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| --- | --- |
| Protocol Number |  |
| Protocol Title |  |
| PI |  |
| Management Core Statistician |  |
| QAP Date |  |
| QAP Version |  |

The quality assurance plan (QAP) details the expected steps and processes to be undertaken by PASA Consortium Investigators, Researchers, and Management Core to ensure the proper handling and accounting of data. Adherence to these guidelines will help to ensure confidence in the integrity of data collected and any derived results. Please provide details of your policies and procedures in the spaces provided below as they pertain to each of the quality assurance areas.

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| **Quality Assurance Guidelines** |
| **Maintain Records:** Raw records for data collected can come in many formats (e.g. image or video files, spreadsheets, etc.). In order to investigate suspect data, it is essential that the original recording of all data, or as close to original recording as possible, be maintained. Please detail below the format of the raw data collected for each experiment in the study and how the records of raw data will be maintained. This includes if the data are manually created and documented via observation or if they are extracted from a machine. Maintenance details include how the raw data are extracted and where they are located for storage as well as any data handling that is required as part of maintenance such as file naming, file format conversions etc. |
| **Details:** | *Please provide details in a format that best fits your study and data. A sample table for input is below:*

|  |  |  |  |
| --- | --- | --- | --- |
| *Experiment* | *Data Source* | *Raw File Storage Location* | *Handling Details* |
|  |  |  |  |
|  |  |  |  |

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| **Timely Data Recording and Data Processing:** Data that is recorded and reported in a timely manner will help to identify issues faster and allow them to be addressed in time to minimize their impact. Additionally, data that is fresh in the minds of investigators/researchers is easier to investigate and explain, should questions arise. Please detail below how your data will be recorded/transferred from raw file formats into any compiled formats that may be used for data transfer, summarizing, or analyses, including how data from any instruments is transferred to the final analysis files. |
| **Details:** | *Please provide details in a format that best fits your study and data. If any data do not require processing from their raw format, please specifically note this. A sample table for input is below:*

|  |  |  |  |
| --- | --- | --- | --- |
| *Experiment* | *Completion Timeline* | *Processed File Storage Location* | *Data Recording/Transfer from Raw Files into Compile Format Details* |
|  |  |  |  |
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| **Data Verification:** All data that is collected and reported should be undergo a data verification process (for example, being reviewed by at least 2 individuals). This includes when data is transferred from original records to collated analysis files. Please detail below how your study will verify data that has been obtained. |
| **Details:** | *Please provide details in a format that best fits your study and data. A sample table for input is below:*

|  |  |  |
| --- | --- | --- |
| *Experiment* | *Raw Data Verification Process* | *Processed Data Verification Process* |
|  |  |  |
|  |  |  |

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| **Data Consistency:** Reviewing recorded data for internal consistency can provide a high-level method for identifying data quality issues or experimental problems. The consistency checks of data can be for individual data points and/or on summary information that is sufficiently detailed to enable the identification of suspect data and trends. These consistency checks may include comparing means, quantiles, and standard deviations between experimental groups, plotting raw data, or something as simple as reviewing group counts. Data checks for consistency and quality will be a collaborative effort between the PASA Management Core and the site. Details of the quality checks implemented by the Management Core are defined below. Please detail below how your site will ensure data is consistent with expectations and how suspect data will be identified and investigated.\*\* |
| **Details:** | *Please provide details in a format that best fits your study and data. A sample table for input is below:*

|  |  |  |
| --- | --- | --- |
| *Experiment* | *Consistency Check Frequency* | *Consistency Checks Planned* |
|  |  |  |
|  |  |  |

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| **Data Reporting:** Data will be transmitted to the PASA Management Core via a secure website per a pre-defined schedule with updated transfers occurring no less frequently than monthly. These data transfers are required to allow for study status reporting and data quality and consistency checks to be performed by the Management Core. Please detail below the agreed upon data transfer schedule for your study including expected start date, routine day(s) of transfer, and who will be responsible for the transfer. |
| **Details:** |  |

\*\* Note of warning: Data calculations that are performed in Excel are dependent on selected cell ranges and may not update when data is added or subtracted. Please be careful when using dynamic calculations when data is being summarized.

In addition to the quality assurance procedures implemented at your site, the Management Core will perform some data checking and summarization for quality assurance purposes and to ensure the proper transfer of data. As noted above, data quality is a collaborative effort; the Management Core activities supplement, but do not replace, QA procedures followed by your institution. At a minimum, the Management Core will perform the following with all data that is received from your study. If any issues arise during these checks, the Management Core will contact you to help identify the cause. Any necessary revisions to already reported data would then be expected at your next scheduled data delivery. The Management Core activities outlined below will be performed for data transfer.

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| **Data Receipt:** The Management Core statistician will confirm the receipt of each data transfer via email within 2 business days. Any missing or incomplete transfers will also be followed up within this same timeframe. |
| **Data Storage:** Data that is delivered to the Management Core will be kept in a central location with nightly backups in dated folders. Along with the data, any documentation that can help to identify the source of the data and any necessary manipulation, including emails, will be included. These data will also be used to keep the study dashboard updated. |
| **Randomization Information Confirmation**Randomization information, including experimental group assignment by randomization ID, included with any delivered data will be compared to the randomization information provided by the Management Core at the start of the study. **If your site uses any internal animal identifiers, please ensure that the randomization ID provided by the** Management Core **is also included with any data reported to the** Management Core**.** |
| **Experimental Group Counts:** The counts of observations for each experimental group and phase of the study, where applicable, will be calculated ensure that no unaccounted missing data or extra data has been provided |
| **Study Dashboard:** The dashboard will be updated by the Management Core data manager within 5 business days of data receipt. The Management Core statistician will routinely review the dashboard to ensure the summary reflects data received. |
| **Descriptive Statistics:** The Management Core will calculate basic descriptive statistics (including means, standard deviations, etc.) for each experimental group and phase, where applicable. These data will also be plotted. Values will be examined for visually obvious differences to help identify potential issues (e.g. unit conversion problems, systematic missingness) and any concerns communicated back to your site. |