Plot 38717D, Great East Road
P.O. Box 35440, Lusaka.
+260 77 067 3333
admin@africaresearchuniversity.com
www.africaresearchuniversity.com

Africa Research University
grow | prosper | excel

ONLINE EXAM COVER SHEET

Please complete all areas of this form, sign, and attach to each submitted exam. Submit each exam according to the instructions provided.

A. STUDENT/S TO COMPLETE

Program Name: master of public health	**Course Name: Research method and protocol development**
Student ID Number: 20245108	**Student Names: Mwale banda**
Postal/ Email Address: mwale.banda@gmail.com	**Phone Number: +260961423073**

Date Submitted: 6th march 2026	**Lecturer Name: Dr Belemu/Dr Ndalama**

Declaration

I declare that this assessment item is my own work, neither was I assisted by anyone or any other foreign material in answering this Examination, and acknowledge that the assessor of this item may, for the purpose of assessing this item:

Communicate a copy of this assessment item to the University for Marking

I certify that I have read and understood the University Rules in respect of Student Academic Misconduct.

Student Signature:

Date: 6th March 2026

Question 2

The essential components of Public Health Research Protocol: A critical discussion with application to HIV and Key Populations in Zambia.

1 Introduction

A research protocol is basically your study's roadmap. Without it, you are driving blind. In public health research, where we are dealing with people's lives and sensitive issues, having a solid protocol is not just good practice it is a non-negotiable ethical requirement. It forces you to think through every step before you start, to spot potential problems early, and to convince ethics committees and funders that you know what you are doing.

In this essay, I will critically discuss the key parts of a public health research protocol and explain why each one matters. Then, to make it real, I will show how I would develop a protocol for a public health challenge that is highly relevant to Zambia and Sub-Saharan Africa: understanding barriers to HIV prevention and treatment among key populations. Key populations including female sex workers, men who have sex with men, people who inject drugs, and transgender person's account for a disproportionate share of new HIV infections in the region, yet they remain underserved and under-researched due to stigma, criminalisation, and programme blind spots. Getting the protocol right for this kind of research is particularly critical because of the ethical complexities involved.

2 What is a Research Protocol and Why Does It Matter

A research protocol also known as a research proposal, is a document that explains what you plan to study, why it matters and exactly how you will do it. It is not just paperwork for the ethics committee, it is a guide through the project. When things get confusing, you go back to your protocol to remind yourself what you originally set out to do.

The main reasons to write a good protocol are:

- It helps you catch flaws in your thinking before you waste time and money
- It lets other researchers review your plan and give feedback
- It ensures everyone on the team works the same way
- It proves to ethic committee that you have thought about participants safety
- It gives funders confidence that their money will be spent well
- It provides a foundation to writing up your findings later

For anyone conducting a research with vulnerable populations like key populations, a solid protocol is even more essential.

3 Key components of a Research protocol

In this essay we will go through each component and explain what it does and why it is important. I will use examples from HIV research with key populations to illustrate.

3.1 Title, Introduction and background

The title should be clear and descriptive. Anyone reading it should know immediately what the study is about, where it is happening, and who is being studied. For example: barriers to HIV prevention and treatment access among female sex workers in Lusaka and the Copperbelt. A mixed-method study.

The introduction and the background set the scene. You start broad and then narrow the global HIV targets 2030, the regional burden in Sub-sahran Africa, and then narrow down in on Zambia's epidemic. You have to cite data showing that key populations face disproportionate HIV risk E.g. Studies estimating HIV prevalence among female sex workers in the region at nearly 60% in some context Phaswana-Mafuya (2025). You would note that while we know key populations are affected, we do not fully understand the specific barriers they face in accessing services in the Zambia. Stigma, criminalisation and mistrust of health institution are likely factors but the exact extent remains unclear.

