



## Memorandum

To: Trialists  
Fr: Curtis Meinert  
Re: When is fraud fraud?

Fraud is deceit or trickery. For an act to be fraudulent, it has to be intentional. The element of intent is evident in definitions in the *Oxford English Dictionary* (1970) and *Black's Law Dictionary* (1990).

### Oxford English Dictionary

*1. The quality or disposition of being deceitful; faithlessness, insincerity. 2. Criminal deception; the using of false representations to obtain an unjust advantage or to injure the rights or interests of another. 3. An act or instance of deception, an artifice by which the right or interest of another is injured, a dishonest trick or stratagem. 4. A method or means of defrauding or deceiving; a fraudulent contrivance; in modern colloquial use, a spurious or deceptive thing.*

### Black's Law Dictionary

*An intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right. A false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives and is intended to deceive another so that he shall act upon it to his legal injury. Anything calculated to deceive, whether by a single act or combination, or by suppression of truth, or suggestion of what is false, whether it be by direct falsehood or innuendo, by speech or silence, word of mouth, or look or gesture.*

Show me a trial and I will show you a little fraud. Recording anything on a study form that is false or entering something into a data system that is false is fraud, if intentionally done.

Coordinating centers have responsibility for data integrity. They have to exercise due diligence in monitoring for illicit practices and they have responsibility for taking corrective action when indicated. They walk a narrow line between policing and collaborating.

Although directors of coordinating centers know what to do when confronted with fraud, detecting fraud is another matter. Sometimes detection is easy, for example, in the National Surgical Adjuvant Breast and Bowel Project (NSABP) when the coordinating center received forms labeled "false" (in French) from a Montreal-based clinic.

When is fraud fraud?  
13 December 2011

---

But what do you do if you suspect fraud, but there is no smoking gun, no confession, just suspicion? How much suspicion do you need before you take your concerns up the line? What do you do if:

The variance between repeat blood pressure readings suggests a reader is making up the 2nd reading in a protocol where two readings, a minute apart, are required?

You suspect a person in a clinic is "gaming" the system to avoid having to do double data entry?

A clinic has a disproportion of visits logged on the last day of the time window, sometimes even for end dates that fall on Saturdays or Sundays?

A clinic backdates forms so they fit within time windows?

You think personnel at a clinic are lying about transactions represented on study forms?

No doubt, the best way to avoid the questions is by not looking. By not doing site visits. By not looking for differences in data patterns. By not tracking changes to data forms. By not doing edit checks. But "not looking" is not an option for responsible coordinating centers.

Hence, coordinating centers need to have processes and procedures in place for addressing suspicious behaviors. They are well-advised to outline those processes and procedures before the start of data collection and to have buy-in regarding them by study officers and steering committees before questions arise.

A single piece of fraudulent data in a sea of data is virtually undetectable. Coordinating centers rely primarily on differences in data patterns for detection. It was the difference in pattern and spread of data at the Harvard site in a multicenter dog heart study compared to other study sites that led people at the coordinating center to start probing for the reasons. Eventually, after a couple years of effort, they discovered the reason – data fabrication (John Darsee case).

Act on suspicions of fraud too soon and the director of the coordinating center risks legal action for defamation of character. Fail to act and the director risks censure. The fact that the coordinating center and study chair in the NSABP had evidence of fraud at a Montreal clinic and did nothing about it almost brought the NSABP down. The fact that the National Library of Medicine labeled dozens of papers by the NSABP study chair as suspect brought legal action against the library by the study chair.

Every institution receiving federal funds has to have processes for receiving and dealing with charges of fraud as well as other aspects of scientific misconduct that concern personnel associated with the institution. But most cases of fraud for coordinating centers relate to personnel at other institutions. When does the director take the concern to the institution where the suspicious activity is centered?

The suggestions that follow are relevant to dealing with issues of data fraud.

When is fraud fraud?  
13 December 2011

---

**Suggestion 1:** Familiarize study staff with acts constituting fraud and the consequence of fraud to the study and to persons engaging in acts of fraud.

*Comment:* The place and time to do this is at an in-person kickoff training meeting before the start of data collection.

**Suggestion 2:** Instruct coordinating center personnel what to do if they suspect data fraud and who to turn to report their concerns

**Suggestion 3:** Instruct coordinating center personnel what to do if they suspect people in the center of illicit practices and who to turn to if they think the center director is suborning fraud

**Suggestion 4:** Outline plans as to how the director of the coordinating center will deal with suspicions of data fraud; commit to writing and have plans reviewed by study leaders

*Comment:* Although there is no way to write plans that anticipate all situations, a general plan is useful. Even a sketchy plan is better than none at all.

**Suggestion 5:** Seek the counsel of trusted colleagues for opinions before voicing suspicions beyond the confines of the coordinating center

*Comment:* Remember. Voicing concerns beyond the coordinating center can have a corrosive effect on relationships.

**Suggestion 6:** Seek the counsel of the study chair or another study officer before acting on suspicion

**Suggestion 7:** If data are purged because of fraud, report the purge in publications

**Suggestion 8:** If the suspicion rises to the level of being reportable, the route should be through the director of the center housing the personnel suspected of fraud or to officials of the institution if the suspicion is focused on the center director

**Suggestion 9:** Fraud should be reported to the IRBs of the coordinating center and the center where the fraud occurred

**Suggestion 10:** Be mindful of the difference between carelessness, error, misunderstanding, misinterpretation and fraud

*Comment:* Fraud requires intent. Carelessness, error, misunderstanding, and misinterpretation are without intent.

**Suggestion 11:** Do not assume intent to deceive in data collection or entry if there are more parsimonious explanations for the behavior

