**Procedures and regulations:**

Applications approved with a full board review are valid for a period of time not to exceed twelve (12) months. The TBR IRB shall conduct continuing review of research requiring a full board IRB review at intervals appropriate to the degree of risk, but not less than once per year. (Procedures, §VII.I.) All modifications to the research project must receive the TBR IRB approval before they are implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subject. (Procedures, §II.C.3, 45 CFR 46.108(a)(3), 21 CFR 56.108(a)). Implementing changes without IRB approval may violate federal regulations and the TBR IRB Procedures and can lead to the suspension of IRB approval and other consequences. Any proposed changes must fit within the original aims and scope of the study; otherwise, a new application must be submitted for IRB approval.

Requests to renew IRB approval should be submitted at least four (4) weeks before the expiration date listed on the original Form A Cover Sheet to allow for continuing review by the TBR IRB. Requests to review proposed modifications should be submitted at least eight (8) weeks before the TBR IRB approval expires.

**Instructions:** If your application requests continuing review without modification, complete Part A and Part B of this form and attach a copy of the approved TBR IRB application. If your application requests continuing review with any modifications, complete Part A and Part C, providing the reasons for all proposed changes, and attach a copy of the approved TBR IRB application. If the changes affect the study protocol (e.g., changes to procedures or inclusion/exclusion criteria) or other documents (e.g., informed consent form), also submit the revised protocol and any other revised study documents.

Please type detailed responses in the gray boxes below. Do not leave any boxes blank (unless the entire section is not applicable). Please submit completed Form D with a copy of the approved TBR IRB application to IRB@tbr.edu. Consolidate all supporting documentation into a single PDF document, but please submit Form D as a signed PDF document separately.

**Part A. Information on the project previously approved by TBR IRB**.

**Project Title**:

**Principal Investigator**:

**Date of the initial TBR IRB approval**:

**TBR IRB Approval Number**:

**Are any modifications/changes being proposed for this study?**

No [ ]

Yes [ ]

If you answered No, please complete Part B. If you answered Yes, please complete Part C.

**Part B. Request for renewal without modification.**

Complete this part if you request renewal without modification. Do not complete Part C.

Please type below your request for the renewal of the previously approved application and, if the original application was for a year or less, provide reasons for extending the study beyond 12 months. Briefly describe the progress and the current status of the approved research project and include the new projected end date of the study.

|  |
| --- |
| **NOTE: This section is to be completed by the TBR IRB Chair (co-Chair).** |
| **Approved for renewal without modification** [ ]  |
| Name: Signature: Date:  |

-------------------------------------------------------------------------------------------------------------------------------

**Part C. Request for renewal with modifications.**

Complete this part if you request review with modification(s). Do not complete Part B.

**What modifications are being proposed to the study?**

Investigator(s) [ ]

Study population(s) [ ]

Research site(s) [ ]

Sampling procedure(s) [ ]

Study objective(s) and/or hypothesis [ ]

Research method(s) [ ]

Data storage/protection/destruction procedure(s) [ ]

Handling of personally identifiable information [ ]

Survey instrument(s) [ ]

Interview procedure(s) /guide [ ]

Focus group procedure(s) / guide [ ]

Informed consent documentation or procedure(s) [ ]

Any other supporting documents [ ]

None of the above [ ]

Please explain all proposed modifications, provide rationale for these changes, and attach supporting documentation. Use as many details as necessary for the IRB members to make an informed decision about the required level of IRB review. For each modification, list the expected impact on the protocol, subject safety, and informed consent, if applicable.

|  |
| --- |
| **NOTE: This section is to be completed by the TBR IRB Chair (co-Chair).** |
| **Approved by TBR IRB Chair:** [ ]  | **Approved via Expedited or Full Review:** [ ]  |
| Name: Signature: Date:  | Name: Signature: Date:  |

**In signing this, I certify that the information in this form is accurate and that the research outlined in this Renewal and Modification Form will be conducted only as approved by the TBR IRB. I acknowledge that changes to this research protocol may not be implemented until approved by the TBR IRB.**

**Principal Investigator:**

Typed Name:

Signature/ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_