IRB Reviewer's Proposal Checklist

(Form used by the IRB to review research study proposals)

Research Proposal Title: _____

Principal Investigator: _____

Review Type: ☐ Exempt ☐ Expedited

TCCD IRB Reviewer: _____

HUMAN RESEARCH PROTECTIONS CHECKLIST

Required Documents Submitted	YES ☐	NO ☐	N/A ☐	IRB Approval form PI's University, Human Subjects Testing Training Certificate, Proposal, Proposal Form.
Required Signatures Provided	YES ☐	NO ☐	N/A ☐	
Consent Document & Consent Checklist Provided	YES ☐	NO ☐	N/A ☐	
Recruitment Material Included	YES ☐	NO ☐	N/A ☐	
Data Collection Instrument Included	YES ☐	NO ☐	N/A ☐	
Location Site Permission Letters	YES ☐	NO ☐	N/A ☐	If research is conducted at a non-TCCD site, an **Off-Site Locations Form** is required.
Source of Funding Identified	YES ☐	NO ☐		
Federal Funded	YES ☐	NO ☐	N/A ☐	If federal monies will be used in connection with the proposed project, provide name of funding source, grant award number, and a copy of the grant proposal.
Special Populations Identified	YES ☐	NO ☐	N/A ☐	If vulnerable populations are used, **Vulnerable Populations Form** is required (Children/Prisoners/Women, Human Fetuses, Neonates).
Use of student population in research defended, if applicable.	YES ☐	NO ☐	N/A ☐	

ADMINISTRATIVE QUESTIONS/NOTES
(Questions and notes directed to the committee.)

MAJOR CONCERNS
(Ethical concerns, risk/benefit issues, subject capacity, consent issues, Privacy and confidentiality issues.)

MINOR ISSUES
(Typographical errors, grammar, pagination, and/or required UCI template language missing from consent.)

Conflict of Interest:
Please specify whether you have a conflict of interest with the review of this proposal.

☐ **I DO NOT HAVE A CONFLICT OF INTEREST ON THIS PROPOSAL**

☐ **I DO HAVE A CONFLICT OF INTEREST ON THIS PROPOSAL**

The IRB has the expertise needed to review this research. ☐ Yes ☐ No

Criteria for IRB Review and Approval*:* Please review and confirm that the research meets the outlined following criteria by checking the corresponding box. Document each concern that you would like to be communicated to the researcher in the corresponding comments box or in the open space below.

<table>
<tr><th colspan="2">CRITERIA FOR EXEMPT REGISTRATION</th></tr>
<tr><th>BACKGROUND AND RESEARCH DESIGN</th><th>INFORMED CONSENT</th></tr>
<tr><td>▪ Statement of purpose/hypothesis is adequate.
▪ Study procedures in the narrative match the consent documents.
▪ Study personnel appear appropriate/qualified..

☐ Yes ☐ No</td><td>Is an informed consent process appropriate?

☐ Yes ☐ No
If yes, the researcher will disclose:
▪ That the activity involves research.
▪ A description of the procedures.
▪ That participation is voluntary.
▪ There are adequate provisions to maintain privacy and confidentiality.
▪ The name and contact information for the researcher.</td></tr>
<tr><td>Comments:</td><td>Comments:</td></tr>
<tr><th>SUBJECT RECRUITMENT</th><th>SUBJECT PROTECTION</th></tr>
<tr><td>▪ Selection of subjects is equitable.
▪ Selection of subjects is appropriate.
▪ Selection of Recruitment procedures are proper (undue influence or coercion is minimized, compensation is not coercive, recruitment materials are appropriate).

☐ Yes ☐ No</td><td>▪ Unanticipated problem reporting is adequately addressed.
▪ Provisions to protect subject privacy are adequate.
▪ Provisions to maintain confidentiality are appropriate.
▪ Additional protections for vulnerable populations are addressed.

☐ Yes ☐ No</td></tr>
<tr><td>Comments:</td><td>Comments:</td></tr>
<tr><th colspan="2">RISK/BENEFIT ANALYSIS</th></tr>
<tr><td>▪ The research does involve subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with intellectual disabilities or economically or educationally disadvantaged persons.

If YES, the research plan does include additional safeguards to protect their rights and welfare.

☐ Yes ☐ No</td><td>▪ The risks described in the narrative adequately cover all of the study risks and are consistent with the consent document.
▪ Risks to subjects will be minimized by using procedures which are consistent with a sound research design, are already being performed on the subjects for diagnostic or treatment purposes, and which do not unnecessarily expose subjects to risk.

☐ Yes ☐ No</td></tr>
<tr><td>Comments:</td><td>Comments:</td></tr>
</table>

RISK/BENEFIT ANALYSIS	
Risks to subjects are reasonable in relation to both: ▪ Anticipated benefits, if any, to subjects; and ▪ The importance of the knowledge that may reasonably be expected to result. ☐ Yes ☐ No	▪ Risks are relatively non-existent. ▪ Potential direct benefit to subjects or societal benefit included Acceptable risk/benefit relationship. ☐ Yes ☐ No
Comments:	Comments:

Risk Assessment:
*** Risks** include possible physical, psychological, economic, social, and legal harms.

