Tarrant County College District

Institutional Review Board
Reviewer's Modifications Request Checklist
(Form used by the IRB to review proposals)

Research Proposal Title: _____

Principal Investigator: _____ **IRB#** _____

Review Type: ☐ Exempt ☐ Expedited ☐ Full Committee

TCCD IRB Reviewer: _____ **Date of Last IRB Review:** _____

HUMAN RESEARCH PROTECTIONS CHECKLIST

Last Approved Research Proposal	YES ☐	NO ☐		If yes, attach one copy of last approved proposal, with any deletions highlighted.
Revised/Amended/Modified Proposal	YES ☐	NO ☐		If yes, attach one copy of revised/amended proposal with any revisions or amendments highlighted.
Last Approved Consent Form(s)	YES ☐	NO ☐		If yes, attach one copy of the last approved consent form(s) with any deletions highlighted.
Revised Consent Document Provided	YES ☐	NO ☐	N/A ☐	If yes, attach one copy of revised/amended consent form(s) with any revisions or amendments highlighted. If the modification involves significant new findings that may affect a subject's willingness to participate, a revised consent form/letter of notification is required.
Special Populations Added and Identified	YES ☐	NO ☐	N/A ☐	If vulnerable populations are used, **Vulnerable Populations Form** is required (Children/Prisoners/ Women, Human Fetuses, Neonates).

<table>
<tr><td colspan="4">Significant New Findings (If the modification request appears to involve significant new findings that may relate to participants' willingness to continue in the research; if not already addressed, contact the researcher to see how they plan to notify participants and to obtain the revised consent form/letter/etc.):</td></tr>
<tr><td rowspan="6">Does this modification request involve significant new findings that should be provided to participants?</td><td>YES ☐</td><td>NO ☐</td><td></td></tr>
<tr><td colspan="3">If yes,
a. Check below to specify who should be notified of these new findings.</td></tr>
<tr><td colspan="2">☐</td><td>Current participants.</td></tr>
<tr><td colspan="2">☐</td><td>Participants who completed the study since the new findings have long term implications.</td></tr>
<tr><td colspan="2">☐</td><td>Other, please specify:</td></tr>
<tr><td colspan="3">b. Specify how the researcher should notify subjects of this information (i.e., revised consent, letter, etc.)
Specify:</td></tr>
<tr><td colspan="4">INCLUDE THIS QUESTION IF A NOTIFICATION DOCUMENT <u>WAS</u> PROVIDED:</td></tr>
<tr><td>The researcher has provided the following as a plan for notification of subjects of significant new findings. Is the researcher's plan adequate? (Provide summary of the plan – i.e., who the LR plans to notify and how. Also provide a copy of the notification document).</td><td>YES ☐</td><td>NO ☐</td><td>If no, specify what needs to be changed.</td></tr>
</table>

ADMINISTRATIVE COMMENTS

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 language missing from consent.)

REVIEWERS:

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**

Criteria for IRB Review and Approval of Modification

Please review the federal criteria for IRB approval and indicate whether the research meets each criterion by checking the appropriate box. Please document **each** concern that you would like to be communicated to the researcher in the corresponding comments box or in the open space below.

Risk*/Benefit Assessment		**Yes**	**No**	**NA**	**Reviewer's Comments/Notes**
1	The change in the research protocol alters the risk to subjects, but the risk to benefit ratio is still acceptable.	☐	☐	☐	
2	Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	☐	☐	☐	
3	Risks to subjects will be minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	☐	☐	☐	
4	Risks to subjects are still reasonable in relation to both: 1. Anticipated benefits, if any, to subjects. 2. The importance of the knowledge that may reasonably be expected to result.	☐	☐	☐	
5	Risks to subjects are reasonable in relation to both: 1. Anticipated benefits, if any, to subjects. 2. The importance of the knowledge that may reasonably be expected to result.	☐	☐	☐	
Informed Consent Process		**YES**	**NO**	**N/A**	**Reviewer's Comments/Notes**
6	The change in the research protocol prompts a change in the consent document and the consent form has been adequately revised to reflect the change.	☐	☐	☐	
7	The change in the research protocol involves significant new findings that may affect a subject's willingness to continue participation. **If yes,** subjects already enrolled in the study should be notified of these new findings.	☐	☐	☐	**Note:** If yes, IRB approval letter should document that re-consent (or other method of notification) is required for subjects already enrolled.

8	Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with, and to the extent required by 45 CFR §46.116 and §46.117, and 21 CFR §50 and §50.27 as applicable.	☐	☐	☐	
Additional Criteria for IRB Review and Approval		**YES**	**NO**	**N/A**	**Reviewer's Comments/Notes**
9	Selection of subjects is equitable.	☐	☐	☐	
10	When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	☐	☐	☐	
11	When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	☐	☐	☐	

Risk Assessment: If approved, would the proposed modifications change the risk of harm to subjects?

☐ The changes present no more than Minimal Risk [Expedited review]

☐ The changes present greater than Minimal Risk [Full Committee review]

Please provide a brief rationale for your risk assessment – Full Committee or Expedited review.