PURPOSE
The purpose of this policy is to differentiate between items, services or assistance offered to research participants as incentives and those items, services or assistance offered to research participants as compensation. Additionally, this policy describes circumstances when the Human Investigation Committee (HIC) may determine offering incentives to research participants is acceptable and when it is unacceptable. This policy also outlines incentive guidelines and compensation guidelines used by the HIC.

DEFINITIONS

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 subject to participate in the research.

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

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 subjects, educational materials, pill boxes, and cooler bags for storing test article at protocol-required temperatures.

APPLICABILITY
This policy applies to investigators, key research personnel, and HIC members and staff.

POLICY
Everything provided to subjects during the course of a study must be prospectively approved by the HIC, either as a study activity, study material, compensation or incentive described in the iMedRIS project submission, including the HIC Application and informed consent and authorization document. The appropriateness of offering proposed incentives or compensation to research participants during the course of a particular study will be reviewed by the HIC on a case-by-case basis.

Incentives - Specific Guidelines
The investigator must describe all proposed incentives in the HIC Application. The HIC will not approve incentives to research participants for studies which pose greater than minimal risk. If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms associated with participation in the research to be no greater than those encountered by the subject in his or her everyday life, then the HIC regards the research to pose minimal risk. When a research study poses more than minimal risk, the HIC believes it warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects, and believes offering incentives to research participants is unacceptable.

Compensation - Specific Guidelines
Compensation to research participants may be provided when the demands made on the participants are significantly more than would be

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expected for the 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 subject’s participation. Compensation should be commensurate with study demands; inconveniences or costs incurred by subjects 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.

The HIC will review both 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 subject to volunteer).

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

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 on a 1099 per IRS guidelines. This information must be included in the informed consent and authorization document.

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 HIC reviewers:

- Surveys or phone follow ups: $10 - $25.
- 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.
- Visits requiring a moderate amount of time or moderate/extremely invasive study procedures: $50 - $100 per study visit.

Guidelines Common to Both Incentives and Compensation
All forms of compensation or incentives, monetary or other must be approved in advance by the HIC, regardless of the value. Examples of items potentially used as compensation or incentives include but are not limited to:
Subject stipend, or money in any amount.
- Medical expenses, co-pays, deductibles, meals, or mileage.
- Gift items, e.g., pens, t-shirts.
- Food items.
- Coupons for entertainment events, e.g., movies.
- Coupons for gifts or food, e.g., free pizza.
- Lotteries, in which participants have the chance to win a prize.

Gift cards or gift certificates as compensation or incentives for research are discouraged. Their use must be approved by the Administrative Director of the Research Institute.

Compensation or incentives must be offered to all study subjects equally. The approved informed consent and authorization document will clearly explain any compensation or incentives, including subject stipends, free care or other non-medical benefits for participating in the research. The total amount and the schedule for proration must be included in the informed consent and authorization document.

Monetary compensation or incentives to participants are incorporated into the study schedule in the clinical trial management system (e.g., Reveal or DDOT). Checks are mailed to the participant’s home, or otherwise distributed, as described in the HIC study approval.

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 HIC Application.

Products used as compensation, incentives or study supplies must be securely stored and disbursement tracked by the principal investigator (PI) and other key research personnel. A log must be maintained to track disbursement of gifts and study materials, and the PI and key research personnel must reconcile distributed stock. If gifts 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.

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. Subjects 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 subjects are required to minimize undue influence:

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- Officers are not permitted to influence decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.
- When research involves U.S. military personnel, limitations on dual compensation are required.
  - 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.

**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

**REFERENCES TO OTHER POLICIES**

- HIC Policy #216 *HIC Initial Review of Research Protocol*
- HIC Policy #221 *Informed Consent and Authorization Process*
- Corporate Administration Policy #178 *Financial Assistance Policy*

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Research Institute Compliance Committee Review Date: __________________

Corporate Administration Approval: __________________ Date: ________________

  V.P. of Research or Chief Medical Officer

Research Institute Board Approval: __________________ Date: ________________

Research Administration Approval: __________________ Date: ________________

  Administrative Director

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