



# USER'S GUIDE FOR SCIENTIFIC REVIEW ADMINISTRATORS AND GRANTS TECHNICAL ASSISTANTS FOR THE PREPARATION AND FORMATTING OF IMPAC II SUMMARY STATEMENTS FOR R01/U01/R03/R15/R18/R21 APPLICATIONS

## V 6.3

The following guidance to Scientific Review Administrators and Grants Technical Assistants on summary statement formatting is presented in the interest of implementing uniform review and summary statement preparation across all of NI. Applicability of these guidelines begins with summary statements prepared in IMPAC II for the May2002 council.

Summary statements must be prepared by the SRAs/GTAs and entered into IMPAC II using

Font: ARIAL

Size: 11

Color of Font: Black

Headers: **UPPER CASE BOLD**

Section Headings: **UPPER CASE BOLD (see examples for specific exceptions)**

All margins (top, bottom left side, right side): ¾ inch

All reviewer critiques must be in ARIAL 11.

Do not underline headers and do not underline section headings.

Species names may be underlined or species names may be in *italic*

Scientific notation and formulas etc. permitted in the text



- A. INTRODUCTION.....3**
- B. STANDARD IMPAC II SUMMARY STATEMENT PREPARATION FORMAT.....3**
- C. HEADERS AND SECTION HEADINGS .....3**
- D. HEADERS.....4**
- E. SECTION HEADINGS .....5**
  - R01XX000000-01 PI NAME .....5
  - RESUME AND SUMMARY OF DISCUSSION:.....5
  - DESCRIPTION (PROVIDED BY APPLICANT): .....5
  - CRITIQUE 1:.....5
  - CRITIQUE 2:.....5
  - CRITIQUE 3:.....5
  - CRITIQUE N:.....5
  - THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:.....5
  - PROTECTION OF HUMAN SUBJECTS (RESUME):.....5
  - INCLUSION OF WOMEN PLAN (RESUME): .....6
  - INCLUSION OF MINORITIES PLAN (RESUME):.....6
  - INCLUSION OF CHILDREN PLAN (RESUME): .....6
  - VERTEBRATE ANIMALS (RESUME):.....6
  - COMMITTEE BUDGET RECOMMENDATIONS:.....6
- F. PROTECTION OF HUMAN SUBJECTS: SECTION HEADING OPTIONS .....7**
  - PROTECTION OF HUMAN SUBJECTS (RESUME): ACCEPTABLE .....7
  - PROTECTION OF HUMAN SUBJECTS (RESUME): UNACCEPTABLE.....7
- G. INCLUSION OF WOMEN PLAN: SECTION HEADING OPTIONS.....7**
  - INCLUSION OF WOMEN PLAN (RESUME): ACCEPTABLE .....7
  - INCLUSION OF WOMEN PLAN (RESUME): UNACCEPTABLE .....7
- H. INCLUSION OF MINORITIES PLAN SECTION HEADING OPTIONS .....8**
  - INCLUSION OF MINORITIES PLAN (RESUME): ACCEPTABLE.....8
  - INCLUSION OF MINORITIES PLAN (RESUME): UNACCEPTABLE .....8
- I. INCLUSION OF CHILDREN PLAN SECTION HEADING OPTIONS.....8**
  - INCLUSION OF CHILDREN PLAN (RESUME): ACCEPTABLE .....8
  - INCLUSION OF CHILDREN PLAN (RESUME): UNACCEPTABLE .....8
- J. VERTEBRATE ANIMAL SECTION HEADING AND OPTIONS.....8**
  - VERTEBRATE ANIMAL (RESUME): ACCEPTABLE .....8
  - VERTEBRATE ANIMAL (RESUME): CONCERN .....9
  - VERTEBRATE ANIMAL (RESUME): COMMENT.....9
- K. OTHER SECTION HEADINGS .....9**
  - BIOHAZARD COMMENT: .....9
  - FOREIGN INSTITUTION:.....9
  - SCIENTIFIC REVIEW ADMINISTRATOR'S ADMINISTRATIVE NOTES:.....9
  - BUDGETARY OVERLAP:.....9
- L. COMMITTEE BUDGET RECOMMENDATIONS: SECTION HEADING OPTIONS .....9**
  - COMMITTEE BUDGET RECOMMENDATIONS: THE BUDGET WAS RECOMMENDED AS REQUESTED.....9
  - COMMITTEE BUDGET RECOMMENDATIONS:.....9
- M. REFERENCE WEBSITES .....10**
  - PROTECTION OF HUMAN SUBJECTS .....10
  - DATA AND SAFETY MONITORING .....10
  - INCLUSION OF WOMEN .....10

