



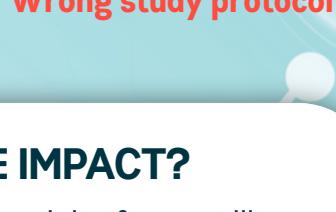
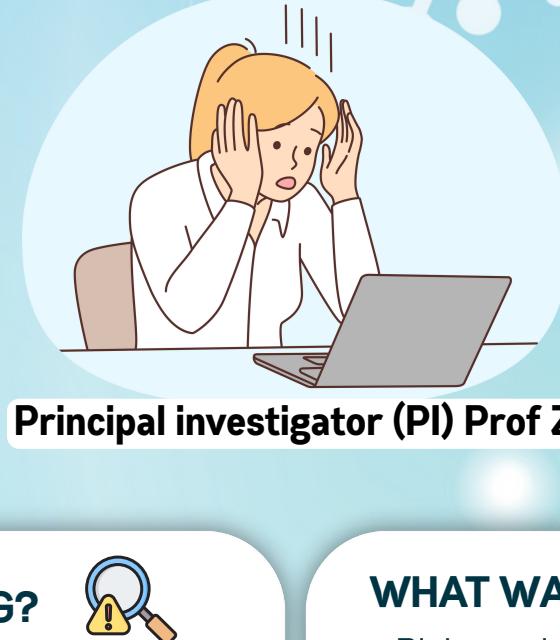
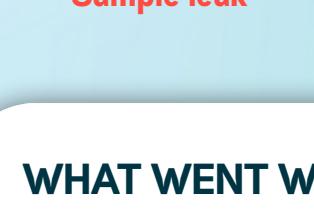
Chicken Soup

for the Busy Coordinator

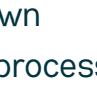


AUGUST 2025 Biological Samples Non-Compliances: Lessons Learned

Professor Z encountered a cascade of biological sample management issues that threatened research integrity and safety when transporting the biological samples to the laboratory for his new research study.



WHAT WENT WRONG?



- Insufficient/ inaccurate sampling
- Containment failures in transport due to spillage
- Temperature control breakdown
- Protocol deviation in sample processing

WHAT WAS THE IMPACT?

- Biohazard exposure risks from spillage
- Samples unusable from temperature fluctuations affecting result validity
- Participant burden - samples collected but unusable
- Compromised data reliability

AS A RESULT...

- This lead to multiple non-compliances reported to the Institutional Review Board (IRB) for failure to adhere to the approved protocol and applicable regulations.
- The PI & study team would need to review its management of biological samples and implement a Corrective & Preventive Action (CAPA) Plan.

HOW TO PREVENT NON-COMPLIANCES?

THE 4C APPROACH



CHECK

- Verify sample labels using 2-person check
- Inspect container integrity
- Test monitoring devices
- Review protocols regularly



CONTAIN

- Use certified transport containers
- Complete seal verification
- Maintain spill kits
- Calibrate equipment



CONTROL

- Install backup cooling systems
- Monitor temperatures real-time
- Follow standard workflows
- Document processing steps



COMMUNICATE

- Implement clear labelling procedures
- Follow transport guidelines
- Document processing protocols
- Report incidents promptly

Refer to Institution's SOPs for more information on proper biological sample management.

References: PCR SOP 501-C05 Biological Specimen Collection and Handling

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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.