Last Name _____
IRB# _____

TEXAS A&M INTERNATIONAL UNIVERSITY

IRB Review Checklist

*Bottom Line: Human research must be done in a way that is **valid** and of **value**. All reasonable efforts must be made to **minimize risk**, while providing a benefit if possible to the participant of the research. The human participant must be **informed** unless there is a reasonable reason that prevents the research from being accomplished.*

Study Name:	
Principal Investigator(s):	
Student Investigator(s):	
	☐ Exempt ☐ Expedited ☐ Full Review

I. SCHOOL STUDIES ONLY

TAMIU's IRB will NOT approve any study that has not already been approved by the appropriate school district.

YES	NO	N/A		
☐	☐	☐	**1.**	Has LISD/UISD – or the school district IRB approved the study?

II. PURPOSE OF THE STUDY

YES	NO	N/A		
☐	☐	☐	**2.**	Are the objectives of the study clearly specified?
☐	☐	☐	**3.**	Are adequate preliminary data, references, justifications provided to justify the research?

III. RISKS AND BENEFITS

YES	NO	N/A		
☐	☐	☐	**4.**	Are the risks adequately identified and described?
☐	☐	☐	**5.**	Are the benefits adequately identified and described?
☐	☐	☐	**6.**	Are the risks reasonable in relationship to the benefits/importance of the knowledge to be gained?
☐	☐	☐	**7.**	Are risks minimized to the greatest extent possible?

IV. SUBJECT RECRUITMENT

Bottom Line: All races, all genders must be included unless justification is provided.

YES	NO	N/A		
☐	☐	☐	**8.**	Are inclusion and exclusion criteria clearly stated and reasonable?
☐	☐	☐	**9.**	Is subject selection equitable (all races, all genders)? If not, is reasonable justification provided?
☐	☐	☐	**10.**	Are vulnerable subjects included (children, prisoners, women – in some cases – e.g. pregnant, employees)?
☐	☐	☐	**11.**	If vulnerable subjects are included, are appropriate safeguards in place?
☐	☐	☐	**12.**	Are the methods for recruiting subjects well defined? Is the process acceptable?
☐	☐	☐	**13.**	Are recruitment materials submitted appropriate?

V. CHILDREN STUDIES ONLY

YES	NO	N/A	
			14. If children are involved which category does this research fall into:
☐	☐	☐	**a.** Research not involving greater than minimal risk [45 CFR 46.404]
☐	☐	☐	**b.** Research involving greater than minimal risk, but with **direct** benefit to the individual [45 CFR 46.405] **REQUIRES FULL REVIEW**
☐	☐	☐	**c.** Research involving greater than minimal risk, with **no direct** benefit to the individual [45 CFR 46.406] **REQUIRES FULL REVIEW** **REQUIRES ALL GUARDIANS CONSENT (BOTH PARENTS USUALLY)**
☐	☐	☐	**d.** Research not otherwise approvable, but which present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children [45 CFR 46.407] **REQUIRES *FEDERAL* REVIEW**
☐	☐	☐	**15.** Is a parental consent form included and understandable to the parent?
☐	☐	☐	**16.** Is a child assent form included and understandable to the child? *Note assent should be obtained in most cases.*

VI. CONSENT

YES	NO	N/A	
☐	☐	☐	**17.** *Review the informed consent checklist.* Are all elements of informed consent included?
☐	☐	☐	**18.** Were there any exceptions to the informed consent checklist? Are they acceptable?
☐	☐	☐	**19.** Is a waiver of informed consent requested? If so:
☐	☐	☐	**a.** Have the criteria for a waiver/modification of informed consent been met? ➢ The consent form would be the only document linking the subject to the research and a potential risk would be a breach in confidentiality ➢ Study has no more than minimal risk, and involves no procedures for which consent is normally required outside of the research environment
☐	☐	☐	**b.** If informed consent is waived, should the researcher provide the subject with a written statement regarding the research?
☐	☐	☐	**c.** If children are included, have the criteria for waiver of parental consent been met? ➢ IRB must determine that parental permission is not a reasonable requirement to protect the subjects ➢ Appropriate mechanisms must be implemented to protect children as subjects
☐	☐	☐	**d.** If a waiver or modification of the required consent elements was proposed, have the criteria been met? ➢ The research involves no more than minimal risk to the subjects ➢ The waiver/alteration will not adversely affect the rights and welfare of the subject ➢ The research could NOT be practically carried out without the waiver/alteration, and when appropriate the subject will be provided with pertinent information after participation

VII. COMPENSATION / COURSE CREDIT

YES	NO	N/A	
☐	☐	☐	**20.** Is the amount/type of compensation or reimbursement non-coercive?

