**NIH/NCATS Prior Approval Checklist (for Applications)**

1. **Does your study involve human or animal subjects?**

Human subjects [ ]

Animal subjects [ ]

None of the above [ ]

Not sure [ ]

1. **What regulatory approvals will be required to perform the proposed research?**

Involvement of Human Subjects (IRB) [ ]

Use of Recombinant DNA (IBC) [ ]

Use of Human Embryonic Stem Cells [ ]

Use of Vertebrate Animals (IACUC) [ ]

None of the above [ ]

Not sure [ ]

**2a. If human subjects are involved, does your study involve them exclusively in one or more of the following categories, which may qualify for Institutional Review Board (IRB) exemption?**

*Please check all applicable categories below, then answer Yes, No, or Not sure at the end.*

1. Research that involves normal educational practices that are not likely to adversely impact students' opportunity to learn or the assessment of educators who provide instruction. [ ]
2. Research that involves educational tests, survey procedures, interview procedures, or observation of public behavior that do not place the human subjects at risk. [ ]
3. Research that involves benign behavioral interventions in conjunction with the collection of information from consenting adults that do not place them at risk. [ ]
4. Research that involves secondary analysis of publicly available or de-identified private information or biospecimens for which consent is not required. [ ]
5. Federally-supported or -conducted research and demonstration projects that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. [ ]
6. Research that evaluates taste and food quality and studies consumer acceptance. [ ]
7. Storage or maintenance of identifiable private information or biospecimens for secondary research use for which broad consent is required. [ ]
8. Research involving the use of identifiable private information or biospecimens for secondary research use for which broad consent is required. [ ]

**Does your study involve exclusively the types of human subjects research listed above?**

Yes [ ]

No [ ]

Not sure [ ]

**If Yes,** your study may qualify for IRB exemption. Please consult with the IRB for confirmation and further instruction

**2b. If human subjects are involved, does the proposed research meet the NIH definition of a clinical trial?**

*A clinical trial, as defined by the NIH, is a research study that prospectively assigns human participants to one or more health-related interventions to evaluate the effects of those interventions on health outcomes.*

Yes [ ]

No [ ]

Not sure [ ]

**2c. If the proposed study meets the NIH definition of a clinical trial, what is the clinical trial phase of it?**

Early Phase-Phase 2b (i.e. trials that are a combination of Phases 2 and 3) [ ]

Phase 3-4 [ ]

1. **Does the proposed research involve a foreign component, as defined by NIH?**

*A foreign component, as defined by the NIH, refers to any significant research activity that takes place outside of the United States, which may include collaborations with foreign institutions, the use of resources or facilities located in a foreign country, or the involvement of foreign personnel in a project. This definition encompasses both the performance of research and the collection of data in a foreign setting.*

Yes [ ]

No [ ]

Not sure [ ]

 **If Yes**, please provide a description of the foreign component, including the role of any foreign collaborators or sites.

**If Not sure**, please describe any potential involvement of foreign entities or resources that may apply.

Description: