This decision tree will help you determine if an entity is a “business associate” under HIPAA, as defined in 45 CFR § 160.103.

Will an entity (“Entity”) provide services to or on behalf of a Covered Entity? A “Covered Entity” is a healthcare provider or health plan, including most employee benefit plans.

[Note: This does not apply to (1) an employee, volunteer, trainee, or other person whose conduct is under the direct control of a Covered Entity (i.e., “workforce members”), (2) an Entity who is performing functions as part of a Covered Entity’s organized health care arrangement,¹ or (3) Entities who receive info for their own purposes, and not to provide services to or on behalf of a Covered Entity (e.g., payors, government agencies, independent researchers, etc.).]

Will the Entity create, receive, maintain or transmit protected health info (“PHI”) in the course of providing services to or on behalf of a Covered Entity?

[Note: This does not apply to Entities who may periodically see or hear PHI, but whose job duties for a Covered Entity do not involve the creation, receipt, maintenance, or transmission of PHI (e.g., a janitor, delivery person, or electrician who happens to be providing services in the building)].

Is the Entity a healthcare provider who is receiving the PHI for purposes of treating the individual?

Does the Entity perform a function or activity for the Covered Entity involving PHI that is regulated by HIPAA (e.g., healthcare operations or payment functions), including claims processing or administration; data analysis, processing or administration; or utilization review, quality assurance, patient safety activities, billing, benefit management, practice management, or repricing services? OR

Does the Entity provide legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services for a Covered Entity? OR

Is the Entity a health information organization, e-prescribing gateway, or other Entity that provides data transmission services with respect to PHI and the Entity requires access to the PHI on a routine basis (i.e., the Entity is not merely the conduit for the PHI)? OR

Does the outside entity person offer a personal health record to one or more individuals on behalf of a Covered Entity?

The Entity is a business associate. You must execute a valid business associate agreement with the Entity before disclosing PHI to the Entity. The business associate agreement must contain the elements in 45 CFR §§ 164.314(a) and 164.504(e).
Organized health care arrangement means:

1. A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;
2. An organized system of health care in which more than one covered entity participates and in which the participating covered entities:
   (i) Hold themselves out to the public as participating in a joint arrangement; and
   (ii) Participate in joint activities that include at least one of the following:
       (A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;
       (B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or
       (C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if PHI created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.
3. A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to PHI created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;
4. A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or
5. The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to PHI created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.