Mass General Brigham

Title:	Renumeration for Research Subjects
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Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board

Subject Payment

PURPOSE:

The purpose of this policy is to describe requirements for renumerating subjects for participation in research.

DEFINITIONS:

See Definitions in Human Subject Research

Remuneration for Research Subjects

Research subjects may be compensated for the time and effort they devote to clinical studies. It is not necessary, required, or desirable that all subjects involved in clinical research receive monetary compensation for their participation. Some subjects derive medical benefit as a result of their participation; some subjects volunteer out of altruism, a desire to further medical research into diseases that affect them and their families, or for other personal reasons. Even when subjects derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Therefore, many investigators reimburse these and similar expenses for research subjects routinely, when funding is available, either with or without a small additional stipend as compensation for the individual's time. Often it is not possible to compensate very ill subjects, pediatric subjects, or those with rare diseases for their unique and generous contributions to medical research. Sometimes compensation may represent only a small symbolic gesture in recognition of the major contributions that these individuals make to research, and it is hoped, to the health of future patients.

Most often healthy volunteers who will derive no medical benefit from their participation in the research study

are compensated reasonably for the time they devote to research projects. Monetary compensation is not intended to be the only motivating force to induce subjects to participate. The goal of IRB oversight of research subject compensation is to ensure that stipends paid to research subjects provide fair compensation without undue pressure (coercion) to participate. Excessive monetary compensation may cause subjects to undertake risks or discomforts that they otherwise would not assume. This unfairly targets subjects of lower socioeconomic groups and places more of the "risk burden" of medical research on these groups. In the case of healthy volunteer studies, the IRB is often in the position of suggesting decreased compensation over that suggested by investigators, in an effort to decrease the element of financial coercion.

The IRB is responsible for reviewing and approving participant compensation. The IRB reviews proposed participant compensation to ensure that:

1. The amount and proposed method of payment and the timing of disbursement are not coercive and do not unduly influence participants;
2. Credit for payment accrues as the study progresses and is not contingent upon a participant completing the entire study;
3. Any amount paid as a bonus for competing the study is reasonable and not so large as to unduly influence participants to stay in the study when they would otherwise have withdrawn; and
4. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

Prorated Compensation

It is a general policy that compensation for participation in research projects is pro-rated according to the amount of time devoted to the project. Research subjects have the right to withdraw from a study at any time, for any reason. In many protocols where completion of all visits or procedures is paramount, there is some element of "incentive" provided by withholding some compensation until the end of the study or providing a "bonus" for completion of all segments of the study. Such procedures should be explained and rationalized in detail in the research protocol, and clearly outlined in the informed consent documents. Particularly where discomforts, stress or risks are involved, it is not acceptable to withhold all compensation from an individual who made a good faith effort to participate but withdrew prior to completion of all of the study procedures. It may be appropriate to pay compensation to subjects in "installments", provide parking or meal vouchers with each visit, or in other ways compensate healthy volunteers in a "rolling" fashion based upon ongoing participation in the study.

Compensation for Minors

Appropriate compensation of minor subjects involves additional considerations and may be viewed differently for children and adolescents. While it may be acceptable to compensate some adolescents monetarily, similar to adults, it may be more appropriate to compensate younger children in another manner. Monetary compensation for participation of younger children may be provided to the parents for the time and inconvenience to them associated with their child's participation. Although parents will have expenses for travel, babysitting for siblings, time off work to bring children in for appointments, it should be recognized that the children are the research subjects. They may undergo stress, discomfort or inconvenience as a result of participation in research studies, and there should be some effort made to compensate the children directly and personally.

Parking and Parking Vouchers

We recommend you provide parking vouchers whenever possible, so subjects do not need to be reimbursed at a later time or be concerned about having enough cash on hand to pay hourly parking rates, which are high at Mass General Brigham. If vouchers are given, note this on your forms or submission: e.g. Parking: (voucher). If a single payment is given to cover a stipend and transportation costs, as is the case in some studies, this could be noted as: $75 to compensate for time and parking expenses.

Suggested Monetary Compensation for Certain Routine Research Procedures

In an effort to guide investigators, a list of approximate monetary compensation for a variety of frequently

performed clinical activities is listed below. This list is meant to guide investigators and is based upon active protocols currently approved by the Mass General Brigham IRB. Although not every procedure is listed, these amounts may guide investigators by allowing comparison of new procedures with these in terms of time and discomfort. There may be some cases in which no compensation is warranted or needed. There may be special instances where modifications of these procedures might merit additional compensation.

Investigators are welcome to contact the Mass General Brigham IRB staff if additional guidance is needed.

Suggested Monetary Compensation	
Blood draw for research purposes from healthy volunteer subjects	$5 - 25
Noninvasive psychological testing or memory tasks, pencil paper activities	$5 – 30/hr
Focus groups (1-3 hrs)	$20 – 75
Outpatient visit: depending upon time, discomfort, inconvenience, need to take medications, bringing in timed samples (e.g. 24 h urine collections), diary completion or other activities beyond simply appearing for the visit	$30 – 75
Laser/UV treatments with no direct benefit to subjects	$30 – 75/visit
Skin biopsy	$50
Muscle biopsy, at the higher end of the range if special preparation required	$50 - 100
MRI scan, depending upon duration of scan and use of contrast agent	$50 – 200
Oral glucose tolerance test or other infusion tests, more if special preparation or diet required	$50 – 150
Lumbar Puncture	$100
24-hour stay in sleep center or clinical research center, for relatively non-invasive activities: blood draws, IV lines, vital signs or other non-invasive clinical monitoring	$100 – 200/ 24-hour stay
Bronchoscopy with lavage in healthy volunteer subjects	$150 – 300
PET scan with radiolabelled material, more if arterial or IV line placed	$200 – 300
Swan Ganz catheter placement in healthy volunteer subjects	$200 – 400