

**Policy Statement on Publication and Conflict of Interest  
Pertaining to Clinical Research Involving Persons with  
Huntington's Disease (HD)**

Huntington Study Group Executive Committee

Stewart Factor, DO  
Steven Hersch, MD, PhD  
Elise Kayson, MS, RNC  
Karl Kieburtz, MD  
Carol Moskowitz, RN  
David Oakes, PhD  
Oksana Suchowersky, MD  
Aileen Shinaman, JD  
Ira Shoulson, MD  
Francis Walker, MD  
Anne Young, MD, PhD

All research involving human participants should have initial and ongoing review of the research plan or protocol reviewed by an institutional review board (IRB) composed of scientists, physicians, other healthcare professionals, and advocacy representatives from the community. Even with these protections in place, interested research participants must carefully weigh the potential benefits and risks of the research. However, there are issues and concerns that may escape the attention of IRB's and the consent process but are nevertheless crucial in considering research participation. The Executive Committee of the Huntington Study Group (HSG) has developed and affirmed the following policy statement for publication and conflict of interest pertaining to clinical research involving persons with Huntington's disease (HD).

**Publication of Data:**

Research is of limited value if the data and information from the study are not made publically available, especially to the community that might be affected by the results. Publication of data should ideally be made by reports in peer-reviewed scientific publications, providing an opportunity for independent experts who are not directly involved in the research to review and critique the data and conclusions prior to publication.

Unfortunately the results and outcomes of too many studies are never published, often because the sponsors of the research perceive financial or other risks by publishing what it considers to be "negative data". While this may be the sponsors' prerogative in protecting its proprietary interest, the community affected by a particular illness or disease (e.g., HD) also has the prerogative not to participate in research unless assurances are provided that the results of the study will be published in a timely fashion and in a peer-reviewed scientific journal. Furthermore, potential research participants and research investigators should receive (written) assurances that all data from the study will be made available for scientific review by all participating investigators who will have free and unfettered access to publish these data. This

position has been an explicit policy of the HSG since its inception and is clearly articulated in the HSG Constitution.

The HSG Executive Committee and participating investigators and coordinators in the HSG who carry out cooperative research caution prospective research investigators and research participants from engaging in research if assurances about free, timely and unrestricted right to review and publish data are not explicitly guaranteed. In the HSG, we receive such guarantees from research sponsors through explicit written assurances and legal contracts. Any other agreement should be viewed as an act of faith without the possibility of enforcement.

**Conflict of Interest:**

An issue closely related to publication is the real and potential financial conflict of interest facing research investigators who are engaged in the study. It is reasonable and even desirable for investigators to be appropriately compensated for their work and reimbursed for research-related expenses, usually overseen by institutions such as not-for-profit universities or medical centers. Such compensation and reimbursement should be fully disclosed. The investigators, unlike the sponsors, should not have a vested financial interest in the outcome of the study such as stock ownership, equity options or other equity holdings in the company or receive remuneration in the form of personal compensation, bonuses, free trips or financial payments to family members. While it is not illegal for investigators to have financial conflicts of interest, the HSG regards such conflicts as contrary to the role of investigators as honest, dispassionate research advocates for our patients and families.

The HSG Constitution precludes research investigators from having any personal financial relationship with a research sponsor, and that any potential financial conflicts of interest be appropriately disclosed in research publications. The HSG cautions any potential research participants from engaging in research without assurances from the investigators that there are no personal financial relationships with the sponsor. If such relationships exist, full disclosure should be made. Relationships between the investigators' institution and the sponsor should also be disclosed.

**Summary:**

The community of individuals and families affected by diseases, especially those with serious illness who are prone to desperate measures, should be assured that the sponsor of the research guarantees the investigators free and unfettered right to publish the research findings. The research investigators need to be honest analysts and reporters of the research findings in peer-reviewed publications that are adequately scrutinized and of high standards. Investigators should not have any personal financial relationship with the sponsor during the study, and all relationships including those between sponsors and the investigators' institution should be disclosed. These standards for publication and conflict of interest will advance our common research mission to develop safe and effective treatments to relieve the burden and advance treatments for HD. (Reviewed and approved by the Huntington Study Group Executive Committee on October 24, 2002.)