Fraud and Misconduct

Module 7 Topic 7

Drivers Of Non Compliance

Honest Error

- Failure to see the “experiment”
- Complicated study procedures
- Poor infrastructure
- Miscalculation/ misjudgment

Compliance → Noncompliance

Difference of opinion

- Study protocol ambiguous
- Rationale of study unclear
- Patient inconvenience
- Overrated techniques/ equip.

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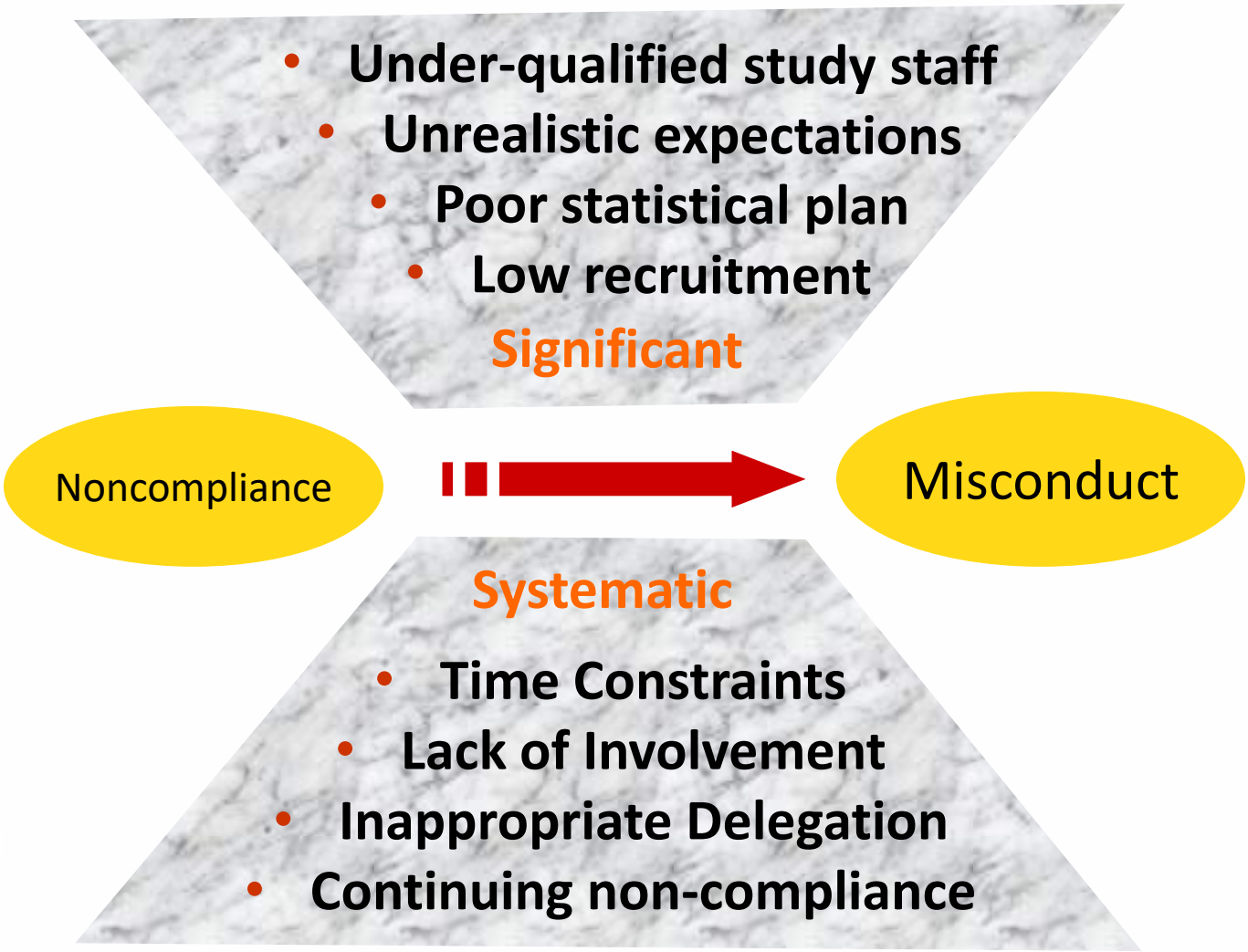
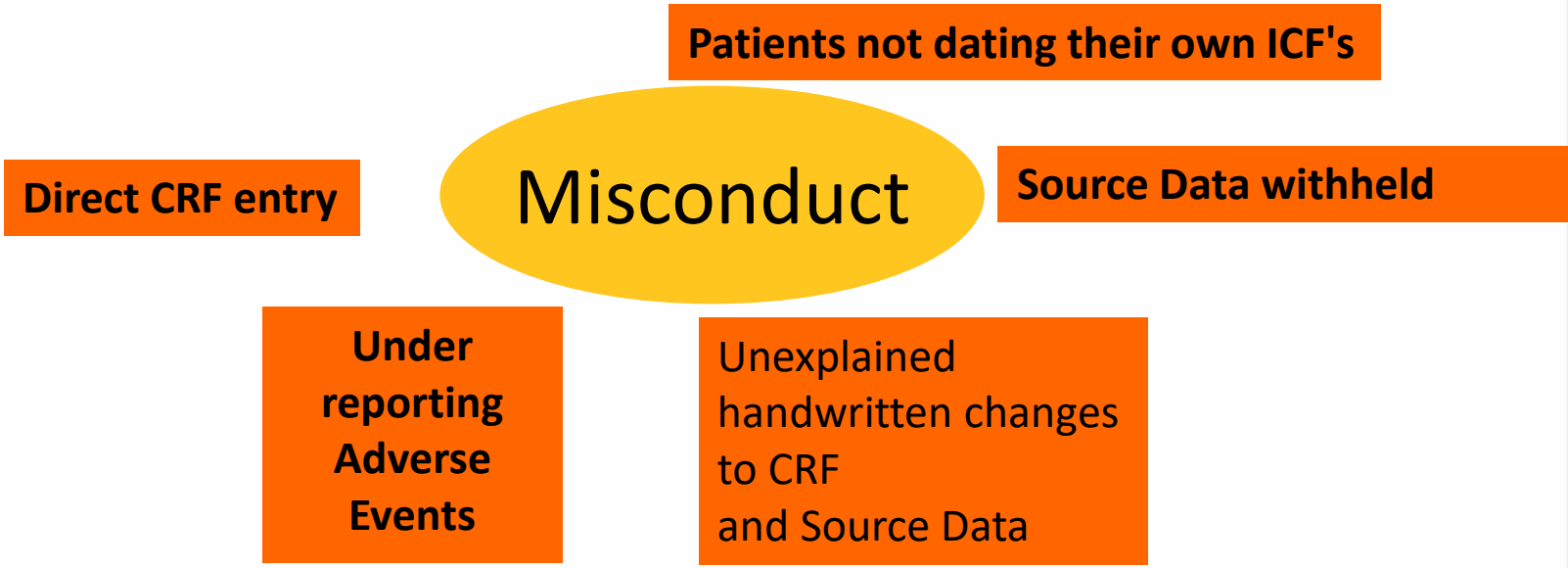
Major Drivers Of Misconduct



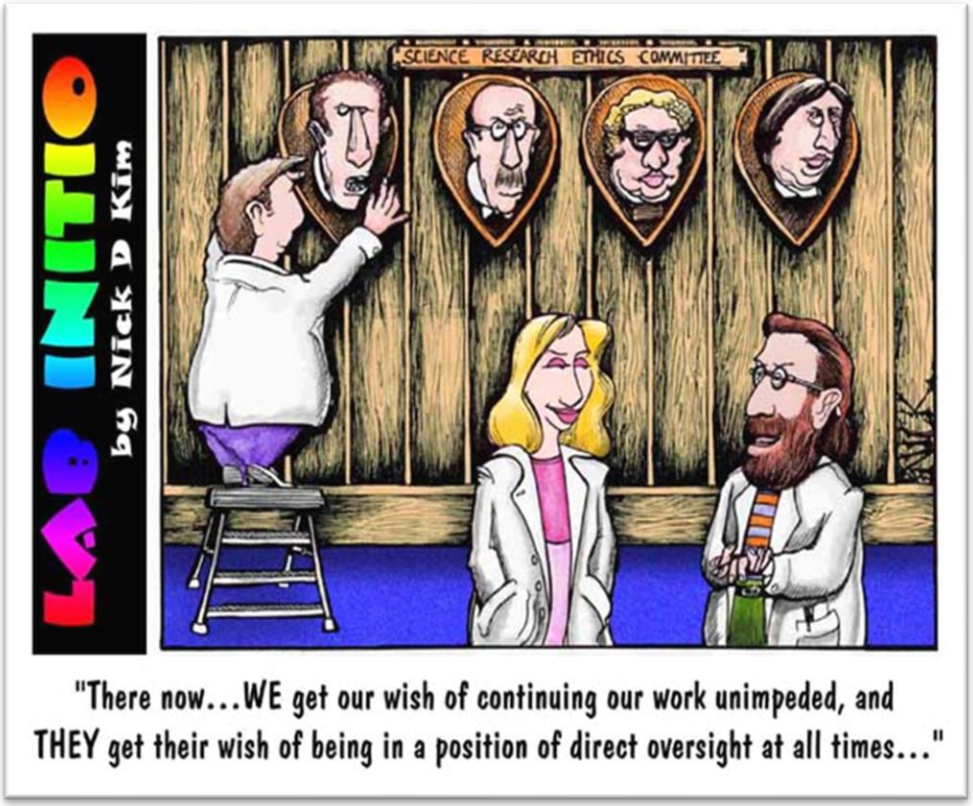
Examples Of Scientific Misconduct



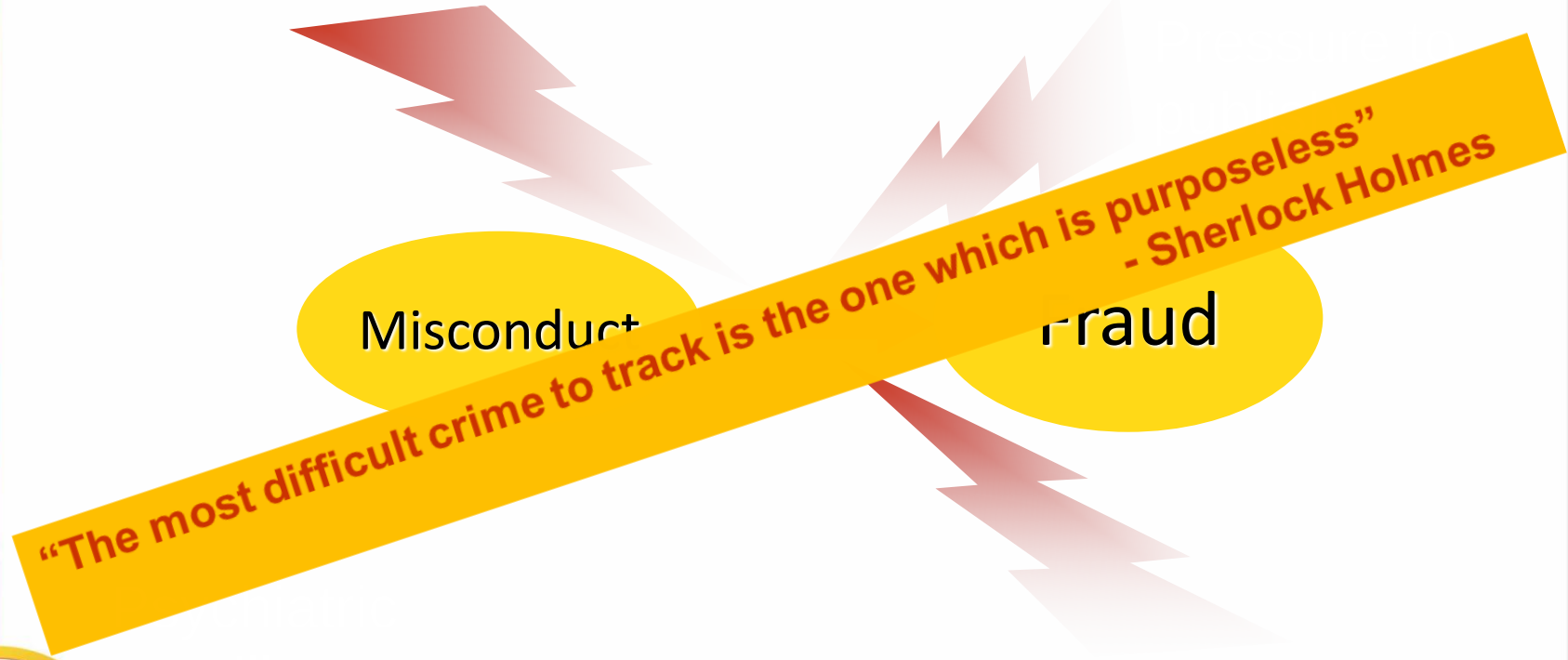
Fraud

"Scientists aren't saints. The field is so competitive that many misbehave in many ways; few falsify results."

