Title: **Compensation and Incentives Offered to Research Participants**	*Applicable to: **Beaumont Health**	Effective Date: **03/16/2018**
		Last Periodic Review Date: **03/16/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, Research Institute**

***For This Document, Beaumont Health Includes**:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE:

The purpose of this policy is to differentiate between items, services or assistance offered to Beaumont research participants as incentives and those items, services or assistance offered to research participants as compensation at a Beaumont facility. The Institutional Review Board (IRB) of record for Beaumont research may be the Beaumont IRB or an approved external IRB, in accordance with IRB policy *Review by an External Institutional Review Board*. The policy distinguishes between the requirements pertaining to all participant compensation and incentives for Beaumont research and those applying strictly to studies reviewed by the Beaumont IRB.

II. DEFINITIONS:

A. **Compensation -** Any item, service or assistance offered to a research participant to reimburse them for time expended and/or expense incurred as a result of participation in the research. Compensation is not considered a benefit of study participation. Compensation must not interfere with the voluntary dimension of the participant's participation and must not serve as inducement to the participant to participate in the research.

B. **Incentive -** Any item, service, assistance, bonus, gift or benefit given to a participant in order to motivate them to participate in the research.

C. **Study Supplies for Participants -** Study supplies are items or services integral to study conduct, and may include but are not limited to test articles, diaries to be maintained by participants, educational materials, pill boxes, and cooler bags for storing test article at protocol-required temperatures.

D. **Minimal Risk -** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

III. APPLICABILITY:

This policy applies to Beaumont investigators and key research personnel. A section of the policy, under the header *Requirements when Beaumont IRB is IRB of Record*, pertains to investigators, key research personnel, and the Beaumont IRB (when the Beaumont IRB serves as IRB of record for a particular study). The IRB of record for Beaumont research may be the Beaumont IRB or an approved external IRB, in accordance with IRB policy *Review by an External Institutional Review Board*.

IV. POLICY:

A. **Incentive and Compensation Requirements, Regardless of the IRB of Record**

The appropriateness of offering proposed incentives or compensation to research participants during the course of a particular study will be reviewed by the IRB of record on a case-by-case basis, in accordance with that IRB's specific policies. Incentives, supplies, compensation, stipends, free care, etc. to be provided to participants must be described in the IRB application and clearly disclosed in the informed consent and authorization document. The total amount and the schedule for payment or provision must be included. Compensation or incentives must be offered to all study participants equally.

All forms of compensation or incentives, monetary or other must be approved in advance by the IRB of record, regardless of the value. Examples of items potentially used as compensation or incentives include but are not limited to:

1. Participant stipend or money in any amount.
2. Medical expenses, co-pays, deductibles, meals, or mileage.
3. Gift items, e.g., pens, t-shirts.
4. Food items.
5. Coupons for entertainment events, e.g., movies.
6. Coupons for gifts or food, e.g., free pizza.
7. Lotteries, in which participants have the chance to win a prize.

Gift cards or gift certificates as compensation or incentive for Beaumont research are discouraged. Their use must be approved by the Administrative Director of the Research Institute. Monetary compensation or incentives to participants are entered into the study visit schedule in the clinical trial management system (e.g., Reveal or DDOTs). As part of the

research billing review, check requests will be submitted and checks will be mailed to the participant's home, or otherwise distributed, as described in the IRB study approval.

Products used as compensation, incentive or study supplies (generically referred to as "products" below) must be securely stored and their disbursement tracked by the principal investigator (PI) and other key research personnel. A log must be maintained to track disbursement of items and the PI and key research personnel must reconcile distributed stock. When possible, research participants must sign a disbursement log to confirm their receipt of products. If products remain at the completion of the study, they must be returned to the source. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the research activity.

Compensation or incentives for participation in a clinical trial offered by a sponsor may not include future discounts towards the purchase price of the product once it has been approved for marketing.

Under federal regulations, remuneration for participating in research is considered compensation rather than a benefit of the study. Monetary compensation exceeding $600 in a calendar year will be reported to the IRS on a 1099 per IRS guidelines. This information must be included in the informed consent and authorization document.

