

Payments for Referring or Enrolling Subjects in Clinical Research

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Contact Office:

Assistant Dean for Research
PO Box 800419
Charlottesville, VA 22980
phone: 434-243-7088
fax: 434-982-0874

Oversight Executive:

Senior Associate Dean for Research
PO Box 800419
Charlottesville, VA 22980
phone: 434-243-7088
fax: 434-982-0874

Applies to:

Any University of Virginia School of Medicine employee, student, volunteer, or other individual who has an affiliation with the institution (“Covered Person”).

Policy Statement:

No Covered Person may accept or offer incentives for the referral or enrollment of subjects in any clinical study. Incentives include, but are not limited to, gift certificates, books, conference attendance, the payment of travel expenses, and finder’s fees paid by or to investigators, or bonus payments based on subject accrual that are made to either investigators or study staff. Incentives may not be paid directly to Covered Persons or through grants or contracts supporting clinical studies.

Definition of Terms:

Clinical study - includes any study involving human subjects, regardless of where that study is being conducted.

Reason for Policy:

Institutional Review Boards (IRBs) and clinical research programs across the nation are under increased scrutiny to ensure the highest possible level of protection of human participants. While Department of Health and Human Services guidelines do not address the payment of incentives for referring and enrolling patients in clinical trials, its Office of Inspector General has recommended that the FDA and NIH implement such regulations (<http://oig.hhs.gov/oei/reports/oei-01-97-00195.pdf>). Similarly, in 2004 the Institute of Medicine recommended to the FDA that “payments in the form of finder's fees or bonuses for enrolling a specific number of children or adolescents

are unethical and should not be permitted” (http://www.fda.gov/ohrms/dockets/ac/04/slides/2004-4050S1_15_Nelson_files/frame.htm#slide0001.htm). The American Medical Association states that “offering or accepting payment for referring patients to research studies (finder’s fees) is unethical” (see <http://www.ama-assn.org/ama/pub/category/8366.html>) and the American College of Physicians *Ethics Manual*, 5th Edition, states that “Giving or accepting finder’s fees for referring patients to a research study generates an unethical conflict of interest for physicians” (http://www.acponline.org/running_practice/ethics/manual/). One area of concern is that the payment of incentives for referrals or enrollments could cause investigators or administrators to stretch enrollment criteria, to distort information provided to potential participants, or to pressure subjects to participate.

The greatest assets of the University of Virginia School of Medicine are its reputation and the public’s confidence in the integrity of its health care services and research programs. The School wishes to protect those involved in clinical studies by helping to ensure the investigator does not have a financial conflict of interest, and to protect its investigators and their staff by providing clear guidelines to help maintain the public’s confidence and respect.

Related Policy:

Resolution of Conflicts of Interest as They Relate to Research Contracts

<http://www.virginia.edu/finance/polproc/pol/viib1.html>

Objectivity in Research

<http://www.virginia.edu/vprgs/objectivity.html>

Research Conduct

<http://www.virginia.edu/vpr/researchconduct.html#ethics>

Research Misconduct

<https://etg07.itc.virginia.edu/policy/policydisplay?id='RES-004'>

Next Scheduled Review: June 2013

Revision history: Implemented 9/1/2001; revised 10/8/10