generalized estimating equations, identify the assumed correlation structure and whether robust (or sandwich) variance estimators were used.

- For an analysis based on mixed-effects models, identify the assumed structure for the random effects, such as the level of random intercepts and whether any random slopes were included. Fixed-effects estimation should be described as conditional likelihood. Avoid the term fixed effects for describing covariates.

7.1.5. Time-to-Event Data or Survival Analyses

- Estimates of the hazard ratio (HR) are not directly interpretable when the assumption of proportional hazards (PH) is not consonant with the data. When reporting HR estimates, the manuscript should address the appropriateness of the PH assumption and provide corroborating evidence. If the PH assumption appears to be inconsistent with the data, HR estimates should not be reported, and alternative metrics should be used to report comparisons.
- When some censoring may be due to dependent competing events, Kaplan–Meier estimates of event-time distributions may be biased and should be replaced by appropriate estimates of cumulative incidence. HRs estimated with a Cox PH estimate may also be biased and should be replaced by measures of association that account for dependent competing risks.

7.1.6. Clinical Trials

- The analysis of the primary outcome in results of clinical trials should match the analyses pre-specified in the final protocol and SAP, except in unusual circumstances. Analyses that do not conform to the protocol should be justified in the methods section of the manuscript.
- P values should not be included in the traditional Table 1 of a randomized trial manuscript showing the distribution of baseline variables by treatment group. However, researchers should note imbalances in potential confounders that could be due to chance or inconsistencies in randomization.
- Forest plots are often used to present results from an analysis of the consistency of a treatment effect across subgroups of factors of interest. Such plots can be a useful display of estimated treatment effects across subgroups, and the editors recommend that they be included for important subgroups. However, multiplicity considerations continue to apply to forest plots. Thus, if these analyses are not covered in the pre-specified plan for multiplicity adjustment, the forest plots should not include P values for treatment by subgroup interactions.
- When safety outcomes do not constitute primary end points in a study, no adjustment for multiplicity is necessary for their analysis. Because information contained in the safety end points may signal problems within specific organ classes, the editors believe that experiment-wide type I error rates larger than 0.05 are acceptable. In particular, the editors may request that P values be reported for comparisons of the frequency of adverse events among treatment groups, regardless of whether such comparisons were pre-specified in the SAP.
- Per protocol analyses that are based on an analysis dataset constructed by eliminating cases based on post-randomization events (e.g., treatment discontinuation because of side effects or dose changes not specified in the protocol) are generally biased and are generally not allowed. More principled methods of analyzing a trial subject to non-adherence should be used.
- When possible, absolute event counts or rates should be reported before relative risk or hazard ratio estimates. The goal is to provide the reader with both the actual event frequency and the relative frequency.

- In general, relative risk estimates are the preferred quantities to report. If researchers plan to rely on odds ratios in the analysis, a justification should be provided in the methods section addressing the concerns that odds ratios may overestimate the relative risks and may be misinterpreted.
- Researchers should provide a flow diagram in CONSORT format. Researchers should submit all the relevant information included in the CONSORT checklist. Although all this information may not be published with the manuscript, it should be provided in either the manuscript or a supplementary appendix at the time of submission. The CONSORT statement, checklist, and flow diagram are available on the CONSORT website (https://www.equator-network.org/reporting-guidelines/consort/)
- In assessing robustness of findings about the primary end point, researchers should distinguish between sensitivity analyses and other types of analyses (such as analyses of particular subsets). A sensitivity analysis is designed to assess the impact of statistical assumptions, analysis method, or model choice on inferences about an end point.

7.2. Qualitative Data Analysis

Qualitative research in TB could shed light on why particular TB control efforts are successful or failed and how they can be improved. Qualitative research could focus on experiences of diverse actors and their implications. Qualitative research helps to overcome challenges of health care delivery (including TB prevention, access to services, diagnosis, and adherence).

In general, qualitative findings are expected to be more relational, context-driven, and reflexive than quantitative discoveries. The social, gender, cultural, economic, or political variables that affect transmission, case discovery, diagnosis, and treatment outcomes will be clarified through good qualitative research.

