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EPA Publishes Human Subjects Final Rule

The Environmental Protection Agency (EPA) has issued a final regulation that adopts changes necessary to harmonize with the revised Common Rule governing human subjects research. “In addition to the core protections found in the Common Rule, EPA has promulgated regulations that are specific to research involving human subjects conducted or sponsored by EPA or submitted to EPA for regulatory purposes. The revisions to the Common Rule create discrepancies within some of these EPA-specific regulations. This final rule harmonizes the EPA-specific regulations with revisions to the Common Rule in order to resolve those discrepancies,” EPA explained in the July 23 *Federal Register*.

Effective Sept. 23, EPA is “updating numerical references in subparts C and D to accurately refer to exemption text in subpart A and to eliminate language concerning tribal laws that is no longer necessary due to the revisions in subpart A. These revisions are necessary to ensure that the exemptions will apply as intended to research conducted or sponsored by EPA and avoid unnecessary confusion about the applicability of tribal law.” It also is making revisions to “subpart K to harmonize, as appropriate, language governing third-party research with the revisions in subpart A and to clarify the timing and applicability of these revisions.” The rule finalizes a proposed regulation issued in December.

[Link to final rule](#)

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