UT Health San Antonio
The University of Texas Health Science Center at San Antonio

EXEMPT DETERMINATION

February 5, 2025

Kirk Evoy
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San Antonio, TX 78229

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Dear Kirk Evoy:

On 2/5/2025, the IRB Office reviewed the following submission:

Protocol Information	Submission Details
Type of Review:	Initial Study
Title:	Kratom Temporal Use Survey
Investigator:	Kirk Evoy
IRB ID:	STUDY00001351
Funding:	None
Grant ID:	None
IND, IDE or HDE:	None
Documents Reviewed:	• Draft Survey with Consent Form.pdf, Category: Consent Form; • HRP-211a _ Form A (2).pdf, Category: Other; • HRP-211b _ Institutional Form.pdf, Category: Other; • HRP-211d _ Request for Determination of Exempt Research (4).pdf, Category: Other; • HRP-503b _ Template _ Protocol _ Exempt Research (19).pdf, Category: IRB Protocol; • Recruitment materials, Category: Recruitment Materials;
Sites:	Local Research Locations: UT Health San Antonio

The IRB determined that this protocol meets the criteria for exemption from IRB review on 2/5/2025 in accordance with 45 CFR 46.104, under the following category (or categories), and limited IRB review has been conducted for those categories marked with *.

☐ 1	Research evaluating different instructional strategies or comparing effectiveness of instructional techniques, curricula, or classroom management methods in an established or commonly accepted educational setting.
	Research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), where:
☒ 2i	The information obtained is not identifiable, either directly or through identifiers linked to the subjects.
☐ 2ii	Any disclosure of human subjects' responses outside the research would not reasonably place subjects at risk of criminal or civil liability; or be damaging to the subjects' financial standing, employability, insurability, or reputation.
☐ 2iii	Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. *
	Research that involves benign behavioral interventions, in conjunction with collection of information, from adult subjects through verbal or written responses or consensual audiovisual recording, where:
☐ 3i	The information obtained is not identifiable, either directly or through identifiers linked to the subjects.
☐ 3ii	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, insurability, or reputation.
☐ 3iii	Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. *
	Research involving collection of data and/or specimens that are originally collected for other purposes (i.e., educational records, medical records, specimens in pathology, etc.), where:
☐ 4i	The identifiable private information or biospecimens are publicly available.
☐ 4ii	The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects. Access to the information will occur only once, and no study codes will be assigned to the subjects, their biospecimens, or their data.
☐ 4iii	The secondary research activity is regulated under HIPAA, and a HIPAA waiver is required. Access to the information may occur more than once, and/or study codes or other links may be created linking the subjects to the biospecimens or data.
☐ 4iv	The secondary research activity is conducted by, or on behalf of, a federal entity; involves the use of federally generated non-research information; and its original collection was subject to federal privacy protections and continues to be protected.
☐ 5	Research or demonstration projects conducted, supported, or approved by a federal department or agency head, and designed to study, evaluate, or otherwise examine public benefit or service programs.
☐ 6	Research involving taste or food quality evaluation or consumer acceptance studies.

Ongoing IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made, please submit a new request to the IRB for a determination.

In conducting this protocol, you are required to follow the requirements listed in HRP-103 - INVESTIGATOR MANUAL.

This determination is for research conducted at UT Health San Antonio and its affiliates (University Health and South Texas Veterans Health Care System). Exempt research conducted at other research locations should be deferred to the IRB of record for that location.

Please note that studies involving an affiliate will require separate institutional approval prior to initiating research at those research locations.

Sincerely,

Institutional Review Board Office
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