Digital Financial Disclosure Form

Veeva SiteVault

SiteVault's Digital Financial Disclosure Workflow transforms a historically manual, fragmented process into a centralized, digital standard. By moving away from dozens of unique Sponsor templates toward a single, industry-standard FDF, research sites reduce administrative burden, eliminate "wet-ink" errors, and accelerate study start-up.

The Problem vs. The SiteVault Solution

The Status Quo (The Problem)	The SiteVault Standard (The Solution)
Variability: Sites manage 10+ different Sponsor FDF templates, increasing the risk of missing specific clauses.	**Uniformity:** One standard template covers all FDA/AAHRPP requirements across every study.
Manual Tracking: Paper and PDF forms require generation of individual forms for every PI and sub-I, manual "chasing" of signatures and physical filing.	**Automation:** Digital workflows automate FDF creation and distribution, tracking, and filing for every investigator in a single click.
Compliance Risk: Clerical errors, missing signatures, or lost dates lead to audit findings.	**Data Integrity:** 21 CFR Part 11-compliant signatures with a validated, timestamped audit trail.

SiteVault's FDF isn't just "easier"—it is built to satisfy the most stringent global regulatory requirements. Use these points to satisfy Sponsor Quality Assurance (QA) teams:

- **FDA 21 CFR Part 54:** The template explicitly captures all four categories of disclosable financial interests (Compensation affected by outcome, Proprietary interest, Equity interest in public entities >$50k, and Significant payments >$25k).
- **FDA 21 CFR Part 11:** All digital signatures meet the requirements for electronic records, ensuring authenticity, integrity, and non-repudiation.
- **The "One-Year Rule":** The workflow includes built-in reminders and fields for investigators to report changes for up to one year following study completion.
- **AAHRPP Standards:** Aligns with accredited IRB reporting needs for conflict of interest (COI) transparency.

Supporting Language for Site SOPs

Sites can incorporate the following into their Internal SOPs or "Letter of Intent" to Sponsors:

> "[Site Name] leverages the SiteVault Industry-Standard FDF workflow as our primary method of Financial Disclosure collection. This supports a robust, institutional Conflict of Interest (COI) policy. By using a validated, digital system, we ensure that every investigator is screened against the same rigorous criteria, reducing the risk of non-disclosure and ensuring that all reporting to the IRB is accurate and timely."

For more information, visit our website: https://sites.veevavault.help

Sponsor Objection Handling

Scenario 1: The Sponsor insists on their "Legal Branding."

- **The Response:** "We understand the importance of legal consistency. However, our institution has standardized on the SiteVault FDF to ensure 100% compliance with FDA 21 CFR Part 54 across all investigators. This eliminates the risk of our team missing a disclosure due to template fatigue or clerical error."

Scenario 2: The Sponsor requests a "Wet-Ink" signature.

- **The Response:** "Our site has moved to a paperless environment to improve audit readiness. The SiteVault electronic signature is 21 CFR Part 11 compliant and provides a more robust audit trail than a scanned PDF or wet-ink document."

Scenario 3: The Sponsor claims their form is "Required by the FDA."

- **The Response:** "The FDA does not mandate a specific *form* (like Form 3455) for investigator collection; they mandate the *collection of specific data*. The SiteVault FDF captures all data points required by the FDA and provides a cleaner, more defensible record for inspection."

Value Realization for the Sponsor

*When talking to Sponsors, highlight how this helps **them**, not just the site:*

- **Faster FPI (First Patient In):** Digital FDFs are completed in minutes, not days, removing a common bottleneck in Study Start-Up.
- **Clean TMF (Trial Master File):** Sponsors receive high-quality, legible, and fully executed digital documents that are "inspection-ready" upon receipt.
- **Reduced Queries:** Standardization means fewer back-and-forth emails regarding missing dates or illegible handwriting.