NCCIH Regulatory Tracking Form:
Investigational New Drug Application (IND)

Version 3/23

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)*: _____

		Yes	No
1.	**List all study product name(s) of FDA-regulated drug(s) proposed by the grant:**		
2.	**Have you contacted the FDA to inquire about IND requirements?** ***If No:*** *Please initiate discussion with the FDA.*	☐	☐
3.	**Has the FDA indicated that an IND is required for the study compound(s)?** ***If No****: Submit a date stamped Exemption letter from the FDA indicating that an IND is not required for the study-specific use/ indication with this completed form.* ***If Yes (IND Required):*** *Complete Questions 4-9. Please submit copy of FDA Acknowledgment Letter with the completed form.*	☐	☐
4.	**How many IND applications are associated with this grant?**		
5.	**Is the study being conducted under a pre-existing IND in an amended filing?** ***If Yes****: What is the existing IND number?*	☐	☐
6.	**Will the proposed study be conducted via a new IND filing?** ***If Yes:*** *What is the new IND number?*	☐	☐
7.	**Who will serve as the IND sponsor?**		
8.	**Was the new or amended IND filing placed on clinical hold?** ***If No:*** *The IND 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?**	☐	☐

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)*: