

Supporting Participants. Simplifying Payments. Enhancing Study Experience.

Reimbursement and stipend structures are essential tools for reducing financial burden and enabling equitable participation in clinical trials. Sponsors and CROs must understand how these payments function, what they cover, and why standardization matters for participant experience, retention, and diversity. When financial support is predictable, transparent, and timely, participants can stay engaged and sites can operate more efficiently.

Key Definitions

Reimbursement

- Payment for out-of-pocket expenses that participants incur, supported by documentation such as receipts or mileage logs.

Stipend

- A flat-rate payment provided per visit or study activity. Amount varies based on time, complexity, burden, or required tasks (e.g., diary completion). No receipts required.

Typical Ranges:

- Office Visit: \$70–\$150
- Phone / Telehealth Visit: \$30–\$60
- Diary or App Completion: \$20–\$40

Per Diem

- A fixed daily rate used to cover meals and incidental expenses during study participation.

Compensation

- A general term that may include both reimbursement and stipend payments.

1099 Form

- In the U.S., the paying entity must issue this tax form when required by IRS rules.

Allowable Reimbursement & Stipend Categories

Reimbursements cover participants' out-of-pocket expenses and reduce the financial barriers that often prevent individuals from enrolling or remaining in a study. Sponsors should support broad, reasonable reimbursement categories to ensure equitable access for participants with varying personal circumstances.

Participants may be reimbursed for reasonable and study-related expenses including:

- Transportation
 - Rideshare (Uber/Lyft)
 - Bus
 - Train/Subway
- Airfare (special circumstances)
- Mileage
- Parking
- Lodging (special circumstances)
- Meals
- Child Care
- Elder Care
- Pet Care
- Caregiver Support

Actual amounts vary by study and must follow protocol guidelines. Consider urban vs. rural and cost of living within a specific city on appropriate stipend & reimbursement coverage amounts. As well, if rescue medications and/or study supplies are out of pocket for participants.

Transportation, lodging, meals, childcare, eldercare, and caregiver support address major real-world barriers to participation. Sponsors who fund these categories proactively enable broader recruitment and reduce inequities that disproportionately affect underserved populations.

Frequently Asked Questions

When should completion or milestone bonuses (e.g., retention, end-of-study) be considered?

- Determined by therapeutic area, study duration, and participant burden.

Is overhead (OH) included in stipends?

- Yes – when stipends & reimbursements are managed directly by the site.
- No – when a third-party vendor manages participant payments.

For pediatric studies, who should receive the funds?

- Funds typically go to the mature minor. Otherwise, consider caregiver + minor as joint recipients, following jurisdiction-specific regulations.

Are unscheduled visits or additional procedures covered?

- Yes. Payments should cover all required visits and procedures (scheduled, unscheduled, or location-specific) outlined in the study protocol.

How should Phase I or overnight stays be compensated?

- Options include:
 - Per-visit payments
 - Daily flat rates
 - Stipends for time or wage loss
 - Choose the option aligned with standard business practices and appropriate justification.

What is the best approach for managing site cash flow?

- High-volume trials should consider:
 - Advanced payments to sites
 - Pre-payments for participant reimbursements/stipends
 - Monthly payment terms
 - Routine reconciliation to maintain accuracy

Timely reimbursement requires predictable payment terms, advanced funding, and consistent reconciliation cycles. Sponsors that support administrative workflows lighten site burden, accelerate participant payments, and improve overall study management.

A well-structured reimbursement and stipend strategy is fundamental to participant-centered research and equitable trial access. When Sponsors and CROs proactively define, fund, and streamline these payment mechanisms, they reduce barriers, improve retention, and create a more inclusive research environment. Robust financial support is not only good practice, it is essential to running successful and representative clinical trials.