

## Reminder: Authentication of Key Biological and/or Chemical Resources

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Key Dates

**Release Date:** May 31, 2017

Related Announcements

[NOT-OD-16-011](#)

[NOT-OD-16-012](#)

Issued by

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

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

Purpose

This Notice provides reminders for research grant applicants and mentored career development award applicants that propose the use of key biological and/or chemical resources. As described in [NOT-OD-16-011](#) and [NOT-OD-16-012](#), applicants proposing the use of established key biological and/or chemical resources are expected to include a plan to authenticate these resources in the "Authentication of Key Biological and/or Chemical Resources" attachment.

"Key biological and/or chemical resources" refers to established reagents or resources that will be used in the proposed research. This includes but is not limited to cell lines, specialty chemicals, antibodies or other biologics. Key biological and/or chemical resources are integral to the proposed research and may or may not have been generated with NIH funds.

Key resources that require validation are likely to:

- Differ from laboratory to laboratory, or over time
- Vary in qualities or qualifications that could influence the research data

Applicants proposing to use established key biological and/or chemical resources are expected to include an authentication plan in the "Authentication of Key Biological and/or Chemical Resources" attachment, even if the key resources were purchased or obtained from an outside source that provided data on prior authentication. The authentication plan must include only a description of the methods proposed to authenticate key resources prior to use and at regular intervals, if appropriate. The plan should be no more than one page.

For example:

- Applicants proposing to use cell lines could describe the method they plan to use to verify the identity and purity of the lines, which might include short tandem repeat (STR) profiling and mycoplasma testing.
- Applicants proposing to use chemicals that are key to the research could describe the method used to validate the chemical, which might include liquid or gas chromatography, or mass spectrometry.
- Applicants proposing to use genetically modified animals or cells could describe the method used to confirm the genome modification, which might include PCR amplification or Southern blot.

When published consensus standards exist, these may be cited in this section as the procedures that will be used for validation.

The "Authentication of Key Biological and/or Chemical Resources" attachment is only for established key biological and/or chemical resources.

- **Do not include** plans for authentication of data sets, databases, machinery, or electronics in the "Authentication of Key Biological and/or Chemical Resources" attachment.
- **Do not include** plans for the development and authentication of new key biological and/or chemical resources (such as a new human cancer cell line or a new antibody). Applicants proposing to generate a new key biological and/or chemical resource must describe the development and authentication of the resource in the Approach section of the Research Strategy.
- **Do not include** plans for authentication of standard laboratory reagents that are not expected to vary. Examples are buffers and other common biologicals or chemicals.
- **Do not include** authentication or other data in the "Authentication of Key Biological and/or Chemical Resources" attachment. Include only a description of the methods proposed to authenticate key resources.

Reviewers will discuss the information provided in this section after the application has been scored. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Information in this section **must focus only** on authentication and/or validation of key resources to be used in the study as described above. All other methods and any data must be included within the [page limits](#) of the research strategy. **Applications identified as non-compliant with this limitation will be withdrawn from the review process** (see [NOT-OD-15-095](#)).

Please see the Frequently Asked Questions (FAQs) about the [Authentication of Key Biological and/or Chemical Resources plan](#) and Dr. Mike Lauer's [blog post on Authentication](#).

Inquiries

Please direct all inquiries to:

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