**Instructions:** Please use this checklist as a helping tool to determine whether the proposed study may involve human subject research, which must be reviewed by an IRB. A formal determination should be done in consultation with the TBR IRB. If written confirmation of non-human subject determination is required, please submit this checklist with Part B completed in full to the TBR IRB at IRB@tbr.edu. The TBR IRB chair’s signature at the end of completed Part B will serve as formal written confirmation of non-human subject determination.

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**Part A. Is the proposed study/project human subject research? Check a box for Yes.**

***Panel 1: Is it research?***

Is the project designed to test/generate a hypothesis/theory or answer a research question? [ ]

Can the research question(s) be only answered using systematic investigation? [ ]

Will the study contribute to generalizable knowledge / knowledge beyond the individual study? [ ]

Does the project fall outside quality improvement, program evaluation, or case reports? [ ]

Does the project fall outside scholarly/journalistic activities focusing on specific individuals, public health surveillance, data collection for criminal investigation, intelligence/national security activities? [ ]

***Panel 2: Is it human subject research?***

Does the study involve living individuals? [ ]

Will the study collect private information that is individually identifiable? [ ]

Will the study collect data via intervention or interaction with the individuals? [ ]

Is the focus on experiences, opinions, perceptions, characteristics, or behavior of individuals? [ ]

Will the study manipulate the behavior or environment of individuals? [ ]

Will the study be more than solely observational in nature? [ ]

Will observation occur in a private setting or when privacy is reasonably expected? [ ]

Does the study involve more than analysis of aggregate data or secondary data analysis? [ ]

**NOTE**: If you checked at least one box in both Panel 1 and Panel 2, then consult with the TBR IRB, as your study ***may*** involve human subject research as defined by federal law.

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**Part B. Complete for a formal confirmation of non-human subject research status.**

**Project Title:**

**Principal Investigator (PI):**

**PI’s Dept.:**       **PI’s Email:**

**Projected Dates of the Study:** **Start:**       **End:**

**Describe your project (under 500 words). State the project’s intent and objectives, and, if applicable, research question(s) or hypotheses. Describe the type of information to be collected, data collection method(s), and, if applicable, study population(s) or survey respondents.**

**In signing this, I certify that the information provided in Part A and Part B of this checklist is accurate and the project will be conducted only as described.**

**Principal Investigator:**

Typed Name:

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

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| **NOTE: This section is to be completed by the TBR IRB Chair (co-Chair).** |
| As described in Part A and Part B above, this study is determined to be non-human subject research [ ]  |
| Name: Signature: Date:  |