7.2.1. Data Transcription

Qualitative researchers are interested in learning about people's opinions and why they behave in certain ways. They may record video or audio to capture and save the resulting data. These interviews and other events generate critical data. However, unstructured data must be sorted through and organized before researchers can make sense of it.

This is where qualitative data transcription is incredibly important. Transcription converts any original audio or video recording into a text-based version. Qualitative data transcription is an excellent starting point for organizing and analyzing your data.

Transcription is essential for qualitative research because it:

- Converts qualitative data and information into a text-based format
- Makes data easier to analyze and share
- Allows researchers to become more immersed in the data they collect
- Allows researchers to create a narrative with their data
- Makes patterns easier to find
- Helps preserve the accuracy and integrity of the data

After data has been transcribed in text format, it can be entered into a spreadsheet or similar type of document, or it can be entered into a qualitative data analysis tool.

7.2.2. Data Coding

Coding is a crucial component of qualitative data analysis. Coding is the process of creating a structure for organizing data in preparation for analysis. A coding document (code book) is merely a form developed by the researcher to aid in the categorization and tally of behavior. The coding scheme identifies which behaviors are pertinent to the research query and how they are to be recorded and which behaviors are relevant to the research question and how they will be recorded.

Coding also helps researchers to identify research themes. Themes can be summarized using codes. Codebooks are structured dictionaries of concepts. The process of coding involves associating categories with sections of qualitative information.

The following is a list of various types of codes:

- Structural codes
  - ✓ Describe characteristics of the data itself
  - ✓ Answers who, what, where and how the data were collected
- Thematic codes
  - ✓ Link themes with specific instances in a set of data
- Memos
  - ✓ Used to annotate data with running thoughts of the investigators
    - Detailed ideas about themes
    - Emerging hypotheses or theories
    - Additional comments on data themselves

7.2.3. Data Analysis

Researchers should describe if codes or themes were generated a priori or ad hoc during the processing of data because merely stating in the publication “a qualitative approach to analysis was undertaken” is not sufficient. In contrast to quantitative methodologies, qualitative research frequently uses concurrent data collecting and processing.

Researchers should be transparent and accountable regarding who contributed to the analysis, the methodology used, and any necessary references to previous work. Researchers should indicate whether and how inter-coder reliability was ensured if the data were coded by more than one analyst. When using qualitative software, researchers should make sure to clearly explain how it was utilized and any problems that could have limited its applicability.

Researchers should conduct qualitative data analysis following the framework method:

- Produce a list of codes (descriptive conceptual labels) based on the study’s aims and questions and preliminary findings from the written field note, observations, and team briefings.
- The analytical framework is further refined through discussion and consultation with the broader research team.
- Apply the working analytical framework to the transcripts following a combination of deductive and inductive approaches. The process involved categorizing the information in the transcripts into pre-determined codes and recording and organizing any new codes emerging from the data.

- Look for patterns in the codes, which are called themes (recurrent patterns of meaning—ideas, thought, feelings).
- Analysts read through transcripts, adding new codes to the framework and refining its structure as needed.

Researchers should examine their qualitative data through the following analytic steps:

- Word repetitions: Identify frequently used words
- Indigenous categories: Search for indigenous phrases and categories
- Metaphors and analogies: Identify metaphors, similes, and analogies
- Compare and contrast: How is this different/similar from previous examples.
- Missing data: What isn't said? What topics are avoided? What topics are assumed and therefore not mentioned?

NVivo is a software program commonly used for qualitative and mixed-methods research. NVivo helps qualitative researchers to organize, analyze and find insights in unstructured or non-numerical data (qualitative data), including:

- Unstructured text: Audio, video, image data
- Non-numerical data: Interviews, FGDs, open-ended surveys, social media, and journal articles.

NVivo allows researchers to classify, sort, and arrange information; examine relationships in the data; and combine analysis by linking shaping, searching, and modeling.