INCLUSION OF WOMEN AND MINORITIES ..... 10  
INCLUSION OF CHILDREN ..... 10  
**N. SUMMARY STATEMENTS TEMPLATES ..... 11**  
TEMPLATE: NO HUMAN SUBJECTS, NO VERTEBRATE ANIMALS AND NO BUDGET CHANGES ..... 11  
TEMPLATE: HUMAN SUBJECTS PROTECTION ACCEPTABLE ..... 12  
TEMPLATE: HUMAN SUBJECTS PROTECTION UNACCEPTABLE ..... 13  
TEMPLATE: INCLUSION OF WOMEN PLAN UNACCEPTABLE ..... 14  
TEMPLATE: INCLUSION OF MINORITIES PLAN UNACCEPTABLE ..... 15  
TEMPLATE: INCLUSION OF CHILDREN PLAN UNACCEPTABLE ..... 16  
TEMPLATE: BUDGET CHANGES ..... 17

## A. INTRODUCTION

The following guidance, on summary statement formatting, is presented in the interest of uniform review and summary statement preparation across all of NIH. Applicability of these guidelines begins with summary statements prepared in IMPAC II for the May 2002 council.

This document is intended to assist Scientific Review Administrators (SRA) and Grants Technical Assistants (GTA) and contains a partial update to instructions and guidance contained in Manual Chapter 4512 SUMMARY STATEMENTS. This document provides policy guidance and instructions for preparing SUMMARY STATEMENTS. This document describes only the headers and section headings that are prepared by SRAs and GTAs (reviewer instructions are contained in a separate document titled: [NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications](#)).

The summary statement formats, presented below, were developed to address the needs of NIH staff who rely increasingly upon automated searches of summary statement information in IMPAC II to respond to inquiries from Congress and regulatory agencies on NIH's compliance with federal laws and policies. The validity of the information retrieved from the summary statements depends on the ability of the search software to locate unique text strings identifying specific sections of the summary statements. Thus, it is extremely important that all SRAs and GTAs strictly adhere to the standard formatting requirements for summary statements presented below.

The guidance and instructions for the SRAs and GTAs are presented in italic text. Examples of formats for headers and section headings are presented in non-italic text. These instructions apply to the preparation of all summary statements of R01, U01, R03, R15, R18 and R21 applications.

## B. STANDARD IMPAC II SUMMARY STATEMENT PREPARATION FORMAT

All summary statements must be prepared by the SRAs/GTAs and entered into IMPAC II using ARIAL 11 font with ¾ inch margins.

The SRAs/GTAs are responsible for preparing the headers and section headings described below in UPPER CASE BOLD (except as noted in the illustrations below). SRAs/GTAs should not underline headers or section headings.

The section headings formats prepared by the SRAs are designed to provide NIH staff with the capability to perform automated searches for unique text strings that identify specific sections of the summary statements. In addition, the formats are designed to allow for greater automated identification and discrimination of SRA prepared material (Resumes) from peer reviewer prepared critiques. The SRA prepared Resumes document the final and official outcome of the peer review discussion on each application. Thus, the wording and format of the section headings prepared by the SRAs/GTAs are designed to be different from the wording of section headings prepared by peer reviewers (see: [NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications](#) for reviewer formats).

## C. HEADERS AND SECTION HEADINGS

Headers are text used as a means of alerting the reader to the presence of specific issues, problems or concerns identified by the reviewers and are used as selection keys to carry out automated searches. Headers are placed at the beginning of the document prepared by the SRA/GTA (see examples below).

Section heading are strings of words that are used to identify a topic in the summary statement and are used as selection keys to carry out automated searches. Examples of section heading are provided below..

The headers and section headings presented in this document should be used when appropriate to the content of the summary statement. Most of these headers and section headings are in current use at NIH, while a few others are new headers and new section headings that were created or modified in response to additions and changes to NIH policy. In some instances the format of traditional section headings were modified to allow for the expanded capability of IMPAC II to search the contents of electronic summary statement documents.

The following are the new or revised headers. See templates for examples of their use:

**PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE**  
**INCLUSION OF WOMEN PLAN UNACCEPTABLE**  
**INCLUSION OF MINORITIES PLAN UNACCEPTABLE**  
**INCLUSION OF CHILDREN PLAN UNACCEPTABLE**  
**COMMITTEE BUDGET RECOMMENDATIONS**

The following are the revised or new section headings that are prepared by the SRAs/GTAs and will appear in the summary statement following the Reviewer critiques (see Templates for examples of their use).

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS: (Resume):** *if human subjects research is involved*  
**INCLUSION OF WOMEN PLAN (Resume):** *if clinical research*  
**INCLUSION OF MINORITIES PLAN (Resume):** *if clinical research*  
**INCLUSION OF CHILDREN PLAN (Resume):** *if human subjects research is involved*  
**COMMITTEE BUDGET RECOMMENDATIONS:**

#### **D. HEADERS**

Headers should appear in alphabetic order. Headers are used as a means of alerting the reader to the presence of specific issues, problems or concerns identified by the reviewers. HEADERS are entered in UPPER CASE ARIAL 11 FONT that is bolded as shown. Headers precede the **RESUME AND SUMMARY OF DISCUSSION** section. In the case of summary statements that do not have a **RESUME AND SUMMARY OF DISCUSSION** section, then the headers precede the first critique. None of the headers are immediately followed by text; they are just identifier flags to alert the reader to issues. Use headers only when they are appropriate for the applications you are preparing. The following is a listing of acceptable summary statement headers:

**BIOHAZARD COMMENT**  
**BUDGETARY OVERLAP**  
**CHIMPANZEES**  
**COMMITTEE BUDGET RECOMMENDATIONS**  
**FOREIGN INSTITUTION**  
**INCLUSION OF CHILDREN PLAN UNACCEPTABLE**  
**INCLUSION OF MINORITIES PLAN UNACCEPTABLE**  
**INCLUSION OF WOMEN PLAN UNACCEPTABLE**  
**NEW INVESTIGATOR**  
**PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE**  
**REVISED: (date of summary statement revision goes here)**  
**SCIENTIFIC REVIEW ADMINISTRATOR'S NOTES**  
**VERTEBRATE ANIMAL COMMENT**  
**VERTEBRATE ANIMAL CONCERN**

## E. SECTION HEADINGS

Sections headings are prepared by the Scientific Review Administrator to document the discussions of the review committee.

Section heading are strings of words that are used to identify a topic in the summary statement and are used as selection keys to carry out automated searches. The following are examples of the formats of the section headings in a simple summary statement. All of the section headings should be used in the summary statement exactly as illustrated and in ARIAL 11 BOLD FONT. All text that follows the section headings must be entered in ARIAL 11. Do not underline section headings.

The following illustrates the sequential order for sections headings in summary statements.

### **R01XX000000-01 PI Name**

Grant number and Principal Investigator's last name and first initial of first name.

### **RESUME AND SUMMARY OF DISCUSSION:**

This section must appear on all summary statements that are either scored or Not Recommended For Further Consideration. The Scientific Review Administrator prepares text for this section based on the discussions by the reviewers. The RESUME AND SUMMARY OF DISCUSSION is used to document the outcome of the discussion on the scientific and technical merit of the application. It must summarize the basis for the priority score. If issues, problems or concerns are present, these must be documented in this section. Unscored applications are not discussed; therefore, this section is not prepared for unscored applications. If an application is designated as Not Recommended For Further Consideration, then this section is used to document the basis for the designation.

