REQUEST FOR CONTINUATION/CHANGE FORM Tennessee Tech University Institutional Review Board for the Protection of Human Subjects

Instructions: This form should be completed for requests for continuation of and/or changes to <u>an approved</u> IRB application. <u>This form should only be used if the original, approved application use the NEW Application for</u> **Research Involving Human Subjects.**

Changes: This form should be completed if the PI wishes to change any aspect of the research outlined in a IRB application that was certified as Exempt or approved through Expedited Review or Full Board Review. This application must be approved before the research proceeds with the requested changes.

Continuation: For projects that received IRB approval *only through Expedited Review or Full Board Review* that continue for more than 12 months, the PI must complete, sign, and submit this application for review and approval of project continuation. This application must be submitted no later than <u>one week</u> prior to the expiration of the initial 12-month approval.

Do not staple documents; print one-sided. Handwritten applications will not be accepted. Submit this application and all supporting documents to the Office of Sponsored Programs: Campus mail (Box 5164); scan & email (irb@tntech.edu); or in person (Derryberry Hall, Room 432). For additional information, please visit the TTU IRB website or email the IRB Chair, Dr. Chad Rezsnyak (crezsnyak@tntech.edu)

Please select the type of request(s) being made:

Request for <u>Continuation</u> for an IRB Application approved through Expedited Review or Full Board Review (Complete Sections I, II, and III)

Request for <u>Changes</u> to an IRB Application certified for Exempt Status or approved through Expedited Review or Full Board Review (Complete Section I, II, and IV)

SECTION I: CURRENT PROJECT INFORMATION

This information should be identical to the Cover Page and Part B on the approved Application for Research Involving Human Subjects.

Project Title:

Principal Investigator (PI):		Student: Yes 🗌 No 🗌		
PI's Dept:		PI's Email:		
Co-Investigators				
1.	Dept.	Student: Yes 🗌 No 🗌		
2.	Dept.	Student: Yes 🗌 No 🗌		
3.	Dept.	Student: Yes 🗌 No 🗌		
4.	Dept.	Student: Yes 🗌 No 🗌		
5.	Dept.	Student: Yes 🗌 No 🗌		
6.	Dept.	Student: Yes 🗌 No 🗌		
If PI is a student:				

Dept.

Faculty Supervisor:

Email:

Information from original approval email from the Research Office:

Original Approval Date: mm/dd/yyyy

Application #:

SECTION II: STATEMENT OF COMPLIANCE

This section addresses the state of the project since the initial approval date.

1. Indicate to what extent all procedures described in the current project are being/have been followed:

2. Total number of subjects involved in the project to date or, if existing data study, number of individuals whose records have been obtained.

3. Listing of any adverse events or unanticipated problems. If none, state so.

4. Number of subjects who withdrew and the reason(s) (if known) for withdrawal. If none, state so.

5. Listing of any complaints regarding the project. If none, state so.

6. Discussion of any new information (such as recent literature, interim findings, etc.) since the last IRB approval that may affect the assessment of the risks or benefits or possibly impact any participant's willingness to continue to take part in the research. If none, state so.

7. Discuss any changes to the project that have been implemented without being approved by the IRB. If none, state so.

8. Address whether data are still being collected.

9. Provide information about any activities in the original application that have not yet been completed.

SECTION III: CONTINUATION REQUEST: RENEWAL INFORMATION

Complete this section only if requesting an extension to the original end date of an application approved through Expedited Review or Full Board Review

New	End	Date	Req	uested:
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12 month after renewal

Less than 12 month after renewal: (Specify: mm/dd/yyyy)

SECTION IV: REQUEST FOR CHANGE TO PREVIOUSLY APPROVED APPLICATION

Complete this section only if changes to an original application certified for Exempt Status or approved through Expedited Review or Full Board Review are being requested.

Basic Summary of Requested Changes

Summarize the changes to the current project and the reason for each change.

Specific Changes

Are changes applicable to the following Parts of the Application for Research Involving Human Subjects?

1. Addition of Co-Investigators Yes

No

If yes, please provide the first and last name, department, email address, and whether she or he is faculty, staff, or student. (If the additional Co-PI is not affiliated with Tech, please include her or his university/organizational affiliation.)

NOTE: A certificate of completion of CITI training must also be submitted for each new Co-PI.

2. Removal of Co-Investigators

Yes No No

If yes, please provide the first and last name of the Co-PI being removed.

3. Change to the Data Collection Method or Medium

Yes 🗌 No

If yes, explain the change(s) and reason(s) for the change(s).

4. Change to the Role of Participants

Yes 🗌 No

If yes, explain the change(s) and reason(s) for the change(s).

5. Change to the Research Instrument(s) (e.g., survey, interview protocol)

Yes 🗌 No

If yes, explain the change(s) and reason(s) for the change(s).

NOTE: If changes are made to the research instrument(s), include with this application a copy of the revised research instrument(s).

6. Change to the Number of Participants or Target Population

 □ Yes
 □ No

If yes, explain the change(s) and reason(s) for the change(s).

7. Change to the Recruitment Procedures ☐ Yes ☐ No

If yes, explain the change(s) and reason(s) for the change(s).

8. Change to the Costs, Compensations, or Incentives
 ☐ Yes
 ☐ No

If yes, explain the change(s) and reason(s) for the change(s).

9. Change to the Risks or Risk Management Procedures □ Yes □ No

If yes, explain the change(s) and reason(s) for the change(s).

10. Change to the Confidentiality, Anonymity, or Privacy
 ☐ Yes
 ☐ No

If yes, explain the change(s) and reason(s) for the change(s).

11. Change to the Informed Consent Process or the Informed Consent Form.

Yes
No

If yes, explain the change(s) and reason(s) for the change(s).

NOTE: If changes are made to the Informed Consent Form, include with this application a copy of the revised Informed Consent Form.

12. Change to Any Aspect of a Secondary Data Analysis.

Yes

🗌 No

If yes, explain the change(s) and reason(s) for the change(s).

In signing this, I certify that the information in this application is accurate and the research outlined in this application will be conducted <u>only</u> in accordance with the approved application.

Principal Investigator:

Typed Name:

Signature/ Date: _____

Faculty Supervisor, if PI is a student: Typed Name:

Signature/ Date: _____