Quality Assurance (QA) in the Design of Data, Specimen, and Measurement Collection in Fielding Epidemiology Research Projects: A QA Tool

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Overview: Obtaining high quality results from data and specimen collection in epidemiologic research is the primary goal of investigators. Challenges at multiple levels exist; however, with careful planning, high quality data, specimen, and measurement collection are achievable. Successful studies incorporate thorough proactive, QA plans to prevent defects in the data, and quality control (QC) procedures to detect and remedy defects in the collected data. While both QA and QC plans are designed to ensure data and sample integrity, the QA plan must be established during study development. This requires anticipating issues and risks to the project that may occur during data and specimen collection.

Methods: To address the need for a systematic approach to building QA into the development of epidemiologic research projects, Social & Scientific Systems (SSS) developed a model QA plan that is applied to all data and specimen collection activities prior to initiation of the study. As the basis for the QA plan for each unique project, SSS designed a template which documents QA steps for each data collection instrument or form. The SSS QA plan template begins with an overview of the purpose of the study. Each type of data that is to be collected – including questionnaires, interviews, measurements, and specimens is listed. For each data type, the training objectives, certification requirements, and monitoring processes are detailed, and the roles and responsibilities of all project staff are clearly defined (including forms designers, programmers, data collectors, operations staff, data processors, and lab staff). The plan documents all of the data management technology tools developed to support the QA process and manage the flow of study data and operations.

Additional Information: Implementation of the QA plan based on this model has resulted in more streamlined data processing efforts, better documentation of expectations at each stage in the project lifecycle, and more effective field monitoring. The QA template is routinely presented as a tool for the scientific investigators SSS supports, and serves as the basis for identifying risks and challenges to data quality during project development.