**HEI Quality Assurance Plan Form**

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| **Principal Investigator:** |  |
| **Institution:**  |  |
| **Title of Study:** |  |
| **Version and date:** |  |
| **Signature PI:** |  |

*(No page limit: please insert your text in the spaces provided below)*

**I. Brief Description of Study Aims and Design and Data Flow** (refer to the study protocol for details; the original Project Plan submitted with the HEI application may serve as an initial study protocol that can be updated for changes in study design/approach as study progresses. Provide a flow chart that shows the data flow.)

**II. List of Standard Operating Procedures (SOPs) and Data Protocols** (for HEI studies, whether they generate new data, and/or make use of previously collected data, SOPs and data protocols need to be in place for critical procedures. SOPs cover routine and repetitive procedures in lab or field for which variability must be minimized. Data protocols also includes standardized procedures for data processing, data cleanup and other repetitive data steps.).

**III. Quality Control Procedures for Data Collection** (data collection includes, but is not limited to, field or lab measurements, chemical analysis, health data collection, survey, or obtaining previously collected data and/or leveraging other ongoing studies. For each type, describe quality control checks to be taken; acceptance criteria and corrective actions.)

**IV. Data Processing Procedures, Data Linkages and Data Analyses** (how the data will be treated, cleaned, transformed, linked, and statistically analyzed. For each step, describe quality control checks to be taken; acceptance criteria and corrective actions. Develop code book or data dictionary for all the variables in the statistical models.)

**V. Data and Records Management** (recordkeeping procedures, tracking practices, backup/archival, data security, data confidentiality, data access and data transfer processes, hardware and software to be used.)

**VI. List of Qualified Personnel** (list name, position, role in the project and qualifications for key personnel. Refer to biographical sketches for details. Also list training procedures for new personnel.)

**VII. Attachments** (QA plan version history, study protocol, SOPs if not readily available online, data protocols, biographical sketches, statistical code, other items.)