

DHS – Public Health Division

CONFLICT OF INTEREST IN RESEARCH

In compliance with federal requirements pertaining to "Objectivity in Research" (42 CFR Part 50 and 45 CFR Part 94), the Public Health Division requires that researchers disclose to the IRB any actual or potential significant financial conflicts of interest. A conflict of interest in research exists when a research investigator or IRB member's financial interests or other obligations compromise, or appear to compromise, his/her professional judgment in the design, conduct, or reporting of research. In addition, investigators that carry out research through contractors or collaborators must obtain similar statements from those individuals or provide assurance that they will comply with this policy. A "significant financial conflict of interest" is defined as income or equity interests over \$10,000 per year or 5 percent or greater ownership in a company with interests related to the research. This definition includes the spouse or domestic partner and/or dependent children of the researcher.

If the IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. Conditions or restrictions that might be imposed include:

- Public disclosure of significant financial interests to the research participant in the consent form;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.

If an investigator fails to comply with this policy and failure to comply has biased the design, conduct or reporting of the research, the IRB will notify institutional officials. Institutional officials will notify the funding agency of actions to be taken.

IRB members who have a potential or actual significant financial conflict of interest in any study being reviewed by the Public Health IRB must disclose the conflict. IRB members with such a conflict will not participate as a primary or secondary reviewer on the study that poses the conflict. Board member may be present for discussion and may provide information requested by the IRB. These members must abstain from any vote with respect to such a project.

Applicable Regulations:

21 CFR 50
21 CFR 56.107(e)
42 CFR 50.601 – .606
45 CFR 46
45 CFR 94.1 – .6