

## **LONGITUDINAL SUMMARY**

SAIC will prepare a summary report that provides a compilation of key findings from the conduct of the AFHS and analysis of data collected for the AFHS. SAIC envisions that the report will have a structure similar to the outline presented below:

### Introduction

- Background
- History
- Participation statistics
- Overview of types and amount of data gathered and stored
- Description of the writing strategy

### Historical Measures of Exposure

- Group
- Exposure index
- Dioxin
  - Extrapolated to tour
  - Categorized
  - Measured level

### Results (to be arranged in order of importance or amount of findings seen)

- General Health
- Neoplasia
- Neurology
- Psychology
- Gastrointestinal
- Dermatology
- Cardiovascular
- Hematology
- Renal
- Endocrine
- Immunology
- Pulmonary
- Reproductive Outcomes.

Each of the subsections under the Results section will include, where applicable, findings from the baseline and follow-up reports, findings from journal articles prepared by the U.S. Air Force, and findings from mortality studies conducted by the U.S. Air Force.

The results of the AFHS will also be compared to the Department of Veterans Affairs' Agent Orange Registry's compensable conditions. For example, SAIC will provide information on the number of AFHS veterans with non-Hodgkin's lymphoma, a compensable condition on the Agent Orange registry, under the description of results from the Neoplasia clinical area.

Rather than organizing the results by examination period, they will be organized according to health endpoint within each of the clinical areas, with discussion of trends, if present, across AFHS examinations. This organization will simplify the presentation of the findings.

SAIC will gather the materials necessary to compose the summary report, which is estimated to be approximately 50 pages long. SAIC will work with U.S. Air Force technical staff to identify and request necessary electronic documents or hard-copy reports. SAIC plans to submit a working outline of the report to Air Force technical staff during the report writing process to determine if all topics are being addressed in an appropriate manner.

The report shall be written in simple language in a narrative format. No p-values or graphs shall be used in this report. Only statistically significant ( $p < .05$ ) results from adjusted analyses shall be discussed. The

term “statistical significance” or any variation thereof shall not be used. Negative results across an entire clinical area shall be summarized in sweeping generalities, and isolated significant results having no apparent interpretation shall not be mentioned or be mentioned only briefly without emphasis. Statistically significant increases or decreases shall be stated as “increases” or “decreases.” Summary statistics shall be used infrequently and, when used, shall include a 95% confidence interval.

The report will contain a list of references to indicate to the reader the materials that have been used in the compilation of the report. To improve readability, SAIC suggests that individual sentences not reference a citation, but rather that a list of all citations to be provided as a stand-alone section.

SAIC is assuming that the U.S. Air Force will provide a maximum of two sets of unified comments for the report (unified across all Air Force reviewers). The draft report will be in Microsoft Word and Portable Document File (PDF) formats. SAIC will provide an initial draft, which will be followed by a first set of comments by the U.S. Air Force. SAIC will then prepare a revised draft, to be followed with a second set of U.S. Air Force comments. After resolution of the second set of comments, SAIC will submit a final report in Microsoft Word and PDF formats once all comments are resolved.

### **SUGGESTED INSERTS TO THE 2002 AFHS STATEMENT OF WORK FOR THE TASKS OUTLINED IN THE STATEMENT OF OBJECTIVES**

**3.8.1 Longitudinal Summary.** The contractor shall prepare a summary report that describes key aspects of the history of the AFHS. The report shall include summaries of results from each of the six physical examinations and journal articles co-authored by AFHS investigators. The report shall be written in simple language and in a narrative format.

**3.8.1.1** The report shall include an introduction section that describes the background of the AFHS. A description of historical measures of exposure, including exposure group status, the exposure index that was used in 1982, 1985, and 1987, and the serum dioxin measures used in 1987, 1992, 1997, and 2002, shall also be included.

**3.8.1.2** The primary focus of the report shall be twofold: (1) the results from the analysis of data collected at the six physical examinations, and (2) comparing the AFHS results with the Department of Veterans Affairs' Agent Orange Registry's compensable conditions. The analysis section shall include results from analysis reports and journal articles written by the U.S. Air Force on the following topics or areas: General Health, Neoplasia, Neurology, Psychology, Gastrointestinal, Dermatology, Cardiovascular, Hematology, Renal, Endocrine, Immunology, Pulmonary, and Reproductive Outcomes. The report shall also contain a list of references to indicate to the reader the materials that have been used in the compilation of the report.

**3.8.1.3** The report shall be written in simple language in a narrative format. No p-values or graphs shall be used in this report. Only statistically significant ( $p < .05$ ) results from adjusted analyses shall be discussed. The term “statistical significance” or any variation thereof shall not be used. Negative results across an entire clinical area shall be summarized in sweeping generalities, and isolated significant results having no apparent interpretation shall not be mentioned or be mentioned only briefly without emphasis. Statistically significant increases or decreases shall be stated as “increases” or “decreases.” Summary statistics shall be used infrequently and, when used, shall include a 95% confidence interval.

**3.8.1.4** The U.S. Air Force shall furnish papers, abstracts, reports, and other electronic documents as needed to complete the overview report.

**3.8.1.5** The contractor shall provide a draft report to the U.S. Air Force in Microsoft Word and Portable Document File (PDF) formats. The U.S. Air Force shall make one unified set of written comments on the document, to which the contractor will respond using a comment resolution sheet. The contractor shall submit a final report in Microsoft Word and PDF formats once all comments are resolved. [INSERT CDRL REFERENCE, INCLUDING TWO DRAFTS AND ONE FINAL]