

**CONFIDENTIALITY AGREEMENT**  
*for participation on a NINDS-supported*

This agreement is made by and between the National Institute of Neurological Disorders and Stroke (“NINDS”), part of the National Institutes of Health (“NIH”), an agency of the United States Government and \_\_\_\_\_, a person residing at \_\_\_\_\_ (“Participant”).

WHEREAS, NINDS is either fully or partially supporting a clinical trial to be conducted within its intramural program \_\_\_\_\_ (the “Study”) and has established a to

\_\_\_\_\_ oversee the conduct, safety, and integrity of the Study; and

WHEREAS, NINDS is either overseeing the \_\_\_\_\_ directly or indirectly through its contractor, \_\_\_\_\_; and

WHEREAS, the Study involves the support of [*the company \_\_\_\_\_*] (“Entity”); and [*this is optional*]

WHEREAS, the Participant has the background and expertise necessary to be an active member on the DSMB; and

WHEREAS, the Participant agrees to fulfill his/her duties in accordance with the DSMB Charter, a copy of which is attached as Appendix A; and [*this is optional*]

WHEREAS, a major duty of the Participant is to maintain all confidential information as confidential and NINDS would like to memorialize these obligations below.

NOW, the parties hereto agree as follows:

1. NINDS will disclose and transmit Confidential Information to Participant as necessary to fulfill the functions of the \_\_\_\_\_. “Confidential Information” may include but not be limited to: business, technical, financial, personal and clinical information; intellectual property; reports, drawings, videos; data (raw and/or aggregate); information from the Entity regarding the Study treatment or marketing/strategy of such treatment [*edit this as needed*]; and any other information provided as part of Participant’s duties on the \_\_\_\_\_. Confidential Information may or may not be marked confidential and Participant should maintain information as confidential even if not marked when the confidential nature of such information would be reasonably apparent from the subject matter.
2. Participant agrees to accept the Confidential Information and employ all reasonable efforts to maintain the Confidential Information as secret and confidential, such efforts to be no less than the degree of care employed by Participant to preserve and safeguard his/her own confidential information. Participant will not disclose to, discuss or share Confidential Information with any person or third party *except as permitted under the DSMB Charter [use the italics only if this is discussed under the charter]*.
3. NINDS acknowledges that Participant will not incur any liability merely for examining and considering the Confidential Information; however, Participant agrees that it will not use the Confidential Information for any purpose except as set forth herein and will not use it for his/her personal benefit.

4. Participant's obligations above will not extend to any part of the Confidential Information:
  - (a) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or
  - (b) that can be demonstrated to have been in Participant's possession or that can be demonstrated to have been readily available to Participant from another source prior to the disclosure; or
  - (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Participant; or
  - (d) that can be demonstrated as independently developed or acquired by Participant without reference to or reliance upon such Confidential Information; or
  - (e) that is required to be disclosed by law or court order.
5. Participant's obligations hereunder will begin on the date of last signature below (the "Effective Date"). Participant understands that this obligation of non-disclosure extends beyond his/her participation as a member of the \_\_\_\_\_ as long as the material associated with the review and the substance of any confidential discussions are not within the public domain. If Participant becomes aware that a breach of confidentiality has occurred due to his/her or others' actions, Participant will immediately notify NINDS [*and Entity, if appropriate*] and will assist as requested in mitigating the extent or damage of such disclosure. At the expiration of this agreement, or at the termination of Participant's role on the \_\_\_\_\_, Participant agree to either return or destroy all Confidential Information, as directed by NINDS.
6. All identifiable private information concerning the Study's subjects will be kept confidential indefinitely.
8. It is understood that nothing herein shall be deemed to constitute, by implication or otherwise, the grant to Participant of any license or other rights under any patent, patent application or other intellectual property right or interest belonging to NINDS [*or the Entity*].
9. The illegality or invalidity of any provision of this agreement shall not impair, affect or invalidate the other provisions of this agreement. This agreement constitutes the entire agreement between the parties with respect to the subject matter and supersedes any prior agreements and understandings (whether written or oral). No modification of this agreement will be effective unless made in writing and signed by both parties.
10. The construction, validity, performance and effect of this agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia.
11. [*reserved for additional terms*]

**ACCEPTED AND AGREED**

**National Institute for Neurological Disorders and Stroke**

\_\_\_\_\_  
Avindra Nath, M.D.  
Clinical Director, NINDS

\_\_\_\_\_  
Date

**Notices to:**

Dietrich Haubenberger, M.D.  
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**Participant**

\_\_\_\_\_  
[Printed Name]

\_\_\_\_\_  
Date

Address:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**“Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH” Acknowledgement Form**

NAME:

Primary employer:

I have read the **“Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH”**.

- I do not have a conflict of interest (COI)

*OR*

- I have a real or apparent COI, which has been discussed and will be resolved
  - List COI(s):
  - List resolution:

I acknowledge I cannot participate as a member of a NINDS DSM entity for which I have a COI and agree to immediately disclose any change that creates a real or apparent COI. I will provide information as needed to support an assessment of the potential COI.

By my signature below, I agree that the above statements are accurate and I will comply with the rules set forth in the guide.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_