### **DESCRIPTION (provided by applicant):**

This section must appear on all applications that are Scored or Not Recommended For Further Consideration. The text for this section is copied verbatim from the applicant's description in the 398 applications and entered into the summary statement by the GTA/SRA. This section is not required for applications that are not scored.

### **CRITIQUE 1:**

Reviewer text begins here. This section must appear on all summary statements. This section consists of the essentially unedited reviewer comments.

### **CRITIQUE 2:**

Reviewer text begins here. This section must appear on all summary statements. This section consists of the essentially unedited reviewer comments.

### **CRITIQUE 3:**

Reviewer text begins here. This section appears on all summary statements where a third reviewer is assigned to an application. This section consists of the essentially unedited reviewer comments.

### **CRITIQUE n:**

Reviewer text comments by other assigned or unassigned reviewers begin here. This section appears on all summary statements where "n" reviewers are assigned to an application. This section consists of the essentially unedited reviewer comments.

### **THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

The SRA/GTA places this boilerplate text at the end of the last reviewer comments and is required on all applications that are scored or receive a designation of Not Recommended for Further Consideration. This boilerplate is used to separate reviewer-generated text from SRA generated text. This section heading is not required for unscored applications.

### **PROTECTION OF HUMAN SUBJECTS (Resume):**

This section is prepared by the SRA to summarize the outcome of discussions of the review committee and must appear on all applications that propose involvement of human subjects and are either scored or receive a designation of Not Recommended for Further Consideration.

When the proposed research includes a clinical trial, issues related to the Data and Safety Monitoring Plan are discussed as part of the **PROTECTION OF HUMAN SUBJECTS (Resume)** section.

The **Protection of Human Subjects** section heading is not required for unscored applications since there is no discussion of these issues. However, if any reviewer indicates issues, problems or concerns with human research protection, then the SRA should indicate that the application is unacceptable with respect to the protection of human subjects by entering an appropriate code in the IMPAC II system.

**INCLUSION OF WOMEN PLAN (Resume):**

This section is prepared by the SRA to summarize the outcome of discussions of the review committee and must appear on all applications that propose human clinical research and are either scored or receive a designation of Not Recommended for Further Consideration. This section heading is not required for unscored applications.

**INCLUSION OF MINORITIES PLAN (Resume):**

This section is prepared by the SRA to summarize the outcome of discussions of the review committee and must appear on all applications that propose clinical research and are either scored or receive a designation of Not Recommended for Further Consideration. This section heading is not required for unscored applications.

**INCLUSION OF CHILDREN PLAN (Resume):**

This section is prepared by the SRA to summarize the outcome of discussions of the review committee and must appear on all applications that propose involvement of human subjects and are either scored or receive a designation of Not Recommended for Further Consideration. This section heading is not required for unscored applications.

**VERTEBRATE ANIMALS (Resume):**

This section is prepared by the SRA to summarize the outcome of discussions of the review committee and must appear on all application involving vertebrate animals and is either scored or receives a designation of Not Recommended for Further Consideration. It is used to document comments or concerns. Without this documentation it is not possible for the applicant and NIH staff to know what the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern.

**COMMITTEE BUDGET RECOMMENDATIONS:**

This section is prepared by the SRA and must be included on all applications that are scored. The SRA uses this section to document the recommendations of the review committee. The SRA can document: Budget Recommended as Requested or document the specific modifications recommended by the committee. This section heading is not required for unscored applications or applications designated as Not Recommended for Further Consideration.

## **THE FOLLOWING PROVIDES ADDITIONAL DETAILS AND GUIDANCE ON SPECIFIC SECTION HEADINGS**

### **F. PROTECTION OF HUMAN SUBJECTS: SECTION HEADING OPTIONS**

*The following section describes the options available to the SRA for formatting the Human Subjects section headings. The following section headings are created by the SRA. Text may include material copied from the reviewer's critiques, that explains the outcome of the discussion. It is important that the reviewer's critiques on these issues also remain in their respective sections.*