3.2 Problem Statement, Aims and Objectives

The problem statement comes directly from the background. It is where you state, in clear and direct language, the specific issue your research will address. It should be brief but powerful. For a key populations HIV study, it might read:

"Despite national policies that include key populations in HIV strategies, female sex workers and men who have sex with men in Zambia continue to experience low rates of HIV testing, low uptake of pre-exposure prophylaxis (PrEP), and poor engagement in treatment. The specific barriers whether health system-related, legal, social, or structural remain poorly documented, limiting the effectiveness of targeted interventions." The aim is your overall goal: "To investigate the barriers to HIV prevention and treatment access among key populations in Lusaka and the Copperbelt provinces of Zambia."

The objectives break this aim down into specific, manageable pieces. They should be SMART: Specific, Measurable, Achievable, Relevant, and Time-bound. Good objectives use action verbs like "to determine," "to identify," you have to avoid vague verbs like "to understand" or "to appreciate."

For this study, objectives might be:

1. To determine the prevalence of HIV testing, PrEP use, and ART adherence among key populations in selected sites
2. To identify individual, social, and structural factors associated with low service uptake
3. To explore key populations' lived experiences of accessing (or avoiding) HIV services
4. To examine healthcare workers' attitudes and practices regarding key populations
5. To develop evidence-based recommendations for more inclusive HIV programming

3.3 Literature Review and Conceptual Framework

The literature review is where you engage with what other researchers have found. It is not just a list of summaries you need to be critical. Ask yourself: What did they find? How did they study it? Were their methods sound? What questions did they leave unanswered?

For a key populations HIV study, I would look at research on stigma and healthcare access, studies on criminalisation and its effects on health-seeking behavior, and interventions that have worked elsewhere to reach marginalized groups. I would pay attention to studies from similar settings in Sub-Saharan Africa, not just global North research.

The conceptual framework is your own map of how you think things are connected. For this study, I might draw on the socio-ecological model, which recognizes that health behaviors are influenced by factors at multiple levels: individual (knowledge, beliefs), interpersonal (social networks, partner dynamics), community (norms, stigma), and structural (laws, policies, health system organisations). This framework helps me think systematically about where the barriers might be and how they interact.

3.4 Methodology

This is the nuts and bolts of your study, how you will actually do it. For research with key populations, methodology choices are particularly important because of the sensitivity and potential risks involved.

3.4.1 Study Design

I would use a mixed-methods cross-sectional design. This means collecting data at one point in time, using both quantitative methods (a survey to measure the size and distribution of barriers) and qualitative methods (in-depth interviews to understand people's experiences and perspectives). Mixed methods are valuable when you need both to count and to understand.

3.4.2 Study Population and Sampling

The study population would be key populations specifically female sex workers and men who have sex with men in selected urban and peri-urban areas of Lusaka and the Copperbelt. Sampling is tricky with

hidden populations. You cannot just do random sampling because there is no list. I would use respondent-driven sampling, a peer-referral method that works well for hard-to-reach populations. For the qualitative part, I would use purposive sampling to ensure diversity in age, location, and experiences.

3.4.3 Data Collection

For the quantitative survey, a structured questionnaire would be administered by trained peer researchers' members of key population communities who are trained as data collectors. This builds trust and improves data quality. The questionnaire would cover demographics, HIV testing history, PrEP and ART use, experiences of stigma and discrimination, and interactions with health services.

For the qualitative part, I would conduct in-depth interviews with a smaller number of participants, using a semi-structured guide that allows people to tell their stories in their own words. Interviews would be conducted in private, in the participant's preferred language (likely Nyanja or Bemba), and would be audio-recorded with permission.

3.4.4 Data Analysis

Quantitative data would be entered into STATA or SPSS. I would start with descriptive statistics (frequencies, percentages, and means) to describe the sample and key variables. Then I would move to inferential statistics chi-square tests and logistic regression to identify factors associated with not testing for HIV or not using PrEP.

Qualitative data would be analyzed thematically. This means reading through transcripts, generating initial codes, grouping codes into themes, and interpreting what the themes mean.

3.5 Ethical Considerations

This section is critical especially when researching key populations. These are people who face stigma, discrimination, and in some cases, criminalisation. Research can unintentionally put them at risk if not done carefully.

3.5.1 Informed Consent

Every participant must understand what the study is about, what will happen to their data, and that they can withdraw anytime without penalty. Information sheets and consent forms must be translated into local languages and read aloud for participants with low literacy. Consent must be voluntary no coercion, no pressure.

