

Research Conflicts of Interest

The Institutional Review Board (IRB) is responsible for reviewing various types of potential conflicts of interest (COIs) during its review and approval of research protocols. COIs have gained increased attention with the recent allegations made against senior officials at the National Institutes of Health (NIH), as well as questions regarding sponsored research and financial interests of institutions providing oversight for research studies.

Government agencies such as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, National Institutes of Health and the Department of Health and Human Services (DHHS) have all recognized that several factors involving conflicting interest may have a potential impact on human subject research. IRB member and Investigator conflicts of interest are addressed in the Office of Human Research Protections (OHRP) and DHHS regulations. The regulations state that an IRB member, with a conflict of interest, “cannot participate in the review and approval process for any project and must be “absent from the meeting room during the discussion and voting phases of

PolyHeme® and the FDA

Northfield Laboratories’ Phase III pivotal trial for PolyHeme® has sparked some interest as it is only the 15th clinical trial that allows its use without subject consent under certain circumstances. Doctors and those involved in patient ethics questioned whether communities were adequately being educated about the trial. (To opt out of the trial one would be required to wear a wristband). The company completed the study in June 2006 and the preliminary data published in December of 2006 was disappointing.

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the review and approval processes”. 21 CFR 54 provides guidance for the financial disclosure by clinical investigators which assist IRBs in determining potential COIs among researchers.

Disclosing financial COIs has become standard text in informed consent documents to ensure that any financial interest that would impact the informed consent decision process should be disclosed. In the California case of *Moore v. Regents*, the courts found that the research physician had an obligation to disclose his financial interest in the materials harvested from the subject. *793 P.2d 479 (Cal. 1990)*

Guidelines and Standard Operating Procedures (SOPs) that address an IRB’s conflict of interest policy is essential to ensuring research is conducted with minimal bias. For more information regarding COIs, please contact Harrison IRB at 937 568 4772.

The Vault™ – IRB Site Information

Harrison IRB’s secure, online IRB site information is available by accessing *The Vault™*. Sponsors will be provided a login and password so that they can monitor the site approval process. Once an investigator submits the Site Submission Form and the documents have been reviewed by Harrison IRB, site information will be posted and will be updated as new information becomes available. For more information on how to access a demo of our system, please contact Harrison IRB at 937 568 4772.