*There is no separate section heading for issues related to the evaluation of the Data and Safety Monitoring Plan. Issues raised by reviewers related to the Data and Safety Monitoring Plan are part of the consideration of the protection of human subjects who are involved in clinical trials; consequently, documentation of the issues that impact on the acceptability or unacceptability of the plan are documented in the section on the **PROTECTION OF HUMAN SUBJECTS**.*

#### **PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

*(Acceptable Risks And/Or Adequate Protections) Although no text is required, in some instances this section may also include some indication that issues appearing in the critiques were discussed and resolved by the reviewers. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the **PROTECTION OF HUMAN SUBJECTS (Resume): section**.*

*Or*

#### **PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE**

*Requires additional text to explain the basis of the concerns, unacceptable risks and/or inadequate protections. Without this documentation it is not possible for the applicant and NIH staff to know what is the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the **PROTECTION OF HUMAN SUBJECTS (Resume): section**.*

### **G. INCLUSION OF WOMEN PLAN: SECTION HEADING OPTIONS**

*The following section describes the options available to the SRA for formatting the Inclusion of Women section headings. The following section headings are created by the SRA. Text may include material copied from the reviewer's critiques, that explains the outcome of the discussion. It is important that the reviewer's critiques on these issues also remain in their respective sections.*

#### **INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

*If the plan is **ACCEPTABLE**, then this section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

*If the proposed research involves a NIH-defined Phase III Clinical Trial, then it is important that there be documentation that the reviewers evaluated the applicants presentation of the plans to conduct valid analyses to detect significant differences in intervention effect.*

*Or*

#### **INCLUSION OF WOMEN PLAN (Resume): UNACCEPTABLE**

*Requires additional text to explain the basis of the concerns. Without this documentation it is not possible for the applicant and NIH staff to know what is the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer critiques.*

*If the proposed research involves a NIH-defined Phase III Clinical Trial, then it is important that there be documentation that the reviewers evaluated the applicants presentation of the plans to conduct valid analyses to detect significant differences in intervention effect.*

## H. INCLUSION OF MINORITIES PLAN SECTION HEADING OPTIONS

The following section describes the options available to the SRA for formatting the Inclusion of Minorities section headings. The following section headings are created by the SRA. Text may include material copied from the reviewer's critiques, that explains the outcome of the discussion. It is important that the reviewer's critiques on these issues also remain in their respective sections.

### **INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

If the plan is *ACCEPTABLE*, then this section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. The text may be copied from the reviewer critiques.

If the proposed research involves a NIH-defined Phase III Clinical Trial, then it is important that there be documentation that the reviewers evaluated the applicants presentation of the plans to conduct valid analyses to detect significant differences in intervention effect.

Or

### **INCLUSION OF MINORITIES PLAN (Resume): UNACCEPTABLE**

If the plan is *UNACCEPTABLE*, then additional text is required to explain the basis of the concerns. Without this documentation it is not possible for the applicant and NIH staff to know what is the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer critiques.

If the proposed research involves a NIH-defined Phase III Clinical Trial, then it is important that there be documentation that the reviewers evaluated the applicants presentation of the plans to conduct valid analyses to detect significant differences in intervention effect.

## I. INCLUSION OF CHILDREN PLAN SECTION HEADING OPTIONS

The following section describes the options available to the SRA for formatting the Inclusion of Children section headings. The following section headings are created by the SRA. Text may include material copied from the reviewer's critiques, that explains the outcome of the discussion. It is important that the reviewer's critiques on these issues also remain in their respective sections.

### **INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

If the plan is *ACCEPTABLE*, then this section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.

Or

### **INCLUSION OF CHILDREN PLAN (Resume): UNACCEPTABLE**

Requires additional text to explain- text comments may be copied from the reviewer critiques

## J. VERTEBRATE ANIMAL SECTION HEADING AND OPTIONS

The following section describes the options available to the SRA for formatting the Vertebrate Animal section headings. The following sections are generated by the SRA and may include material copied from the reviewer critiques, that explains the outcome of the discussion. It is important that the reviewer critiques on these issues also remain in their respective sections.

If chimpanzees are involved in the proposed research this should be identified and documented as part of the Vertebrate Animal Section and the **CHIMPANZEE** header should appear in the appropriate location.

