

# Reporting to OHRP

## The Implications of “checking the box” on Your Federalwide Assurance

By Crystal M. Kelly



In the [preamble](#) to the 2018 revision to the Federal Policy for the Protection of Human Subjects (also known as the “2018 Common Rule” or “2018 Requirements” and codified for HHS at 45 CFR part 46, subpart A), the Office for Human Research Protections (OHRP) announced its intention to remove the option to “check the box” from the Federalwide Assurance (FWA). When an institution “checks the box” on their FWA, they are voluntarily electing to apply the Common Rule to all nonexempt human subjects research (HSR) conducted at their institution regardless of the funding source, unless the research is covered by separate assurance issued by another U.S. federal agency that has adopted the Common Rule. When institutions select this option, it means that OHRP may conduct compliance evaluations or investigations of nonexempt HSR that is not conducted or supported by HHS.

However, OHRP has not yet updated its assurance process, forms, and software tools to reflect this change. As the “check the box” concept is not part of the regulations at 45 CFR 46, implementation of the 2018 Requirements did not automatically “uncheck the box” on institutions’ FWAs; nor did it remove the option from the FWA submission process. Institutions are often surprised to learn that OHRP continues to have authority over research that does not receive HHS funding or support. This confusion can cause FWA-holding institutions to fail to promptly report incidents to OHRP, as specified in the 2018 Requirements at [45 CFR 46.108\(a\)\(4\)](#) and [45 CFR 46.113](#) as well as the [terms of the FWA](#).

Incident Reports include any:

- unanticipated problems involving risks to subjects or others;
- serious or continuing noncompliance with the Common Rule or the requirements or determinations of the IRB; and
- suspensions or terminations of IRB approval.

As specified in OHRP’s 2022 guidance on reporting incidents, incidents occurring under an OHRP-approved FWA that applies to research regardless of funding (i.e., “checks the box”) should be reported to OHRP.

For more information on reporting incidents to OHRP, including guidance and mini tutorial videos, please see our website: <https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html>

### Potential alternatives to “checking the box”

The preamble to the 2018 Requirements also notes:

“Importantly, institutions could, if they so desire, continue for purposes of their own internal rules to voluntarily extend the regulations to all research conducted by the institution, but this voluntary extension will no longer be part of the assurance process and such research will not be subject to OHRP oversight.”

In other words, institutions may opt to create a policy stating all nonexempt HSR will adhere to the standards specified in the Common Rule regardless of funding source. Along with “unchecking the box” on their FWA, this policy would give institutions the flexibility to use the Common Rule provisions to oversee research themselves, without also giving OHRP compliance authority for research that is not conducted or supported by a Common Rule department or agency.

However, it is important to note that some states have laws or regulations that apply to research not subject to the Common Rule. Institutional leadership should be aware of any state requirements when considering whether “checking the box” on their FWA is appropriate for their institution. It remains OHRP’s intention to remove the option to “check the box” from the FWA submission process, and institutions should consider this future change in their long-term planning.

OHRP encourages FWA holding institutions to review their FWAs to ensure that they accurately reflect their institutions’ preferences. Information on updating an FWA may be found on OHRP’s website: [www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwass/update-renew-fwa/index.html](http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwass/update-renew-fwa/index.html). ■

### References

- Office for Human Research Protections (OHRP). (2022, May 3). Excerpts from the January 19, 2017 Revised common rule preamble. HHS.gov. [www.hhs.gov/ohrp/regulations-and-policy/regulations/2018-req-preamble/index.html](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/2018-req-preamble/index.html)
- Office for Human Research Protections (OHRP). (2022, October 20). Reporting incidents to OHRP. HHS.gov. [www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html](http://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html)
- Office for Human Research Protections (OHRP). (2021, June 16). Federalwide Assurance (FWA) for the protection of human subjects. HHS.gov. [www.hhs.gov/ohrp/register-irbs-and-obtain-fwass/fwass/protection-of-human-subject/index.html](http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwass/fwass/protection-of-human-subject/index.html)
- Office for Human Research Protections (OHRP). (2021, June 16). Update or renew a Federalwide assurance (FWA). HHS.gov. [www.hhs.gov/ohrp/register-irbs-and-obtain-fwass/fwass/update-renew-fwa/index.html](http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwass/fwass/update-renew-fwa/index.html)
- Office of Management and Budget (OMB). (n.d.). Federalwide Assurance (FWA) - OMB 0990-0278. <https://omb.report/omb/0990-0278>
- Hartsmith, L. (2020, November 19). Surprise! “Checking the box” is still an option on the Federalwide Assurance (FWA). Advarra. [www.advarra.com/blog/surprise-checking-the-box-is-still-an-option-on-the-federalwide-assurance-fwa](http://www.advarra.com/blog/surprise-checking-the-box-is-still-an-option-on-the-federalwide-assurance-fwa)



Crystal M. Kelly, MPH, serves as a Compliance Analyst in the Division of Compliance Oversight of the HHS Office for Human Research Protections. Ms. Kelly has more than 17 years of experience in the field of human subjects research protection including IRB administration and the conduct of clinical research. She can be reached at [Crystal.Kelly@hhs.gov](mailto:Crystal.Kelly@hhs.gov).