

|  |  |
| --- | --- |
|  | **Title:** User Requirements Specification (URS) |
| **Study title:** *Give study title to which this applies* |
| **System name:** *Give system name to which this applies* |

|  |
| --- |
| 1. **Operational Requirements**
 |
| 1. **Data**

*Description of data (refer to Data Dictionary if available)**Capacity requirements**Archive Requirements*1. **Interfaces**

*Data Entry Screen - I/O interface**Back-end accessibility**Reporting and selective data view**Interface with other systems e.g. statistical software, excel, data import/export, etc.**Interface with equipment e.g. handheld GPS, diagnostic equipment, etc.*1. **Environment**

*Is there a supported and validated Unit application or equipment that will meet the above requirement? (e.g. SPSS, OpenClinica)**Is there an off-the-shelf pre-validated computer system that will meet the above requirement?**Operating System - MS Windows, Linux, Web-based or Desktop, Networked, etc.**Compatibility - with any existing systems or hardware, and any laboratory strategy.**Constraints – Limited bandwidth, slow internet connection, etc.* |
| 1. **Training and Support**
 |
| 1. **Documentation**

*Functional Specification, Testing Plans, Design Specifications, etc.* 1. **Training Materials**

*User Manuals and General Guidelines, etc.**Practical training to staff* 1. **Support**

*On-line and off-line support – regular support system and maintenance requirements* |
| 1. **Delivery**
 |
| 1. **Installation**

*On turnkey basis, with setup media (CDs, DVDs), dongles, etc.*1. **Timelines and milestones**

*What to provide and by when* |

##

## **Approvals**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name** | **Role** | **Signature** | **Date** |
| **Author** |  |  |  |  |
| **Reviewed By** |  |  |  |  |
| **Approved By** |  |  |  |  |