

**U. S. Department of Health and Human Services (HHS)  
Office of Research Integrity (ORI)  
Data Management Standard Operating Procedures Survey**

**Supporting Statement B**

**Introduction**

The overall scope of this project is to investigate the practice of a broad array of data management, data processing, and data analysis standard operations. A 53-item Data Management Standard Operating Procedures (DMSOP) survey was developed and will be administered to a random sample of U.S. biostatisticians from the American Statistical Association (ASA) and bio-science researchers from the American Society for Cell Biology (ASCB). The purpose of the project is to: 1) conduct research on responsible data management and stewardship approaches and practices among biostatisticians and bio-science researchers; and 2) based on the results of this research, develop a toolkit related to the DMSOP survey that can be implemented by researchers, research institutions, and research administrators. Several products will be developed to disseminate survey results and findings, including a DMSOP toolkit, social media posts, YouTube video, webinar, and summary report for the Public Health Service-funded research community.

**B1. Respondent Universe and Sampling Methods**

The DMSOP survey will include 53 questions or items to respond to. The respondents will be a random sample of biostatisticians from the ASA registered list and/or bio-science researchers from the ASCB registered list. The ASA and ASCB will work with the Awardee Institution (the University of Maryland (UMD)) to identify potential respondents from their registered members lists. The eligible potential respondents will be those who self-identify themselves as having specialization in (1) data management, (2) data processing, and/or (3) data analysis. A procedure using Statistical Analysis System (SAS) software will be used to randomly select 1200 members from the two lists. After selection by the random procedure, an email invitation will be sent to the first batch of 300 members, introducing the purpose of the survey, asking if they agree to participate in the survey, and if they agree, asking them to read the informed consent form. Based on the response rate from the first 300 members, it will be decided whether or not an email invitation will be sent to a second batch of 300 members. This process will continue up to two more times until 300 respondents have completed the survey.

**B2. Procedures for the Collection of Information**

Survey information will be collected via a web-based data collection system using Qualtrics (<http://www.qualtrics.com/>) to allow responses to be validated before the data are stored in a database. The system allows for text fields, dropdowns, checkboxes, radio buttons, and other

features, which will enhance the data quality. Such a convenient platform is expected to be attractive to respondents because it does not require mail and it ensures anonymity.

The invitation email that will be sent to up to 1200 randomly selected ASA and ASCB members will include an introductory recruitment letter explaining the survey purpose, the manner in which potential respondents were selected, the survey duration, and anonymity and confidentiality information. The email will also offer a \$50 Amazon gift card to compensate them for their time, if they choose to participate.

The invitation email also will include screening questions such as “Have you conducted data management tasks during the past five years?” with Yes/No response options. If a member answers “No,” then the message “Thank you, but you are not eligible for the survey!” will appear. If a member answers “Yes,” the message “Thank you, please read the informed consent form!” and the consent form will appear.

Agreement to participate will then be indicated by the member selecting the “participate” button (as opposed to the “decline” button). Participating members will immediately receive an email providing them with a website link with the DMSOP survey, as well as survey completion instructions. It will not include names or any personal identifying information (such as social security numbers, email addresses, or phone numbers). The DMSOP survey will take approximately 30-45 minutes to complete. The survey asks what procedures and processes the respondent has adopted regarding data management operations.

The survey instructions will reiterate the survey’s overall confidential nature and emphasize the anonymity of DMSOP survey responses. Respondents wishing to participate may complete the DMSOP survey at that time or use their individualized survey link to re-enter the website and complete all or part of the DMSOP survey at a later time.

Respondents who choose to participate will receive up to two post-participation agreement reminders to complete the survey, at week 2 and week 3. If, after two reminders, the respondent still does not complete the survey, a replacement member will be sent a survey invitation letter. The survey will terminate when 300 respondents have completed the survey.

### **B3. Methods to Maximize Response Rates and Deal with Non-Response**

As stated above, survey respondents wishing to participate may complete the DMSOP survey at the time they agree to participate or use their individualized survey link to re-enter the website and complete all or part of the DMSOP survey at a later time.

Respondents who choose to participate will receive up to two post-agreed to participate reminders to complete the survey, at week 2 and week 3. If, after two reminders, a respondent still does not complete the survey, a replacement ASA or ASCB member(s) will be sent a survey participation invitation letter.

Based on an enthusiastic response from ASA and ASCB leadership, we anticipate that the survey response rate will be both “of high interest” to professional ASA and ASCB members as well as “of novel interest,” as this would be the first investigation into this topic. In addition, the \$50

Amazon gift card offer for completing the survey should prove attractive and serve to enhance response rate and in turn generalizability of the findings.

#### **B4. Tests of Procedures or Methods to Be Undertaken**

A pilot study to test the survey was conducted. The pilot study non-federal government respondents were made up of seven researchers in biostatistics and bioscience from the University of Maryland(7). The introductory email, sent to University of Maryland pilot study respondents, included a recruitment letter explaining the survey purpose, the manner in which potential respondents were selected, the survey duration, information on anonymity and confidentiality, and offer of a \$50 Amazon gift certificate upon completion of the survey. The pilot survey information collection was successful, and the collected data were analyzed without errors.

#### **B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The following individuals outside of HHS contributed to, reviewed, and/or approved the design, instrumentation, sampling, and will collect the survey information.

Name	Affiliation	Telephone Number
Min Qi (Mitch) Wang, PhD	University of Maryland	301-405-6652
Alice Yan, PhD	Stanford Healthcare	650-649-9684