

National Human Exposure Assessment Survey (NHEXAS)

Region 5 Study

Quality Systems and Implementation Plan for Human Exposure Assessment

Research Triangle Institute
Research Triangle Park, NC 27079
Cooperative Agreement CR 821902

Standard Operating Procedure

NHX/SOP-100-003

Title: Preparation of a Protocol

Source: Research Triangle Institute

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Human Exposure Research Branch

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TITLE: STANDARD OPERATING PROCEDURE FOR PREPARATION OF A
PROTOCOL

SOURCE: Research Triangle Institute
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Analytical and Chemical Sciences
Research Triangle Park, NC 27709-2194

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APPROVED BY:

Principal Investigator: _____

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revision 0 is the original version.

PREPARATION OF A PROTOCOL

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1.0 SCOPE AND APPLICATION

Protocols are an integral part of a good quality assurance program. A protocol states the objectives and methods that will be used to conduct a study or experiment. For the RTI/EOHSI NHEXAS Pilot Study, protocols provide an overview of complex operations. Protocols may include some detailed information specific to a program area, but in general that should be prepared as an overview and guide, rather than a set of step-by-step instructions.

The protocol format is sufficiently flexible to accommodate a variety of information types of developing methodology.

2.0 SUMMARY

The organization of protocols will depend on the complexity and nature of the procedures; the most appropriate outline for a given protocol will be decided on a case-by-case basis. Example components of an protocol are listed below. This intended only as a guide; there must be sufficient flexibility to accommodate all situations.

- 2.1 Title Page
- 2.2 Table of Contents, if protocol has more than 10 pages
- 2.3 Scope and Application (or Introduction)
- 2.4 Summary (or Principle) of Procedures (or Concept)
- 2.5 Materials and Reagents, including preparation
- 2.6 Procedure(s)
- 2.6 Quality Assurance Procedures, if applicable
- 2.7 References

3.0 COMPONENTS OF A PROTOCOL

3.1 Title Page

An example of a Title Page for RTI/EOHSI protocol is shown in Figure 1.

3.1.1 Protocol Number

Each protocol will be identified by a unique reference number of the form ABC-AP-MNO-XYZ.

ABC	Originating Organization, RTI or EOHSI, for example
AP	Protocol
MNO	Indicates program; 209 for NHEXAS pilot program
XYZ	Sequential order

The protocol numbers will be issued by the Field Supervisor.

3.1.2 Date of Issue

The data of issue is the date when the protocol becomes effective. It is the date of the last approval signature on the Title Page.

3.1.3 Title

The title of each protocol will describe, as briefly as possible, the procedure(s) included.

3.1.4 Signature Approvals and Dates

Signatures (dated) are shown below.

Author	Signature
QA Officer	Signature approval
Principal Investigator	Signature approval

3.2 Table of Contents

A Table of Contents must be generated for any protocols that are 10 pages or more; it is optional for shorter documents.

3.2.1 Title

The title "Table of Contents" should be typed as a centered, dropped heading.

3.2.2 Headings

The heading "Section" should be typed flush left and underlined. The heading "Page" should be typed flush right and underlined.

3.2.3 Body of Table of Contents

The major elements of the Table of Contents should include the section number, main headings, dot leaders, and page numbers.

The Title Page is page one.

3.3 Body of the Protocol

The text will be complete, factual, and written in clear, understandable text. The description of the step-by-step operations will be expressed in the second person imperative.

3.3.1 Notes

Notes should provide additional information about a particular operation or list item.

Notes do not require action and are written in the third person indicative.

Notes may appear under second, third, and fourth order headings.

Format for Notes is shown in Figure 2.

3.1.2 Cautions and Warnings

Cautions are statements which indicate that a particular operation must be performed as described or result in possible compromise or invalidation of the procedure.

Warnings are statements which indicate that a particular operation must be performed as described or result in possible personal injury or loss of life.

Cautions and Warnings will be stated in the second person imperative and will include the consequences of not heeding the warning.

Cautions and Warning must alert the reader; suggested format is shown in Figure 2.

4.0 TYPES OF HEADINGS

The protocol text should be organized subsections using a consistent format. Format flexibility is needed to accommodate information from many sources covering a wide range of topics. A recommended format is presented in this section.

A summary of the format, including first through fourth order headings is shown in Figure 2.

4.1 First Order Heading

- 4.1.1 The title of each major section will be placed flush left following a sequentially ordered arabic number, a period, a zero, and spaces.
- 4.1.2 Type heading in capital letters, without underline
- 4.1.3 Triple-space between heading from the preceding section and the descriptive text or second order heading which follows.
- 4.1.4 Indent the first line of descriptive text; subsequent lines are started flush left.

4.2 Second Order Heading

A second order heading may be an underline subsection title, one in a series of stepwise operations, or part of a listing.

