



NUMBER: Directive 0310.17

SUBJECT: Delegation of Authority to the Executive Director and the General Counsel to Update the Federal Policy for the Protection of Human Subjects (Common Rule)

DIRECTIVE OWNER: The Office of Hazard Identification and Reduction, Directorate for Health Sciences

EFFECTIVE DATE: December 13, 2022

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1. **PURPOSE.** This Directive memorializes the Commission’s delegation of authority to the Executive Director and the General Counsel to evaluate and initiate regulatory actions, as necessary, when the Department of Health and Human Services (HHS) notifies CPSC of changes to the Federal Policy for the Protection of Human Subjects (Common Rule).
 2. **AUTHORITIES.** 15 U.S.C. § 2076(b)(10); 16 C.F.R. part 1028
 3. **DEFINITIONS.**
 - **Common Rule** is the Federal Policy for the Protection of Human Subjects, promulgated by HHS, which is followed by many departments and agencies, including CPSC. The rule protects human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.
 4. **SCOPE.** This delegation applies to updates made to the Common Rule by HHS.
 5. **DELEGATION.**
 - The Commission delegates authority to the Executive Director to evaluate any changes to the Common Rule made by HHS, and to make recommendations regarding conforming changes to 16 C.F.R. part 1028, with concurrence by the General Counsel.
 - The Commission delegates authority to the General Counsel to make revisions to the Common Rule at 16 C.F.R. part 1028, in accordance with the recommendations made by the Executive Director, and to publish in the *Federal Register* notice of such changes.



- The authority delegated in this Directive may not be redelegated.

6. RESPONSIBILITIES.

- The General Counsel shall notify the Commission that they intend to exercise the authority granted in this Directive at least 5 business days before submitting a revised rule to the *Federal Register*. Upon such notification, the Commission may reject the proposed revision, but shall do so within 5 business days of notification. If the Commission does not reject the revision within that timeframe, the General Counsel may publish a revised rule in the *Federal Register*.

7. **CANCELLATION.** This Directive supersedes and cancels D202.9, *Delegation of authority to the Executive Director and the General Counsel to make recommendations and to take regulatory actions on the Federal Policy for the Protection of Human Subjects (Common Rule)*, dated September 19, 2019, as directed in a vote of the Commission on December 13, 2022.

Alberta E. Mills
Commission Secretary

Date