Compensation or incentives to research participants is separate and distinct from financial assistance provided to patients who have difficulty paying for services, in accordance with corporate policy. Participants who may require financial assistance must be referred to a Beaumont Financial Counselor.

When research involves U.S. military personnel additional protections for military research participants are required to minimize undue influence:

1. Officers are not permitted to influence decision of their subordinates.
2. Officers and senior non-commissioned officers may not be present at the time of recruitment.
3. Officers and senior non-commissioned officers have a separate opportunity to participate.
4. When recruitment involves a percentage of a unit, an independent ombudsman is present.
5. When research involves U.S. military personnel, limitations on dual compensation are required.
    a. Individuals are prohibited from receiving pay from more than one position for more than 40 hours of work in one calendar week. This prohibition includes temporary, part-time, and intermittent appointments.

B. **Requirements when the Beaumont IRB is the IRB of Record**

1. ***Incentives-specific requirements.*** Incentives are items, services, assistance, bonuses, gifts or benefits given to a participant in order to *motivate* them to participate in the research. The PI must describe all proposed incentives in the Beaumont IRB application in iMedRIS. The Beaumont IRB will review the incentives to research participants to determine appropriateness. When a research study poses more than minimal risk, the Beaumont IRB believes a higher degree of scrutiny is warranted to protect the interests of prospective participants, and believes offering incentives to research participants should be limited.

2. ***Compensation - specific requirements.*** Compensation is any item, service or assistance offered to a research participant to reimburse for time expended and/or expense incurred as a result of participation in the research. The investigator must describe all proposed compensation in the Beaumont IRB application in iMedRIS. Compensation to research participants may be provided when the study demands made on the participants are significantly more than would be expected for routine standard of care. Such demands might include additional office visits, uncomfortable or lengthy testing procedures, or prolonged hospitalization. Compensation must never interfere with the voluntary dimension of a participant's participation. Compensation should be commensurate with study demands (inconveniences or costs incurred by participants as a result of participation in the research) and should not be in an amount or manner which could be considered coercive. Examples include parking fees, meals, travel, lodging, time off of work, or childcare. Stipends of a larger amount must have sufficient justification in the iMedRIS application for IRB consideration.

   The Beaumont IRB will review the amount of the compensation, and the proposed method and timing of disbursement, to assure neither constitutes coercion. The nature, amount and method of the stipend or other remuneration should not constitute inducement to participate (i.e., the payment alone should not induce the participant to volunteer).

   Compensation to participants should be prorated, i.e. partial participation in research activities would obligate partial compensation, unless the Beaumont IRB determines the expected time of participation is of sufficiently short duration that a single disbursement is adequate. The Beaumont IRB may authorize a compensation schedule in which the final sum is larger than prior sums. However, the total compensation should not be of sufficient value to induce participants to remain in a study when they would have otherwise withdrawn.

3. ***Reasonable compensation guidelines.*** Stipends should only be offered when the research participant is subjected to inconveniences or additional expenses as a direct result of study participation. It is acceptable to offer no compensation or compensation of lesser amounts.

The following ranges of compensation are suggested guidelines for investigators and IRB reviewers:

a. Surveys or phone follow-up: $10 - $25.
b. Visits including minimal time and minimally invasive procedures: $5-$50 per study visit. These study visits may involve minimally inconvenient or minimally invasive procedures (blood draws, urine specimens, vital signs, x-rays, etc.) and/or lengthy questionnaire or survey.
c. Visits requiring a moderate amount of time or moderate/extremely invasive study procedures: $50 - $100 per study visit.

Due to the susceptibility of children to undue influence, stipends to children involved in research are discouraged. Any stipend to be offered to children must be thoroughly justified within the IRB application in iMedRIS.

V. APPLICABLE REGULATIONS AND GUIDELINES:

21 CFR 50.20 – Elements of Informed Consent
21 CFR 56.111 – Criteria for IRB Approval of Research
45 CFR 46.206 – General Limitations

VI. REFERENCES TO OTHER POLICIES:

IRB policy *IRB Initial Review of Research Protocols*
IRB policy *Informed Consent and Authorization in Research*
IRB policy *Review by an External Institutional Review Board*
Beaumont Health policy *Beaumont Health Business Ethics and Compliance Policy*
Beaumont Health policy *Financial Assistance*

CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.