UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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BETHESDA, MD 20814

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BALLOT VOTE SHEET

Date: August 2, 2017

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director

FROM : Patricia M. Pollitzer, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT : Federal Policy for the Protection of Human Subjects (Common Rule)
Final Rule

BALLOT VOTE due: Tuesday, August 8, 2017

On January 19, 2017, the U.S. Department of Health and Human Services (HHS), published a final rule amending the Federal Policy for the Protection of Human Subjects (referred to as the Common Rule) on behalf of all federal departments and agencies that adhere to the Common Rule, including the Consumer Product Safety Commission (CPSC). Because CPSC's current regulations on the protection of human subjects, codified at 16 C.F.R. part 1028 follow the HHS regulations in 45 C.F.R. part 46, subpart A, CPSC adopts the Common Rule final rule by cross-reference to the HHS regulations in 45 C.F.R. part 46, subpart A, in the draft final rule.

Please indicate your vote:

I. Approve publication of the attached document in the *Federal* Register, as drafted.

_____ _____
Signature Date

II. Do not approve publication of the attached document in the *Federal* Register.

_____ _____
Signature Date

III. Take other action (Please specify).

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_____ _____
(Signature) (Date

Attachment: *Common Rule Final Rule-Memorandum from the Office of Hazard Identification and Reduction (July, 2017)*

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1028

Protection of Human Subjects

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: On January 19, 2017, the federal departments and agencies that are subject to the Federal Policy for the Protection of Human Subjects (referred to as the Common Rule) published a final rule amending the Common Rule. The Consumer Product Safety Commission (CPSC or Commission) adopts the Common Rule.

DATES: The rule is effective on January 19, 2018.

FOR FURTHER INFORMATION CONTACT: Alice Thaler, Associate Executive Director for Health Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850: 301-987-2240, or by email to: *athaler@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

On June 18, 1991, the U.S. Department of Health and Human Services (HHS) issued a rule setting forth the Common Rule requirements for the protection of human subjects. (56 FR 28003). The HHS regulations are codified at 45 CFR part 46. At that time, 15 other agencies, including CPSC, joined HHS in adopting a uniform set of rules for the protection of human subjects, identical to subpart A of 45 CFR part 46. The Common Rule is codified in CPSC's regulations at 16 CFR part 1028. The basic provisions of the Common Rule include, among other things, requirements related to the review of human subjects research by an institutional

review board, obtaining and documenting informed consent of human subjects, and submitting written assurance of institutional compliance with the Common Rule.

On September 8, 2015 (80 FR 53933), HHS, on behalf of many of the same agencies that were signatories to the original Common Rule, proposed revisions to the Common Rule to modernize and strengthen the rule. Although CPSC was not a signatory to the Common Rule NPR, CPSC proposed to amend the Commission's regulations at 16 CFR part 1028, to cross-reference the HHS regulations in 45 CFR part 46, subpart A. 80 FR 57548 (Sept. 24, 2015). In addition, CPSC directed that any comments on the proposed Common Rule be sent to the HHS docket for the proceeding at HHS-OPHS-2015-0008.

On January 19, 2017, HHS issued a final rule on the Common Rule, which, among other things, establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process. 82 FR 7149. HHS also reviewed and addressed more than 2,100 comments. Although CPSC instructed that any comment on the Common Rule be submitted in the HHS docket, 22 comments were submitted, instead, to the CPSC docket. CPSC reviewed the comments and determined that all of the substantive issues were addressed in the Common Rule final rule.

Because CPSC's current regulations on the protection of human subjects, codified at 16 CFR part 1028, follow the HHS regulations in 45 CFR part 46, subpart A, CPSC adopts the amended regulatory text provided in the Common Rule final rule by cross-reference to the HHS regulations in 45 CFR part 46, subpart A. The effective date of the Common Rule is January 19, 2018, with a compliance date of January 19, 2018, except for the section on cooperative research (section 11.114), which has a compliance date of January 20, 2020. CPSC does not generally conduct cooperative research projects that would come under that provision.

List of Subjects in 16 CFR Part 1028

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Consumer Product Safety Commission amends 16 CFR part 1028, as follows:

PART 1028 – PROTECTION OF HUMAN SUBJECTS

1. The authority for part 1028 continues to read as follows:

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b)

2. Revise part 1028 to read as follows:

The provisions set forth at 45 CFR part 46, subpart A, concerning the protection of human research subjects, apply to all research conducted, supported, or otherwise subject to regulation by the CPSC.