3.5.2 Confidentiality

This is important. No real names will be used in data collection. Participants will have unique ID numbers only. Data will be stored securely paper forms in locked cabinets, electronic files on password-protected computers. I will not keep identifying information longer than necessary.

3.5.3 Community Engagement

Research on key populations should involve key populations. I would work with community-based organisations run by and for key populations from the start in designing the study, developing materials, collecting data, and interpreting findings. This is not just nice to do; it improves the science and the ethics.

3.5.4 Participant Safety and Referrals

Some participants may become distressed during interviews, especially if discussing experiences of violence or discrimination. I will have a referral pathway in place connections to counselling services, peer support, and legal aid if needed.

3.5.5 Ethics Approval

The protocol would be submitted for ethical review to the University of Zambia Biomedical Research Ethics Committee (UNZABREC) and the National Health Research Authority. No data collection starts until they say yes. Independent review is a fundamental protection.

3.6 Data Management Plan

Data management sounds boring but it matters enormously. You need to say who collects data, how it is stored, how it is cleaned, and how it will eventually be destroyed. For this study:

- Paper questionnaires will be kept in a locked cabinet in a secure office
- Electronic data will be on a password-protected computer, backed up on an encrypted external drive
- Audio recordings will be transcribed and then deleted
- Data will be anonymised no names or identifying details in the analysis files
- After five years, all data will be securely deleted or shredded

I also need to think about data sharing. If I plan to share anonymised data with other researchers, this must be explained in the consent process and approved by the ethics committee.

3.7 Dissemination Strategy

Research that is not shared has not really happened. Findings must reach people who can use them and that includes participants and communities, not just academics.

For this study, I would:

- Write a detailed report for the Ministry of Health and the National AIDS Council
- Prepare a policy brief with clear, actionable recommendations
- Present findings at national conferences and community forums
- Submit articles to peer-reviewed journals (open access if possible)
- Hold feedback sessions with key population communities, presenting findings in plain language and in local languages

Participants gave us their time and their stories. They deserve to know what we found and how it might help.

3.8 Work Plan and Budget

The work plan shows when things will happen. A Gantt chart is useful listing activities (protocol writing, ethics submission, community engagement, data collection, analysis, writing up) with dates and who is responsible. The budget lists what things will cost: research assistants, peer researcher stipends, transport, stationery, participant incentives, transcription services, dissemination. It must be realistic and justified. For research with key populations, I would include budget for community engagement and for security measures to protect participants and staff.

4 Conclusion

A good research protocol is not just a document you write to get ethics approval and then forget about. It is your guide, your defense, and your commitment to doing research properly. For research with key populations where the stakes are high and the risks are real a solid protocol is absolutely essential.

The protocol forces you to think through every step, to anticipate problems, and to prove to others (especially ethics committees) that you are ready to do research that is both scientifically sound and ethically responsible. It ensures that when you finally go out to collect data, you are not making it up as you go along.

In Zambia, key populations continue to be left behind in the HIV response. A well-designed research protocol cannot solve that problem by itself. But it can generate the knowledge needed to understand

what is really going on and that knowledge can, with luck and effort, lead to better programmes and fewer infections. That is why getting the protocol right matters so much.

References

MPH651 Reader (2025) *Research Methods and Protocol Development*. Malawi: Ministry of Health.

Phaswana-Mafuya, R.N. et al. (2025) 'Harnessing Big Heterogeneous Data to Evaluate the Potential Impact of HIV Responses Among Key Populations in Sub-Saharan Africa: Protocol for the Boloka Data Repository Initiative', *JMIR Research Protocols*, 14, e63583.

Rampilo, M. et al. (2024) 'Piloting the Inclusion of the Key Populations Unique Identifier Code in the South African Routine Health Information Management System: Protocol for a Multiphased Study', *JMIR Research Protocols*.

HIV Prevention Trials Network (2024) *Ethics Working Group*.

UNAIDS (2000) *Ethical Considerations in HIV Preventative Vaccine Research*.

National Health Research Authority, Zambia (various years) *Guidelines for Ethical Review*.