VIII. PROCEDURES

YES	NO	N/A	
☐	☐	☐	**21.** Is the scientific design adequate to answer the questions(s)?
☐	☐	☐	**22.** Are the aims/objectives likely to be achievable within the given time period?
☐	☐	☐	**23.** Are the research procedures described in sufficient detail to allow evaluation of the research protocol? Are the procedures acceptable?
☐	☐	☐	**24.** Is there a clear differentiation between procedures for research purposes only, and procedures for normal life/care of the subject?
☐	☐	☐	**25.** Are there adequate plans to inform subjects about specific research results that might affect the subject's health and/or decision to continue participation?

IX. SUBJECT PRIVACY AND CONFIDENTIALITY

YES	NO	N/A	
☐	☐	☐	**26.** Are there adequate provisions to protect subjects' privacy and assure confidentiality of the results, both during and after the research?
☐	☐	☐	**27.** Is the use of identifiers necessary?

X. STATISTICAL ANALYSIS:

YES	NO	N/A	
☐	☐	☐	**28.** Is the rationale for the proposed number of subjects reasonable?
☐	☐	☐	**29.** Are the plans for data and statistical analysis defined and justified?

XI. OTHER ISSUES – ALL STUDIES

YES	NO	N/A	
☐	☐	☐	**30.** Next review in one year? If no, specify when review needs to occur: _____
☐	☐	☐	**31.** Are there appropriate resources to conduct the research safely?
☐	☐	☐	**32.** Has the investigator assured appropriate support services are available – counseling, referrals?
☐	☐	☐	**33.** Are there adequate provisions for possible injury/liability coverage?
☐	☐	☐	**34.** Are there provisions included for research related injuries if applicable?

XII. EXPEDITED / FULL REVIEW ONLY

YES	NO	N/A	
☐	☐	☐	**35.** Has the investigator completed CITI training?

COMMENTS:

CONSENT / ASSENT FORM CHECKLIST:

YES	NO	N/A	
☐	☐	☐	Does the title of the study appear at the top of the form?
☐	☐	☐	Is the form written in first person and in simple lay language?
☐	☐	☐	Is the number of potential subjects clearly specified?
☐	☐	☐	Is the form written in the native language of the potential subject?
☐	☐	☐	Does the form state purpose of the study, what the researcher expects to learn?
☐	☐	☐	For students, does the form state how the study relates to project, thesis, dissertation?
☐	☐	☐	Does the form indicate that a Certificate of Confidentiality has been obtained?
☐	☐	☐	Does the form state if the study is confidential or anonymous?
☐	☐	☐	For sensitive subjects, does the form indicate that in certain cases of detected abuse, this information must be reported to proper authorities?
☐	☐	☐	Does the 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 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 detailing possible expected discomforts/inconveniences?
☐	☐	☐	Does the form describe any participant risks that are involved in the project?
☐	☐	☐	If pregnancy presents a risk, have specific precautions been taken?
☐	☐	☐	Are benefits to the subject identified in the form? If none, is that stated as well.
☐	☐	☐	If the project requires that any standard treatment is withheld, is this clearly designated in the form? If alternative treatments are available, are they described
☐	☐	☐	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 identified specifically for the subject?
☐	☐	☐	Are company's employees being used as research subjects?
☐	☐	☐	If so, does form state the subjects' status with regard to Workman's Compensation insurance while they are participating in the investigation?
☐	☐	☐	Does the form indicate where the subject can contact the Principal Investigator (PI) and /or research advisor to have questions answered?
☐	☐	☐	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 form have the TAMIU IRB statement along with the address, telephone number and e-mail address of the IRB Chair?
☐	☐	☐	Does the 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 form indicate to the subject that he/she is entitled a written copy?
☐	☐	☐	Does a statement exist expressing that the subject's signature indicates a willingness to participate?
☐	☐	☐	Does the form have a place for the subject's signature, witness 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 7-17)?
☐	☐	☐	Is this a high-risk protocol?
☐	☐	☐	If so, is TAMIU statement regarding non-availability of medical care in the consent form?
☐	☐	☐	If appropriate, does the consent form have statement regarding FDA review of all records?