- 4.2.1 Position second order heading number flush left. The heading identified number will consist of the first order heading number, a period, and a sequentially ordered arabic number, and spaces.
- 4.2.2 Separate second order heading and any following material with 1.5 spaces. Likewise between the last line of material and the nest heading.
- 4.2.3 Indent the first line of descriptive text; subsequent lines are started flush left.

4.3 Third Order Heading

A third order heading may be an underlined sub-subsection title, a statement defining one in a series of stepwise operations, or a general listing defined in the previous second order heading.

Fourth order material is possible only if the third order heading is a sub-subsection title.

Descriptive text is discouraged after a third order heading. In those instances where it does occur, it will appear in block format under the heading.

4.3.1 Indent the third order heading number, directly under the underlined second order title. The heading identified will consist of the second order heading number, a period, a sequentially ordered arabic number, and spaces.

4.3.2 Separate third order heading from preceding and following material with 1.5 spaces.

4.4 Fourth Order Heading

Fourth order material will consist of either a statement defining one in a series of stepwise operations or a general listing defined by the preceding third order heading.

Descriptive text is discouraged after a fourth order heading. In those instances where it does occur, it will appear in block format under the heading.

4.4.1 Indent the fourth order heading number the same as third order. The heading identifier number will consist of the third order heading number, a period, a sequentially ordered arabic number, and spaces.

4.4.2 Separate third order heading from preceding and following material with 1.5 spaces.

4.5 Higher Order Headings

No heading higher than fourth order will be used.

5.0 MILESTONES

5.1 Initiation

The Principal Investigator and Field Supervisor will decide which program activities must be written in protocol format.

5.2 Preparation

The Principal Investigator or Field Supervisor will assign responsibility for protocol preparation to an individual who is experienced with the methodology. The document will be reviewed by another individual with similar experience in the subject area.

At this point, the protocol may be issued as a "Draft" protocol. In this way, the protocol can be "tested" and improvements made before it is implemented.

5.3 Approval

The Principal Investigator and the QA Officer (unless the QA Officer is the author) must approve the draft document before it can be issued as a formal protocol. Once signature approval is complete, the protocol may be cited, and utilized as such. Two signature pages will be utilized for NHEXAS SOPs and protocols.

5.4 Distribution

Approved protocols will be issued to the personnel assigned to perform the procedure. The original, signed copy will be filed in a secure location approved by the QA Officer. The QA Officer will also maintain a master listing of all protocols.

Approved documents will be transferred to the lead secretary with a distribution list. The field supervisor is responsible for providing the distribution list. The lead secretary will be responsible for making copies and distributing them. She will then transfer the original documents to the SOP custodian who will file originals and the distribution list in the ACS secure files. Requests for additional copies should be routed to the custodian, and she will append the distribution list. In this way, revised versions can be distributed to everyone who received the original version.

The second original copy of each document will be provided to the Principal Investigator.

STANDARD OPERATING PROCEDURE	RESEARCH TRIANGLE INSTITUTE POST OFFICE BOX 12194 RESEARCH TRIANGLE PARK, NC 27709-2194	NHX/AP-000-000 Page 9 of 10
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Standard Operating Procedure for the
Preparation of a Protocol
NHX/AP-000-000

1.0 FIRST ORDER HEADING - Flush left, capital letters without underline.

Text - All text should be typed with 1.5 line spacing unless otherwise indicated.

Indent first line of descriptive text 5 spaces under heading. The second and subsequent lines will be started flush left. Triple-space before and after each First Order Heading.

2.0 FIRST ORDER HEADING

2.1 Second Order Heading - Underlined, flush left.

Text - Separate heading and text with 1.5 line spacing. Use the same spacing between the last line of material and the next heading (subsection). Indent first line 5 spaces or directly below the beginning of the underlined title. The second and subsequent lines will start flush left.

2.1.1 Third Order Heading - Indented under the underlined second order title.

Text - Separate 1.5 spaces and indent text under underlined heading.

CAUTION

Caution headings are in capital letters centered on the page and enclosed in a rectangle block. It is placed 1.5 line spaces below the section text and 1.5 line spaces above the caution text. Caution text is typed in a single-line, block format directly under the SOP section that it modifies.

2.1.1.1 Fourth Order Heading - Same distance from left margin as the third order headings. The heading material should not be underlined. There should not be any headings higher than fourth order used.

NOTE: Organize Note material in a single-space, block format 1.5 line spaces below and directly under the SOP section that it modifies. The text should start two spaces after the colon.

WARNING

Warning headings are in capital letters centered on the page and enclosed in a rectangle block. It is placed 1.5 lines below the section text and 1.5 lines above the warning text. Warning text is typed in a single-line, block format directly under the SOP section that it modifies.

Figure 2. Format Summary for a Protocol.