NCCIH Regulatory Tracking Form (*4/24/2020 version*)

This form should be completed by the NCCIH grantee to accompany the response to the NCCIH Clarification Letter for studies that propose the use of FDA- or DEA-regulated products. This form should not be submitted to the NCCIH Program Officer until all pertinent information and supportive documentation are available.

Principal Investigator:

Grant Number:

Grant Title:

Study Name (if applicable):

1. List all study product name(s) of FDA-regulated drug(s), device(s) or vaccines proposed by the grant.

2. Have you contacted the FDA to inquire about IND/ IDE requirements? **Y** ☐ **N** ☐

If No, please initiate discussion with the FDA.

3. Has the FDA indicated that an IND/ IDE is required for the study compound(s)? **Y** ☐ **N** ☐

If No: submit a date stamped Exemption letter from the FDA indicating that an IND/ IDE is not required for the study-specific use/ indication with this completed form.

Note: in general, an IDE is required ONLY for high risk medical devices.

If Yes (IND/ IDE Required): **complete Questions 4-9**. Please submit copy of FDA Acknowledgment Letter with the completed form.

4. How many IND/ IDE applications are associated with this grant?
5. Is the study being conducted under a pre-existing IND/ IDE in an amended filing? **Y** ☐ **N** ☐
   If **Yes,** what is the existing IND/ IDE number?

6. Will the proposed study be conducted via a **new** IND/ IDE filing? **Y** ☐ **N** ☐
   If **Yes,** what is the **new** IND/ IDE number?

7. Who will serve as the IND sponsor?

8. Was the new or amended IND/ IDE filing placed on clinical hold? **Y** ☐ **N** ☐
   If No: The IND/ IDE filing is accepted by FDA if a clinical hold is not issued within the 30-day submission period.
   If Yes: What are the additional requirements?

9. Will the FDA require additional pre-clinical testing prior to allowing human studies to commence? **Y** ☐ **N** ☐

Complete this section *ONLY* if the grant proposes use of controlled substances (Schedules I-V) that are regulated by the DOJ/ DEA. The complete list of scheduled controlled substances can be found at: https://www.dea.gov/drug-scheduling

10. List the controlled substances that will be used in the grant and the assigned Schedule (I-V) for each substance

11. Identify the individuals who will serve as the responsible entities for the controlled substances used in the award.

Responsible Individual(s):

Facility *(Must be listed for Schedule I controlled substances*):