

Conflict of Interest Certification Data and Safety Monitoring Board (DSMB)

I have carefully reviewed the description of the clinical trials as described in the grant application (and Manual of Procedures [MOP] for a phase III trial) and have used the description to assess whether I have any real or perceived conflicts of interests that could affect my impartiality in serving on this DSMB. I acknowledge that real and perceived conflicts could arise if I have financial or professional relationships with individuals and organizations that:

- a) Are involved in designing or carrying out the study;
- b) Have products or services used or tested in the study; or,
- c) Have products, services, or other financial interests that would be directly and predictably affected by the outcome of the study, including
 - Competitors of the companies involved in carrying out the study, and
 - Companies that provide consulting or other business services related to the design, data analysis, or outcome of the study to those involved in conducting the study, to competitors, or to potential competitors.

1. **To the best of my knowledge and belief:**

I am currently not, nor in the past 12 months have I been a part-time, full-time, one-time, paid, or unpaid employee, consultant, scientific advisor, speaker, researcher, or contractor, of/to the organizations or individuals listed in the grant application (or MOP, if applicable).

I am currently not, nor in the past 12 months have I been, a coauthor or other type of scientific collaborator with the organizations or individuals listed in the grant application (or MOP, if applicable).

I am not negotiating future employment with any individuals or organizations listed in the grant application (or MOP, if applicable) nor do I have an arrangement for future service to these individuals and organizations.

I am currently not, nor in the past 12 months have I been an officer, director, trustee, or general partner of, nor am I otherwise similarly associated with the organizations listed in the grant application (or MOP, if applicable).

I do not have any financial or equity interests in the organizations listed in the grant application (or MOP, if applicable) or any other financial or equity interest that would be affected by the conduct or outcome of the study.

I do not have any intellectual property interests in the study or the organizations listed in the grant application (or MOP, if applicable).

I do not know of any other conflict of interest or apparent conflict of interest that might cause my objectivity as a member of the DSMB to be questioned.

2. **Please check the option below that reflects your status:**

___ I certify to all the above statements and, thus, have NO exception to report.

___ Exception – I will contact the NIDCD's Program Officer regarding this matter.

___ Exception – I have voluntarily chosen to list the exceptions on the attached sheet.

3. I am aware that I am responsible for identifying conflicts of interest and interests that may appear to be conflicts during the tenure of my membership, and:

I will notify the NIDCD's Program Officer promptly if a change occurs in any of the above that may affect my objectivity. In such an event, I will abstain from participation in the Board until instructed otherwise by the NIDCD's Program Officer. When in doubt, I will seek a determination from the NIDCD's Program Officer.

4. I am aware that I am responsible for:

Maintaining the confidentiality of any non-public information that I become aware of through this activity and avoiding any use of such information other than to carry out my responsibilities as a member of the DSMB. I understand that this prohibition includes disclosure or use of such non-public information for any scientific purpose, such as in my own research, as well as for any financial benefit, such as making investments based on the outcome of the study.

Signature

Date

5. NIDCD Certification

This certification and other pertinent information has been reviewed and discussed with the candidate and it has been determined that:

___ There is no conflict of interest. Thus, the candidate may become a member of the DSMB.

___ There is an appearance of a conflict of interest, but the interest of the Government in the candidate's participation outweighs the appearance of a conflict as determined in the attached authorization. Thus, the candidate may become a member of the DSMB.

NIDCD Program Officer

Signature

Date