7.2.4. Data Interpretation

The questions posed and the theoretical and methodological approaches used will all affect how the evidence is interpreted. It is crucial to provide convincing evidence that analytical techniques are rigorous and open, producing both fascinating and useful results. A logical focus in qualitative research is on the nature and quality of relationship between the researchers and the participants. It is customary to examine how the researcher's social status may affect the data collected and to address it in the publication by using a reflective approach.

Due to the difficulty of making adjustments in the middle of a quantitative project, there is a tendency to defend one's methodology. A strong qualitative study, however, may evolve over time and yield unexpected findings. It can be challenging to predict in advance who will have the answer and the best way to get it. Therefore, it is critical to summarize the project's accomplishments as well as any changes that were made to the research questions or methodology along the way. This methodological flexibility is commonly misunderstood to mean that data collection is acceptable if it is driven more by impulse or realism than by theoretical requirements. The analysis of qualitative data should provide a convincing justification for the development of research procedures or instruments.

Most responses could be summarized into one or more general statements, with an emphasis on the most frequently expressed opinions. A percentage could be calculated to show the proportion of one important opinion among participants in some cases. A quote derived from the original words of a participant could be used to emphasize the significance of an opinion or behavior.

7.2.5. Quotations and Thick Description

It is critical for researchers to search for themes and patterns in their qualitative data. The final sets of themes (e.g., pressions of research topics) are summarized and placed into an Excel table or similar structure where evidence from the text is given to back up the themes and produce a quote from the text. To identify important themes, researchers could examine their data with the following questions:

- How often it appears
- How pervasive it is across different types of cultural ideas and practices
- How people react when the theme is violated

Quotes are words and phrases taken from transcripts of the interviews to demonstrate the concepts or meanings based on the analysis. Quotes should be utilized cautiously and to highlight the important points of the developing analytical argument and interpretation. Even though the identities of participants are often confidential, it is expected that certain relevant characteristics will be provided to enhance quotation interpretation. It should be simple to tell between the “voices” of the participants and the researchers. Qualitative findings can also be successfully represented in diagrammatic, tabular, and numerical form with careful evaluation of theories and data.

7.3. Limitations

Results from qualitative studies do not necessarily need to be representative or broadly generalizable, but it is crucial to evaluate how useful they are. In some cases, the theoretical implications of the study might be important. Researchers should evaluate the effect of relationships, cultural, class or gender disparities, limited access and other factors that might impact the quality of the collected data. Sharing study findings with skeptical colleagues might help you anticipate and address journal reviewers’ concerns.

8. Research Publication and Dissemination

8.1. Authorship

As the *International Journal of Tuberculosis and Lung Disease* suggests, authorship should be based on the following four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
2. Drafting the work or revising it critically for important intellectual content;
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

When a multicenter group has conducted the study, all individuals who accept direct responsibility for the manuscript should be identified. When submitting a group author manuscript, the corresponding author should clearly identify all individual authors, as well as their affiliations.

8.2. Types of Research Articles

As stated in the *Journal of the American Medical Association*, one of the most prestigious research journals, research articles are generally classified into the following types:

8.2.1. Original Investigation

Without overlapping or replicating previous published research, these reports typically include randomized trials, intervention studies, cohort studies, case-control studies, epidemiologic assessments, observational studies, surveys with high response rates, cost-effectiveness analyses and decision analyses, and studies of screening and diagnostic tests.

8.2.2. Clinical Trial

A clinical trial is any research project that prospectively assigns human participants to intervention or comparison groups to study the cause-and-effect relationship between an intervention and a health outcome. Interventions include but are not limited to drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, process-of-care changes, and the like.

All manuscripts reporting clinical trials, including those limited to secondary exploratory or post hoc analysis of trial outcomes, must include a copy of the trial protocol including the complete statistical analysis plan, a CONSORT flow diagram, and a completed CONSORT checklist. All clinical trials must be registered at an appropriate online public registry. Authors are required to indicate if data will be shared or not.

