

Changes will be effective for **applications submitted on or after May 25, 2016**. Any applications due prior to May 25th should continue to use the current instructions and set of forms.

A new set of NIH forms (**FORMS-D**) will accompany these updates. New checklists and templates are available on the [ORSP website](#) now.

Changes

Topic	Change	What this means for MU Investigators?
Rigor and Transparency*	<p>We are adding a new "Authentication of Key Biological and/or Chemical Resources" attachment to the following forms in FORMS-D application packages:</p> <ul style="list-style-type: none"> • PHS 398 Research Plan • PHS 398 Career Development Supplemental Form • PHS Fellowship Supplemental Form 	<p>You will need to determine if your project requires an Authentication of Key Biological and/or Chemical Resources form and if needed, send it to ORSP with the rest of your application documents. This change only reflects where the document is uploaded in your application package.</p>
Vertebrate Animals*	<p>We are adding new questions regarding euthanasia to the following forms in FORMS-D application packages to replace the euthanasia criteria in the vertebrate animals section:</p> <ul style="list-style-type: none"> • PHS 398 Research Plan • PHS Fellowship Supplemental Form <p>Note: These changes do not apply to AHRQ applications.</p>	<p>Continue using the revised vertebrate animal section guidance that was released earlier this year. ORSP may ask another question in completing your actual NIH application package. New question:</p> <p>Are animals euthanized? Yes/No</p> <ul style="list-style-type: none"> • If Yes, is method consistent with AVMA guidelines? Yes/No • If No to AVMA guidelines, describe method/provide scientific justification
Inclusion Forms*	<p>We are adding an optional PHS Inclusion Enrollment Report form to FORMS-D application packages. The new form, with additional study descriptors, will replace the optional Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms found in FORMS-C application packages. We will provide more details about these changes prior to release of the updated forms.</p>	<p>Combines Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms into a single form. <u>The new form is attached.</u></p> <p>Questions used to identify type of report:</p> <ul style="list-style-type: none"> • Delayed onset study? Yes/No • Enrollment Type? Planned/Cumulative (Actual) • Using an Existing Dataset or Resource? Yes/No • Enrollment Location? Domestic/Foreign • Clinical Trial? Yes/No <ul style="list-style-type: none"> ○ NIH-Defined Phase II Clinical Trial? Yes/No
Data Safety Monitoring Plans	<p>We are adding a new "Data Safety Monitoring Plan" to the following forms in FORMS-D application packages:</p> <ul style="list-style-type: none"> • PHS 398 Research Plan • PHS 398 Career Development Supplemental Form • PHS Fellowship Supplemental Form 	<p>If proposing a clinical trial, the Data Safety and Monitoring Plan will be uploaded separately from the Protection of Human Subjects document, which is where the information has previously been provided.</p>

	<ul style="list-style-type: none"> • PHS 398 Research Training Program Plan <p>This new attachment must be included with all applications involving clinical trials. Although the requirement of a data and safety monitoring plan for clinical trials is not new, the use of a separate attachment to collect this information will emphasize its importance and facilitate systematic enforcement of its presence.</p>	
Research Training	<p>We are changing the research training data table format. Changes include:</p> <ul style="list-style-type: none"> • Reducing the number of tables from 12 to 8 • Minimizing the reporting of individual-level information • Extending the tracking of trainee outcomes from 10 to 15 years <p>NIH's xTRACT system to help applicants prepare the new tables will be available October 16, 2015. See NOT-OD-16-007.</p>	Only applies to training grants.
Appendix Policy	<p>We are reevaluating the current appendix policy. A notice describing specific appendix policy changes will be issued by spring 2016. Update 2/29/2016: Appendix policy changes on hold until further notice and will not be part of the initial roll-out of FORMS-D forms.</p>	Nothing at this time.
New PHS Assignment Request Form	<p>We are adding an optional PHS Assignment Request Form to FORMS-D application packages to provide a consistent way to collect application referral information, including:</p> <ul style="list-style-type: none"> • Awarding component (NIH institute) assignment preference • Study Section preference • List of potential reviewers in conflict, and why • List of scientific expertise needed to review the application • <p>See NOT-OD-16-008.</p>	<p>Instead of including this information in the cover letter, a separate form within the application package will be available to request review from an institute and study section. This form will also allow you to request reviewers and/or special scientific expertise needed. <u>The new form is attached.</u></p>
New Font Guidelines	<p>We are providing additional flexibility regarding the fonts allowed in PDF attachments included in grant applications. Although we will continue to recommend specific fonts, we will also allow other fonts (both serif and non-serif) as long as they comply with specific type density and line spacing guidelines. See NOT-OD-16-009.</p>	<p>While we still suggest using the recommended fonts (Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana typeface) any font that meets the spacing criteria is now allowed in proposal documents.</p>

Biosketch Clarifications	We are clarifying biosketch instructions. Clarifications include: <ul style="list-style-type: none">• Indicating that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography• Allowing publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections• Explicitly stating that graphics, figures and tables are not allowed	Clarifications for information provided in the biosketch. <u>See new template and instructions attached.</u>
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Additional information about these changes is attached for your reference. You can also find information here: <http://grants.nih.gov/grants/how-to-apply-application-guide.htm>.