DIRECTIVE NUMBER: D202.9

SUBJECT: 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).

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

EFFECTIVE DATE: September 19, 2019

CERTIFIED CURRENT DATE: September 19, 2019

1. PURPOSE. The purpose of this Directive is to delegate authority to the Executive Director and the General Counsel to make recommendations and to take regulatory actions, as necessary, on changes to the Common Rule that are provided to CPSC staff by the Department of Health and Human Services (HHS).

2. AUTHORITY. 15 U.S.C. § 2076(b)(10); 16 CFR part 1028

3. DEFINITIONS.

Common Rule means the departments and agencies, including CPSC, that follow the Federal Policy for the Protection of Human Subjects to protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

4. SCOPE.

This Directive is intended for all CPSC employees and all contractors engaged by CPSC who review actions or changes to the Common Rule.

5. RESPONSIBILITIES.

• The Commission delegates authority to the Executive Director to evaluate any changes to the Common Rule, as provided by the Department of Health and Human Services (HHS),
and to make any recommendations regarding such changes, with concurrence by the General Counsel.

- The Commission delegates authority to the General Counsel to take regulatory actions on any changes to the Common Rule, as provided by HHS, and to publish in the Federal Register notice of such changes, as necessary, in accordance with the recommendations made by the Executive Director.

- The Executive Director shall notify the Commission that he/she intends to exercise the authority in this Directive at least 3 days before doing so. Upon such notification, the Commission may revoke the delegated authority set forth within this Directive, but shall do so within 3 days of notification by the Executive Director. If the Commission does not revoke authority within that timeframe, the Executive Director may exercise the authority.

- The Commission authorizes redelegating this authority.

6. **CANCELATION.** This Directive cancels Order No. 0310.17, Directives System, dated March 15, 2018

[Signature]

Ann Marie Buerkle
Acting Chairman

[Date] September 19, 2019

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