

**Lifespan System-wide Policy**

**Subject: Prohibition On Use of Enrollment Incentives and Finder's Fees in Human Research Studies**

**File under: CCPM-78  
ORA Gen 010**

**Issuing Department:  
Corporate Compliance**

**Latest Review Date:**


**Latest Revision Date:**

**Original Policy Date:  
May 2016**

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**Approved by:**

  
Administrative Director, Research  
Administration

  
Senior Vice President, Chief  
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**I. Purpose:**

Lifespan prohibits the use of finder's fees or enrollment incentives paid to investigators, research staff, physicians, collaborators, intermediaries or subcontractors to recruit participants to take part in a research activity. Such incentives create a potential for conflict of interest and may have deleterious effects on human subjects' protections.

**II. Eligibility:**

All Lifespan Employees and Lifespan affiliate employees, practice plan foundation employees, community physicians and affiliates involved in research, research training or research-related activities pursued at Lifespan or Lifespan affiliates or under the sponsorship of Lifespan or Lifespan affiliates.

**III. Policy:**

**3.1 Introduction:**

Incentive payments for subject recruitment and finder's fees for subject referral may compromise the integrity of a research study by giving an appearance of affecting the judgment of the investigator/research team and in some case may violate federal law. Payment arrangements among sponsors, organizations, investigators and those referring research participants may place participants at risk of coercion or undue influence or cause inequitable selection. The ethical conduct of research requires that participation of all human volunteers be

completely voluntary. Specifically, the investigators may be motivated by financial interest to refer patients when such a referral might not be of any benefit to, or in the best interest of the subject. Finder's fees to physicians or nurses may diminish the patient's free choice in deciding whether to volunteer for a clinical study.

The American Medical Association has issued guidelines suggesting that finder's fees and incentive payments may represent real and perceived cases of fee-splitting, an unethical behavior.<sup>1</sup> Researchers participating in the conduct of research should be reimbursed only for activities directly related to performance of the research and at a rate not exceeding the fair-market value for the level of activity performed. Federal Medicare anti-kickback laws may also prohibit finder's fees and incentive payments if there is a real or apparent billing of standard of care costs as part of the research activity.

### **3.2 Unacceptable Payments:**

Finder's fees, referral fees, enrollment incentives, or similar payments or consideration in exchange for referring or enrolling prospective participants into research studies is not permitted and is a violation of ethical guidelines, Lifespan policy, and may implicate Federal Medicare anti-kickback laws. Examples of remuneration prohibited under this policy include but are not limited to:

- Any fee to an investigator and/or research staff for recruitment that exceeds the actual cost of recruiting research participants;
- Bonuses or other forms of additional payments for timely, early, or over-enrollment of research participants, for retention of participants, or for timely or early IRB approval;
- Use of per subject payment rates that vary based only upon the number of research participants enrolled, including increased per subject rates paid for over-enrollment of research participants that are not made based on the actual costs incurred by such activities;
- Extra contractual benefits such as unrestricted research gifts, medical or office equipment, payment of conference fees, authorship rights, journal subscriptions, educational stipends, software, personal gifts, favors or similar inducements provided in exchange for enrolling research participants;
- Cash payments or other financial or non-monetary incentives to physicians for referral of patients ("Finder's Fees").

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<sup>1</sup> AMA Opinion 6.03, Fee Splitting: Referral to Health Care Facilities

**3.3 Acceptable Payments:**

A reasonable payment made to Lifespan to reimburse a researcher for engaging in an activity that incurs actual cost is not an enrollment incentive. Fair Market Compensation for recruitment and screening-related activities (i.e., advertising, administrative and personnel costs) that are not related in any manner to whether the participant actually enrolls or completes the study is permissible. Working with the Office of Research Administration/Clinical Trials Office, Investigators should document their development of a reasonable budget, directly related to the value of services provided to the study that substantiates how the compensation was determined.

- For example, payments made to individuals may be made on a flat hourly basis for recruitment and screening potential participants (regardless of whether the participants enroll) and documentation of effort should be maintained on time sheets.
- Staff should not be paid a fee for each successful recruitment (i.e., \$10 for every participant who signs the consent document to participate in the study).

**3.4 Definitions:**

- A. "Finder's Fee" is any payment in the form of money, goods, or services to a professional (usually, but not limited to, a physician) made in the exchange for the referral of a research participant.
- B. "Enrollment Incentive" is any financial reward paid to an investigator or research staff tied to the number and/or rate of subject enrollment.

**IV. Procedure:**

If a Lifespan Employee or a Lifespan Professional Staff member has a *question concerning the interpretation or applicability* to a particular circumstance of any of the laws or regulations referred to in this Policy, such Lifespan Employee or Lifespan Professional Staff member should first consult with his/her supervisor(s) and if his/her supervisor(s) is unable to answer the question or provide any guidance, or if because of the circumstances it would be inappropriate to discuss the matter with his/her supervisor(s), then such Lifespan Employee or Lifespan Professional Staff member should contact either Corporate Compliance or General Counsel offices for advice. If any Lifespan Employee or Lifespan Professional Staff member is aware of any violation or threatened or potential violation of this Policy, or *suspects* a violation of this Policy has occurred, such Lifespan Employee or Professional Staff member should contact the Corporate Compliance Office or Office of General Counsel for instruction as to what action to take.