Handling of fraud, misconduct and serious breaches

Reporting issues is a valuable contribution to the safety and well-being of trial participants and consumers.

Thank you for following this guide.

There are **two** responsibilities:

- **IDENTIFY and**
- **COMMUNICATE**

any case of suspected **fraud**, **misconduct**, or **serious breach**.

- Here's a quick **guide** to help you through the process.
- Please read and follow it carefully.

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IDENTIFY – definitions at glance:

- **FRAUD**

  Always **intentional falsification** of data in proposing, designing, performing, recording, supervising, reviewing or reporting research.

- **MISCONDUCT**

  Either **intentional or unintentional failure** to follow proper conduct.

- **SERIOUS BREACH**

  Any deviation of the approved clinical trial protocol version or the Regulation (EU) No 536/2014 or local regulation that is likely to **significantly** affect **safety, rights or well-being of clinical trial participants,** and/or **data reliability and robustness.**

By anyone:

investigator,
site staff,
contractor,
CRO,
third party,
sponsor staff

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IDENTIFY – examples of warning signs:

FRAUD

- Accrual of **too many participants** in a short time.
- **Data that are reported more efficiently** by one investigator than other investigators.
- **Difficulty in scheduling site visits** / failure to adhere to the protocol visit schedule.
- **Attempts to limit document access**, reluctance to provide full and complete source documentation as per GCP requirements
- **Doubts about** the authenticity of the handwritten **Informed consent signature.**
- Major **failure to the ALCOA** principle.
- Major and **repeated drug accountability issues.**
- Creation of **source data for non-existing patients** or non-existing procedures.
- Filling in the eCRF or subject's diaries with **fictitious information.**
- **Violating eligibility criteria** in order to boost recruitment.
- **…etc.**

MISCONDUCT

- Generation of false data due to carelessness, inexperience or misunderstanding, but with no intent to deceive.
- Failure to follow the protocol.
- Inexperienced site-staff.
- Perceived unawareness of the Investigator's Brochure (IB) or SmPC
- Too many studies at the same time at a site with the limited staff-capacity.
- Disregard for participant safety and/or data integrity,
- Lack of GxP knowledge in site personnel,
- Inadequate or inaccurate record-keeping.
- …etc.

SERIOUS BREACH

- A breach of regulation and/ or protocol that resulted in a **serious adverse event (SAE).**
- A **systematic non-compliance with GCP or protocol** resulting in significant impact on the integrity of the scientific value of studies
- participant was dosed with the **incorrect IMP** from a different clinical trial.
- Safety evaluation required by the protocol were **consistently not performed.**
- The investigator would not allow sponsor **access** to the trial participants' notes.
- **Loss of data.**
- Participants **incorrectly randomised.**
- **…etc.**

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COMMUNICATE

If you are suspicious of fraud, misconduct or serious breach:

- inform the sponsor **within 24 hours of detecting the issue** by sending an email to sb@zentiva.com

The report should contain at least:

- Data of Incident
- Description of Incident
- Supporting Evidence

In case of a suspected **Serious Breach**, please complete the **FORM**

The sponsor may arrange a meeting to discuss it.

NOTE: Please stay available in case the sponsor has any follow-up questions.

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