HT Institutional Review Board Continuing Review Request

Huston-Tillotson University Research Standards Committee and Institution Review Board requires an annual review of continuing projects at least once per year. This review must take place on or before the one-year anniversary of the IRB review, regardless of when the research project itself began. Investigators must also report to the HT IRB any planned changes in the protocol of the study because these may affect the protection of human research participants.

Study:

Principal Investigator: **Approval Type:** Expedited Full-Board

Faculty Sponsor (If applicable):

Initial IRB review date: **Last IRB review date:**

Is your IRB approval still current:

Please complete the following items as they apply to your project during the period following your last IRB review. If this study is no longer being conducted, submit a closure request.

1. Has the research begun?

   Yes No

2. Is enrollment of subjects ongoing?

   Yes No

3. Date that first subject was enrolled (mm-dd-yyyy or mm/dd/yyyy format):

4. The most recently IRB-approved number of subjects IRB for this study is:

_____ Total number actually enrolled as of this date

_____ Total Cumulative Number of subjects that have withdrawn or dropped out

_____ Total Cumulative Number of subjects that have dropped out because of unanticipated problems (should match previously submitted adverse events / unanticipated problem forms)

Why did participants withdraw or drop out? Please summarize below:

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5. Have you've been notified of any complaints issued about the research?

   Yes No

   If yes, please include a brief summary.

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6. Have you been notified of, or have any participants experienced any harm?

   Yes No

   If yes, then since the last IRB review, has the profile of harm experienced by participants in terms of frequency, severity, or specificity been different than expected?

   Yes No

   If yes, please include a summary of the differences.

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7. Are Study interventions or data collection (e.g. Surveys, questionnaires, etc) ongoing?

   Yes No

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consent type:

8. You stated in your original IRB application that Informed Consent would be obtained for this study.

9. Was consent obtained for all subjects?

   Yes No

10. Did all subjects receive a copy of the signed consent form?

    Yes No

11. Where are signed consent forms stored (bldg and room number)?

12. Did you encounter any problems in obtaining consent?

    Yes No

    If yes, please describe.

13. The IRB **has not approved** any amendments to this study during the **past** IRB approval year.

Please document if changes have **ALREADY** occurred (and not yet reported) to the following:

Protocol?
Consent?
Questionnaires?
Study Interventions?
New Investigators/Consent obtainers?
New/Changed DRC or Faculty Sponsor?

If you plan to submit **NEW/PROPOSED AMENDMENTS (not listed above)** with this continuing review, complete an amendment using the IRB amendment form

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14. Has any new scientific information (such as recently identified risks of participating in research of this type or new treatment/alternative approaches) been found since the last IRB approval?

    Yes No

    Please upload a description of this new information. Please describe how the risk to subjects in your study may be affected by these findings.

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15. Has any new literature been published since the last review that is relevant to your research?

    Yes **No**

    If yes, please attach a brief description.

The IRB **has not received** any unanticipated problem reports for this study during the **past** IRB approval year.

16. For the following three items below, please summarize ALL unanticipated problems (previously reported AND not yet reported) associated with this study:

    1. Total Cumulative Number of unanticipated problems:
    2. Total Cumulative Number of anticipated problems:
    3. Total Cumulative Number of deaths:
    4. Were the events listed above promptly reported to the IRB? Yes No

       If no, please explain:

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17. Please provide a summary of participant benefits:

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18. If participant benefits or risks have changed since last review, please describe:

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19. Has a data safety monitoring board been established? Yes No

    If yes, please list the significant findings of the board:

    If yes, was the safety monitoring plan complied with? Yes No

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20. If this is a multi-site study, have there been any multi-center trial reports since the last IRB review? Yes No

If yes, please attach/upload a copy of all multi-center trial reports and multi-site IRB letters of approval.

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21. Since the last IRB review, have there been any interim findings from the research?

    Yes No

    If yes, please summarize (in 8 lines or less) INTERIM study ACTIVITIES and FINDINGS to date Or, attach a brief summary of the interim findings.

Required: : Don't forget to include a current copy of the study proposal, current consent forms, and all other additional documents and materials, including questionnaires, payment, schedules, recruitment materials, and scripts. HT asks for your most current copies of these documents - even if they have not changed.
