



Policy or Procedure Subject: Business Associate Agreements		LC.PY.012.r00
Department or Section: Office of Ethics and Compliance		7/15/2021
Prepared By: W. Dalton, Quality Officer	Supervisor Approval: D. Henderson, VP Lab Operations	Laboratory Director Approval: A. Almradi, M.D. Medical Director

Policy:

HIPAA 45 CFR 164.50(e) states, "The Privacy Rule requires that a covered entity obtain satisfactory assurances from its business associate(s) that the business associate(s) will appropriately safeguard the protected health information (PHI) it receives or creates on behalf of the covered entity. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the covered entity and the business associate."

The new HIPAA Omnibus Final Rule, also referred to as the "Mega Rule" requires investigators to review complaints or compliance issues, where there is possible willful neglect, and assess fines if willful neglect is confirmed. A business associate now includes all entities that create, receive, maintain, or transmit PHI on behalf of a covered entity.

Business associates are directly liable for uses and disclosures of PHI that violate the BAA or the Privacy Rule. Covered entities must ensure that their business associates maintain appropriate privacy practices as part of their HIPAA audit protocol. All BAA's must be tracked with at least the following elements: Name of the Business Associate, the type of service they provide, two points of contact (as well as their titles, addresses, fax and phone numbers and emails) and the business associate's web URL.

Procedure: For Helix generated BAA's, the Office of Ethics and Compliance holds the only acceptable, counsel vetted template that should be used.

1. Helix Business Associate Agreements (BAA) executed through the Office of Ethics and Compliance.
2. When outside BAA's are sent to Helix Diagnostics for review and signatures, the BAA will be reviewed, signed and sent back to the sender. The fully executed BAA will be stored and logged per steps 5 and 6 below.
3. Send request for BAA to the following email address for action. Compliance@helixmdx.com
4. Compliance office will create the BAA and send it back to the requestor for applicable signatures.
5. After all signatures are complete, the Compliance office will log the BAA on the tracking log located on the Compliance Share Point site.
6. Hard copies of the BAA's are stored in the Compliance office.

Printed copies of this document are not considered up to date. Please verify current version with master document online.

Reviewed By	Date
Lab Director: <u>Amro Almradi</u> Signed: <u>Amro Almradi</u>	8/16/21
Lab Manager: <u>Jay Anderson</u> Signed: <u>Jay Anderson</u>	8/4/21
Technical Supervisor: <u>Amber Macumber</u> Signed: <u>Amber Macumber</u>	8/4/21

Printed copies of this document are not considered up to date. Please verify current version with master document online.