

Report on the Peer Review of the Draft NTP Research Report on the CLARITY-BPA Core Study

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The National Toxicology Program (NTP) convened a Peer Review Panel on April 26, 2018, to peer review the Draft NTP Research Report on the CLARITY-BPA Core Study.

The Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity (CLARITY-BPA) is a consortium-based research program between the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH) and the National Center for Toxicological Research (NCTR) of the US Food and Drug Administration (FDA). The aim of the CLARITY-BPA program was to attempt to bridge guideline-compliant research conducted at the FDA with hypothesis-based research investigations conducted by academia on the toxicity of bisphenol A (BPA). A more detailed overview of the CLARITY-BPA program is covered on the NTP website:

https://ntp.niehs.nih.gov/results/areas/bpa/clarity_bpa/clarity-bpa-program.html

CLARITY-BPA has two components:

Core Study: A two-year guideline-compliant study of potential BPA toxicity in rats, which was conducted according to federal regulatory and statutory guidelines for toxicity testing.

Grantee Studies: Studies conducted by university researchers but testing a broader range of health endpoints, including genetic impacts, cardiovascular disease, obesity, and behavior. The Grantee Studies used animals raised in the same conditions and exposed to the same doses of BPA as the Core Study.

These two components combined to produce a robust [study design](#).¹ One key strength was identical BPA exposure conditions for both components of the study, which were provided at the same facility in the FDA's National Center for Toxicological Research (NCTR). A second strength was that grantees received blinded Core Study samples, meaning they did not know whether samples had been dosed with BPA or how much, to minimize the potential for bias.

The National Toxicology Program (NTP) research report reviewed at the peer review meeting only covers the "Core Study". Final CLARITY-BPA conclusions, integrating the Core Study research report and [grantee studies](#)² currently in progress, are expected in 2019.

There was extensive discussion by the Peer Review Panel on the NTP's draft scientific interpretations for the CLARITY-BPA Core Study. The Panel's comments on the draft interpretations will be captured in the peer review report, which will be posted with other

¹ Shug *et al.*, A new approach to synergize academic and guideline-compliant research: The CLARITY-BPA research program. *Reproductive Toxicology*. (2013) 40:35-40. <https://doi.org/10.1016/j.reprotox.2013.05.010>

² Information about the grantee studies is available at https://ntp.niehs.nih.gov/results/areas/bpa/clarity_bpa/grantees/grantees.html

meeting materials when completed.³ NTP will carefully consider the Panel's recommendations when finalizing the research report, which will be published on the [NTP website](https://ntp.niehs.nih.gov/results/pubs/rr/reports/index.html)⁴ in fall 2018.

Dr. Walker will present an overview of the CLARITY-BPA program, a summary of the peer-review meeting, recommendations by the peer reviewers, and next steps for the CLARITY-BPA program.

³ Meeting materials for the peer review are available at <https://ntp.niehs.nih.gov/go/rrprppastmtg>

⁴ <https://ntp.niehs.nih.gov/results/pubs/rr/reports/index.html>