A Cup of Joe and a Chat? That Could Be Exempt... Under Certain Circumstances: A Story of an Exemption Category 7
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Problem Statement: A vast number of requests for determinations of exemption status submitted by investigators to our institution’s IRB for social, behavioral, and educational (SBE) research apply under category 2, specifically for the use of minimal risk surveys. Many of these proposals include surveys following exposure to non-physically invasive stimuli such as playing video games or holding a cup of coffee while viewing pictures. Despite being viewed as negligible risk, these studies did not strictly fall into the category 2 exemption. Instead, they would receive expedited approval and remain subject to IRB oversight and annual review. That required investigators providing more thorough proposals on lengthy applications and IRB staff spending time performing continuing review of proposals that felt exempt, yet did not actually meet any of the criteria. In order for such projects to receive exemption determination, in the spring of 2013, our institution developed an additional exemption category for non-federally funded projects – Special Exemption Category 7: Research Involving Response to Non-Physically Invasive Stimuli as a demonstration project.

Methods: Additional restrictions that would preclude exemption status were maintained, e.g., inclusion of prisoners or children, need for Certificate of Confidentiality, etc. We revised our policies and created a checklist to evaluate studies falling into category 7. To prevent potential noncompliance with regulations, in case federal funding is obtained after the IRB review, several mechanisms were put in place, including initial confirmation with the investigator that there are no plans for federal money to support the study. In addition, the determination letter informs the investigator about the limitations of the exemption under category 7. Most importantly, no federal money should be released to the investigator by the Grants and Contracts Department before an IRB congruency check between a grant and the research is performed. Should our IRB receive a request for a congruency review on an exempt protocol under category 7, the status of the study would change to a full protocol under the IRB oversight.

Conclusions: The implementation of the new category has provided a more accurate means of reviewing SBE exemptions, with no loss of regulatory scrutiny. Institutions that review many non-federally funded studies, especially student projects, and have not “checked the box” on their FWA, may benefit from development of exemption categories in addition to federally designated ones. We will provide examples of the studies, the checklist used by the IRB staff, and the guidance for investigators.