

# CRSO: IN THE KNOW

*Business Associate Agreements*

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**As clinical research professionals, we focus on maintaining privacy, confidentiality, and data security for our participants. To ensure appropriate handling of Protected Health Information (PHI) and HIPAA compliance when sharing PHI with external parties, be sure to assess whether a business associate agreement (BAA) is required!**

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Generally, an external vendor or entity will be considered a business associate (BA) if a UNC HIPAA covered component contracts with the external party to perform services on its behalf that requires the external party to have access to PHI. Additionally, a subcontractor can be a BA if it creates, receives, maintains, or transmits PHI on behalf of another BA.

A BAA is a contract, generally required by the HIPAA Rules, between a covered entity (CE) and a BA to ensure that the BA appropriately safeguards PHI. Additionally, BAAs document how PHI may be used and disclosed by the BA. If a BA violates the terms of a BAA, the BA is directly liable under the HIPAA Rules and subject to potential civil and/or criminal penalties. However, if a BAA is required but not in place before disclosing PHI, UNC, as the CE, could face penalties under HIPAA.

Common clinical research services that may require a BAA include:

- Transcription of interview or focus group data
- Voice, video, and texting platforms
- External and/or mass email platforms
- Electronic or hard-copy data storage
- Data mining services
- Any type of data processing services

Whether a BAA is required is made on a case-by-case analysis. Therefore, it is imperative that clinical research teams carefully consider all circumstances where PHI will be shared with, or accessible by, an external vendor so the question of whether a BAA is required can be analyzed.

[Click here for more information on how to initiate a BAA](#)



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