FDA CERTIFICATION/FINANCIAL DISCLOSURE FORM

FOR CLINICAL INVESTIGATORS

***Scope:***  The information in this form is required by the FDA for FDA-regulated drug and device studies. This information collected by this form is not the same as the information collected by Emory’s Conflict of Interest Office, and the completed form should not be turned into the Conflict of Interest Office. This form should be provided to the Sponsor or Sponsor-Investigator of the drug or device study when completed.

***Directions:*** This form is to be completed by investigators and sub-investigators who are participating in the conduct of an FDA-regulated clinical investigation except for phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted as multiple sites, treatment protocols and expanded access protocols. This form should be completed by all individuals listed on Form 1572 (drug studies)/investigator agreement (device studies). Sponsor-investigators should collect this form from all participating investigators and sub-investigators at all sites involved in the clinical investigation. Persons completing this form should retain a copy of the completed form for their records. For more information on FDA expectations, see: *Guidance for Clinical Investigators, Industry and FDA Staff, Financial Disclosure by Clinical Investigators*, Feb. 2013 at

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators>

**Sponsor Name**: Click or tap here to enter text.

**Clinical Investigation (“Study”) Name**: Click or tap here to enter text.

**Investigational Product**: Click or tap here to enter text.

**Party(ies) supporting the study**: Click or tap here to enter text.

**Your Name**: Click or tap here to enter text. **Your Institution**: Click or tap here to enter text.

**Indicate by marking YES or NO if any of the financial interests or arrangements of concern to FDA (as described below) apply to you or to your spouse, domestic partner or dependent children. As used in this form, the term “You” includes you, your spouse, domestic partner or dependent children.**

**YES NO** (1) Do You have any arrangements with any sponsor\* of the Study in which the value of

the compensation that You receive from the Sponsor could be affected by the outcome of the Study? For example, an arrangement in which a Study sponsor pays you royalties

that increase if more of the product is sold. *If yes, please describe*: Click or tap here to enter text.

*\*****NOTE****: In answering all of these questions, please note that “sponsor” is not limited to the person or entity that holds an IND or IDE. Rather, “sponsor” means any party supporting the Study at the time it is carried out. For example, if one entity designed the Study, another provided funding, and a third provided a drug being tested in the Study, then all of those entities would be “sponsors” for purposes or questions (1) through (5).*

**YES NO** (2) Do You have any proprietary interest (e.g., a patent, trademark, license, copyright)

in the test article being used in the Study? *If yes, please describe*: Click or tap here to enter text.

**YES NO** (3) Is any sponsor of the Study a private entity that does not sell its stock on the public

stock market? *If yes, please answer question 3a below*.

**YES NO** (3a) Do You now have or do You expect that during the time that the Study is being performed and for one year after completion of the Study, You will have any equity or other ownership interest in the Sponsor? “Completion of the Study” means that at Your site, all study subjects have been enrolled and follow-up of primary endpoint data on all subjects has been completed as described in the protocol.

*If yes, please describe*: Click or tap here to enter text.

**YES NO** (4) Is any sponsor of the study a public company (i.e., it trades its stock on the public

stock market? *If yes, please answer question 4a below*.

**YES NO** (4a) Do You now have or during the time that the Study is being performed and for one year after it is completed, do You expect that You will have any equity or other ownership interest in the Sponsor that is more than $50,000 in value.

*If yes, please describe*: Click or tap here to enter text.

**YES NO** (5): Do You or Your Institution now receive or do you expect that during the time the Study is being conducted and for one year after it is complete, You or Your institution will receive any significant payments of other sorts (SPOOS) that have a cumulative monetary value of $25,000? This could include a grant to You or to Your Institution to fund Your research; the donation to Your Institution of a piece of equipment that you will use in Your research; or payment to You of retainers and honoraria for participating on committees or providing consulting services. In calculating the value of SPOOS, you do not need to include the cost of conducting the Study or amounts the Sponsor pays to your Institution that are not made on Your behalf or targeted to You.

*If yes, please describe*: Click or tap here to enter text.

**CERTIFICATION:**

In accordance with 21 CFR Parts 54.1 and 54.6, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interests and arrangements, or those of my spouse and depended children, change from the information provided above during the course of the Study, or within one year after Completion of the Study, I will notify the Sponsor promptly.

**Signature**: **Date:** Click or tap to enter a date.

This completed form needs to be provided to Click or tap here to enter text, the Sponsor.