Note to File Re: Statement of Investigator, Form FDA 1572

February 15, 2018

Dear Advarra Customer,

As previously announced, Chesapeake Research Review, LLC ("Chesapeake IRB") and Schulman Associates Institutional Review Board, Inc. ("Schulman IRB") have merged to create Advarra, Inc. ("Advarra IRB").

Schulman IRB, by an amendment to its certificate of incorporation through the Ohio Secretary of State dated December 12, 2017, has changed its corporate name to Advarra, Inc. Both Schulman IRB and Chesapeake IRB will retain d/b/a status for an interim period and continue to operate under the current structure.

On February 5, 2018, Schulman IRB updated its Institutional Review Board (IRB) Organization (IORG) registration with the Office for Human Research Protections, U.S. Department of Health and Human Services. The registered name has been changed from Schulman Associates Institutional Review Board, Inc. to Advarra d/b/a Schulman Associates Institutional Review Board, Inc. with an address of 4445 Lake Forest Drive, Suite 300, Cincinnati, OH 45242 (IORG0000635). On May 1, 2018, Chesapeake IRB will de-activate its IORG registration (IORG0000468). All ongoing studies under Chesapeake IRB oversight will be transferred to Advarra IRB oversight at that time, and all of those studies will fall under the IRB registration number IORG0000635.

Effective February 5, 2018, Advarra IRB now serves as the IRB providing oversight for the study (ies) currently listed on 1572s as falling under Schulman IRB oversight. Effective May 1, 2018, Advarra IRB will serve as the IRB providing oversight for the study (ies) listed on 1572s as falling under Chesapeake IRB oversight. FDA does not require that an updated or new 1572 be completed to reflect this change in information; however, FDA recommends that the investigator document the change in the clinical study records and inform the sponsor of these changes.[1] This Note to File may serve as this documentation.

We look forward to continuing our relationship with your company.

Sincerely,

Michele Russell-Einhorn
Chief Compliance Officer and Institutional Official, Advarra

[1] *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs, Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*, May 2010, available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf