Ultimate Guide to Purchasing a Clinical Research Participant Payment System: 10 Areas to Consider

**Overview**

**BACKGROUND**
Research sites use a few methods to pay clinical research participants for:
- a) out of pocket expenses (travel, food, lodging), and
- b) milestone completion (study visits, surveys/tasks, time and effort).

Common payment methods: checks, cash, gift cards, bank debit cards.

**OPPORTUNITY**
Understanding limitations of each payment method creates opportunity to remove “pain points” and identify areas to consider during procurement, including:
1. HIPPA Compliance
2. IRS 1099 Compliance
3. FDA Guideline Adherence
4. Automated Financial Reporting
5. Internal Controls
6. Data Security
7. Patient Engagement
8. Participant Travel Assistance
9. System Integrations
10. Site Excellence

**Pain Point #1**
HIPPA Compliance
Maintaining blinded participant identifying information (PII) and confidential reporting
3rd party information technology security (e.g. SSAE SOC1; ISO 27000/27001 certification)

**Pain Point #2**
IRS 1099 Compliance
Reliable 1099 reporting of taxable payments
Differentiation of taxable study visit payments vs. tax exempt (travel and out-of-pocket reimbursement) payments
Validation of participant Tax Identification Number (i.e., SSN)

**Pain Point #3**
FDA Guideline Adherence
In 2018, FDA issued *Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators*. This guidance noted that study participation payments are helpful for recruitment and not coercive.
There are requirements to document these payments:
- Audit-ready accounting of payments made (by whom, when, for what reason).

**Pain Point #4**
Automated Financial Reporting
Real-time access to participant payment data (paid by, date, time, payment type, payment description) for study reconciliation

**Pain Point #5**
Internal Controls
Systems that allow configuration for auditing compliance (e.g., secondary approval of payments)

**Pain Point #6**
Data Security
A system should include:
- Permission-based payment workflows
- IT secure platform and audit trail
- Blinded patient data

**Pain Point #7**
Patient Engagement
Participants benefit from solutions that are user-friendly, including:
- Immediate replacement of lost funds (unlike checks, gift cards, or cash)
- Flexible use of payments (point of sale, ATM, on-line, direct deposit)
- Same-day payment

**Pain Point #8**
Participant Travel Assistance
Travel support to many participants is critical. Missed visits are costly and adversely impact budget and data collection.
Simplifying travel to minimize missed visits helps all stakeholders. These may include:
- Automatic calculation of mileage reimbursement
- Integration with a rideshare service (Lyft, Uber, etc.)
- Text or email ride/appointment reminders

**Pain Point #9**
System Integrations
Possible integration with the other systems using an open API framework. This includes:
- Single sign on
- CTMS triggered payments
- Integration with other platforms (e.g., RedCap, CTMS, financial, etc.)

**Pain Point #10**
Site Excellence
A payment solution should be more robust than a transactional payment and support the efficiency of managing the study, including:
- Payment system configuration and training of staff
- Guidance regarding best practices for system usage
- Ability to leverage the system across all departments