

## Conflicts of Interest

In order to comply with the Department of Health and Human Services (DHHS) guidance entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," SERRG, Inc. has established a policy for reviewing financial conflicts of interest of investigators, research staff and institutions.

The investigator or study staff will be considered to have a financial conflict of interest if the investigator, investigator's immediate family, the study staff, or the study staff's family

1. has a financial interest in the research with value that cannot be readily determined;
2. has a financial interest in the research with value that exceeds \$10,000 or 5% ownership;
3. has received or will receive compensation with value that may be affected by the outcome of the study;
4. has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
5. has received payments from the sponsor that exceed \$10,000;
6. is an executive or director of the agency or company sponsoring the research; or
7. has an interest that the investigator believes conflicts with his or her ability to protect participants.

Diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund are not considered to present a conflict of interest.

A financial conflict of interest is not intrinsically wrong. Rather, the purpose in analyzing a financial conflict of interest is in trying to determine when the interest offers incentive to the investigators or other party to breach a duty to subjects or to society, and how to address the conflict of interest. As individuals vary in their personal integrity, there are two reasonable, person standards for analysis:

- First, if the financial conflict of interest could challenge the integrity of a reasonable individual.
- Second, if the financial conflict of interest would appear to a reasonable member of the general public to be a conflict that could challenge the integrity of the conflicted party.

In addition, the following factors in analysis of the reported conflict of interest are considered:

- Amount of Risk

The degree of risk and discomfort faced by subjects in research varies greatly. In high-risk studies, such as those involving the use of a medical device in invasive surgery, a conflict of interest could greatly affect the risks faced by subjects. In a study involving the analysis of human tissue studies, the risks to the subjects are generally limited to confidentiality issues.

- Effect of the Conflict of Interest on Subjective Decision-Making

The participation of the party with the conflict of interest could affect subjective decision-making, both consciously and subconsciously, and thus influence the conflicted party's judgment and behavior. Subjective decisions that could be influenced by a conflict include the design of the research, choosing which subjects to enroll, clinical care provided to the subjects, use of subjects' confidential medical information, data collection and analysis, adverse event reporting, and the presentation of research findings.

- Amount of Interaction Between the Conflicted Party and the Subjects

Many of the concerns about the conflicted party's decisions will be lessened if the conflicted party does not interact directly with subjects. For example, in many tissue studies the conflicted investigator simply receives waste samples from a surgery facility, and has no contact with the subjects. On the other hand, in a similar study the investigator may also perform the surgery, in which case the concerns over the effect of the conflict are greater.

- Other Parties Involved in Overseeing the Conflict of Interest
  - Large institutions will often have a separate conflict of interest committee. (The standards for these committees are highly variable.)
  - For FDA-regulated studies, the FDA will be providing a scientific review of the research results.
  - NIH does detailed reviews of research proposals in advance, and inquires about conflicts of interest at certain procedural steps.
  - Some institutions have assigned subject advocates who sit in on the consent process.
  
- Training in Conflict of Interest

The investigator or other conflicted party may have participated in training on the ethical analysis of conflict of interest and, therefore, may be more aware of the ethical issues and in need of less oversight.

- Nature of the Interest, and Relationship to the Research

The interest may be one in which large change is possible based on the outcomes of the study under review. An equity interest in a start-up company could be drastically affected by the research results, whereas stock in a large pharmaceutical company is not as likely to be affected. Is it a single site study or a multi-center study? The ability of the investigator or other conflicted party to affect the financial interest varies greatly in these different situations.

- Unique Investigator or Institution Qualifications to Conduct the Research

Occasionally, the investigator or institution is uniquely qualified to conduct the research. For instance, the investigational article may be a surgical device that has been developed by a surgeon who specializes in a surgical technique that only he or she performs.

- Compensation to Investigators for the Conduct of Research

Financial compensation to investigators should be at fair market value for the procedures and services provided.