-David Goodstein



Drivers Of Fraud



Incidence of Fraud

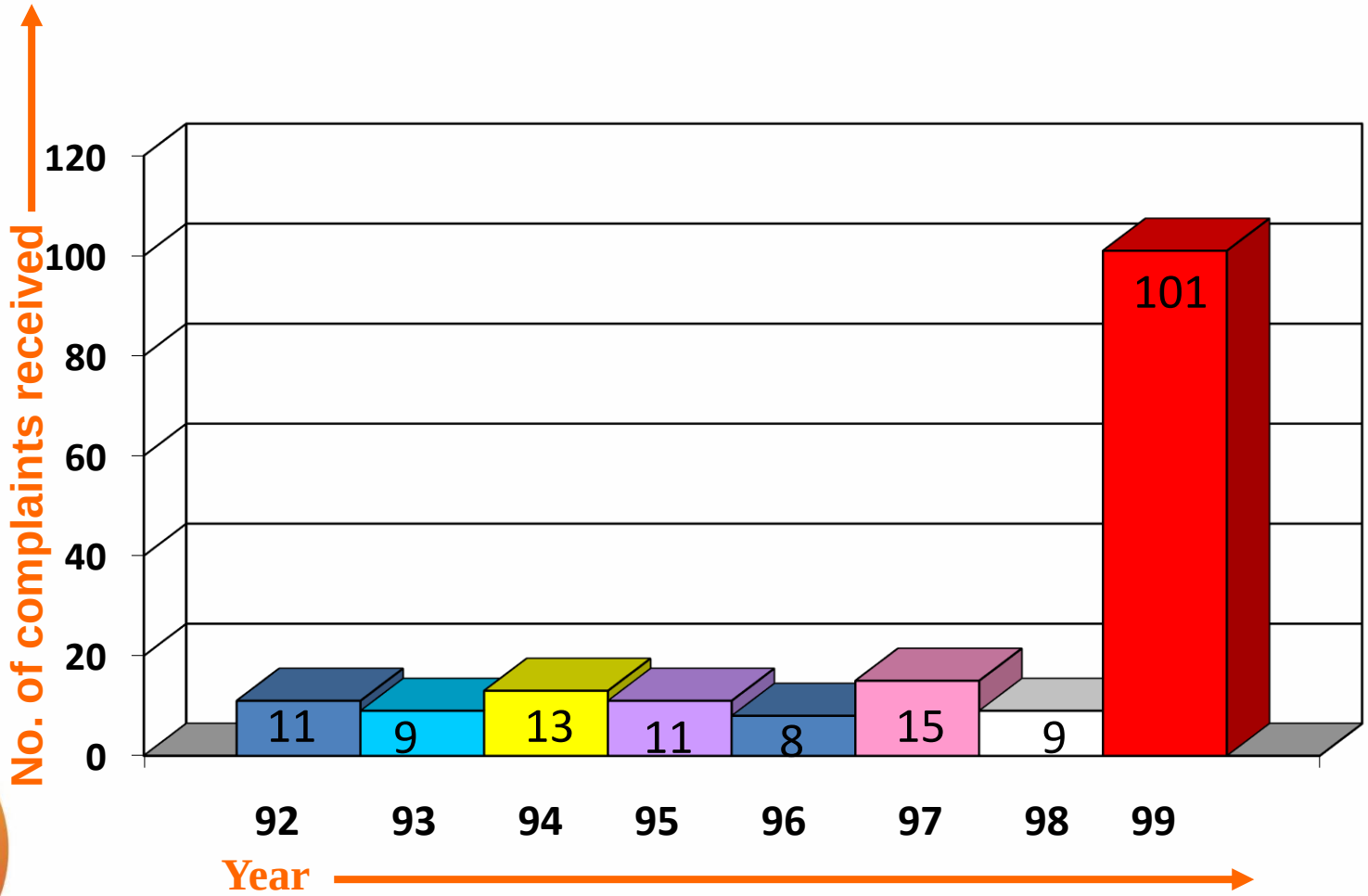
Believed to be uncommon

- Estimated to be 4-5% annually
- No systematic registration

(except UK, Denmark & USA)

"We believe probabilities and choose the most likely. This is very scientific use of imagination"

Complaints Lodged at the US FDA



The incidence of reporting fraud is on the increase

Falsification of Data

- Falsification of data includes:
  - creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred

Examples of falsification of data include but are not limited to

- Creating data that were never obtained;
- Altering data that were obtained by substituting different data;
- Recording or obtaining data from a specimen, sample or test whose origin is not accurately described or in a way that does not accurately reflect the data
- Omitting data that were obtained and ordinarily would be recorded

Examples of Fraud

- Tampering with eligibility criteria for inclusion/ continuation
- Pt. disguised & entered several times
- Pts. enrolled in other concurrent studies
- Investigator enrolling himself in study

Examples of Fraud (contd)

- Forged Consent Forms
- Falsifying EC approval
- Fabricating lab results
- Charging for test article
- Plagiarizing Publications

"As to the (forged) signatures of 4 out of 80 patients...we are talking of a margin of error of 5%- this is within recognized statistical limits."

- Dr. Robert Fiddes

Impact of Fraud

- Patient abuse & exploitation
- Integrity of submitted/ published data – questionable
- Rejection of data/ reanalysis without suspect data
- Licenses issued based on unreliable data - Public health endangered
- Waste of public finances

