**FORM 3.2B-CLAIM OF EXEMPTION**

Project or Protocol Title:

Principal Investigator:

Phone:

**Contact person**

Phone:

Address:

Fax:

E-mail:

**SPONSOR / FUNDING INFORMATION**

Will this project/protocol be supported by an external funding agency?

No Yes

List Sub-investigator/Co-investigators: None

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Faculty Sponsor (if applicable)

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**LOCATION OF RESEARCH**:

**Where will the study take place?** Include all locations for Study related activities here or on separate sheet.

Will the PI be conducting and/or supervising study related activity at any sites not under the jurisdiction of this REC? If yes, please provide name and address for each location AND documentation of approval to conduct research at these sites. Note: Additional REC approval may be required from these sites if an individual at this site, not an employee/student of this institution/organization, is performing research under this application.

Yes No

**EXEMPT CATEGORY CLAIMED**

Identify all that apply to your research (check applicable boxes)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. This category may include children.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which participants cannot be identified, or release of the information would not be harmful to the participant. This category may include children.
3. Research involving the use of survey procedures or interview procedures or observation of public behavior for which participants cannot be identified, OR release of the information would not be harmful to the participant. This category may not include children. If participants are 18 years of age or younger parental consent is required. Research may be reviewed by expedited procedures – do not use this form!
4. Survey or interview of public or elected officials. Testing of public officials.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available OR if the information is recorded by the Investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
6. Research and demonstration projects that are conducted by or participant to the approval of Federal Department or Agency heads, and which are designed to study or evaluate public benefits or services (e.g., evaluation of public benefits programs: Medicare, Public Assistance). This category may include children.
7. Taste and food quality evaluation and consumer acceptance studies. This category may include children.
8. Unidentifiable human body parts, sections or samples obtained from a morgue

**If your research involves only those procedures listed in one or more of the categories above, it may be exempt. Please provide a rationale for each exempt category claimed for this research.**

**RATIONALE FOR EXEMPT CATEGORY CLAIMED**

The information **must** include a brief specific description of the procedure(s) involving the human participants in sufficient detail to demonstrate to the IDI REC reviewer that the research protocol meets the requirements for each category of exemption claimed in this human participants research protocol. The text should be approximately 300 words or less on separate sheets in sufficient detail to allow the reviewer to judge exemption criteria.

**RATIONALE FOR EXEMPT CATEGORY** # (s)

**SYNOPSIS OF THE PROJECT OR PROTOCOL, INCLUDE:**

1. The objective of the research project and background of study.
2. The rationale for the use of the selected participant population & plans for recruitment & consent.
3. The procedures that will be performed to generate research data & risks, if any, to participants.
4. Steps to be taken to protect the privacy and/or confidentiality of participants.
5. Include copy of questionnaires, surveys or brief outline of questions to be asked.

**INVESTIGATOR’S ASSURANCE**

I certify that the information provided in this claim of exemption is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants and the ethical conduct of this research protocol. I agree to comply with all IDI REC policies and procedures, as well as with all applicable national and local laws regarding the protection of human participants in research, including, but not limited to, the following:

* The project will be performed by qualified personnel according to the research protocol,
* Maintaining a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human participants for at least three years following termination of the project,
* Necessary review by the IDI REC will be sought if changes made in the research protocol may result in the research no longer meeting the criteria for exemption.

I will complete the required educational program on ethical principles and regulatory requirements in human participants’ research in a timely manner.

I have read and understand the above policy concerning IDI REC exempt protocols.

Principal Investigator Date

**FACULTY SPONSOR’S ASSURANCE (For student and fellow projects)**

By my signature as Sponsor on this research application, I certify that the student or guest Investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

* I agree to meet with the Principal Investigator on a regular basis to monitor study progress.
* Should problems arise during the course of the study, I agree to be available, personally, to supervise the Principal Investigator in solving them.
* I assure that the Principal Investigator will complete the required educational program on ethical principles and regulatory requirements in human participants’ research in a timely manner.
* If I will be unavailable, as when on sabbatical, leave or vacation, I will arrange for an alternate Investigator to assume responsibility during my absence, and I will advise the IDI REC by letter of such arrangements.

Faculty Sponsor\* (if Principal Investigator is a student or fellow) Date

\*The faculty Sponsor must be a member of the Institution’s faculty. The faculty Sponsor is considered the responsible party for legal and ethical performance of the project.

**INSTITUTION/ DEPARTMENT HEAD SIGNATURE (If Investigator is a staff)**

As department head, I acknowledge that this research is in keeping with the standards set by our institution/ department and I assure that the Principal Investigator has met all institutional/ departmental requirements for review and approval of this research.

Institution/ Department/Unit Head Signature Date

Typed/printed Name of Institution/ Department/Unit Head