NAMI Maryland
Standards for Protecting the Well-being of Individuals Participating in Research

1. NAMI Maryland accepts the critical necessity for research using human subjects, acknowledges the important contribution of persons who become human subjects, and affirms that all such research should be conducted in accordance with the highest medical, ethical, and scientific standards.

2. National standards to govern voluntary consent and a process for determination of competence, comprehensive exchange of information, and related protections of persons with cognitive impairments who become research subjects must be developed and they must include the interests of persons who become human subjects, their families, and other caregivers.

3. Participants in research, their involved family members and other caregivers must be fully and continuously informed, orally and in writing, about all aspects of the research throughout the process. Research investigators must provide information in a clear, accessible manner to ensure that participants and their involved families fully understand the nature, risks, and benefits of the research.

4. The consent protocol must provide information that is clear and understandable on an individual basis for each participant and his or her family members/other caregivers. The consent protocol must provide information about the purposes and scale of the research, what is hoped to be learned, prospects for success, and potential benefits and risks to the individual (including options for treatment other than participation in research, since research is not the same as treatment). The consent protocol should also contain information about the function of the institutional review board (IRB), the identity of the IRB administrator, the address and telephone number of the IRB administrator and other information, as appropriate.

5. Whenever consent is given by someone other than the research participant, the participant and involved family members/caregivers must receive information on the same basis as the person actually giving consent.

6. Research participants should be carefully evaluated before and throughout the research for their capacity to comprehend information and their capacity to consent to continued participation in research in accordance with the national standards referred to above in item 2. The determination of competence shall be made by someone other than the principal investigator or others involved in the research. Except for research protocols approved by the institutional review board (IRB) as minimal risk, whenever it is determined that the subject is not able to continue to provide consent, consent to continue participation in the research shall be sought from families/caregivers or others legally entrusted to act in the participant's best interests.

7. Research protocols should clearly describe the risks involved in the research and should include effective safeguards for those who participate in research involving greater than minimal risk, such as washout, placebo and challenge studies.

8. Institutional review boards that regularly review research proposals for brain disorders must include consumers and family members/caregivers who have direct and personal experience with brain disorders.

9. Members of IRBs approving research on individuals with brain disorders must receive specialized training about brain disorders and other cognitive impairments and the needs of individuals who experience these disorders. Persons with brain disorders and members of their families/caregivers must be integrally involved in the development, provision, and evaluation of this training.

10. Without penalty, a research participant must be free to withdraw consent at any time, with or without a stated reason. Any time a participant terminates participation, regardless of the reason, investigators will make every effort to ensure that linkages to appropriate services occur with follow-up to assist that participant to establish contact with appropriate service providers. If a participant disappears or terminates his or her continued consent, the investigator shall contact his or her family/caregivers or others designated to receive notification and information.

11. When participation by an individual in a research protocol is completed, participants and/or their families/caregivers are entitled to be informed of results as soon as this information is available, to have the opportunity to receive feedback concerning their individual participation in the protocol, to critique the protocol, and to provide input concerning possible additional research.

12. All participants in research protocols involving assessment of new medications will be provided with opportunities by the investigator for a trial on the medication being studied, so long as research on the new medication has demonstrated potential safety and efficacy.

13. All individuals who have benefited from the administration of experimental medications in research will be provided continual access to the medication by the investigator without cost until a source of third-party payment is found.

14. NAMI Maryland endorses the development of a uniform, standard definition of “brain disorders” to help all states obtain priority funding and services for the population that suffers the most severe disabilities.

15. NAMI Maryland encourages its members to participate in research, but recommends that its members participate only in those research protocols that adhere to these standards.

Approved by the board on February 19, 2000