



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION**

DIRECTIVE NUMBER: D201.2

SUBJECT: Delegation of authority to the Human Subjects Committee to protect human subjects involved in research.

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 Human Subjects Committee to protect human subjects involved in research in accordance with the Federal Policy for the Protection of Human Subjects (Common Rule).

2. **AUTHORITY.** 15 U.S.C. § 2053(f)(1); 16 CFR part 1028

3. **DEFINITIONS.**

(a) **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.

(b) **Human Subjects Committee** means the committee established by the CPSC Chairman that (i) acts as the CPSC Institutional Review Board (IRB) when CPSC conducts research involving human subjects, (ii) reviews and comments on a proposed test procedure that will be used by an outside institution contracting with, or otherwise supported by CPSC, and (iii) reviews an outside institution's application for certification of compliance with the Common Rule.

4. **SCOPE.**

The Directive is intended for all CPSC employees and all contractors engaged by CPSC involved in human subjects research.

5. **RESPONSIBILITIES.**

- The Chairman shall designate the members of the Human Subjects Committee.
- The Chairman delegates authority to the Human Subjects Committee to establish policies and procedures and assign responsibilities to employees, experts and

consultants to develop, implement, and operate an agency program that takes into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained, for the protection of human subjects involved in research.

- 6. CANCELLATION.** This Directive cancels Order No. 0305.2, Directives System, dated July 21, 2003

Supporting Policies and Guidance:

IP D201.2 Implementing Procedure for the CPSC's Human Subjects Committee


Ann Marie Buerkle
Acting Chairman

September 19, 2019
Date