Texas A&M International University
Form I Summary Cover Sheet
Protocol for Human Subjects in Research

TAMIU#:_____

Please check off or provide details on the following (enter N/A if not applicable). ☐Expedited Review
See Page 2

Principle Investigator Name: _____☐ Faculty ☐Graduate Student*

College Dept._____ E-mail _____ Phone_____

Project Title _____

Subjective Estimate of Risk to Subject: ☐ None ☐ Low ☐ Moderate ☐ High

Gender of Subjects: ☐ Male ☐ Female

Invasive/Sensitive Procedure: ☐ Yes ☐ No Sensitive Subject Matter: ☐ Yes ☐ No

☐ Blood samples	☐ Urine samples	☐ Alcohol, Drugs, Sex
☐ Physical measurements	☐ Stress Exercise	☐ Depression/Suicide
☐ Psychological Inventory	☐ Review of Medical Records	☐ Learning Disability
☐ DNA	☐ Other (specify) _____	☐ Other (specify)_____

Use of ☐ Video or ☐ Audio Tapes (please indicate) Provisions for Confidentiality/Anonymity

Retained ☐ Yes ☐ No
Length of time retained _____
Destroy/Erase ☐ Yes ☐ No
Other (explain) _____
Use specified in consent form? ☐ Yes ☐ No
Use/Access to tapes:_____

☐ Replies Coded
☐ Secure Storage
☐ Anonymous Response
☐ Confidential Response

- Must include signature of committee chair on protocol

REQUEST FOR EXPEDITED REVIEW:

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories qualify for expedited review by the IRB. Please check the box that indicates which criterion you believe applies to your research:

- ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - ♦ research on regular and special education instructional strategies, or
  - ♦ research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - ♦ information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - ♦ any disclosure of the human subjects' responses outside 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.

- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, and achievement), survey procedures, interview procedures, or observation of public behavior that is not except under the second bullet of this section, if:
  - ♦ the human subjects are elected or appointed public officials or candidates for public office, or
  - ♦ federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- ☐ 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 subject cannot be identified, directly or through identifiers linked to the subjects.

- ☐ Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
  - ♦ public benefit or service programs;
  - ♦ procedures for obtaining benefits or services under these 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.

- Taste and food quality evaluation and consumer acceptance studies:
  - if wholesome foods without additives are consumed; or
  - 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 containment 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.

Texas A&M International University
Institutional Review Board
Form II (revised January 200)

1. Project Title: _____

   Principal Investigator: _____

Affidavit: I have read the Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"
(http://grants.nih.gov/grants/oprr/humansubjects/guidance/Belmont.htm)
and subscribe to the principles it contains.

_____ _____
Signature Date

In light of this Declaration, I present for the Board's consideration the following information which will be explained to the subject about the proposed research:

2. SELECTION AND SOURCES OF SUBJECTS:

   (A) Source:
   (B) Number:
   (C) Method of Recruitment and Selection:

   (D) Ages
   (E) Compensation, if any
   (F) Location of Experiment:
   (G) Duration of Experiment:
   (H) Specific Steps to Assure Anonymity or Confidentiality:

   (I) Special Physical or Psychological Conditions:

   (J) Gender and Minority Inclusion:

3. DESCRIPTION OF EXPERIMENTAL PROCEDURE (including steps and time required):

4. RISKS AND BENEFITS TO SUBJECTS:
   (A) Risks—including physical, psychological, social

   (B) Benefits—specific to participants

   (C) Alternatives to participation/opportunity to withdraw

5. SIGNATURES:

   Principal Investigator/Student_____

   Supervising Faculty if Student_____

6. DATE:_____

FOR IRB USE

_____ Approved, Expedited Review (signed) _____ (date) _____

_____ Referred for Full Review (signed)_____ (date) _____

_____ Approved, Full Review (signed) _____ (date) _____

CONSENT FORM CHECKLIST

NOTE: This checklist is for your use in the preparation of a consent/assent form. Please refer to the Texas A&M Guide to the IRB Application, Elements of the Informed Consent Document, for additional information related to this list.

