

MASAC STANDARD ON DISCLOSING CONFLICTS OF INTEREST FOR INDIVIDUALS CONDUCTING CLINICAL RESEARCH ON BLEEDING AND CLOTTING DISORDERS

The following standard was approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) on November 2, 2002, and adopted by the NHF Board of Directors on November 3, 2002.

The National Hemophilia Foundation and its Medical and Scientific Advisory Council are committed to clinical and basic research endeavors aimed at improving the care of or providing the cure for bleeding and clotting disorders. This includes advocating for and sponsoring research to achieve genetic cures and improved treatments for hemophilia and other clotting disorders. Intrinsic to this commitment is a determination to foster research practices that ensure that no personal or corporate interest, financial or otherwise, by any investigator, institution or sponsor affects or appears to affect the design, conduct, or reporting of clinical or basic research. Furthermore, these practices must never knowingly compromise the health or well being of any human subjects participating in such research.

NHF and MASAC endorse the requirements of the Office for Human Research Protections and the Association of American Medical Colleges documents: "Protecting Subjects, Preserving Trust, Promoting Progress-Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research" (December 2001) and "Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research" (October 2002). These documents should serve as guides and models of the most basic standards and practices that must be adhered to when performing clinical bleeding and clotting disorder research.

Therefore, NHF and MASAC endorse vigilance to identify and acknowledge real or potential conflicts of interest (COI) and aggressive measures to eliminate them. If COIs persist, they must be fully disclosed to sponsors, to regulatory agencies, and, most importantly, to potential research subjects. Furthermore, such disclosures should be included in the informed consent document that patients review prior to agreeing to participate in the research.

References:

1. Office for Human Research Protections, National Institutes of Health, Department of Health and Human Services. Protection of Human Subjects. 45 CFR 46. Washington, DC: November 2001.
2. Association of American Medical Colleges. Protecting Subjects, Preserving Trust, Promoting Progress-Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research. Washington, DC: December 2001.
<http://www.aamc.org>.

3. Association of American Medical Colleges. Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research. Washington, DC: October 2002.
<http://www.aamc.org>.