For additional guidance on preparing manuscripts reporting cluster trials, non-inferiority and equivalence trials, and pragmatic trials. Each manuscript should clearly state an objective or hypothesis; the design and methods (including the study setting and dates, patients or participants with inclusion and exclusion criteria, or data sources, and how these were selected for the study); the essential features of any interventions; the main outcome measures; the main results of the study; a discussion section placing the results in context with the published literature and addressing study limitations; and the conclusions.

8.2.3. Brief Report

These manuscripts are short reports of original studies or evaluations or unique, first-time reports of clinical case series. A structured abstract and a list of three key points or keywords are required. Recommended length: 1200 words (not including abstract, tables, figures, acknowledgments, references, and online-only material) with no more than a total of three tables and/or figures and no more than 15 references. However, it is very rare for most journals to publish case reports.

8.2.4. Research Letter

Research Letters are concise, focused reports of original research. Letters must not duplicate other material published or submitted for publication.

In general, research letters should be divided into the following sections: introduction, methods, results, and discussion. They should not include an abstract or any key points (key words). These should not exceed 600 words of text and six references and may include up to two tables or figures.

Research letters may have no more than seven authors. The text should include the full name, academic degrees, and a single institutional affiliation for each author and the email address for the corresponding author. Other persons who have contributed to the study may be indicated in an Acknowledgement, with their permission, including their academic degrees, affiliation, contribution to the study, and an indication if compensation was received for their role.

8.2.5. Letter to the Editor

Letters discussing a recent article in this journal should be submitted within four weeks of publication of the article in print. Letters received after four weeks will rarely be considered. Letters must not duplicate other material published or submitted for publication and should not include unpublished data.

Letters should not exceed 400 words of text and five references, one of which should be to the recent article. Letters may have no more than three authors. The text should include the full name, academic degrees, and a single institutional affiliation for each author and the email address for the corresponding author.

Letters being considered for publication ordinarily will be sent to the authors of the original article, who will be given the opportunity to reply. Letters will be published at the discretion of the editors and are subject to abridgement and editing for style and content.

8.3. Components of Research Manuscript

Each research manuscript should clearly state the following components[7]:

- A structured abstract and a list of three key points (or key words) are required;
- An objective or hypothesis;
- The design and methods (including the study setting and dates, patients or participants with inclusion and exclusion criteria and/or participation or response rates, or data sources, and how these were selected for the study);
- The essential features of any interventions;
- The main outcome measures;

- The main results of the study: data included in research reports must be original and should be as timely and current as possible.
- A discussion section placing the results in context with the published literature and addressing study limitations; and
- The conclusions and relevant implications for clinical practice or health policy.

The maximum length of research manuscript is usually around 3000 words of text (not including abstract, tables, figures, acknowledgments, references, and online-only material) with no more than a total of five tables and/or figures.

How to prepare tables and figures for a manuscript is described as follows:

- Restrict tables and figures to those needed to explain and support the argument of the article and to report all outcomes identified in the methods section.
- Number each table and figure and provide a descriptive title for each.
- Every table and figure should have an in-text citation.
- Verify that data are consistently reported across text, tables, figures, and supplementary material.
- Frequency data should be reported as "No. (%)," not as percentages alone (exception, sample sizes exceeding ~10,000). Proportions and percentages should be accompanied by the actual numerator and denominator from which they were derived. This is particularly important when the sample size is less than 100. Do not use decimal places (i.e., xx%, not xx.xx%) if the sample size is less than 100.
- Tables that include results from multivariable regression models should focus on the primary results. Provide the unadjusted and adjusted results for the primary exposure(s) or comparison(s) of interest. If a more detailed description of the model is required, consider providing the additional unadjusted and adjusted results in supplementary tables.
- Tables have a minimum of two columns. Comparisons must be read across the table columns.
- Do not duplicate data in figures and tables. For all primary outcomes noted in the methods section, exact values with measures of uncertainty should be reported in the text or in a table and in the abstract, and not only represented graphically in figures.
- Pie charts and 3D graphs should not be used and should be revised to alternative graph types.
- Bar graphs should be used to present frequency data only (i.e., numbers and rates). Avoid stacked bar charts and consider alternative formats (e.g., tables or splitting bar segments into side-by-side bars) except for comparisons of distributions of ordinal data.
- Summary data (e.g., means, odds ratios) should be reported using data markers for point estimates, not bars, and should include error bars indicating measures of uncertainty (e.g., SDs, 95% CIs). Actual values (not log-transformed values) of relative data (for example, odds ratios, hazard ratios) should be plotted on log scales.
- For survival plots, include the number at risk for each group included in the analysis at intervals along the x-axis scale. For any figures in which color is used, be sure that colors are distinguishable.
- All symbols, indicators, line styles, and colors in statistical graphs should be defined in a key or in the figure legend. Axes in statistical graphs must have labels.
- Units of measure must be provided for continuous data.

