Marshfield Clinic

Compensation for Identifying and Enrolling Subjects

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. None

3. PROCEDURE BODY

3.1. Federal Guidance

a. Federal regulations on human subjects protection do not directly address the payment of compensation or other incentives for enrolling subjects. The only indirect reference comes under the regulations concerning the general requirements for informed consents (45 CFR 46.116 and 21 CFR 50.20), which state, "An investigator shall seek such consent only under circumstances that . . . minimize the possibility of coercion or undue influence."

b. A Food and Drug Administration (FDA) guidance document entitled "Recruiting Study Subjects" states the following:

- "An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of the proposed research. The IRB should also review the methods and materials that investigators propose to use to recruit subjects."

c. A December 2001 report of the Association of American Medical Colleges (AAMC) Task Force on Financial Conflicts of Interest in Clinical Research states:

- "Payments for subject enrollment or for referral of patients to research studies should be permitted only to the extent that such payments:
  - (a) are reasonably related to costs incurred, as specified in the research agreement between the sponsor and the institution;
  - (b) reflect the fair market value of services performed; and
  - (c) are commensurate with the efforts of the individual(s) performing the research."

d. A 2008 report from the AAMC and the Association of American Universities (AAU) also reiterates that any payments should be in connection with the reasonable cost of research.

e. The American Medical Association Code of Ethics (opinion E-8.0315) has also indicated:

- "(4) Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the

rate of compensation per patient, should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements. Furthermore, according to Opinion 6.03, 'Fee Splitting: Referral to Health Care Facilities,' it is unethical for physicians to accept payment solely for referring patients to research studies;" and

- "(6) The nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process.'"

f. The Department of Health and Human Services' (DHHS) Office of Inspector General issued a report entitled "Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research" in June 2000. The report recommends that DHHS issue guidance to IRBs about appropriate recruiting practices, but the DHHS has yet to issue this guidance. However, the June 2000 report outlined two relevant concerns about current recruitment practices and incentives:

- Erosion of Informed Consent: The consent process may be undermined when, under pressure to recruit quickly, for example, investigators misrepresent the true nature of the research, or when patients are influenced to participate in research due to their trust in their doctor; and
- Enrollment of Ineligible Subjects: Some investigators may be led to enroll subjects who are ineligible, or are of questionable eligibility, in order to meet quotas and satisfy sponsors.

g. A May 2004 DHHS guidance document, "Financial Relationships and Interests in Research Involving Human Subjects," raises points to consider when determining whether specific financial interests in research affect the rights and welfare of human subjects, and identifies actions that could be considered to protect them. This document advises institutions, IRBs, and investigators to establish and implement methods to protect the rights and welfare of subjects from conflicts of interest created by financial relationships of parties involved in research. In doing so, parties are encouraged to consider, among other things, whether individuals or the institution receive payments per participant or incentive payments, and if so, whether payments are reasonable. However, it does not suggest what payments or incentives are or are not reasonable.

3.2. Compensation or Incentives for Enrollment of Research Subjects At Marshfield Clinic

a. Investigators and staff of studies approved by MCRF's IRB may not accept recruitment bonuses or incentives for enrolling or referring patients to research studies. This includes bonuses for achieving certain levels of accrual by specified dates.

b. Additional funding that is built into sponsor funding agreements, and intended to cover expenses related to extra recruitment efforts, are allowed as long as any payment is commensurate with the work being performed, goes to the institution and not an individual, and conforms with all other institutional policies. These additional payments to cover expenses commensurate with the work being performed do not require IRB approval.

Related to the payment of compensation or incentives for subject enrollment, Marshfield Clinic policy on conflict of interest prohibits the acceptance of gifts or favors from

pharmaceutical companies because of the potential (real or perceived) for the gifts or favors to influence prescribing behavior.

4. ADDITIONAL RESOURCES

4.1. References:
- None

4.2. Supporting documents available:
- None

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library - #1530.1. (No changes made)
2.0	
3.0	

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
Co-Author(s):
Approver(s): This document has been electronically signed and approved by: Ziemba, Steven J PHD on: 8/21/2015 1:18:23 PM