ITEMS	YES	NO	N/A	COMMENTS
Does the title of the study appear at the top of the consent/assent form?				
Is the consent/assent form written in first person?				
Is the number of potential subjects clearly specified?				
Is the consent/assent form written in simple lay language?				
Is the consent/assent form written in the native language of the potential subject?				
Does the consent/assent form state the general purpose of the study, what the researcher expects to learn?				
In the case of students, does the consent/assent form state how the study relates to your program of work (project, thesis, dissertation)?				
Does the consent/assent form indicate that a Certificate of Confidentiality has been obtained? If so, do you have it in your possession?				
Does the consent/assent form state if the study is confidential or anonymous? It cannot be both.				
For sensitive subjects, does the consent/assent form indicate that in certain cases of detected abuse, this information must be reported to proper authorities?				
Does the consent/assent form indicate to the subject his/her right to choose to participate?				
Is there a statement indicating why and how this subject was selected as a possible participant? Are the population and sample clearly identified?				
Does the consent/assent form clearly explain the procedure to be followed in implementing the project (time, frequency, nature of information, questions asked, observations made)?				
Is there a statement, which addresses possible discomforts and inconveniences that the participant might expect?				
Does the consent/assent form describe any participant risks that are involved in the project? If pregnancy presents a risk, have specific precautions been taken?				
If there are any benefits to the subject, are they identified in the consent/assent form? Otherwise, does it state that there are no personal benefits to the subject?				
If the project requires that any standard treatment is withheld, is this clearly designated in the consent/assent form? If alternative treatments are available, are they described?				

ITEMS	YES	NO	N/A	COMMENTS
Is the subject's confidentiality explained in the consent/assent form? Is the use of any tapes or other materials (such as audio tapes, videotapes, photos, use of data for other purposes) explained and the final disposition made clear?				
Are compensation and costs included in the project, and are they identified specifically for the subject?				
Are you using a company's employees as research subjects?				
If so, have you stated in the consent form the subjects' status with regard to Workman's Compensation insurance while they are participating in the investigation?				
Does the consent/assent form indicate where the subject can contact the PI and /or research advisor to have questions answered?				
Address				
Phone Number				
E-mail address				
In the case of faculty member PI s, is there someone else identified as a contact person, i.e., department head, section leader, etc?				
Does the consent/assent form have the Texas A&M IRB statement along with the address, telephone number and e-mail address of the IRB Coordinator?				
Does the consent/assent form indicate to the subject that he/she can withdraw at any time from the project? Does the form indicate any procedures that might be necessary for ordinary withdrawal from a complex study? Are situations where the subject's participation can be terminated described?				
Does the consent/assent form indicate to the subject that he/she is entitled a written copy of said form?				
Does a statement exist expressing that the subject's signature indicated a willingness to participate?				
Does the consent/assent form have a place for the subject's signature, investigator's signature and date?				
Does a parental consent form have a blank line for the child's printed name?				
Is there a child's assent form (required for children ages 7-18)?				
Is this a high-risk protocol?				
If so, is the Texas A&M statement regarding non-availability of medical care in the consent form?				
If appropriate, does the consent form have the statement regarding FDA review of all records?				

Debriefing Statement

If deception is a part of the research study, the subjects must be informed—at the end of their participation—why deception was used. Inform the IRB whether the subjects will be debriefed verbally or in writing. Attach a copy of the debriefing form. If oral debriefing is to be conducted, indicate what will be told to the subjects and attach a copy of the script. For further information, refer to the publications and guidelines of the American Psychological Association regarding deception research.

Mail-out Surveys

Mail-out surveys may not require consent forms as completing and returning the surveys may constitute consent in some instances. Never the less, the cover letter or instruction sheet must provide all of the elements of consent including contact persons other than the PI. This includes a description and purpose of the study, how confidentiality or anonymity of the subject's responses will be maintained, and how many people will be surveyed.

Telephone Surveys

If the research involves telephone surveys, include the telephone scripts, which gives the elements of consent and the questions to be asked.