Management Strategies

Prevention

- Identify and eliminate/ minimize risk factors

Detection

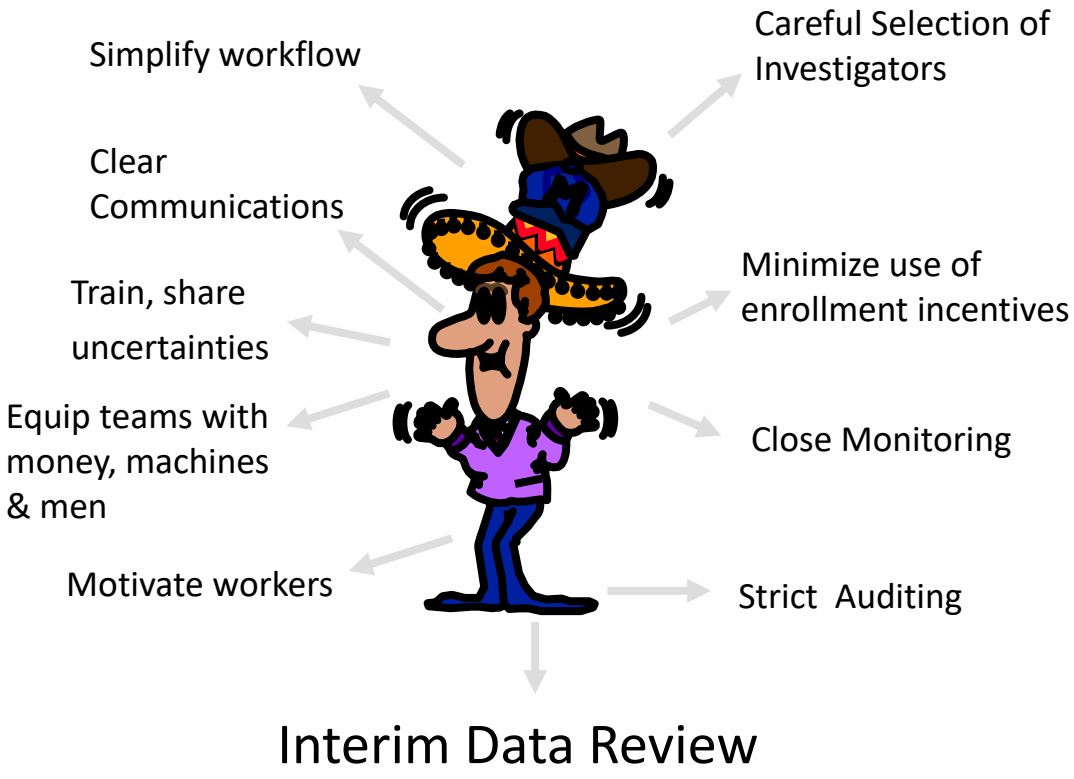
- Monitor and recognize signs

Correction

- Promptly investigate and report findings

One should be able to Prevent, Recognize and Report

Preventive Modalities



Gathering Proof

- Remain discreet – do not accuse!
- Look for:
  - Perfect documentation
  - Patterns across patients
  - Spurious data
  - Tampering of documents
  - Deviation from other centers
  - Suspicious behavior

"There is nothing like first-hand evidence"

Detection Tools

- Get Technical- Read ECGs, lab results, don't just inventory
- Fill in the Blanks - Question missing dates & time
- Don't be intimidated - tell the emperor he has no clothes
- Don't shoot the messenger - believe the monitor, put the burden of proof on the person suspected
- Beware of blame shifting
- Cultivate whistleblowers - establish rapport with study staff, be approachable and available, listen to grievances

"There is nothing more deceptive than an obvious fact"

When First Detected

- Do not suppress suspicions
- Handle discretely
- Do not reveal suspicions at site
- Do not immediately start using terms such as “fraud”
- Seek advice and help
- Confirm suspicions with objective evidence
- Collect circumstantial evidence and data

Action against Misconduct

- Warning letter to investigator; demand improvement
- Increasing monitoring activity and training
- Act to save data at the site – where feasible
  - **Correct the documentation**
  - **Reconsent all patients**
  - **Validate all data → modify the database**
- Justify exclusion of data from final report
- Worst case : close centre and avoid using again

Principal steps on detecting misconduct: saving the data and ensuring patient safety

Responding to Fraud

- Vital to have a company SOP to follow
- Initiated by suspicion by any member of staff
- Suspicion reported to line manager
- Suspicion relayed to operational manager and/or QA

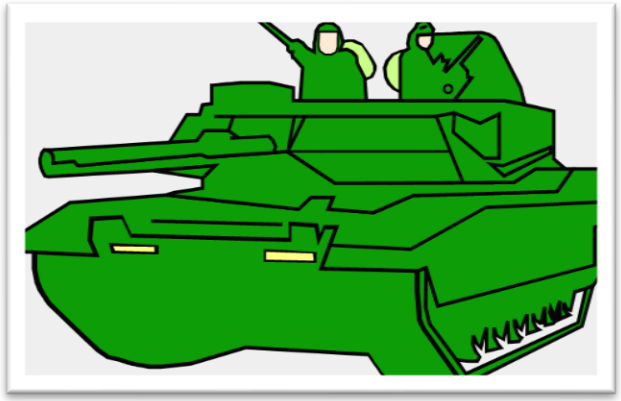
Responding to Fraud (contd)

- Evidence reviewed to substantiate or remove suspicion
- If substantiated, promptly notify senior management (& sponsor)
- Undertake for cause audit and statistical data review/ analysis
- If confirmed, determine course of action as per SOP

Data probably compromised beyond recovery

Action against Fraud

- Close errant centre and prevent future use
- Inform the relevant regulatory agency
- Inform the errant investigator's institution/ professional body
- Inform the Ethics Committee



Understand that fraud cannot be fully eliminated and work towards minimizing it