

Essential Information

That you may not know

Sometimes a Principal Investigator or a Sub-investigator may have a conflict of interest, or situation in which a financial or other non-financial/personal situation has the potential to compromise professional judgment in conducting the research. The most common conflict of interest is financial. The Principal Investigator may own stock, be a paid consultant, or be paid by the sponsoring company to conduct the research. He/she may also hold a patent on the drug or medical device being studied, and in that case, the Principal Investigator would benefit if it was approved for general use. When a conflict of interest is identified, every effort is made to minimize the potential it has to influence the outcome of the research.

Another conflict of interest is when employees of the research facility at which a study is being conducted participate in the study. This could lead to problems because as employees, they may feel pressure to participate in order to avoid negative effects on their employment. Likewise, they may feel unduly influenced to participate due to their perception or expectation of a job promotion in exchange for study participation. When a participant feels pressured to participate for any reason other than his/her own best interests, it is called coercion. Coercion can compromise a participant's capacity to make an autonomous decision regarding study participation.

It is possible that, as a research participant, you may have to pay for some or all of the tests that are related to the research. Sometimes everything is paid for and sometimes your insurance company will cover some or all of the costs, but there are some health insurance companies that do not provide coverage for research studies. **This should be discussed with your health insurance company before entering the research study.**

On the other hand, sometimes participants are reimbursed or compensated to be in research studies. For individuals with medical problems, the amount of compensation is generally based on how inconvenient it is for them to come to the research facility. Studies that enroll healthy participants generally compensate more, as these individuals do not have any medical problems and it can sometimes be difficult to get them to join the research study.

It is important to know that individual participants' names will remain confidential and will not be mentioned in study reports. When a study participant enrolls in a research study, he/she may be given a privacy/confidentiality (HIPAA) form to sign in addition to the main consent form. This allows the Principal Investigator to share and use their health information for the purposes of research. If you, as the study participant, decide

that you no longer wish to have your protected health information (PHI) shared, you may withdraw at any time. This withdrawal must be submitted in writing to the Principal Investigator. However, once you do so, you can no longer continue to participate in the study.