



# Temperature Excursions & Storage Deviations

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*What to do when investigational product or specimens are exposed to out-of-range temperatures*

## WHAT IS IT?

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### Temperature Excursion:

Investigational product or biological specimens are exposed to temperatures outside the protocol-specified acceptable range for any period of time — including refrigerator or freezer malfunctions, power outages, improper storage, or breaks in the cold chain during transport.

## WHEN DOES THIS APPLY?

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- A temperature monitoring device records a value outside the acceptable storage range
- A refrigerator, freezer, or storage unit malfunctions or loses power
- IP or specimens are left outside proper storage conditions
- A break in the cold chain occurs during shipment or transport
- A temperature alarm is triggered

## PROCESS AT A GLANCE

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### 1. Identify and Respond to the Excursion

- Confirm the excursion by reviewing temperature logs and monitoring device data
- Document the temperature range reached, duration, and exact time of occurrence
- Move affected IP or specimens to appropriate storage immediately if still viable
- Do not use or ship affected IP until the sponsor has been consulted

### 2. Quarantine the Affected IP or Specimens

- Label affected IP clearly as 'QUARANTINED — DO NOT USE'
- Do not discard or return affected IP without sponsor authorization
- Secure affected specimens according to site and sponsor protocols

### 3. Notify the PI and Sponsor

- Inform the PI immediately
- Contact the sponsor — most require prompt notification of IP temperature excursions

- Provide: product name/kit numbers affected, duration and range of excursion, and quantity affected
- Document all communications

#### 4. Await Sponsor Disposition Guidance

- Do not use or destroy affected IP until the sponsor provides written disposition instructions
- The sponsor may request return, on-site destruction, or in some cases approve continued use
- Document the sponsor's disposition decision and instructions

#### 5. Update IP Accountability Records

- Document the excursion and quarantine in the IP accountability log
- Record the sponsor's disposition decision and final handling of the affected IP
- Ensure all accountability records reconcile accurately

#### 6. Investigate and Repair the Root Cause

- Identify why the excursion occurred: equipment failure, power outage, door left open, improper packing
- Arrange equipment repair or replacement as needed and verify proper function before return to use
- Document the root cause and corrective actions

#### 7. Complete a Protocol Deviation Report

- Initiate a Protocol Deviation form documenting the storage deviation
- Include: affected products, duration and extent of excursion, safety impact, and CAPA
- Report to the IRB and sponsor per requirements

#### 8. Implement Preventive Actions

- Ensure temperature monitoring alarms are functioning and staff know how to respond
- Establish after-hours response procedures for temperature alarms
- Review storage procedures with all staff who handle IP or specimens

### KEEP IN MIND

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**x Avoid:** Do not use quarantined IP without sponsor authorization. Do not discard affected IP or specimens before receiving written disposition instructions.

**✓ Best practice:** Quarantine first, then notify. Document the full excursion timeline. Follow sponsor disposition guidance in writing before taking any further action.

### REFERENCES

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- ICH E6(R2) Good Clinical Practice Guidelines
- Applicable Study Protocol — IP Storage Requirements
- Sponsor IP Management Manual
- Reportable New Information <https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf>