MEMORANDUM

DATE: April 30, 2020

FROM: IMPAACT Management Oversight Group

TO: Clinical Trial Units (CTU) Principal Investigators, Clinical Research Sites (CRS) Leaders, CTU Coordinators, CRS Coordinators

SUBJECT: Protocol Deviation Reporting System: Guidance for IMPAACT Clinical Research Sites

In accordance with the FDA guidance on COVID-19, and due to the anticipated increase in the number of protocol deviations experienced at sites, the Data Management Center (DMC) at Frontier Science has developed a Protocol Deviation Reporting System (PDRS) to facilitate the collection of mass protocol deviations. The PDRS can be used to report protocol deviations that meet the IMPAACT reporting criteria outlined in the Network Manual of Procedures (MOP) that apply to multiple studies or multiple participants enrolled on a study. Individual, participant level reportable protocol deviations should continue to be reported via the DEV0001/DEV10000 eCRF per Network and study guidelines. Please see scenarios below. While this is being introduced in the context of reporting deviations due to the COVID-19 pandemic, it is anticipated that this utility will be used in the future for other reportable deviations impacting large numbers of participants or if the deviation does not involve specific participants. Sites should retrospectively enter mass protocol deviations that have not been reported via the eCRF, dating back to March 15, 2020.

The PDRS can be accessed from the Frontier Science DMC Portal under the IMPAACT Network tab. Protocol deviations should be reported by the communicating staff member, which may be the Investigator of Record or other designee. Within the utility, users will be provided with a data entry screen to report the site, study, site awareness date, deviation start and end date, the type of deviation, and a summary of the deviation that occurred. The user can also indicate whether the deviation was reported to the local IRB/EC, and if the deviation was a result of the COVID-19 pandemic.

This new utility is intended to supplement existing participant level network and study deviation workflows by providing a mechanism for mass deviation reporting and is not a replacement for current participant level deviation reporting procedures. If you have any questions regarding accessing the PDRS or have technical issues with the system, please contact Frontier Science User Support at usersprt@fstrf.org. If you have any questions about how to report protocol deviations for your study, please contact impaact.deviation@fstrf.org. If you need to update a protocol deviation that was previously entered (e.g. to provide a deviation end date), please contact your study Protocol Data Manager (PDM). DMC training announcements for the PDRS will be forthcoming.

As a reminder, documentation of any deviations should be entered in participant study charts in real-time, consistent with DAIDS SOPs for source and essential documentation. Please also continue to follow your site's IRB/EC policies and procedures for reporting protocol deviations.

Thank you for your continued efforts in support of IMPAACT's clinical trials research during these challenging times.

Scenarios:

A – All participants at the site miss all visits between 15 March and 30 April due to COVID-19-related lockdowns. This is a trend and thus would be reportable per Network requirements. Sites should report this deviation using the new PDRS using the “Missed visit trend” deviation type.

B– All participant visits are conducted virtually (e.g., by telephone) starting 15 March due to COVID-19-related lockdowns. No laboratory or physical evaluations are performed. The missed evaluations should be reported as a protocol deviation using the new PDRS, selecting the “Assessment deviation” deviation type. The end date would initially be left blank to indicate an ongoing scenario and once in-person participant visits resume, the PDM should be contacted to update the deviation end date in the PDRS.