STANDARD OPERATING PROCEDURE TEMPLATE · INFORMATION MANAGEMENT, LIS AND PRIVACY

HIPAA Privacy and Patient Confidentiality

Governing requirement: 42 CFR 493.1231 and 45 CFR 164 (HIPAA)

Applies to: ☑ Waived ☑ Moderate complexity ☑ High complexity

Laboratory name		**CLIA number**	
Document number		**Version**	
Effective date		**Next review due**	
Author		**Department / section**	
Approved by (laboratory director)		**Director signature**	
Approval date		**Supersedes document**	

Important: Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

1. Purpose

To protect the confidentiality of patient information.

2. Scope

All patient information in any form.

3. Responsibility

- Laboratory director: approves policies and validations.
- LIS / IT administrator: maintains systems, access and backups and documents changes.
- All staff: protect patient information and report suspected incidents.

4. Definitions

PHI: Protected health information.

Minimum necessary: Use only the information needed for a task.

5. Materials, equipment and records

- Privacy policies
- Training records

6. Procedure

1. Access PHI only as needed for job duties.

2. Release results only to authorized persons.

3. Verify identity before releasing results to patients.

4. Secure paper and screens; lock workstations.

5. Report suspected breaches to **[Privacy officer]** immediately.

Privacy officer	

6. Train staff **[Frequency]**.

Frequency	

7. Quality control

• Review access, audit logs or validation records on the schedule in this SOP and document the review.

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• HHS, HIPAA Privacy Rule summary
https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

• HHS, Breach Notification Rule https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html

• HHS, Individuals' right to access health information (including lab reports)
https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

• eCFR, 42 CFR 493.1231 https://www.ecfr.gov/current/title-42/section-493.1231

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

Review date	Reviewed by	Signature	Changes needed (Y/N)	Comments

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