BACKGROUND:

Bonus 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 cases may violate federal law. Ethical conduct of research requires that the participation of all human volunteers be completely voluntary. Particularly in a health care setting where relationships are hierarchical, it is important that there be no suggestion of subtle encouragement for any person’s participation in a research study by someone who will receive a finder’s fee or bonus payment if that person is enrolled as a subject.

The American Medical Association, and RhPHARMA have issued guidelines suggesting that finder’s fees and bonus payments may represent real or perceived cases of fee-splitting a well recognized and unethical behavior. Individuals 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 bonus payments if there is real or apparent billing of standard of care costs as part of the research activity.

In addition, the University of Pennsylvania IRB believes that finder’s fees and bonus payments to investigators and study staff create a potential conflict of interest. Specifically, the investigator may be motivated by financial interest to refer a patient when such 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. Specifically, the patient may rely unduly on the physician’s or nurse’s recommendation to enroll, against his/her own better judgment.

Finally, the IRB believes that there does need to be guidance for investigators who wish to recruit subjects for research activity and where outside third parties need to be reimbursed for their activities in such manner as to avoid the appearance of fee splitting.

GUIDANCE:
Payment of Finder’s Fees and Bonus Payments to University of Pennsylvania Physicians, Investigators or Study Staff by External Sponsors

The Institutional Review Boards do not approve of finder’s fees being paid to University of Pennsylvania or UPHS investigators, physicians, nurses, and others who have a treating and/or counseling relationship to a subject being referred for enrollment in a clinical trial. The Institutional Review Boards do not approve of finder’s fees being paid to any, house staff or University of Pennsylvania Health System (UPHS), or University of Pennsylvania employee for referring or recruiting prospective subjects. The IRB may review and approve small, nominal value gifts to staff organizations as long as such gifts are not based on any indicator of trial enrollment.

All payments for the conduct of a research project must be negotiated at the beginning of the study and not provide for additional payments based on either number or rate of subject enrollment. Payments tied to the number or rate of subject enrollment are considered to be bonus payments and are not permissible. Supplemental payments, or additional compensation, payments, or other incentives beyond nominal (less than $100 in value) must be negotiated as
part of an addendum to the clinical agreement and reported to the IRB. The investigator, physicians and staff must be aware of the existing reporting requirements under the University Policy on Conflicts of Interest should there be any change in their financial relationship with any sponsor during the performance of a research study.

Payment of Finder’s Fees to Referring Physicians or Others Outside the University of Pennsylvania or University of Pennsylvania Health System

Finder’s fees include any payment or gift to an individual who identifies or assists in the recruitment of prospective subjects.

The use of finder’s fees to elicit recruitment of research subjects from outside the University of Pennsylvania or University of Pennsylvania Health System is discouraged. In some cases, it may be acceptable for investigators to offer a nominal incentive if the IRB can be assured that the person who receives that incentive will in no way encourage subjects to enroll in a study and that applicable laws are not violated. Each case must be considered individually. The use of any compensation (payment, gift, etc.) must be reviewed and approved by the IRB prior to being initiated. Payment to physicians outside of the University of Pennsylvania Health System (UPHS) should be structured as a contract with the referring physician(s) and provide reimbursement for actual services rendered by the physician or their staff for the recruitment purposes.

If an investigator wishes to consult the IRB regarding this issue, the following questions must be answered as part of the protocol submission:

- What compensation will be offered (for example, money, textbook, dinner, movie pass)?
- Who will obtain consent or HIPAA authorization (if applicable) from the subject?
- To whom is the compensation being offered and what is the person being asked to do?
- Could the compensation provided be coercive or appear to be linked to successful enrollment in the study?
- Will the subject or their insurance be charged for any study-related activity?
- If a person is enrolled in the study, will there be a change in the responsibility for patient care? For example, will the study investigators now provide primary treatment for a problem?

The IRB requires that the role of a person not directly involved in the study who is identifying potential subjects be limited to asking the potential subject if he/she would be willing to talk to a researcher about a relevant study. If the potential subject is not interested, no further encouragement should occur.

Compensation to the person assisting in identifying potential subjects should be made whether or not the potential subject enrolls in the study.