NEW MEXICO HIGHLANDS UNIVERSITY
Institutional Review Board
EXEMPTION FROM IRB REVIEW APPLICATION

University procedures provide for departmental review of research involving human participants exempt under federal, state, and university regulations. The exempt categories and exceptions are described on the second page of this form. Exempt research may be approved by any member of the IRB committee. This form, properly endorsed, certifies that the research described here qualifies for exemption, and should be forwarded to the chair of the IRB committee.

Principal Investigator _____ Academic Title _____
School/Department _____ Telephone _____
Project Title _____
Starting Date _____ Anticipated Termination Date _____
Faculty Sponsor (if principal investigator is a student) _____
Grant Title (if different from project title) _____
Principal Investigator on Grant (if different from PI listed above) _____
Funding Agency and Application Due Date (if applicable) _____

I. Check category(ies) under which this research qualifies for exemption (see back of form for description of exempt categories): 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐

II. ABSTRACT: State briefly a) the purpose(s) of the research, b) what subjects will do (if applicable), c) the nature of the data to be obtained, d) how anonymity or confidentiality will be maintained, and e) copies of *ALL* questionnaires/instruments/surveys for planned use. Add sheets if necessary.

III. HUMAN SUBJECTS:	YES	NO
Are any subjects under 18 years of age? ……	☐	☐
Are any subjects confined in a correctional or detention facility? ……	☐	☐
Is pregnancy a prerequisite for serving as a subject? ……	☐	☐
Are fetuses *in utero* subjects in this research? ……	☐	☐
Are any subjects presumed to be legally incompetent? ……..	☐	☐
Are personal records (medical, academic, etc.) used without written consent? …….	☐	☐
Are data from subjects (responses, information, etc.) directly or indirectly identifiable? ….	☐	☐
Are data damaging to subjects' financial standing, employability or reputation? …….	☐	☐

IV. PRINCIPAL INVESTIGATOR: I certify that the information provided above is correct and that, to the best of my ability to judge, this research qualifies for exemption and will be conducted in accord with the general principles stated on the reverse side of this form.

Principal Investigator's Signature _____ Date _____

V. IRB Representative: I certify that this research is exempt from federal regulations and that it is in accord with the general principles stated on the reverse side of this form.

Signature _____Title _____ Date _____

****After this application is completed, with the signature of an IRB representative, please send provide a hard copy and electronic copy to the chair of the IRB committee, David Pan, PhD:**

David Pan, PhD
Department of Psychology
Lora Shields 249
NMHU
Las Vegas, NM 87701
dpan@nmhu.edu

RESEARCH QUALIFYING FOR EXEMPTION FROM FEDERAL REGULATIONS FOR THE PROTECTION OF HUMAN PARTICIPANTS

(Quoted from the Code of Federal Regulations, Title 45, Part 46.101.)

(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.

(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;

(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

(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 §46.111(a)(7).

(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 §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.

(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.

(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.

(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.

(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 §46.111(a)(8).

(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 §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 §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §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.

NEW MEXICO HIGHLANDS UNIVERSITY EXCEPTIONS TO EXEMPTION: REVIEW REQUIRED

1. Research activities involving: *minor subjects* (except in the case of categories 1 and 2, above); *pregnant women* (where pregnancy is the focus of the research); *prisoners*; *fetuses* in utero; or *persons incompetent to provide informed consent*.
2. Research involving the use of tissue obtained at autopsy.
3. Research involving Native American populations.

GENERAL PRINCIPLES OF RESEARCH WITH HUMAN SUBJECTS

A. New Mexico Highlands University and the individual members of its faculty, staff and student body recognize their responsibility for protection of the rights and welfare of human subjects.

B. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.

C. Research involving children (persons under 18 years of age), other legal incompetents, and persons unable to give informed consent may be approved if there is no risk of suffering for the individual subject. On the other hand, research involving a child, other legal incompetent, or a person unable to give informed consent should not be approved if there would be significant risk of suffering without the possibility of benefit to the individual subject.

D. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.

E. Before a subject participates in research involving risk or substantial stress or discomfort, this shall be carefully explained; the investigator shall be satisfied that the explanation has been understood by the subject; and the consent of the subject shall be obtained. The elements of informed consent are established by the federal government and by the University.

F. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled, within the limits of the research.