Laboratory name

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Address

Document

HP-06 Business Associate Agreement Checklist and Log

Business Associate Agreement Checklist and Log

Document no.	Version	Effective date	Supersedes	Approved by (laboratory director)
HP-06	1.4			

How to use this document. Use Part A to decide who needs an agreement, Part B to check an agreement before it is signed, whether it is your form or the vendor's, and Part C to keep track of them. This is a checklist, not a contract. HHS publishes sample business associate agreement provisions on its website, and an attorney should review any agreement you sign.

Part A. Who is a business associate

A business associate is a person or organization, outside the workforce, that creates, receives, maintains or transmits PHI to perform a function or service for the laboratory. Examples to check:

Vendor or contractor	Handles the laboratory's PHI (Y / N)	Agreement needed (Y / N)
Laboratory information system or middleware vendor with access to patient data		
Billing or coding company, clearinghouse		
Cloud storage, hosting, backup or email provider		
IT support with access to systems holding PHI		
Document shredding or media destruction service		
Instrument service provider with remote access to patient data		
Consultant, auditor, accountant or attorney who sees PHI		
Patient portal or results delivery service		

Not business associates: a reference laboratory or other health care provider receiving PHI to treat the patient; members of the workforce; and the postal service or a courier that only carries PHI. A vendor whose staff could see PHI only incidentally, such as a cleaning service, is not a business associate either, but the laboratory still safeguards PHI from them.

Part B. What the agreement must contain

Business associate	
Service provided	

SAMPLE

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Agreement reviewed by	
Date	

45 CFR	The agreement must	Present (Y / N)	Clause
164.504(e)(2)(i)	State the permitted and required uses and disclosures of PHI, and not authorize a use or disclosure that would violate the Privacy Rule if the laboratory made it (other than use for the business associate's own management and administration, or data aggregation, if the agreement allows them)		
(e)(2)(ii)(A)	Bar use or further disclosure other than as the agreement permits or the law requires		
(e)(2)(ii)(B)	Require appropriate safeguards, and compliance with the Security Rule for electronic PHI		
(e)(2)(ii)(C)	Require a report to the laboratory of any use or disclosure the agreement does not allow, including breaches of unsecured PHI		
(e)(2)(ii)(D)	Require any subcontractor that handles the PHI to agree to the same restrictions and conditions		
(e)(2)(ii)(E)	Make PHI available so the laboratory can meet access requests		
(e)(2)(ii)(F)	Make PHI available for amendment and incorporate amendments		
(e)(2)(ii)(G)	Make available the information needed for an accounting of disclosures		
(e)(2)(ii)(H)	Comply with the Privacy Rule requirements that apply to any laboratory obligation it carries out		
(e)(2)(ii)(I)	Make its internal practices, books and records available to the Secretary of HHS		
(e)(2)(ii)(J)	At termination, return or destroy all PHI if feasible. If not feasible, extend the agreement's protections and limit further use to the reasons that make return or destruction infeasible		
(e)(2)(iii)	Allow the laboratory to terminate the agreement if the business associate has violated a material term		
164.314(a)(2)(i)	For electronic PHI: require compliance with the Security Rule, the same of subcontractors, and a report of any security incident, including breaches of unsecured PHI		

Also worth agreeing, although the rule sets no figure: how many days the business associate has to report an incident. The rule gives a business associate up to 60 calendar days after discovery to notify the laboratory of a breach, and your own deadline for notifying individuals may start to run when the business associate discovers the breach if it is acting as your agent.

Part C. Agreement log

Business associate	Service	Agreement signed (date)	Last reviewed	Ended (date)	PHI returned or destroyed (date and evidence)

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Business associate	Service	Agreement signed (date)	Last reviewed	Ended (date)	PHI returned or destroyed (date and evidence)

If the laboratory learns of a pattern of activity by a business associate that is a material breach of the agreement, it takes reasonable steps to end the violation and, if those fail, ends the agreement where feasible. Agreements are kept for six years after they end.

Signatures

Role	Printed name	Signature	Date
Privacy official			

Regulatory basis: 45 CFR 160.103 (definition of business associate); 164.502(e); 164.504(e)(1), (2) and (4); 164.308(b); 164.314(a); 164.410; 164.530(j).

Template notice. Checked against 45 CFR Parts 160 and 164: 16 November 2026. This template is a starting point, not regulatory or legal advice. State law and your contracts may be stricter than HIPAA.

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