Dated:_____

_____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

Staff Briefing Package

Common Rule
Final Rule

July 25, 2017

This document has been electronically approved and signed.

Date: August 2, 2017

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Patricia H. Adkins, Executive Director

Mary T. Boyle, General Counsel

DeWane Ray, Deputy Executive Director for Safety Operations

FROM: George A. Borlase, Assistant Executive Director
Office of Hazard Identification and Reduction

Alice Thaler, Associate Executive Director
Directorate for Health Sciences

SUBJECT : Common Rule Final Rule (the Federal Policy for the Protection of Human Subjects)

I. INTRODUCTION

This briefing package provides information about the final rule from the U.S. Department of Health and Human Services (HHS) to amend the Federal Policy (Common Rule) for the Protection of Human Subjects, which HHS published in the *Federal Register* (FR) on January 19, 2017. 82 FR 7149.[1] The Consumer Product Safety Commission (CPSC or Commission) is one of 15 federal departments and agencies that originally promulgated this policy published by HHS on June 18, 1991, and continues to conform to its requirements. The 2017 HHS final rule simultaneously made identical amendments to the human subjects rules of 15 signatory agencies, with the expectation that CPSC (not a signatory agency), subject to Commission vote, intends to adopt this rule through a separate rulemaking. This is consistent with the approach taken by CPSC when the HHS Notice of Proposed Rulemaking (NPRM) for Protection of Human Subjects, was published on September 8, 2015. 80 FR 53933. On September 24, 2015, CPSC proposed to adopt the Common Rule NPRM by cross-reference to the HHS regulations at 45 C.F.R. part 46, subpart A. 80 FR 57548.

CPSC staff recommends that the Commission adopt the Common Rule final rule by amending CPSC's regulations at 16 C.F.R. part 1028 to cross-reference HHS's regulations at 45 C.F.R. part 46, subpart A. The final rule HHS will be effective January 19, 2018.

[1] https://www.gpo.gov/fdsys/search/pagedetails.action?granuleId=2017-01058&packageId=FR-2017-01-19

II. BACKGROUND

A. Common Rule History

The Federal Policy for the Protection of Human Subjects, or "Common Rule," contains the ethical rules and policies that govern the use of human research subjects in biomedical, social, and behavioral research funded by the federal government. HHS developed the Common Rule in response to the 1979 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report, titled, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly known as the Belmont Report.[2] The Belmont Report identified three fundamental ethical principles for all human subjects research: respect for persons, beneficence, and justice. These three guiding principles form the backbone of the Common Rule.

HHS first promulgated human subjects protection regulations in 1981. In 1991, revisions were made to 45 C.F.R. part 46 Subpart A, Basic HHS Policy for the Protection of Human Research Subjects, and 15 participating departments and agencies codified identical language in their respective chapter of the C.F.R. Before the Common Rule existed, CPSC codified its Protection of Human Subjects rule in 1977 at 16 C.F.R. part 1028.[3] With HHS's 1991 revision, the Common Rule was issued as the Federal Policy for the Protection of Human Subjects, and CPSC codified the policy at 16 C.F.R. part 1028.[4] Minor technical amendments to the rule were made in 2005.[5] The 15 agencies in Table 1 currently follow the Common Rule. At the time the Federal Policy was promulgated, the HHS regulations for the protection of human subjects included three other subparts that provided additional protections for specific subgroups:

- Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research;
- Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and
- Subpart D – Additional Protections for Children Involved as Subjects in Research.

Because the Common Rule is only Subpart A, the additional subparts are not included in the HHS final rule, nor do they appear in the Commission's regulations. However, when CPSC has involved children as human subjects research participants, CPSC followed the rules in 45 C.F.R. part 46 Subpart D. CPSC staff has not conducted, nor are there plans to conduct, research that involves pregnant women, human fetuses, neonates, or prisoners.

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[2] http://www.hhs.gov/ohrp/policy/belmont.html.

[3] 42 FR 36818 (July 18, 1977).

[4] 56 FR 28012, 28019, June 18, 1991; 56 FR 29756, June 28, 1991.

[5] 70 FR 36328, June 23, 2005.

Table 1. Common Rule Agencies

Confided location	Department/Agency
22 C.F.R. Part 225	Agency for International Development (USAID)
16 C.F.R. Part 1028	Consumer Product Safety Commission
7 C.F.R. Part 1c	Department of Agriculture
15 C.F.R. Part 27	Department of Commerce
32 C.F.R. Part 219	Department of Defense
34 C.F.R. Part 97	Department of Education
10 C.F.R. Part 745	Department of Energy
45 C.F.R. Part 46	Department of Health and Human Services
24 C.F.R. Part 60	Department of Housing and Urban Development
28 C.F.R. Part 46	Department of Justice
49 C.F.R. Part 11	Department of Transportation
38 C.F.R. Part 16	Department of Veterans Affairs
40 C.F.R. Part 26	Environmental Protection Agency
14 C.F.R. Part 1230	National Aeronautics and Space Administration
45 C.F.R. Part 690	National Science Foundation

The Office of the Secretary of HHS, in coordination with the Executive Office of the President's Office of Science and Technology Policy (OSTP), published an advance notice of proposed rulemaking (ANPR) on July 26, 2011,[6] as a step toward modernizing the human subjects protection regulations at 45 C.F.R. part 46. At the time the Common Rule was promulgated, research studies were primarily limited to one site; the Internet was in its infancy, data storage was often on paper, making it cumbersome and expensive; and no one had sequenced the entire human genome. In addition, the Common Rule treated all human subjects research similarly, whether the research was biomedical, behavioral, or social. Today, many research studies are conducted across many sites; the Internet is used for human subject recruitment and for data gathering; electronic data storage changes the cost of storage and availability of data for different research; and whole genome sequencing is relatively affordable and accessible. In addition, social and behavioral researchers have noted that many of the protections imparted by the Common Rule add unnecessary administrative burdens on social and behavioral research, where the main risk is inappropriate disclosure of Personally Identifiable Information (PII). For all of these reasons, HHS undertook the effort to overhaul the Common Rule to bring it up to date with modern technology, lower administrative burden for minimal risk research, add protections for whole genome sequence data, and clarify the use of previously collected data for future research.

On September 8, 2015, HHS and 15 other federal departments and agencies, not including CPSC, published a Notice of Proposed Rulemaking (NPRM) proposing revisions to the

[6] 76 FR 44512.

regulations for protection of human subjects in research.[7] CPSC was involved in the development of the NPRM, but due to timing and the need for a Commission vote, CPSC issued a separate NPRM that referenced the HHS NPRM. Like the ANPRM, the NPRM sought comment on how to better protect research subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. Public comments on both the ANPRM and the NPRM have informed the final rule. As discussed below, a few comments were misdirected to the CPSC's docket number. Accordingly, staff has reviewed them. Staff finds that all of the substantive comments were addressed in the HHS final rule.

The final rule also benefits from public comments submitted in response to more recent policy proposals such as the Office for Human Research Protection's (OHRP's) *Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care*[8] and the use of a single IRB for multi-site research studies through the National Institutes of Health's (NIH's) 2016 *Policy on the Use of a Single Institutional Review Board for Multi-Site Research*.[9]

Finally, the final rule more thoroughly addresses the broader types of research conducted or otherwise supported by all of the Common Rule departments and agencies such as behavioral and social science research. It also benefits from continuing efforts to harmonize human subjects policies across federal departments and agencies.

The goals of the final rule are to: (1) increase human research subjects' ability and opportunity to make informed decisions; (2) reduce potential for harm and promote justice by increasing the uniformity of human subject protections; and (3) facilitate current and evolving types of research by reducing ambiguity in interpretation of the regulations, increasing efficiencies in the review system, adjusting categories of exempt research or research not subject to the regulations to better reflect the heterogeneous research environment, and reducing burdens on investigators that do not appear to provide commensurate protections to human subjects.

B. Comments Directed to the CPSC Docket

A few commenters submitted comments to Docket CPSC-2015-0027 instead of following the instructions to submit all comments to Docket HHS-OPHS-2015-0008. Nevertheless, CPSC reviewed the 22 comments. As discussed below, HHS addressed all the substantive issues that were raised by the commenters.

One commenter was opposed to use of a single IRB. Comments regarding a single IRB are addressed at 82 FR 7153. A single IRB requirement for cooperative research was adopted in the

[7] Federal Policy for the Protection of Human Subjects. 80 FR 53931 (Sept. 8, 2015). https://www.federalregister.gov/documents/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects

[8] 79 FR 63630 (Oct. 24, 2014).

[9] National Institutes of Health. Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. 2016, June 21. Notice Number: NOT-OD-16-094. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

final rule. A 3-year compliance date for this requirement was adopted to afford affected institutions sufficient time to prepare for and implement this requirement (e.g., developing institutional policies and procedures). 82 FR 7176.

