

Swaziland HIV Incidence Measurement Survey (SHIMS)

SHIMS Data Use and Research Development Committee (DURDC) Petitioning

Capsules: should be a maximum of three pages and should include the below subject headings:

- **Study title**
- **Proposed investigators:**
 - Lead investigator and affiliation
 - Co-investigators and affiliations
- **Lay summary:** summarize the study and its contributions to HIV prevention in Swaziland and the field. This summary should be *written at a 10th grade reading level* (length: 1 paragraph)
- **Rationale:** describe the study rationale (length: 1 paragraph)
- **Study design:** list the type of proposed study (length: 1-3 sentences)
- **Hypotheses:** list the proposed research hypotheses
- **Objectives:** list the proposed primary and secondary research objectives
- **Study size:** describe the specimen type, number, and volume being requested (length: 1 paragraph)
- **Laboratory methods:** describe the laboratory tests to be used, their method of use, and stage of development (length: 2 paragraphs)
- **For studies generating new laboratory data:**
 - Summarize the type of new data that will be generated from the proposed study (length: 1-2 paragraphs)
 - Summarize the laboratory QA/QC procedures that will be used (length: 1-2 paragraphs)
- **Laboratories:** list the laboratories where testing will be conducted and briefly indicate the lab's current testing capacity
- **Providing results to participants:** describe whether sample results will be provided to the participant. If yes, describe when and how results will be communicated. If no, describe the reason for not providing the test results (length: 1-2 paragraphs)
- **Timeline:** list the key study milestones and relevant dates. Include dates of anticipated analysis, write-up of findings, and dissemination.
- **Ethical review:** indicate whether the anticipated study protocol will receive a human research review or a non-research determination
- **References**

Concepts: should be a maximum of ten pages and should include the below subject headings:

- **Study title**
- **Proposed investigators:**
 - Lead investigator and affiliation
 - Co-investigators and affiliations
- **Lay summary:** summarize the study and its contributions to HIV prevention in Swaziland and the field. This summary should be *written at a 10th grade reading level* (length: 1 paragraph)
- **Rationale:** describe the study background and rationale (length: 1-2 pages)
- **Study design:** describe the type of proposed study (length: ½ -1 page)
- **Hypotheses:** list the proposed research hypotheses
- **Objectives:** list the proposed primary and secondary research objectives
- **Endpoints:** list primary and secondary endpoints
- **Study size:** describe the specimen type, number, and volume being requested (length: ½ page)

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- **Laboratory methods:** describe the laboratory tests to be used, their method of use, and stage of development (length: 1-2 pages)
- **For studies generating new laboratory data:**
 - Summarize the type of new data that will be generated from the proposed study (length: 1-2 pages)
 - Summarize the laboratory QA/QC procedures that will be used (length: ½-1 page)
- **Operational considerations:** list the laboratories where testing will be conducted and describe their role in the research, the lab's current capacity in equipment and human resources (length: ½ -1 page)
- **Ethical considerations:** describe any special ethical considerations, if any, that may be associated with study implementation. Also describe whether sample results will be provided to the participant. If yes, describe when and how results will be communicated. If no, describe the reason for not providing the test results. Indicate whether the anticipated study protocol will receive a human research review or a non-research determination (length: ½-1 page)
- **Timeline and practical considerations:** list the key study milestones and relevant dates. Include dates of anticipated analysis, write-up of findings, and dissemination. Describe potential obstacles to study development and implementation, as well as contingencies. (length: ½-1 page)