MIAMI VAHCS IRB
REQUEST FOR EXEMPTION REVIEW FROM HUMAN RESEARCH OVERSIGHT

NOTE: Exemption does not apply to research subject to FDA regulations (e.g. drug, devices, or biologics). See 21 CFR 56.104 for further guidance.

Principal Investigator:

Project Title:

Exemption is requested under the following category:

☐ 1a. ☐ 1b.	**1.** Research conducted in established or commonly accepted educational settings, involving normal educational practices. Such as: **a.** Research on regular and special education instructional strategies, **OR** **b.** Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. .
☐ 2.	**2.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior, unless: **a.** Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND** **b.** Any disclosure of the human subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
☐ 3a. ☐ 3b.	**3.** Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 above, **IF**: **a.** The human subjects are elected or appointed public officials or candidates for public office; **OR** **b.** Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐ 4a. ☐ 4b.	**4.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. This exemption applies **IF**: **a.** These sources are publicly available, **OR** **b.** The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. NOTE: 1) In order to be eligible for this exemption, all of the materials have to exist at the time the research is proposed. This means that an investigator must not maintain any type of linkage that makes it possible to go back and review the record at a later time. ***If linkage needs to be maintained, the protocol should be submitted for Expedited Review; please review the guidelines and form for Expedited Review.*** 2) Collection of extra blood samples or tissue samples that are obtained at the time of a routine medical procedure are **not** considered to be existing since they were not stored and available prior to submission of the protocol to the IRB. This type of research will not qualify for Exemption, but might appropriately be considered for Expedited Review; please review the guidelines and form for Expedited Review. Collection of existing blood samples or tissue for which additional information must be obtained from medical records will **not** qualify for exemption, since such studies require a link through identifiers to match the samples to records.

☐ 5.	**5.** Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: **a.** Public benefit or service programs; **b.** Procedures for obtaining benefits or services under those programs; **c.** Possible changes in or alternatives to those programs or procedures; **or** **d.** Possible changes in methods or levels of payment for benefits or services under those programs.
☐ 6a. ☐ 6b.	6. Taste and food quality evaluation and consumer acceptance studies, which meet any of the following conditions: a. If wholesome foods without additives are consumed; OR b. 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 US Department of Agriculture.

Will ANY of the following items be recorded?

☐ Yes ☐ No 1. Name

☐ Yes ☐ No 2. All geographic subdivisions smaller than a state, including street address, city, county and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data form the Bureau of Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and (2) the initial three digits of a zip code for all such geographic units containing 20,000 is changes to 000.

☐ Yes ☐ No 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages older than 89 and all elements of date (including year) indicative of such age, except such ages and elements may be aggregated into a single category of age 90 or older.

☐ Yes ☐ No 4. Telephone numbers

☐ Yes ☐ No 5. Fax numbers

☐ Yes ☐ No 6. Electronic mail addresses

☐ Yes ☐ No 7. Social Security Number

☐ Yes ☐ No 8. Medical record number

☐ Yes ☐ No 9. Health plan beneficiary number

☐ Yes ☐ No 10. Account numbers

☐ Yes ☐ No 11. Certificate/license numbers

☐ Yes ☐ No 12. Vehicle identifiers and serial numbers, including license plates

☐ Yes ☐ No 13. Device identifiers and serial numbers

☐ Yes ☐ No 14. Web Universal Research Locators (URLs)

☐ Yes ☐ No 15. Internet Protocol (IP) address numbers

☐ Yes ☐ No 16. Biometric identifiers, including finger and voice prints.

☐ Yes ☐ No 17. Full-face photographic images and any comparable images.

☐ Yes ☐ No 18. Any other unique identifiers, characteristic or code, unless otherwise permitted by the Privacy Rule for re-identification.

Please answer the following questions to the best of your ability:

☐ Yes ☐ No Do you have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information?

☐ Yes ☐ No Will this information be disclosed for purposes other than research, public health, or health care operations.

Signature of Principal Investigator

REVIEWER FORM FOR EXEMPTION REQUESTS
I - CONFLICT OF INTEREST DISCLOSURE

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? ☐ Yes** ☐ No

**If yes, please do not perform the review and contact the IRB Office: 305 575-7241

II – REVIEWER DETERMINATION

A. The research meets the following ethical standards for exempt research:

☐ Yes ☐ No - Research represents no more than minimal risk

☐ Yes ☐ No - Selection of subjects is equitable

☐ Yes ☐ No - Confidentiality provisions adequate (if collecting identifiable data)

☐ Yes ☐ No - Privacy provision are adequate

B. Based on the information in the protocol, I have made the following determination:

Verified as Exempt under:

☐ Category 1a ☐ Category 1b ☐ Category 2

☐ Category 3a ☐ Category 3b ☐ Category 4a

☐ Category 4b ☐ Category 5 ☐ Category 6a ☐ Category 6b

Not Exempt - Request submission for Expedited Review.

Not Exempt - Resubmission Required.

C. If there are interactions with subjects:

☐ I have determined that a consent process is NOT required.

☐ I have determined that a consent process is required to disclose the following information:

- The activity involves research
- A description of the procedures
- That participation is voluntary
- Name and contact information for the investigator

Please list any comments or any additional provisions required to protect subjects (e.g., informed consent)

Signature of IRB Chairperson or Designated Reviewer