

NINDS Data And Safety Monitoring Board Conflict of Interest and Confidentiality Statement

[PI NAME - STUDY NAME]

Members of the Data and Safety Monitoring Board (DSMB) are selected by NINDS Program Officers to reflect the disciplines and medical specialties necessary to interpret the data from the *study(ies)* named above. All members of the DSMB are required to be completely independent of the studies being reviewed and all members are required to sign a DSMB Conflict of Interest and Confidentiality statement.

A conflict of interest exists when a DSMB member has an interest in or link to a study that is likely to bias his or her review of it. An individual who has a real conflict of interest with a study may not participate on its DSMB. Appearance of a conflict of interest should be avoided whenever possible; however, if it is established that there is no real conflict of interest and the responsible NINDS program official determines that the integrity of the process would not be impaired, the individual in question may participate in the DSMB.

It is the responsibility of each DSMB member to notify the NINDS official of any conflict of interest situations that may pertain, whether real or apparent. Conflict of interest can include personal, professional, financial or proprietary interest. Potential conflicts that develop during the member's tenure on the DSMB must also be disclosed. Disclosure will serve to protect the integrity of the DSMB and its role in monitoring and oversight of clinical studies and will also help protect the DSMB member from allegations of inappropriate behavior. Failure to disclose a conflict of interest will lead to removal from the DSMB. The NINDS may independently determine that a particular situation involves a conflict of interest and consequently exclude the member from the DSMB.

The following should be considered in assessing whether or not there is a conflict of interest.

- **Employment:** Current or recent (within the past 6 months) employment (e.g., full- or part-time salaried employee, consultant, or other recipient of honoraria; member of board of directors or advisory committee) with an institution or organization that is directly involved with conducting the research or that could receive financial benefit from the results of the study would generally be considered to be a conflict of interest.
- **Financial Benefit:** An individual who has received or could receive direct financial benefit, other than from employment, of any amount from an individual, institution or organization involved with the study, other than the NIH, may have a conflict of interest. Financial benefit may include stock ownership or prior research funding from an institution or organization involved in the study, whose product is being evaluated in the study or competes with a product being evaluated in the study, or which could otherwise receive financial benefit from the results of the study. Regardless of the level of financial involvement, if the individual feels unable to provide objective advice, he/she must not serve on the DSMB.

- **Intellectual property:** Intellectual property ownership, such as copyrights, patents, trademarks, trade names, or trade secrets related to the study may be considered a conflict of interest.
- **Relatives or Associates:** A conflict of interest may exist if a close relative or professional associate of a member receives or could receive financial benefits from or provides financial benefits to the study or investigators. A professional associate includes any colleague, scientific mentor, or student with whom the DSMB member is currently conducting research or other professional activities or with whom the DSMB member has personally worked within three years.
- **Longstanding Disagreements:** A conflict of interest may exist when a DSMB member has had longstanding scientific or personal differences with the study or its investigator(s) that may compromise objectivity.

CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIALS AND PROCEEDINGS

Materials and information made available to the DSMB that are not in the public domain, as well as the discussions that take place during the meetings, are strictly confidential and must not be disclosed to or discussed with anyone who is not a member of the DSMB. Furthermore, confidential information obtained as a DSMB member may not be used by the member for personal benefit or for the benefit of the member's family, associates, or of organizations with which the individual is associated or has a financial involvement.

DSMB CERTIFICATION REGARDING CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE

NAME: _____

Primary employer: _____

I have read the attached NINDS DSMB Conflict of Interest and Confidentiality Form and hereby certify that I do not have a conflict of interest or have discussed and resolved with the NINDS program official any potential conflict of interest with the **study(ies)** reviewed by this DSMB.

I fully understand the confidential nature of the DSMB process and agree not to disclose or discuss the materials associated with the review or substance of any confidential discussions about the studies with any individual not a member of the DSMB or NINDS staff or to use the information for my personal benefit or the benefit of others.

Signature: _____ Date: _____

To be completed annually.