

# Updated Appendix Policy Eliminates Clinical Trial-Related Materials for NIH/AHRQ/NIOSH Applications Submitted to Due Dates on or After January 25, 2018.

Notice Number: NOT-OD-17-098

## Key Dates

**Release Date:** August 2, 2017

## Related Announcements

[NOT-OD-16-129](#)

[NOT-OD-17-035](#)

## Issued by

National Institutes of Health ([NIH](#))

Agency for Health Research and Quality ([AHRQ](#))

National Institute for Occupational Safety and Health ([NIOSH](#))

## Purpose

This Notice alerts the scientific research community of plans to eliminate Appendix materials related to clinical trials for applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2018. Clinical trial-related materials will be specified and required in the new PHS Human Subjects and Clinical Trials Information Form and no longer allowed in the Appendix unless specifically stated as required in the funding opportunity announcement (FOA). This Notice clarifies the types of Appendix materials allowable after this date.

The NIH, AHRQ, and NIOSH strive to ensure fairness in peer review for all grant applicants by specifying the types and amount of application material that will be accepted for peer review. At the same time, these agencies appreciate both the need for applications to provide sufficient information to allow for an informed, expert review process, and the importance of limiting burden on peer reviewers.

Restriction of Appendix materials is intended to rectify inequities in the peer review process that can arise from submission of inappropriate or excessive appendix materials by some applicants and consideration of Appendix materials in peer review by some, but not all, reviewers.

## Policy

### Appendix Materials in Peer Review

All information submitted with an application except the cover letter, assignment request form, and appendix information is assembled into a single application image for funding consideration. The different sections within the application image are specified in the application instructions and correspond to the standard review criteria.

Therefore:

- All information required for the peer review process must be contained within those designated sections of the application image, unless the FOA specifies otherwise.
- Information that expands upon or complements information provided in any section of the application -- even if it is not required for the review-- is not allowed in the appendix unless it is listed in the allowable appendix materials (below) or specified in the FOA. ([NOT-OD-11-080](#))
- Unless the FOA requires that certain information be included in the appendix, failure of reviewers to address appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review ([NOT-OD-11-064](#))

### Allowable Appendix Materials

**The following information applies to all competing NIH, AHRQ, and NIOSH applications and activity codes.**

Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2018, the only allowable Appendix materials are:

- Blank data collection forms, blank survey forms and blank questionnaire forms -- or screenshots thereof.
- Simple lists of interview questions.

For clarification, these blank forms and lists are not and do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

- Blank informed consent/assent forms
- Other items *only if* they are specified in the FOA as allowable Appendix materials

Some FOAs further restrict allowable appendix materials and/or may specify that some materials listed above must be provided in another part of the application. Applications submitted to those FOAs must follow instructions in the FOA and must not put those items in the Appendix.

***No other items are allowed in the Appendix. Simply relocating disallowed materials to other parts of the application will result in a noncompliant application.***

**Consequence for Submitting Disallowed Materials:**

Applications submitted for due dates on or after January 25, 2018 will be withdrawn as noncompliant if they are submitted with Appendix materials that are not specified in this Notice or specified in the individual FOA as allowed or required.

Please see our Frequently Asked Questions resource for additional information FAQs on the [NIH/AHRQ/NIOSH Appendix Policy](#)

## Inquiries

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