TTU IRB Initial Submission Checklist

Use this checklist as a final review tool to ensure the submission meets all required criteria to support an efficient review. The checklist is designed to verify that all components are complete, accurate, and properly formatted using the provided resources. Address any incomplete or unclear items prior to submission or contact HRPP staff with questions (hrpp@ttu.edu).

PROTOCOL INFORMATION: STUDY DETAILS	**YES**	**NO**	**N/A**
The study title is consistent throughout the submission and on attachment documents where applicable (protocol, consent, assent, information sheet, etc.).			
SUMMARY & PURPOSE	**YES**	**NO**	**N/A**
The information is concise, in lay terms and is consistent with the protocol and consent documents.			
EXPEDITED SUBMISSIONS	**YES**	**NO**	**N/A**
Does this study meet the definition of human subject research?			
The research meets regulatory requirements for an expedited submission:			
No more than minimal risk:			
Involves one or more of the expedited categories:			
The appropriate Expedited Category or Categories are selected:			
PARTICIPANT POPULATION	**YES**	**NO**	**N/A**
Based on review of the protocol all applicable populations have been selected.			
Research Participation is based on gender and/or race/ethnicity with appropriate scientific justification.			
VULNERABLE POPULATIONS INCLUDED:			
Children:			
Prisoners:			
Individuals with Impaired Decision-Making Skills:			

Other:___			
COERCION OR UNDUE INFLUENCE:	**YES**	**NO**	**N/A**
Is there potential for coercion or undue influence of potential participants?			
If yes, has the research team mitigated the coercion and undue influence?			
RECRUITMENT PROCESS https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Recruitment procedures are clearly defined.			
Recruitment material is included (i.e., flyers, notices, advertisements, verbatim scripts, etc.):			
CONSENT PROCEDURES https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Is the consent process clearly defined?			
Are the individuals listed as obtaining consent also included under the Research Team?			
Is the appropriate type of consent/information sheet selected and included with the submission?			
Uses TTU Template(s):			
ASSENT PROCEDURES https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Is the assent process clearly defined?			
Are the individuals listed as obtaining assent also included under the Research Team?			
Is the appropriate type of assent selected and included with the submission?			
Uses TTU Template(s):			

COERCION OR UNDUE INFLUENCE:	**YES**	**NO**	**N/A**
Is there potential for coercion or undue influence of potential participants?			
If yes, has the research team mitigated the coercion and undue influence?			

RECRUITMENT PROCESS https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Recruitment procedures are clearly defined.			
Recruitment material is included (i.e., flyers, notices, advertisements, verbatim scripts, etc.):			
CONSENT PROCEDURES https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Is the consent process clearly defined?			
Are the individuals listed as obtaining consent also included under the Research Team?			
Is the appropriate type of consent/information sheet selected and included with the submission?			
ASSENT PROCEDURES https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Is the assent process clearly defined?			
Are the individuals listed as obtaining assent also included under the Research Team?			
Is the appropriate type of assent selected and included with the submission?			
MANDATORY REPORTING	**YES**	**NO**	**N/A**
College students or TTU employees are asked about sexual misconduct, discrimination, harassment, or violence. https://www.depts.ttu.edu/research/responsible-research/irb/additional-guidance.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
Abuse and Neglect of a Child, Elderly Individual or Adults with Disabilities https://www.depts.ttu.edu/research/responsible-research/irb/additional-guidance.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
Mental Health, Self-Harm, Criminal Behavior, & Substance Abuse https://www.depts.ttu.edu/research/responsible-research/irb/additional-guidance.php			

Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
WAIVER OR ALTERATION OF CONSENT https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Waivers Of Written Consent (use of an information sheet-no signed consent document, ex: online survey)			
If there is an alternative to written consent requested, is the justification stated and appropriate?			
Waiver of Consent (no consent is obtained from the participant or parent)			
Alteration of informed consent or elements of consent (ex: deception)			
If a waiver or alteration of consent is requested (e.g., secondary data, database, chart review), has the PI provided protocol specific justification and have all the regulatory criteria been met?			
PARTICIPANT COMPENSATION	**YES**	**NO**	**N/A**
Participant Compensation meets IRB policy guidelines.			
Details of compensation are noted in the consent form.			
A description of the incentive/compensation:			
Any restrictions or requirements for participant compensation:			
If it is a drawing the odds of winning:			
The time frame of when the participant will receive the incentive/compensation:			
DATA COLLECTION PROCEDURES	**YES**	**NO**	**N/A**
Research procedures are described appropriately:			
Indicates who will conduct the research activities:			
Frequency of study visits and total duration of study participation (total time commitment) is provided.			
Consistent throughout the proposal and **consent form**.			

If there are data collection instruments, all instruments, surveys and/or educational materials are included in the attachments section and are in easy-to-understand language.			
AUDIO/VIDEO RECORDING	**YES**	**NO**	**N/A**
If audio/video recording this information is listed in consent with a statement regarding when recordings will be destroyed.			
USE OF DECEPTION https://www.depts.ttu.edu/research/responsible-research/irb/additional-guidance.php	**YES**	**NO**	**N/A**
When there is a potential for deception is justification provided and the reviewer agrees.			
If yes, the study must meet the criteria for an alteration to informed consent.			
There is an acceptable plan to debrief participants:			
DEBRIEFING https://www.depts.ttu.edu/research/responsible-research/irb/additional-guidance.php	**YES**	**NO**	**N/A**
Participants will be debriefed as the conclusion of the research.			
Deception			
Title IX			
Abuse and Neglect			
Mental Health, Self-Harm, Criminal Behavior, & Substance Abuse			
RISKS	**YES**	**NO**	**N/A**
The nature and degree of potential risks to participants (physical, psychological, legal, economics, and social) is stated.			
Risks are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.			
Are the risks to participants more than minimal?			
Are the risks described accurately and included in the consent/assent forms?			
BENEFITS	**YES**	**NO**	**N/A**
Are the benefits described accurately?			

Are the benefits described also included in the informed consent/assent documents? (Compensation is not considered a benefit.)			
PRIVACY & CONFIDENTIALITY	**YES**	**NO**	**N/A**
Are the measures to maintain confidentiality clearly stated?			
There is an adequate plan for storage and disposal of data (including audio or video recordings).			
There are adequate provisions to protect the personal privacy interests of the participant(s).			
Required Elements Consent https://www.depts.ttu.edu/research/responsible-research/irb/recruitment-consent.php	**YES**	**NO**	**N/A**
Statement it is research			
Purpose of the research			
Description of the procedures			
Identification of any procedures that are experimental			
Participation is voluntary			
Can stop at any moment and skip questions			
That refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits.			
Time of Procedures			
Foreseeable risks or discomforts to the participant			
If there are no such risks or discomforts, the consent form should so state.			
Benefits to the participant			
If there are no such benefits, the consent form should so state.			
Participant Payment			
Not listed as a benefit			
A description of the incentive/compensation:			
Any restrictions or requirements for participant compensation:			
If it is a drawing the odds of winning:			

The time frame of when the participant will receive the incentive/compensation:			
The following statement about participants' rights: “Dr. (Principal Investigator) will answer any questions you have about the study. You can call (phone number) or email (email address). Questions can also be directed to the Human Research Protection Program (HRPP), Office of Research and Innovation, Texas Tech University, Lubbock, Texas 79409, 806-742-2064.”			