Guidance for Investigators:
Business Associate Arrangements Under The HIPAA Privacy Rule

Chart 1: Determining if an Entity is a Business Associate

Is PHI being disclosed to a person or entity other than in the capacity as a member of the covered entity’s workforce?

Yes

Is the PHI being disclosed to a healthcare provider for treatment purposes (e.g. primary/referring physician, contract physicians/specialists/nurses/rehab staff)?

No

Is the PHI being disclosed to a health plan for payment purposes, or to a health plan sponsor with respect to disclosures by a group health plan?

No

Is the PHI being disclosed to a government agency pursuant to an official investigation (e.g. CMS, OCR, FDA, Health Department)?

No

Is the PHI being disclosed to another covered entity that is part of an organized healthcare arrangement in which the originating covered entity participates?

No

Does the entity create, receive, maintain or transmit PHI for a function or activity regulated by the HIPAA Privacy Rule?

No

Does the entity provide legal, actuarial, accounting, consulting, data, management, administrative, accreditation or financial services involving PHI?

Yes

Will the entity be able to access PHI on a routine basis, and/or is there a possibility that the PHI in the entity’s custody could be compromised (e.g. data storage vendor, document shredding company)?

No

Yes

The entity is not a Business Associate and a Business Associate Addendum does not need to be part of a contract for services.

Yes

The entity is a Business Associate and a Business Associate Addendum does need to be included in the contract for services. See page 2 of this Guidance for further instructions.
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Once you have determined that an entity involved in the research is a Business Associate per the HIPAA Privacy Rule, ensure that a Business Associate Addendum (BAA) is included in the contract for services with the entity. A BAA is not a stand-alone agreement, as there should be an underlying contract or agreement with the entity that describes the services to be performed.

When establishing Business Associate arrangements, use the OSF HealthCare BAA Template whenever possible. New Business Associate arrangements, where the OSF HealthCare BAA is attached to the contract for services, should follow the established contract review process.

If modifications to the OSF BAA Template are requested by the entity, or the entity insists on using their own BAA, it should be reviewed by Research Administration and the OSF HealthCare Ministry Privacy Officer before going into the normal contract review process. Please send modified or alternate BAAs to OSF.ClinicalResearch@osfhealthcare.org for review.

How to Complete the OSF HealthCare BAA Template

Fill-in all the fields in red on the first and last pages of the BAA Template:

- Use the tab key to advance from one field to the next.
- Enter the name of the Local OSF Facility and the Company/Business Associate Name at the top of the first page.
- Enter the date of the new BAA in the first paragraph.
- In the second paragraph (the first “Whereas” clause), enter the Company Name, the Date of Underlying Contract and the Heading of Underlying Contract.
- Enter the names and titles of the individuals at OSF and the Company/Business Associate that will sign the BAA.