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Ten Subject Stipend Issues

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This article will discuss some of the unresolved and complex ethical, compliance and implementation issues that surround the practice of offering — or not offering — payments ("stipends") to clinical trial subjects. However, this article is not intended to provide legal or tax advice.

Issue 1. What Do We Call Them?

To start with, stipends often go by other names, including "payment," "allowance," "reimbursement," "compensation," and "remuneration." These names have different connotations, which suggest their philosophy and purpose. For example, "reimbursement" suggests payment for out-of-pocket expenses. In contrast, "compensation" might consider out-of-pocket expenses, study visit time, lost wages, discomfort and care for a research-related harm. It also might include non-monetary compensation. The word "stipend" is not entirely suitable, since it is unfamiliar to many study subjects and commonly refers to a periodic payment, especially a scholarship or fellowship allowance granted to a student. While there are much more pragmatic issues to resolve than naming conventions, naming alone will not avoid scrutiny.

Issue 2. Fairness, Exploitation and Undue Influence

Generally, stipends are designed to neutralize minor financial burdens that preclude study participation. While stipends can be influential in a decision to enroll in a study, they should not be unduly influential, i.e., so big as to cause people to participate against their best interests. On the other hand, stipends that are too small could be characterized as exploitative.

Since subjects vary greatly, it is often impossible to set a stipend amount that would be universally considered not to be coercive or unduly influential for every potential subject, Table 1 presents several types of variation and suggests possible solutions, which are not necessarily fair or practical themselves, thus further perpetuating the issue or creating a new dilemma. OHRP guidance defines "undue influence" as "an offer of an excessive or inappropriate reward or other overture in order to obtain compliance,"[1] noting that this differs from "coercion," which is defined as "an overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance."[2] The Institute of Medicine states, "Unfortunately, no bright line distinguishes proper and reasonable payments…from payments that are inappropriate. A mix of group or individual circumstances may determine when a particular type or level of payment crosses the line. What is excessive in one situation may not be in another, and reasonable people may sometimes differ in their judgments."[3]

The typical methodology for setting stipends relies on an IRB experience and judgment to find or approve of a number that sounds about right. Nevertheless, with a diverse patient population, "sometimes no matter what you do, there's nothing you can do."[4]

Table 1. Examples of Subject Differences with Respect to Stipends

Justification	Subject A	Subject B	Fair (?) Solutions
Take time off work	Earns $9/hour wage	Earns $75/hour salary	Base stipend on individual's hourly rate?
Cover transportation costs	Lives across the street	Needs 60-mile cab ride each way	Reimburse based on receipts for reasonable costs? Differentiate based on type of vehicle, e.g., truck vs. bicycle? Differentiate based on convenience, e.g., bus vs. taxi?
Cover expenses	Has no expenses	Needs babysitter at $10/hour	Reimburse based on receipts for reasonable costs? As resources are generally not unlimited, who determines what is reasonable?
Incentivize (but not unduly influence) participation	Is poor, has no other income opportunity, and needs money to support elderly mother	Is wealthy, so $10 is basically the same as $100.	Use sliding scale based on income or wealth (paying less for lower income people so as to not "unduly influence")? Measure "level of enticement" with psychological/social assessment tool?

Issue 3. Stipends Are "Income"

In the U.S., stipends are taxable income, from which subjects may deduct their out-of-pocket expenses. Payers must report the payment with an IRS Form 1099 if the aggregate amount exceeds $600 across all studies for that payer. A small accounting caveat is that stipends are generally considered "awards," not "wages," and are thus exempt from payroll taxes (i.e., Social Security, Medicare, etc.). However, stipend income may affect government benefits that are based on income levels, such as supplemental security income (SSI) and Medicaid. As a result, some potential subjects refuse stipends or study participation entirely.

A little-known statute, entitled "Improving Access to Clinical Trials Act of 2009,"[5] was signed into law on October 5, 2010, and sunsets five years later. This law allows a recipient to exclude the first $2,000 received during a calendar year for participation in clinical research from the calculation of certain income-limited federal benefits. However, it applies only for IRB-approved studies for "rare diseases or conditions," as defined by the Orphan Drug Act.

One other caveat about stipends as "income" is that a manufacturer's stipend payment (through a research site) to a physician who is a subject in a research study is excluded from being tracked and reported under the U.S. Open Payments (a.k.a. "Sunshine") law.[6]

Clinical research professionals who are not also tax experts should be cautious about giving tax advice to subjects, but they should advise participants that stipends may be subject to income tax.

Issue 4. Financially Motivated Subjects

Although surveys show that many subjects sign up for studies for altruistic reasons, some are primarily interested in the stipend income. While people have every right to participate in a study mostly or exclusively for money, they can be problematic subjects. If their focus is primarily financial, they may lie to get into or stay in a study, not adhere to study requirements for taking medications or entering data, drop out when they find a study that pays better, attempt to negotiate a higher stipend to not drop out, or participate in more

than one study simultaneously. They might even alter the informed consent form or claim they did not receive money they actually received, especially if it was paid in cash. Sites should, therefore, be aware of these risks and clearly document the receipt of stipend payments. When a subject evidences near exclusive interest in payment, sites should be on guard for a wide range of financially motivated misbehavior.