The reference styles vary by different requirements of journals, but the common styles are presented in the Section 4.14. References.

By encouraging accurate and transparent reporting and wider adoption of strict reporting criteria, the EQUATOR (Enhancing the Quality and Transparency of Health Research) Network is a worldwide movement to enhance the dependability and value of published health research literature. It is the first coordinated attempt to tackle the problems of inadequate reporting systematically and on a global scale; and it advances the work done by individual groups over the last 15 years. Many esteemed scientific journals have recommended that researchers should follow several reporting guidelines for different study types.

8.4. Research Manuscript Review

8.4.1. Peer Review

All research publications should undergo peer or expert evaluation inside their own institutions (for internal clearance), or by the scientific journals to ensure their legitimacy and soundness in terms of both science and ethics (for publication purpose). The reviewers may use some of the following checklists during the review process:

Most reviewers are likely to ask the following questions:

- What is the main question addressed by the research? Is it relevant and interesting?
- How original is the topic? What does it add to the subject area compared with other published material?
- Is the paper well written? Is the text clear and easy to read?
- Are the conclusions consistent with the evidence and arguments presented? Do they address the main question posed?
- If the author is disagreeing significantly with the current academic consensus, do they have a substantial case? If not, what would be required to make their case credible?
- If the paper includes tables or figures, what do they add to the paper? Do they aid understanding or are they superfluous?

Examples of possible major flaws found by reviewers are:

- Drawing a conclusion that is contradicted by the author's own statistical or qualitative evidence;
- The use of a discredited method;
- Ignoring a process that is known to have a strong influence on the area under study; and
- If experimental design features prominently in the paper, the methodology might not be sound.

Most reviewers might examine:

- The sampling in analytical papers;
- The sufficient use of control experiments;
- The precision of process data;
- The regularity of sampling in time-dependent studies;
- The validity of questions, the use of a detailed methodology and the data analysis being done systematically (in qualitative research); and
- That qualitative research extends beyond the author's opinions, with sufficient descriptive elements and appropriate quotes from interviews or focus groups.

If methodology is less of an issue, reviewers frequently initially check the data tables, figures, or images. It's all about knowledge, especially in scientific study. If there are significant errors in these data, the paper will probably need to be rejected. These problems include:

- Insufficient data;
- Unclear data tables;
- Contradictory data that either are not self-consistent or disagree with the conclusions; and
- Confirmatory data that adds little, if anything, to current understanding—unless strong arguments for such repetition are made.

If a serious problem were detected, reviewers would make a note of their reasoning and adequate supporting evidence (including citations). Following the initial read, the reviewers would write at least two paragraphs of review, the first describing the research issue addressed and the second explaining the work's contribution. They would refer to their notes from the initial read, identifying any serious problems they noticed.

The first paragraph might state the main question addressed by the research and summarize the goals, approaches, and conclusions of the paper. It should:

- Help the editor properly contextualize the research and add weight to reviewer's judgment;
- Show the author what key messages are conveyed to the reader, so they can be sure they are achieving what they set out to do; and
- Focus on successful aspects of the paper so the author gets a sense of what they've done well.