### **VERTEBRATE ANIMAL (Resume): ACCEPTABLE**

May include additional text to explain issues that were raised, discussed and resolved- text comments may be copied from the reviewer critiques.

Or

**VERTEBRATE ANIMAL (Resume): CONCERN**

*Requires additional text to explain issues that were raised, discussed and were not resolved. The text must explain the basis of the concerns. Without this documentation it is not possible for the applicant and NIH staff to know what the basis for the concerns, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer's critiques to explain the issues.*

Or

**VERTEBRATE ANIMAL (Resume): COMMENT**

*Requires additional text to explain issues that were raised but are not at the level of a concern. Text may be copied from the reviewer critiques to explain the issues.*

**K. OTHER SECTION HEADINGS****BIOHAZARD COMMENT:**

*Requires additional text to explain- text comments may be copied from the reviewer's critiques*

**FOREIGN INSTITUTION:**

*May include some indication that issues were discussed and resolved by the reviewers.*

**SCIENTIFIC REVIEW ADMINISTRATOR'S ADMINISTRATIVE NOTES:**

*This heading is used to bring administrative issues (which do not fit in any of the other sections) raised by the peer reviewers during the discussion to the attention of the applicant and the NIH staff. It may also be used by the SRA to bring administrative issues to the attention of other NIH staff or to the attention of the investigator.*

**BUDGETARY OVERLAP:**

*Requires additional text to explain- text may be copied from the reviewer critiques*

**L. COMMITTEE BUDGET RECOMMENDATIONS: SECTION HEADING OPTIONS**

*This section heading must be the last section heading in the summary statement and must precede the roster.*

*The following section describes the options available to the SRA for formatting the Committee Budget Recommendations section headings. The following sections are generated by the SRA and may include material copied from the reviewer critiques, that explains the outcome of the discussion. It is important that the reviewer comments on these issues also remain in their respective sections.*

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

Or

**COMMITTEE BUDGET RECOMMENDATIONS:**

*The following budget modifications were recommended: SRA enters comments and/or recommendations of reviewers that were agreed on by the committee; however, the comments of individual reviewers should also remain in their critiques whether or not the committee agreed to them in their final decision. This will provide the investigators with an indication of the nature of discussions that occurred relative to their application. This section will always be the last section in the summary statement and will always precede the committee roster.*

**M. REFERENCE WEBSITES****PROTECTION OF HUMAN SUBJECTS**

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

[http://odoerdb2.od.nih.gov/gmac/topics/human\\_main.html](http://odoerdb2.od.nih.gov/gmac/topics/human_main.html)

**DATA AND SAFETY MONITORING**

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

*Instructions to Reviewers*

[http://grants.nih.gov/grants/peer/hs\\_review\\_inst.pdf](http://grants.nih.gov/grants/peer/hs_review_inst.pdf)

**INCLUSION OF WOMEN**

[http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>

<http://www4.od.nih.gov/orwh/inclusion.html>

**INCLUSION OF WOMEN AND MINORITIES**

[http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>

**INCLUSION OF CHILDREN**

<http://grants.nih.gov/grants/funding/children/children.htm>

<http://grants.nih.gov/grants/guide/notice-files/not98-024.html>

<http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html#46.401>

**N. SUMMARY STATEMENTS TEMPLATES****TEMPLATE: NO HUMAN SUBJECTS, NO VERTEBRATE ANIMALS AND NO BUDGET CHANGES**

*The first page of the summary statement will contain IMPACT II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**COMMITTEE BUDGET RECOMMENDATIONS:** The budget was recommended as requested.