One commenter was concerned how determinations of exclusions would be handled. Another commenter was concerned that certain public health surveillance activities of state and local authorities would be excluded. Five commenters supported exclusion of quality improvement and quality assurance research. Comments regarding exclusions are addressed at 82 FR 7156-57. In the final rule, some of the proposed exclusions from the requirements of the Common Rule are addressed in the definition of research, which includes a provision identifying ‘‘activities that are deemed not to be research.’’ In addition, some of the proposed exclusions are included as exemptions in the final rule. *Id.* at 7157.

One commenter supported eliminating continuing review for non-exempt research that poses minimal risk. Comments regarding activities that are minimal risk are addressed at 82 FR 7156. The final rule removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. *Id.*

Several commenters supported requiring informed consent for biospecimens, including eight commenters who submitted brief statements that use of newborn DNA by researchers should require written parental consent. Comments regarding biospecimens and the informed consent process are addressed at 82 FR 7168-69. Under the final rule, secondary research with nonidentified newborn DBS would be treated in the same way as secondary research with any other type of nonidentified biospecimen. Such research would not be considered research with human subjects under the final rule, and thus would not be subject to the rule. 82 FR 7170.

One person commented on the 10-year limit on broad consent for biospecimens and was confused about the 10-year boundary. Comments on the 10-year limit on broad consent are addressed at 82 FR 7219-23. The final rule permits broad consent for either a narrow type of research or a broader scope of research. In addition, there is an exemption for secondary research. 82 FR. 7221.

One commenter opposed eliminating the exemption for research on public officials. Comments regarding exemptions for public officials are addressed at 82 FR 7199. The final rule removes the exemption category which pertained to research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, if the human subjects are elected or appointed public officials or candidates for public office. *Id.*

Several commenters were concerned about the proposed change in the definition of human subject. Comments regarding the definition of human subject are addressed at 82 FR 7153. The final rule does not adopt the NPRM proposal to alter the definition of a human subject to include research involving nonidentified biospecimens under the rule. *Id.*

C. CPSC Participation

In early 2014, the Director of OSTP asked for a CPSC representative to participate on the new Common Rule Modernization Working Group (WG). This interagency working group was formed to review and seek consensus on draft regulatory language consistent with the Administration's commitment to update the Common Rule. The WG was co-chaired by HHS, the National Science Foundation (NSF), and OSTP. The chair of CPSC's Human Subjects Committee (HSC) participated in meetings of the WG, which began its work in March 2014. In addition, the CPSC's HSC chair consulted with the CPSC's Office of the General Counsel and the agency's Associate Executive Director for Health Sciences regarding outcomes of discussions and staff feedback.

On March 3, 2014, CPSC provided public notice[10] that it is a public health authority within the meaning of the Privacy Rule, entitled to receive protected information from hospitals and other health care organizations, without written authorization or consent as permitted under the Privacy Rule 45 CFR 164.502(a)(1)(vi).

In April 2014, CPSC staff expressed general agreement with the initial draft NPRM, specifically noting that the draft added needed clarity in the form of new definitions, additional information on public health authorities and their surveillance activities, and PII protections. Staff expressed concerns that the text drafted for 45 CFR 46.116, which details the informed consent requirements, was overly complicated and may be difficult for researchers and some Institutional Review Board (IRB) members to understand. Staff participated in a sub-working group focused on that section and suggested methods to make this section less complicated. Finally, staff recommended clarifying whether focus groups and interview procedures were exempt or their review could be expedited, because CPSC has sponsored several recent focus groups that required IRB approval under the current regulations.

Late 2016 to early 2017, the Executive Offices of the President (EOP), Office of Management and Budget (OMB), managed the interagency review of the draft final rule. The Associate Executive Director for Health Sciences reviewed and provided comments on the final rule to ensure that CPSC epidemiological surveillance activities as a public health agency would be specifically excluded from the definition of "research" and, therefore, not be subject to the Common Rule. The final rule definition of "research" specifies that CPSC surveillance activities are not subject to the Common Rule

> For purposes of this part, the following activities are deemed not to be research:
> (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, *or increases in injuries from*

[10] 79 FR 11769 (March 3, 2014)

using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (emphasis added)

D. CPSC Human Subjects Research Program

Compared to many Common Rule agencies, CPSC's human subject research program is low volume, with five or fewer minimal risk research studies submitted to an IRB each year over the past 10 years. Contractors have conducted the majority of research studies for CPSC in the past 6 years. In these cases, staff is involved as the contracting technical officer, but has not been involved in recruiting human subjects or collecting data. CPSC's Human Subjects Committee is responsible for tracking all research, whether conducted by contactors or by CPSC staff. A CPSC activity that meets the Common Rule definition of research, because it generates generalizable knowledge using interventions involving human subjects, is subject to Common Rule provisions for the protection of human subjects. CPSC activities that collect information from people about consumer products, but no personally identifiable information about the people themselves, is an information-collection activity and is not human subjects research.

