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**National Institute of Neurological Disorders  
and Stroke Program Directors**

Jeremy Brown, MD  
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Date: 20 March 2020  
To: BOOST Investigators  
From: BOOST CCC Leadership  
Re: Advarra Appeal Approval Notice - BOOST (Pro00030585) - Review 18  
Mar 2020

The purpose of this memo is to clarify a notice received from the BOOST CIRB labeled as Advarra Appeal Approval Notice - BOOST (Pro00030585) - Review Date: 18 Mar 2020. The notice does **not** reflect any operational or status change in the trial, and does **not** require any response or further action. The notice only reflects clarification and explicit documentation of a previously implicit determination by the IRB.

This appeal clarifies a technical regulatory question. In brief, the BOOST IRB approval covers enrollment with exception from informed consent (EFIC) which implicitly includes a full HIPAA waiver, and enrollment with prospective informed consent for which there was an explicit partial HIPAA waiver for purposes of screening prior to enrollment. In response to a query from a site regarding how this is documented in the approval, an appeal was submitted on the investigators' behalf by the IRB to clarify the approval. With the approval of the appeal, this now is documented as a full HIPAA waiver for the entire application. This does not change the status or any operational requirements for the trial. Patients enrolled with prospective informed consent **still require** HIPAA authorizations as part of the embedded or supplemental authorization language included in the informed consent process prior to enrollment. The CIRB has confirmed that the clarification in this appeal does not imply any concerns or compliance problems with the EFIC enrollments occurring prior to this appeal approval notice.

Thank you for continued attention and hard work.