Issue 5. Adding/Deleting/Changing Stipends Mid-Study

If a protocol is amended, it may make sense to revise the stipends. If it is amended because enrollment is lagging, increasing the stipend may be central to the amendment. If the stipend amounts are "hard wired" into the consent form, e.g., "$35 per visit," the IRB is more likely to require reconsent of active subjects. However, few, if any, subjects are likely to withdraw consent due to an increase in the stipends, unless they are right at an income limit for a government benefit program.

Issue 6. Off-Consent Compensation

Stipends are generally described in the informed consent process and documentation, but compensation is often "off consent." Off-consent compensation might consist of gift cards, vouchers or in-kind services that investigators think of as gracious gifts rather than compensation. Pragmatically, trivial items (e.g., taking $5 from petty cash to allow them to eat lunch in the hospital cafeterias vs. offering tickets to a major sporting event the PI can't go to that evening) should not be of ethical concern, but IRBs may take issue with nearly anything in this area.

Issue 7. Cautions with Medicare Recipients

Some studies include routine care that Medicare reimburses, less the patient/subject's copayment. If, for example, the stipend is $25 and the copayment is $25, the site processes a payment for $25 so the subject can turn around and pay the site $25. A much more efficient process would be for the site to deduct the copayment from the stipend amount so, in this case, nobody would have to write checks.

The Center for Medicare and Medicaid Services (CMS) frowns upon sites waiving subject copayments. In the January 7, 2009 issue of MLN Matters,[7] the question,"May a research sponsor pay Medicare copays for beneficiaries in a clinical trial?" was answered "If a research sponsor [through a site] offers to pay cost-sharing amounts owed by the beneficiary, this could be a fraud and abuse problem." Given this opinion, most providers perform both transactions with the subject. However, if there are non-Medicare patients receiving stipends and making different or no copayments based on their insurance coverage, the documentation should make it clear that the site is not actually waiving copayments for Medicare patients.

Caution is also warranted as the Office of Inspector General, in its Special Advisory Bulletin entitled "Offering Gifts and Other Inducements To Beneficiaries"[8] limits "inexpensive (non-cash/cash equivalent) gifts" to Medicare beneficiaries to under $10 per instance and under $50 in annual aggregate. Since the OIG considers greater amounts an undue influence to utilize Medicare benefits, should OIG characterize stipends as gifts, sites will have a lot of explaining to do. Sites and IRBs should therefore set stipends consistently and document their rationales consistent with the burden on the subjects. Large stipends designed to incentivize enrollment may be vulnerable to CMS scrutiny.

Issue 8. Persons on an Eligible/Sanctioned-Persons List

The federal government maintains lists of individuals and entities that are forbidden to provide services to institutions receiving federal funds (such as Medicare funds). The current names of these lists are "List of Excluded Individuals/Entities (LEIE)" and "System for Award Management (SAM)" (formerly known as "Excluded Parties List System" or "EPLS"). OIG issued "Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs",[9] which states "an excluded individual may not provide other types of administrative and management services, such as health information technology services and support, strategic planning, billing and accounting, staff training, and human resources, unless wholly unrelated to federal health care programs." Therefore, if a study is not federally funded, generally there is no prohibition. If, however, the study is federally funded, there is some further trickiness. In informal conversation, an OIG staff member has stated that if the person is only acting in the capacity of a patient, i.e., a study subject, generally there is no prohibition, as there would be if they were acting in a professional capacity. OIG suggests informing the federal sponsor of the situation and letting them make the call. With that said, given the horrendous penalties for noncompliance, many risk-averse institutions have set a simple global policy to not make any payments to, or accept any professional services from, those on an exclusion list, regardless of capacity and funding source.

Issue 9. Stipends for Studies Involving Children

When looking at stipends for studies involving children, you have to look at payments to parents, as well as to the children themselves. Payments to parents can carry the stigma of "selling" their kids into studies.

Remuneration to the children themselves is also controversial, since many believe that children are highly susceptible to undue influence. The American Academy of Pediatrics goes so far as to make the radical recommendation that the payment discussions be held after study completion.[10]

Also, when dealing with wards of the state, stipends to the parental substitute should either be foregone or paid to the state rather than to the caseworker personally for children (outside of foster home settings), since it would give the appearance of personal gain from "selling" wards of the state into studies.

Issue 10. Unclaimed Stipends

Some stipends go unclaimed. For example, checks are never cashed or debit cards are never utilized. The cause might be an incorrect mailing addresses, accounting errors (such as posting to the wrong subject), lost or forgotten checks, or subjects not having the means to cash the check. Each state has its own laws and regulations on unclaimed property, such as uncashed checks or unclaimed cash, many of which require public-notice postings and eventually turning the funds over to the state. In general, unclaimed stipends are not money a research site can just keep.

Conclusion

Subject stipends are not going away and neither will the above issues. Research sites and sponsors simply have to make the best of a situation that is ethically, legally and practically complex and uncertain. Given the challenges, clinical research sites (and perhaps sponsors/CROs) should have well-considered practices (and even policies) for handling clinical research stipends.

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