

## CONFLICT OF INTEREST (COI) DISCLOSURE FORM CONFIDENTIAL

## NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES

NOTE: In this document the term "you" will be used to indicate applicability to you <u>AND</u> your spouse, dependent children, or any household members or relatives with which you currently have close personal relationships.

### **Instructions:**

- Check the appropriate response for each question. If the answer is "yes" to any question, please provide the additional information as requested.
- You must provide a copy of your current detailed curriculum vitae when submitting this disclosure form.

| А. | PKU | 'FE33 | UNAL |
|----|-----|-------|------|
|    |     |       |      |

| 1. | Are you  |  |
|----|----------|--|
|    | a.<br>b. | directly involved in the conduct of the study to be reviewed? in a direct supervisory relationship with one or more members of the research team; or serving in a  |
|    |          | data and safety monitoring role while being supervised by an individual who is part of the research team?  |
|    | C.       | involved as a plaintiff, defendant, or expert witness in litigation related to the interventions or products being tested, or in competing products or interventions?  |
|    |          | Yes  |
| 2. | -        | serving as a part-time, full-time, paid, or unpaid employee of any organizations that are involved in the study under review (e.g., involved in protocol development or supervise a member of the study team)? |
|    | b.       | whose products or services will be used or tested in the study under review? whose products or services would be directly and predictably affected in a major way by the outcome of the study?                 |
|    |          | Yes No   |
|    |          | ease identify the organization; describe employment status of you or your family member(s) and what products or services would be affected.  |
|    |          |  |
|    |          |  |
|    |          |  |

{NOTE: In the case of an ISM, the individual may be permitted to be an employee of the organization(s)

participating in the clinical trial under review.}



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| 3. | Are you   | Are you currently serving as                      |                        |  |                          |  |  |
|----|---|---|------------------------|--|--------------------------|--|--|
|    | <ul> <li>an officer, member, owner, trustee, director, expert advisor, or consultant of an organization with a<br/>direct role or stake in the study under review?</li> </ul> |   |                        |  |                          |  |  |
|    | b.  | a director, officer or research?                  | other decision-mak     | er for a commercial collaborator of  | the human subjects       |  |  |
|    |   |   | Yes                    | No   |                          |  |  |
|    | If yes, p   | lease provide the nam                             | ne of the organization | on and the role of you and/or your f   | amily member(s).         |  |  |
|    | C.  |   | ator (PI) for the pro  | or anticipate serving as a co-author<br>stocol under review, even if the subj<br>viewed. |                          |  |  |
|    |   |   | Yes                    | No   |                          |  |  |
| 3. | PROPRI  | IETARY  |                        |  |                          |  |  |
| 1. | Do you  |   |                        |  |                          |  |  |
|    | a.  |   |                        | ctual property or tangible materials any product being reviewed; or are                  |                          |  |  |
|    |   | an inventor on pater                              | nts or patent applica  | ations relevant to the product(s) bei  | ng reviewed in the human |  |  |
|    | b.  |   |                        | ompetition with the product(s) bein<br>its or other proprietary rights in any            |                          |  |  |
|    | U.  |   |                        | tition with such products under revi   |                          |  |  |
|    |   |   | Yes                    | No   |                          |  |  |
| c. | FINANC  | CIAL  |                        |  |                          |  |  |
|    |   |   |                        |  |                          |  |  |
| 5. |   | currently receive any r<br>r of the human subject |                        | compensation or honoraria, in any fo   | orm from the commercial  |  |  |
|    |   |   | Yes                    | No   |                          |  |  |
|    | If yes, p   | lease provide the nam                             | e of the commercia     | al sponsor and the type of compensa  | ation.                   |  |  |
| ā. | Do you  |   |                        |  |                          |  |  |
|    | a.  |   | =                      | gle entity whose study is under revi   |                          |  |  |
|    | b.  | have financial interest<br>monitoring responsil   |                        | nizations with which the individual v  | with data safety         |  |  |
|    | c.  | receive payments ba                               | sed on the research    | n recruitment or outcomes; receive   | •                        |  |  |
|    |   | consultant/advisor to sponsor?                    | a commercial spo       | nsor; or accept payment from the h   | uman subjects research   |  |  |
|    |   |   | Yes                    | No   |                          |  |  |
|    | If yes, p   | lease provide the nam                             | ne of the organization | on/commercial sponsor and the type   | e of compensation.       |  |  |
|    |   |   |                        |  |                          |  |  |



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#### Member certification:

- I/my spouse, dependent children, or any household members or relatives with whom I have currently personal
  relationships do not have any financial or other interest with any of the collaborating or competing
  pharmaceutical firms or other organizations involved in the study that constitute a potential conflict of
  interest.
- I will notify DMID promptly if a change occurs in any interests or activities during the tenure of my responsibilities that may create a potential conflict of interest.
- I will disclose interests that may create a potential conflict to the DSMB/SMC prior to any discussion so that they can be reflected in the minutes along with the determination of the DSMB/SMC on how to handle such potential conflict(s).
- I am aware of my responsibilities for maintaining the confidentiality of any non-public information that I receive or become aware of through this activity, and for avoiding using such information for my personal benefit, the benefit of my associates, or the benefit of organizations with which I am connected or with which I have a financial involvement.

| ember Name Printed          | Signature   | Date   |
|-----------------------------|---|--|
| This box for DMID Use ONLY: |   |  |
| DMID review of eligibility: |   |  |
|                             | ict of interest disclosure information provide<br>I the member <b>is eligible</b> to serve as a | d, in addition to the current member at this time. |
|                             | mation provided and find the proposed mem<br>t this time due to an unmanageable potentia        | _  |
| member member a             |   |  |
| member a                    |   |  |