The second paragraph might provide a conceptual overview of the contribution of the research. So consider:

- Is the paper's premise interesting and important?
- Are the methods used appropriate? and
- Does data support the conclusions?

After these two paragraphs, reviewers may be able to assess whether this work is significantly flawed and should be rejected, or whether it is publishable after a careful and diligent review.

8.4.2. Revision after the Peer Review

A manuscript is seldom approved for publication without alterations; instead, most articles undergo at least one revision in response to feedback from editors and reviewers. Following a review, the reviewers and editors may conduct the following process when a research article is amended.

The editor frequently reviews minor changes immediately. In most cases, the editor will send the article back to the original reviewers if substantial revisions were needed (unless they opted out of this). Reviewers would pay special attention to how the author updated the work in response to their comments. This is made easier by the requirement that authors in some publications must note the changes in their updated work.

Rarely, the editor may invite comments from a new reviewer; in such cases, the editor would explain why a new perspective is needed. It is important new reviewers acknowledge previous review comments and the efforts the author has made to revise the paper.

Any important revisions should ideally have previously been requested in the initial review. The goal of the follow-up review should be to check that the changes have been implemented rather than to find new concerns. As a result, any examination of a revised article must be quick and confined to confirming that the appropriate actions were completed. Nonetheless, the goal of the review remains the same: to guarantee that the manuscript is publishable.

The editor will usually include both the initial decision letter and the author's reaction to it. This allows reviewers to see what revisions were requested, including those requested by the other reviewer, as well as how the author replied to those changes.

9. Conclusions

A research guideline would have a more specific focus on the research process than other guidelines. The methods for evidence review to develop a research guideline include updating publication databases and other sources of research information as well as the need for a flexible and iterative approach to establishing research protocols, data abstraction, and evidence synthesis.

The core principles and standards for research guidelines include minimizing bias; employing clear procedures and explicit, testable methods; and considering the requirements of the intended audience as well as the interests of the people and organizations who will be impacted by the research recommendations. Applying these principles and meeting these standards involves trade-offs, and expertise in guideline development methods and in the research area of the guideline are required. The guideline's limitations, including its short lifespan, need to be stated in a transparent manner, and the responsible technical unit (i.e., CENAT and CCTBR) would commit to updating this TB Research Guidelines and Protocol as needed.

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Annex

1. NECHR Application Forms

Application Form – Ethics Committee Review

PI code: Submitting institution/organization:	Address: City: Country:
Protocol Title:	
Version Nº: (Dated: / /) (DD/MM/YYYY)	
STUDY TYPE (only one choice):	
☐ Cross Sectional study, ☐ Case-control study, ☐ Cohort, ☐ Randomized control Trial, ☐ Quasi experiment, ☐ Community trials, ☐ Qualitative study, ☐ Mix methods (quantitative & qualitive) ☐ Other:	
RESEARCH TOPIC (multi choices):	
☐ Social behaviors ☐ Laboratory ☐ Clinical trial: (☐ Phase I, ☐ Phase II, ☐ Phase III, ☐ Phase IV, ☐ Other:_____) ☐ Genetics ☐ Health system: (☐ Health service delivery, ☐ Human resource, ☐ Health Policy, ☐ Health economic, ☐ Other:_____)	

☐ One health, ☐ Infectious diseases, ☐ Non communicable disease, ☐ Maternal & child health, ☐ Other:					
STUDY POPULATION:					
☐ Healthy ☐ Patient ☐ Vulnerable groups:_____ ☐ Other: Total Participants to be included:					
CHARACTERISTICS OF PARTICIPANTS PARTICIPATED:					
Age Range: Lowest: Highest:					
Are children included? ☐ None ☐ Yes: (☐ < 1 yr, ☐ 1-3 yrs, ☐ > 3 yrs)					
Gender: ☐ Male ☐ Female ☐ Both					
DURATION OF THE STUDY	From: To :				
MULTI-SITE COLLABORATIONS:	☐ YES; ☐ NO				
FINANCIAL DISCLOSURE:	☐ YES; ☐ NO				
Financial Sponsor : Country of funding: Estimated Budget:					
Implementing Agencies:					
PLACE OF IMPLEMENTATION:					
Name of Provinces	Area		Name of Provinces	Area	
☐ Banteay Meanchey	☐ Rural	☐ Urban	☐ Pailin	☐ Rural	☐ Urban
☐ Battambang	☐ Rural	☐ Urban	☐ Phnom Penh		☐ Urban

☐ Kampong Cham	☐ Rural	☐ Urban	☐ Preah Sihanouk	☐ Rural	☐ Urban
☐ Kampong Chhnang	☐ Rural	☐ Urban	☐ Preah Vihear	☐ Rural	☐ Urban
☐ Kampong Speu	☐ Rural	☐ Urban	☐ Prey Veng	☐ Rural	☐ Urban
☐ Kampong Thom	☐ Rural	☐ Urban	☐ Pursat	☐ Rural	☐ Urban
☐ Kampot	☐ Rural	☐ Urban	☐ Ratanak kiri	☐ Rural	☐ Urban
☐ Kandal	☐ Rural	☐ Urban	☐ Siem Reap	☐ Rural	☐ Urban
☐ Kep	☐ Rural	☐ Urban	☐ Stung Treng	☐ Rural	☐ Urban
☐ Koh Kong	☐ Rural	☐ Urban	☐ Svay Rieng	☐ Rural	☐ Urban
☐ Kratie	☐ Rural	☐ Urban	☐ Takeo	☐ Rural	☐ Urban
☐ Mondul Kiri	☐ Rural	☐ Urban	☐ Tbong Khmum	☐ Rural	☐ Urban
☐ Oddar Meanchey	☐ Rural	☐ Urban			

TYPE OF DATA:		
☐ Institutional Base (e.g., PHD, OD, other research institution, orphanage, nongovernmental organization etc.); ☐ Hospital/ Health center Based (e.g., Treatment center, clinic, health post etc.); ☐ Public Based (e.g., community, market, school, etc.) ☐ Other:		
LIST OF PRINCIPAL INVESTIGATORS		Position on the research
1.	☐ Male; ☐ Female Nationality:	

2. 3.	☐ Male; ☐ Female Nationality: ..... ☐ Male; ☐ Female Nationality:	
Contact of the person in charge to the study	Active Email: ..... Phone number:	
Submitted on...../...../..... Signature and name of applicant		
The submission requirements are met The proposal in registered on ...../...../..... Secretary of NECHR		

សង្ខេបពិធីសារ /Protocol Summary

		English ភាសាខ្មែរ
	Title ចំណងជើង	
1	Background សារជាន	
2	Objective គោលបំណងចម្បង	
3	Secondary objective គោលបំណងបន្ទាប់បន្សំ	
4	Survey Population ពិពណ៌នាពីក្រុមសំណាក	
5	Subject selection criteria របៀបជ្រើសរើសក្រុមសំណាក	
6	Sample design រៀបចំពីទម្រង់នៃការសិក្សា	
7	Data Collection របៀបប្រមូលទិន្នន័យ	
8	Laboratory Procedures ប្រើប្រាស់មន្ទីរពិសោធន៍	
9	Linkage to care and treatment ការថែទាំ និងព្យាបាល	
10	Duration of Study រយៈពេលនៃការសិក្សា	
11	Exposure and Outcome រៀបរាប់ពីកត្តាអ្វីដែលយកមកសិក្សា	
12	Statistical Methods ការវិភាគស្ថិតិ	
13	Sample Size and Power Calculations ការគណនារកចំនួនសំណាក ឬការគណនាកំរិត power	
14	Ethical considerations ការពិចារណាពីក្រមសីលធម៌	
15	Cost and compensation ថវិកា និងការផ្តល់ប្រាក់កំរៃដល់អ្នកចូលរួម	
16	Reporting of results លទ្ធផលដែលអាចនិងបង្ហាញ	
17	Limitations ដែនកំណត់របស់ការសិក្សា (ចំនុចខ្សោយ)	

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