****

**CONCEPT SHEET: REGIONAL ANALYSES**

|  |  |
| --- | --- |
| **Steering Group approval date:** | *(To be added by UCT data centre)* |
| **Tracking number:** | *(To be added by UCT data centre)* |
| **Title:** |  |
| **Lead author:**  **Email:** |  |
| **IeDEA senior investigator:**  **Email:** |  |
| **Type of c0ncept** | *Select as appropriate:*  New concept – no linked conference abstract  New concept – linked to conference abstract which **has not been** approved by SG  New concept – linked to conference abstract which **has been** approved by SG  Existing concept – major revisions requiring SG approval |
| **Type of study** | *Select as appropriate:*  Full research study – multiple sites  Full research study – single site  Study protocol  Fast track study using existing dataset  Mathematical or methodological modelling *(indicate if this will use IeDEA-SA data)*  Systematic review |
| **Statisticians:**  **Email:** |  |
| **Data manager:**  **Email:** |  |
| **Where will statistical analyses be done?** |  |
| **Required variables:** |  |
| **Target journal:** |  |
| **Patient and Public Involvement (PPI)** | *Explain how you are including PPI in the design and implementation of this study or explain why you think that PPI is not relevant or possible for this study.*  Patient and Public Involvement (PPI) is the process whereby patients and members of the public are actively involved in shaping the goals, design, and evaluation of research projects. PPI can be integrated throughout the research process (e.g., identification of research priorities, integration of one or more people living with HIV, dissemination of findings through relevant networks).  For guidance: [Swiss HIV Cohort Study](https://shcs.ch/315-patient-and-public-involvement-ppi), [Swiss Clinical Trial Organisation](https://www.scto.ch/de/patient-and-public-involvement/ppi-resources.html), [BMJ Reporting Checklist](https://www.bmj.com/content/358/bmj.j3453). |
| **Knowledge translation summary slide** | *The UCT Project Management requires a single slide in simple language summarizing the concept publication for circulation to stakeholders via the site investigators.*  *Select as appropriate:*  I undertake to generate a slide summarizing the findings after completion of the concept for stakeholder dissemination. |
| **Ethics:** | *Select as appropriate:*  This concept uses only the IeDEA-SA standard dataset and is covered by the core IeDEA-SA ethics approvals.  This concept requires additional collection of health-related data, measurements or tests, or sampling of biological material not included in the IeDEA-SA standard dataset. Additional ethics approval is required.\* (Describe ethical considerations for any additional data collection here, including responsible IRBs.) |
| **Milestones:** | *Circulation of concept sheet: <date>*  *Ethics approval (for additional data collection): <date>*  *Circulation of mature draft paper: <date>*  *Submission to target journal: <date>* |
| **Abstract:** (about 100 words) | Background and objectives  Methods |
| **Outline:** (about 1000 words) | Background  Objectives and hypotheses  Study design  Eligibility criteria  Key variables and definitions  Outcomes  Statistical methods  Sample size considerations  References |

\* If additional ethics approvals are required, a copy must be sent to the ISPM Program Manager before data collection can begin.