**TEMPLATE: HUMAN SUBJECTS PROTECTION ACCEPTABLE**

*The first page of the summary statement will contain IMPAC II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

*(Acceptable Risks And/Or Adequate Protections) Although no text is required, in some instances this section may also include some indication that issues appearing in the critiques were discussed and resolved by the reviewers. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the PROTECTION OF HUMAN SUBJECTS (Resume): section.*

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

*This template assumes that the application involves human subjects research. If it does not, then, the human subjects related section headings would not be present in the summary statement. If the application involves vertebrate animals then the appropriate vertebrate animal section headings would be included.*

**TEMPLATE: HUMAN SUBJECTS PROTECTION UNACCEPTABLE**

*The first page of the summary statement will contain IMPAC II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE****RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE**

*Requires additional text to explain the basis of the unacceptable risks and/or inadequate protections. Without this documentation it is not possible for the applicant and NIH staff to understand the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer critiques. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the PROTECTION OF HUMAN SUBJECTS (Resume) section.*

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

**TEMPLATE: INCLUSION OF WOMEN PLAN UNACCEPTABLE**

*The first page of the summary statement will contain IMPAC II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**INCLUSION OF WOMEN UNACCEPTABLE**

**RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

*(Acceptable Risks And/Or Adequate Protections) Although no text is required, in some instances this section may also include some indication that issues appearing in the critiques were discussed and resolved by the reviewers. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the PROTECTION OF HUMAN SUBJECTS (Resume): section*

**INCLUSION OF WOMEN PLAN (Resume): UNACCEPTABLE**

*Requires additional text to explain why the plan for inclusion is unacceptable. Without this documentation it is not possible for the applicant and NIH staff to know what is the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer critiques.*

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**COMMITTEE BUDGET RECOMMENDATIONS:** The budget was recommended as requested.

**TEMPLATE: INCLUSION OF MINORITIES PLAN UNACCEPTABLE**

*The first page of the summary statement will contain IMPAC II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**INCLUSION OF MINORITIES PLAN UNACCEPTABLE****RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

*(Acceptable Risks And/Or Adequate Protections) Although no text is required, in some instances this section may also include some indication that issues appearing in the critiques were discussed and resolved by the reviewers. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the PROTECTION OF HUMAN SUBJECTS (Resume): section*

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF MINORITIES PLAN (Resume): UNACCEPTABLE**

*Requires additional text to explain why the plan for inclusion is unacceptable. Without this documentation it is not possible for the applicant and NIH staff to know what is the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer critiques.*

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

**TEMPLATE: INCLUSION OF CHILDREN PLAN UNACCEPTABLE**

*The first page of the summary statement will contain IMPAC II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**INCLUSION OF CHILDREN PLAN UNACCEPTABLE****RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

*(Acceptable Risks And/Or Adequate Protections) Although no text is required, in some instances this section may also include some indication that issues appearing in the critiques were discussed and resolved by the reviewers. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the PROTECTION OF HUMAN SUBJECTS (Resume): section*

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF CHILDREN PLAN (Resume): UNACCEPTABLE**

*Requires additional text to explain why the plan for inclusion is unacceptable. Without this documentation it is not possible for the applicant and NIH staff to know what is the basis for the concern, nor will it be possible for NIH staff and the applicant to know how to resolve the concern. The text may be copied from the reviewer critiques.*

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested**

**TEMPLATE: BUDGET CHANGES**

*The first page of the summary statement will contain IMPAC II generated information. Material generated by the SRA/GTA and Reviewers will begin on page 2 of the summary statement.*

**R01XX000000-01 PI Name**

**COMMITTEE BUDGET RECOMMENDATIONS****RESUME AND SUMMARY OF DISCUSSION:**

**DESCRIPTION (provided by applicant):**

**CRITIQUE 1:**

**CRITIQUE 2:**

**CRITIQUE 3:**

**CRITIQUE n:**

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

*(Acceptable Risks And/Or Adequate Protections) Although no text is required, in some instances this section may also include some indication that issues appearing in the critiques were discussed and resolved by the reviewers. In addition, when the proposed research includes a clinical trial, issues related to Data and Safety Monitoring Plan are discussed as part of the PROTECTION OF HUMAN SUBJECTS (Resume): section*

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

*This section may include a brief summary of the plan and some indication of any issues that were discussed and resolved by the reviewers. Text may be copied from the reviewer critiques.*

**COMMITTEE BUDGET RECOMMENDATIONS: The following changes were recommended:**

*Requires additional text to explain the recommended changes. The text may be copied from the reviewer's critiques.*