NCCIH Regulatory Tracking Form:
Investigational Device and Clinical Decision Support Software

Version 3/23/23

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-regulated device or a Clinical Decision Support Software. This form should not be submitted to the NCCIH Program Officer until all pertinent information and supportive documentation is available.

Principal Investigator: _____ **Grant Number:** _____

Grant Title: _____ **Study Name** *(if applicable)*: _____

		Yes	No
1.	**List all FDA-regulated device(s) proposed by the grant including non-significant risk device(s):**		
2.	**Has the IRB of record determined that the project involves a Clinical Decision Support Tool?** *The FDA regulates software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including software that is intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as clinical decision support software). Please refer to the FDA Guidance on Clinical Decision Support Software.*	☐	☐
3.	**Has the IRB of record determined that the project involves a non-significant risk device?**	☐	☐
4.	**Have you contacted the FDA to inquire about IDE requirements?**	☐	☐
5.	**Has the FDA indicated that an IDE is required for the study intervention?** ***If Yes:*** *Provide date-stamped correspondence with the FDA indicating that an IDE is required for the high-risk medical devices.*	☐	☐
6.	**Is the study being conducted under a pre-existing IDE in an amended filing?** ***If Yes:*** *What is the existing IND/ IDE number?*	☐	☐
7.	**Will the proposed study be conducted via a <u>new</u> IDE filing?** ***If Yes:*** *What is the new IDE number?*	☐	☐
8.	**Who will serve as the IDE sponsor?**		
9.	**Was the new or amended IDE filing placed on clinical hold?** ***If No:*** *The 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?*	☐	☐
10.	**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.

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

12. **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)*: