

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) • 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, MI 48109-2800 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

To: Madeline Endres

From:

Riann Palmieri-Smith

Thad Polk

Cc:

Kaia Newman Madeline Endres Westley Weimer

Subject: Notice of Exemption for [HUM00213745]

SUBMISSION INFORMATION:

Title: A investigation into psychoactive drugs and their impact on programming environments

Full Study Title (if applicable):

Study eResearch ID: <u>HUM00213745</u>

Date of this Notification from IRB: 4/12/2022 Date of IRB Exempt Determination: 4/12/2022

UM Federalwide Assurance: FWA00004969 (For the current FWA expiration date, please visit the <u>UM HRPP</u>

Webpage)

OHRP IRB Registration Number(s): IRB00000246

IRB EXEMPTION STATUS:

The IRB HSBS has reviewed the study referenced above and determined that, as currently described, it is exempt from ongoing IRB review, per the following federal exemption category:

EXEMPTION 2(iii) at 45 CFR 46.104(d) with limited IRB review:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **if**:

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § __.111(a)(7).

Note that the study is considered exempt as long as any changes to the use of human subjects (including their data) remain within the scope of the exemption category above. Any proposed changes that may exceed the scope of this category, or the approval conditions of any other non-IRB reviewing committees, must be submitted as an amendment through eResearch.

Although an exemption determination eliminates the need for ongoing IRB review and approval, you still have an obligation to understand and abide by generally accepted principles of responsible and ethical conduct of research. Examples of these principles can be found in the Belmont Report as well as in guidance from professional societies and scientific organizations.

SUBMITTING AMENDMENTS VIA eRESEARCH:

You can access the online forms for amendments in the eResearch workspace for this exempt study, referenced above.

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ACCESSING EXEMPT STUDIES IN eRESEARCH:

Click the "Exempt and Not Regulated" tab in your eResearch home workspace to access this exempt study.

Riann Palmieri-Smith

Co-chair, IRB HSBS

Thad Polk

Co-chair, IRB HSBS