Storyboard nr. *(provide a reference for tracking storyboards issued)*

Title: Unauthorized Analysis Collection at Site XXXX in Country XXXX *(Give a significant title that supports a clear identification of the issue that occurred)*

Date: *[Insert Date when the storyboard is issued]*

Study Name: *[Insert Study Name]*

Prepared by: *[for example Study Team & GCP QA Assurance, include also external consultant if needed]*

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1. Background *(add as many details and references as possible)*

During the conduct of [*Study Name*], an issue was identified in the ICF process management: at site XXXX, for the following patients (*add the reference codes*) some biological samples were collected as per Protocol and analyzed by the Central Laboratory (*add the reference*) despite the lack of authorization by patients in the Informed Consent Form. (*add the ICF version used*). One of the patients is a minor and another one is a pregnant woman. This situation was discovered during a routine audit performed on *Date* by the GCP QA Assurance team as planned.

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2. Event Description

Timeline of Events (*be very concise and list in chronological order what happened***):**

- **[Date]:** Biological sample collection procedures initiated at Site XXXX.
- **[Date]:** Biological sample analysis by Central Laboratories (*add the reference of the vendor who performed the analysis)*.
- **[Date]:** Routine audit performed by GCP QA identifies non-compliance.
- **[Date]:** Sponsor Study team notified of the issue.
- **[Date]:** Central Laboratory notified of the issue.
- **[Date]:** Legal Department notified of the issue.
- **[Date]:** Data Breach Officer notified of the issue.
- **[Date]:** Meeting Sponsor/CRO to discuss impact and strategy.
- …..

Key Details:

- Biological samples collected from 6 patients (*add references*) at Site XXXX.
- Patient consent was obtained but the authorization for biological sample analysis was not flagged.
- Non-compliance with GCP guidelines.

- Master ICF submitted and approved.
- ICF process at Site – Site Training on the ICF process

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3. Root Cause Analysis

Root Causes Identified:

In this section, it is crucial to identify what step of the process was inadequate or missing and led to the quality issue. A flowchart or a visualization of the process can help and can be implemented here.

- **Lack of Attention:** The study team didn't check the content of the ICF, but only the signature was checked so the missing authorization was not detected.
- **Insufficient Monitoring:** CRA performed on-site monitoring visits as per the monitoring plan but source documents and ISF were never checked. It was found that the CRA was a junior profile with low expertise.
- **Insufficient Training:** Inadequate training provided on GCP requirements and ICF process.
- **Lack of experience:** The site is not familiar with clinical trial and the new staff is not enough trained and prepared.
- **….**

Supporting Evidence:

- Audit report highlighting the discrepancy.
- Training records and material showing no training on ICF processes.
- Emails between CRO and Central Laboratories.

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4. Impact Assessment (*evaluate the impact from different perspectives to better understand what stakeholders must be involved***)**

GCP Impact:

- **GCP Compliance:** Violation of GCP guidelines (*add any specific reference to regulation, but also to internal Policy and/or SOP that cover the management of the ICF*).

Patient Impact:

- Potential risk to patient rights.
- Breach of trust and potential legal actions from patients.

Data Impact:

- Potential loss of data from 6 patients
- GDPR impact

Operational Impact:

- Delay in study timelines due to the need for compliance review and corrective actions.
- Increased scrutiny by CRA during monitoring activities.

Stakeholders Involved:

- Study Team
- GCP QA Assurance
- Regulatory Affairs
- Legal Department
- Site Ethics Committee

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5. Corrective and Preventive Actions (CAPA) (*for all the below actions it is recommended to add references to any document that shows the evidence***)**

Corrective Actions:

- **Immediate Cessation:** Immediate check that all the remaining patients have authorized the analysis of the biological samples in the ICFs signed.
- **EC Notification:** Inform site EC of the non-compliance and action plan.
- **Patient Notification:** Communicate with affected patients about the non-compliance and measures taken.

Preventive Actions:

- **Enhanced Training:** Implement comprehensive training programs focused on GCP requirements for all study team members.
- **ICF process:** Develop a robust process at the site level to manage ICF.
- **Improved Communication:** Establish a robust communication protocol between regulatory affairs and study teams to ensure timely updates on local regulations.

Monitoring and Follow-Up:

- **Follow-up Audit:** Schedule a follow-up Audit to ensure ongoing compliance with ICH-GCP.

- **CAPA Review Meetings:** Conduct periodic CAPA review meetings to assess the effectiveness of implemented actions and make adjustments as necessary.

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6. Conclusion *(if applicable add the evidence that corrective and preventive actions were implemented and were effective because the issue didn't happen again)*

The unauthorized sample collection at Site XXXX highlighted critical gaps in GCP compliance and communication within the study team. Through a collaborative effort involving the study team, GCP QA Assurance, CRO, and central laboratory, comprehensive corrective and preventive actions have been developed to address the root causes and prevent future occurrences. This storyboard is aimed to explain how the issue was managed, and the risk mitigated to avoid impact on study results and patient's rights.

Next Steps:

- Finalize and implement CAPA.
- Schedule follow-up audits and training sessions.
- Continuous monitoring and adjustments based on audit findings.

Attachments & References (*if the list of attachments is too long, a reference to the source can be sufficient***):**

- Audit Report (*see folder XXXXX*)
- Training Records (*see LMS…)*
- Email Communications (*see emails filled in study eTMF at artifact* ….)
- CAPA Plan (*see folder XXXX*)
- Attachment 1 Events flow chart