



# NATIONAL HEMOPHILIA FOUNDATION

for all bleeding disorders

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May 2, 2003

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Dockets Management Branch (HFA-305)  
Docket Number 02N-0475  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Dear Sirs:

Thank you for the opportunity to comment on the draft guidance notice entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" published in the March 31, 2003, *Federal Register*. The National Hemophilia Foundation (NHF) is the nation's largest organization serving the bleeding disorders community and is dedicated to finding the cures for bleeding disorders and to preventing complications of these disorders through education, advocacy and research.

Making informed consent truly an informing process has long been a paramount objective of our organization. NHF's Medical and Scientific Advisory Council (MASAC), in conjunction with NHF's Gene Therapy Working Group, have developed recommendations and provided oversight in this area. Enclosed is MASAC Recommendation #136 on disclosure of conflicts of interest. This recommendation was approved by NHF's Board of Directors in November 2002 and closely mirrors the principles of the FDA draft guidance.

Participants in research trials place tremendous trust in their physicians and in the institutions where research is conducted. Research participants must be treated as peers in the research process and given complete information for informed decision-making. NHF supports the draft guidance and particularly supports the:

- Comprehensive list of questions for evaluating for possible conflicts,
- Call for the elimination of conflicts of interests where possible, and
- Numerous options offered for addressing conflicts when they do occur.

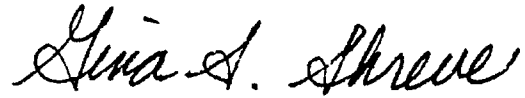
Fully informed research participants are critical to the conduct of sound research. Implementation of the criteria proposed in the draft guidance would ensure that conflicts of interest are appropriately addressed in a timely manner.

02N-0475

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Again, NHF applauds the Office of Human Research Protections for developing this draft guidance and urges its implementation by all research institutions. Thank you for the opportunity to provide these comments.

Sincerely,

A handwritten signature in black ink that reads "Gina A. Shreve". The signature is written in a cursive, flowing style.

Gina Shreve, Ph.D.  
President