Throughout the past 11 years of research, all of the studies funded or conducted by CPSC have been informational in nature or behavioral studies. All these studies have involved minimal risk. Examples of informational studies include: "Durable Nursery Products Exposure Survey" and "Recreational Off-Highway Vehicle Focus Groups." In these studies, participants were asked for qualitative information about how they used products. Examples of behavioral studies include: "Child Resistant Packaging Timing Study" and "Functionality and Usability of a Child-Resistant ATV Ignition." These behavioral studies collect quantitative data on how products are used, such as the time it takes a human subject to complete a task. CPSC staff has not conducted a study with more than minimal risk, a biomedical study; nor has CPSC ever collected any whole genome sequencing data. All current and planned studies involve information collections on the foreseeable use of products, usability of products, or consumer perceptions of products or informational materials.

E. Summary of Major Changes

Although many provisions in the NPRM have been removed from the final rule, none of the changes impact CPSC activities. Most of the removed provisions relate to research with biospecimens and the issue of identifiable data regarding protecting PII.

The final rule differs in important ways from the NPRM. Most significantly, several proposed changes were not adopted:

- The final rule does not adopt the proposal to require that research involving nonidentified biospecimens be subject to the Common Rule, and that consent would need to be obtained in order to conduct such research.

- To the extent some of the NPRM proposals relied on standards that had not yet been proposed, the final rule either does not adopt those proposals or includes revisions to eliminate such reliance.
- The final rule does not expand the policy to cover clinical trials that are not federally funded.
- The final rule does not adopt the proposed new concept of "excluded" activities. Generally, activities proposed to be excluded are now either described as not satisfying the definition of what constitutes research under the regulations or are classified as exempt.
- The proposed revisions to the exemption categories have been modified to better align with the long-standing ordering in the final rule. The final rule does not include the proposed requirement that exemption determinations need to be made in specified ways.
- The final rule does not include the proposed standardized privacy safeguards for identifiable private information and identifiable biospecimens. Aspects of proposals that relied on those safeguards have been modified or are not being adopted.
- The final rule does not adopt the most restrictive proposed criteria for obtaining a waiver of the consent requirements relating to research with identifiable biospecimens.

The final rule makes the following significant changes to the Common Rule:

- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Broad consent will be an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.
- Establishes new exempt categories of research based on their risk profile. Under some of the new categories, exempt research would be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.
- Creates a requirement for U.S.-based institutions engaged in cooperative research to use a single IRB for that portion of the research that takes place within the United States, with certain exceptions. This requirement becomes effective 3 years after publication of the final rule.
- Removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care.

F. Effect of Final Rule on CPSC's Human Subjects Research Program

In addition to this list of major changes, a revised definition of "research," which specifies activities deemed not to be research, and a new definition of "public health" are most relevant to the work done by CPSC. The final rule now defines the term "public health" so that references to it in the definition of public health surveillance (§__.102(k) are understood. Moreover, because the definition of research (§__.102(l)) excludes public health surveillance activities, this change clarifies the scope of activities removed from the definition of research for the purposes of the final rule.

In the final rule, as in the NPRM, the term *public health authority* (consistent with 45 CFR 164.501 in the Privacy Rule) means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Overall, the final rule will have a positive effect on CPSC's human subjects program. As the majority of recent studies have been information-collection studies that would be deemed not to be research, the final rule would reduce the administrative burden for CPSC staff by allowing for processing such studies through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process only; whereas, previously, studies went through both PRA and IRB review. In addition, formalizing a single IRB review for human subjects research will reduce staff administrative burden because the CPSC internal IRB would not need to review contractor IRB submissions, when that contractor has a Federalwide Assurance approved through the HHS OHRP.

III. STAFF RECOMMENDATION

Staff recommends that the Commission adopt the Common Rule and publish the *Federal Register* notice to amend the Commission regulations at 16 CFR part 1028 to cross-reference the HHS regulations in 45 C.F.R. part 46 part A.