**USER REQUIREMENTS SPECIFICATION (URS)**

**Project/System Name: ­\_\_\_\_\_EDEN STUDY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SCC Number (if applicable): |2|2|9|8|9** ❒ N/A

**Principal Investigator (PI)/Project Lead (PL)\_\_\_\_\_MATT SILVER\_\_\_\_**

**System Owner (SO): \_\_\_\_\_\_\_\_\_EBRIMA COMMA\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. Product Perspective

*Why have you chosen to have this system developed? What problem does it solve? Who will benefit from the finished product?*

Redcap is chosen because it is a software that designed for rapid development and deployment but also the experience of using the software within the department. Another reason is that all the data types and product functionalities can be captured with ease.

1. **Current System Summary**

*Is there a system in place? If yes, do you have a process diagram? Do you know if there is an existing URS? Attach all available documentation.*

*There are no previous system in place and no previous URS*

1. Product Functions

*What should the system do? What activities can users perform while using it? List the main functions that you need built into the system here.*

The system provides a data capture system for users to enter primary data electronically. The system should be able to accept signature via touch screen and scan source documents.

1. Data requirements

*What data points should the system allow the user to capture. [Provide a data dictionary of all data field OR sample data collection forms / case report forms].*

See Eden study data dictionary

1. User Characteristics

*Who do you expect to use the finished product? What is their technical background, their training or education, their motivation to use it? What obstacles might they encounter, and what specialized skills will they need (if any)? Identify each type of user of the system by function, location, and type of device. Specify the number of users in each group and the nature of their use of the system.*

*The PI (n=1), sub-investigator (n=1), junior research coordinator (n=1), field coordinators (n=2), supervisors, 13 nurse field workers, one field worker. The field workers, nurse field workers and sub-investigator will use the system for primary data collection. Some field and nurse field workers have been trained or use Redcap before. As such training has been conducted to equip them with the necessary electronic data capture skills.*

1. General Constraints

*Does the system have any constraints such as platform or development environment? Does the system have to be compatible with any existing software or other systems currently in use?*

No constraints in terms of development environment or compatibility issue with other systems as the standalone system.

1. Assumptions and Dependencies

*In this section, list any assumptions you made about your project (for example, did you assume that the finished product would need to be delivered over the internet?). If your project depends on any particular technical infrastructure, or requires administrators or others with specific skills, note that here.*

The Redcap system will be accessible both offline and online. Offline accessibility will be via tablets for data collection which will later be sent to the server via internet. The server will be accessible via the internet.

1. Interfaces (User, Hardware, Software)

*What kind of screens/pages/views do you wish to see the system have?*

*Are there any hardware required to use the system for e.g. barcode scanner, printer, etc.?*

*Does the system need to interact with any other software for e.g. GPS system, drivers for plate/tube scanners, etc.?*

The hardware will be tablets purchased for the study and MRC computers. The system’s data will be exportable to csv, R, Stata, SPSS, SAS files. The tablet hardware should have scanning feature to scan source documents which will be accepted by the system as an image file.

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| **Authored by (PI/Delegate):** | *Name* | *Signature* | *Date*  |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| |
| **Approved by:**  **(Lead Application Developer)** | *Name* | *Signature* | *Date*  |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_| |