Level of Review: Full Expedited

Tarrant County College District
Institutional Review Board
Modification Request Checklist

IRB# : **Researcher:**

Title: **Reviewer:**

HUMAN RESEARCH PROTECTIONS - ADMINISTRATIVE CHECKLIST

All Necessary Documents Provided YES ☐ NO ☐

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 YES ☐ NO ☐

If yes, additional form (Vulnerable Populations) required:

N/A ☐

Date of Last IRB Review Date:

ADMINISTRATIVE QUESTIONS AND NOTES

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.):

1. Does this modification request involve significant new findings that should be provided to participants?

   YES ☐ **NO** ☐

   If **YES:**

   a. Check below to specify who should be notified of these new findings.

      ☐ **Current participants**

      ☐ **Participants who completed the study since the new findings have long term implications**

      ☐ **Other, please specify:**

b. Specify how the researcher should notify subjects of this information (i.e., revised consent, letter, etc.)

SPECIFY:

INCLUDE THIS QUESTION IF A NOTIFICATION DOCUMENT <u>WAS</u> PROVIDED:

2. 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)**

YES ☐ **NO** ☐ **(Specify what needs to be changed):**

MAJOR CONCERNS

MINOR ISSUES

REVIEWERS:

A. Please review the federal criteria for IRB approval as they relate this modification request and indicate whether the research still meets each criterion by checking the appropriate box. List any concern that you would like communicated to the researcher in the corresponding comment box or in the open space below.

CRITERIA FOR IRB REVIEW AND APPROVAL OF MODIFICATION			
			COMMENTS or JUSTIFICATION *(required)*
1	I, the IRB reviewer, have a conflict of interest on this protocol.	☐ YES ☐ NO	*If yes, contact IRB Chair.*
Risk/Benefit Assessment			
2	The change in the research protocol alters the risk to subjects, but the risk to benefit ratio is still acceptable.	☐ YES ☐ NO ☐ N/A	
3	Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	☐ YES ☐ NO	

4	Risks to subjects will be minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	☐ YES ☐ NO ☐ N/A	
5	Risks to subjects are still 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	
Informed Consent Process			
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.	☐ YES ☐ NO ☐ N/A	
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.	☐ YES ☐ NO ☐ N/A --- ☐ YES ☐ NO ☐ N/A	*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.	☐ YES ☐ NO ☐ N/A	
Additional Criteria for IRB Review and Approval			
9	Selection of subjects is equitable.	☐ YES ☐ NO ☐ N/A	
10	When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	☐ YES ☐ NO ☐ N/A	
11	When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	☐ YES ☐ NO ☐ N/A	

B. 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.

C. IRB Recommendation:

- ☐ Approve
- ☐ Minor Changes
- ☐ Tabled to full Committee
- ☐ Tabled to Subcommittee
- ☐ Disapprove

D. IRB Review cycle: ☐ Current review cycle ☐ 6 mos.* ☐ 3 mos.* ☐ Other*:

* Please provide a rationale below if recommended review cycle is less than 12 months.

Additional Comments [optional]:

Reviewer's Signature:

Date:

Note: The information provided on this form may be preliminary and may not necessarily reflect the discussion and final decision and/or recommendation of the full IRB committee.