☐ Virtually no risk [Exempt Registration]
If **Exempt**, *please indicate corresponding category(ies)*: _____

☐ Greater than Minimal Risk [Full Committee review]

☐ No more than Minimal Risk [Expedited review]

If **Expedited**, *please indicate corresponding category(ies)*: _____

Please provide a brief rationale for your risk assessment if the research requires Expedited.

Expedited Review Research Categories

- **Exempt review**, please check the appropriate **exempt category(ies).** Listed below.
- **Expedited review**, please check the appropriate **expedited category(ies)** Listed after exempt categories.

☐ **Exempt Proposal - Categories**

☐	1	**Educational Settings** ▪ Conducted in established educational settings. ▪ Involves normal practices not likely to adversely affect student learning or teacher evaluation. ▪ **Examples:** instructional strategies, curricula, classroom management.
☐	2	**Educational Tests, Surveys, Interviews, Public Observation** ▪ Includes cognitive/diagnostic/aptitude/achievement tests, surveys, interviews, or public behavior (including recording). ▪ Exempt if one of the following is met: • Data not identifiable. • Disclosure would not place subjects at risk. • Identifiable data with limited IRB review §46.111(a)(7). • The research is not subject to FDA regulations and does not involve prisoners as subjects.
☐	**3**	**Benign Behavioral Interventions (Adults Only)** ▪ With consent, information may be collected via responses or audiovisual recording. ▪ Exempt if one of the following is met: ▪ Data not identifiable. ▪ Disclosure would not place subjects at risk. ▪ Identifiable data with limited IRB review (§46.111(a)(7)). ▪ Interventions must be brief, harmless, painless, non-invasive, and not offensive/ embarrassing. ▪ **Examples:** online games, puzzles under noise conditions, small cash allocation tasks.
☐	4	**Secondary Research (Consent Not Required)** ▪ Use of identifiable private information or biospecimens if one of the following is met: • Sources publicly available. • Data recorded without identifiers, with no re-identification or contact. • Use regulated under HIPAA (operations, research, public health). • Conducted by/for a Federal agency under applicable laws (E-Government Act, Privacy Act, Paperwork Reduction Act).
☐	5	**Public Benefit/Service Programs** ▪ Federally conducted/supported or agency-approved projects studying, evaluating, or improving public programs. ▪ Includes: procedures, alternatives, or payment methods. ▪ Must be listed on a publicly accessible Federal website before human subjects research begins.
☐	6	**Taste and Food Quality Studies** ▪ Wholesome foods without additives, or ▪ Foods/ingredients/chemicals/contaminants deemed safe by FDA, EPA, or USDA.

Note: There are two additional Exemptions 7 & 8, they both require Broad Consent, which TCCD does not permit.

☐ **Expedited Review Research Categories**

☐	1	**Clinical Studies of Drugs/Devices** ▪ Drugs: No IND required (not including studies that increase risk of marketed drugs). ▪ Devices: No IDE required or cleared/approved devices used per labeling.
☐	2	**Blood Collection** ▪ Healthy, nonpregnant adults ≥110 lbs.: ≤550 ml in 8 weeks; ≤2 times/week. ▪ Other adults/children: ≤50 ml or 3 ml/kg in 8 weeks; ≤2 times/week in an 8-week period and collection may not occur more frequently than 2 times per week.
☐	3	**Prospective Biological Specimen Collection (Noninvasive)** ▪ **Examples:** hair/nail clippings, deciduous/permanent teeth (if routine care), saliva, placenta, amniotic fluid (during labor), dental plaque, buccal/skin cells, sputum, excreta/secretions.
☐	4	**Noninvasive Data Collection (Routine Clinical Practice, No Anesthesia)** ▪ Devices must be cleared/approved; excludes x-rays/microwaves. ▪ **Examples:** physical sensors, weighing/sensory tests, MRI, ECG, EEG, ultrasound, thermography, doppler flow, exercise/strength/flexibility tests.
☐	5	**Use of Existing Materials** ▪ Data, documents, records, or specimens collected for non-research purposes (e.g., treatment or diagnosis). **NOTE:** Some research in this category may qualify for Exempt Registration under Category 4.
☐	6	**Audio/Visual/Digital Recordings** ▪ Collection of data from voice, video, digital, or image recordings for research.
☐	7	**Research on Characteristics or Behavior** ▪ Includes studies on perception, cognition, motivation, identity, communication, culture, or social behavior. ▪ May use surveys, interviews, focus groups, oral histories, program or quality evaluations. **NOTE:** Some research in this category may be Exempt Registration under Categories 2 and 3.
☐	8	**Continuing Review (Previously Approved by IRB)** ▪ Enrollment closed, all interventions complete, long-term follow-up only; or ▪ No subjects enrolled and no new risks identified; or ▪ Remaining activities limited to data analysis.
☐	9	**Continuing Review (Minimal Risk, No IND/IDE, Not in Categories 2–8)** ▪ IRB determines minimal risk and no additional risks at convened meeting.