MICHIGAN STATE
UNIVERSITY

EXEMPT DETERMINATION
Revised Common Rule

May 28, 2020

To: Richard P Deshon

Re: **MSU Study ID:** STUDY00004221
Principal Investigator: Richard P Deshon
Category: Exempt 2(ii)
Exempt Determination Date: 5/28/2020
Limited IRB Review: Not Required.

Title: Chance Patterns in Requests for Help

This study has been determined to be exempt under 45 CFR 46.104(d) 2 (ii).

Temporary institutional restrictions are in place until further notice for human subject research conducted by MSU employees or agents. All MSU human research activities conducted by MSU employees or agents that take place in Michigan and cannot be done at home or place of residence with no inter-personal interaction with participants and others like research staff must stop unless the project is a clinical trial activity, that if discontinued, would negatively impact the patient's care, or is urgently related to the COVID-19 pandemic. Ongoing clinical trial activity, which if discontinued, would negatively impact the patient's care may continue with already enrolled participants. New enrollment in clinical trials conducted in Michigan is not permitted without additional institutional approval.

For MSU human research activities that take place outside of Michigan, unless there is the potential for direct therapeutic benefit to the participant (drug or device), any in-person participant interaction must immediately pause. This applies to both exempt and non-exempt research studies.

For all human research studies, research procedures involving no direct in-person interactions
with participants may continue (e.g. data analysis, online surveys, telephone interviews) in
otherwise permissible venues, so long as State and local requirements are met.

Please note that the situation is rapidly evolving and may further change. Visit http://hrpp.msu.edu/COVID-19/index.html for the latest information and updates, including the restrictions and their duration as the situation evolves.

Principal Investigator (PI) Responsibilities: The PI assumes the responsibilities for the protection of human subjects in this study as outlined in Human Research Protection Program (HRPP) Manual Section 8-1, Exemptions.

Office of Regulatory Affairs
Human Research Protection Program

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517-355-2180
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Email: irb@msu.edu
www.hrpp.msu.edu

Continuing Review: Exempt studies do not need to be renewed.

Modifications: In general, investigators are not required to submit changes to the Michigan State University (MSU) Institutional Review Board (IRB) once a research study is designated as exempt as long as those changes do not affect the exempt category or criteria for exempt determination (changing from exempt status to expedited or full review, changing exempt category) or that may substantially change the focus of the research study such as a change in hypothesis or study design. See HRPP Manual Section 8-1, Exemptions, for examples. If the study is modified to add additional sites for the research, please note that you may not begin the research at those sites until you receive the appropriate approvals/permissions from the sites.

Please contact the HRPP office if you have any questions about whether a change must be submitted for IRB review and approval.

New Funding: If new external funding is obtained for an active study that had been determined exempt, a new initial IRB submission will be required, with limited exceptions. If you are unsure if a new initial IRB submission is required, contact the HRPP office. IRB review of the new submission must be completed before new funds can be spent on human research activities, as the new funding source may have additional or different requirements.

Reportable Events: If issues should arise during the conduct of the research, such as unanticipated problems that may involve risks to subjects or others, or any problem that may increase the risk to the human subjects and change the category of review, notify the IRB office promptly. Any complaints from participants that may change the level of review from exempt to expedited or full review must be reported to the IRB. Please report new information through the study's workspace and contact the IRB office with any urgent events. Please visit the Human Research Protection Program (HRPP) website to obtain more information, including reporting timelines.

Personnel Changes: After determination of the exempt status, the PI is responsible for maintaining records of personnel changes and appropriate training. The PI is not required to notify the IRB of personnel changes on exempt research. However, he or she may wish to submit personnel changes to the IRB for recordkeeping purposes (e.g. communication with the Graduate School) and may submit such requests by submitting a Modification request. If there is a change in PI, the new PI must confirm acceptance of the PI Assurance form and the previous PI must submit the Supplemental Form to Change the Principal Investigator with the Modification request (available at hrpp.msu.edu).

Closure: Investigators are not required to notify the IRB when the research study can be closed. However, the PI can choose to notify the IRB when the study can be closed and is especially recommended when the PI leaves the university. Closure indicates that research activities with human subjects are no longer ongoing, have stopped, and are complete. Human research activities are complete when investigators are no longer obtaining information or biospecimens about a living

person through interaction or intervention with the individual, obtaining identifiable private information or identifiable biospecimens about a living person, and/or using, studying, analyzing, or generating identifiable private information or identifiable biospecimens about a living person.

For More Information: See HRPP Manual, including Section 8-1, Exemptions (available at hrpp.msu.edu).

Contact Information: If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at IRB@msu.edu. Please visit hrpp.msu.edu to access the HRPP Manual, templates, etc.

Exemption Category. The full regulatory text from 45 CFR 46.104(d) for the exempt research categories is included below. [1234]

Exempt 1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt 2. 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 at least one of the following criteria is met:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
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> (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
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> (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 45 CFR 46.111(a)(7).

Exempt 3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) 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 45 CFR 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exempt 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ``health care operations'' or ``research'' as those terms are

defined at 45 CFR 164.501 or for ``public health activities and purposes'' as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Exempt 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Exempt 6. Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt 7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

Exempt 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

[1]Exempt categories (1), (2), (3), (4), (5), (7), and (8) cannot be applied to activities that are FDA-regulated.

[2] Each of the exemptions at this section may be applied to research subject to subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) if the conditions of the exemption are met.

[3] The exemptions at this section do not apply to research subject to subpart C (Additional Protections for Research Involving Prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners.

[4] Exemptions (1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D (Additional Protections for Children Involved as Subjects in Research) if the conditions of the exemption are met. Exempt (2)(i) and (ii) only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exempt (2)(iii) may not be applied to research subject to subpart D.