

Bronson Research Services

ADMINISTRATIVE

12. Financial Disclosure

Purpose: To establish a guideline for investigator disclosure of financial arrangements in the design, conduct, and reporting of research.

Scope: This guideline applies to Bronson Healthcare Group and each of its subsidiaries (collectively, “BHG”), any of BHG’s employees, any of BHG’s contractors, and any members of the Medical Staff of any BHG hospital who are involved in clinical trials.

Responsibilities: All investigators are responsible for fully disclosing financial conflicts of interest to the IRB. For research submitted in a marketing application to the FDA for approval of a drug, biological product or a device, the investigator is also responsible for submitting financial disclosure information to a sponsor. BHG will designate an institutional signatory official who shall be responsible for the reviewing and signing the financial disclosures submitted to the IRB.

Guidelines:

1. Definitions

Conflict of Interest: A conflict of interest exists if independent reviewers of disclosures, or the investigator, determine that a financial interest “could directly and significantly affect the design, conduct or report of research.”

Investigator: Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research. For purposes of the requirements relating to financial interests, “Investigator” includes the Investigator’s spouse and dependent children.

Financial Interest: Anything of monetary value, including but not limited to:

- Salary or other payments for services (e.g. consulting fees or honoraria);
- Equity interests (e.g. stocks, stock options or other ownership interests);
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights)

The term does not include:

- Salary, royalties, or other remuneration from the applicant institution;
- Any ownership interests in the institution, if the institution is an applicant under the SBIR (Small Business Innovation Research) Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that when aggregated for the investigator and the Investigator’s spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable

Bronson Research Services

measures of fair market value and does not represent more than a five percent ownership interest in any single entity; or

- Salary, royalties or other payments that when aggregated for the Investigator or the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.
2. All investigators are required to disclose financial interests related to research. The investigator must disclose if they or a member of their immediate family (spouse or dependent children) receive financial or other compensation from the study sponsor or have significant financial interest in the sponsoring entity.
 3. The investigator must provide a description of the relationship and include a statement in the informed consent document that addresses the conflict of interest or state why a statement in the informed consent is not necessary for the protection of human subjects.
 4. All financial disclosures must be updated at least annually (at the time of the Continuing Review) or as new reportable significant financial interests are obtained during the duration of the research.
 5. If an investigator conflict of interest develops after IRB approval, the investigator should promptly notify the IRB, submit changes as an amendment to the approved protocol and include a revised consent form including a statement addressing any potential conflict of interest.

Regulations, Guidelines, References: 42 CFR 50; 21 CFR 54

Reviewed and Approved 11/09