

TO: Clinical Trial Investigators

FROM: Clay Marsh MD, Chancellor & Executive Dean for Health Sciences

Fred King PhD, Vice President for Research



RE: New Fees for Clinical Trials

Date: April 11, 2022

Over the past 5 years, clinical trials at West Virginia University have increased nearly threefold while the number of clinical trial participants has increased tenfold. Concurrently, regulatory requirements have also increased, necessitating enhanced institutional oversight. To that end, registration of all clinical trials and an institutional risk assessment process have been implemented through the Clinical Trials Center of Excellence (COE).

Over the past two years, a clinical trial management system (OnCore) has been implemented to facilitate trial efficiency and integrate with EPIC. Though use of OnCore by clinical trial groups has been “required,” there has been no enforcement given the COVID-19 pandemic and the fact that the EPIC integration had not been completed. However, EPIC integration is nearing completion over the next several months and OnCore use will be required to ensure correct billing and allow future importation of patient data (e.g. labs) into OnCore. In addition, the OnCore dashboard is excellent and provides support for Directors of clinical research programs to understand where issues of efficiency are occurring in their programs so further growth may occur while ensuring regulatory compliance and participant safety.

Effective June 1, 2022, to support the clinical trials infrastructure, there will be a one-time \$975 fee for new trial COE registrations. This fee should be a pass-through cost for industry sponsored trials and will be covered for those non-industry funded trials by indirect costs. In addition, the West Virginia Clinical and Translational Science Institute (WVCTSI) will cover the COE registration fee for all Research Scholar and Pilot Projects. Coverage of COE registration fees for any unfunded clinical trials will be at the discretion of the department chair. Noteworthy is that the fee applies to new clinical trials registered on or after June 1, 2022 – any trial registered before this date will not be subject to the fee.

In addition, for the next fiscal year, a clinical trial management system (OnCore) fee will be implemented based on the number of clinical trials registered with the COE. The WVCTSI will cover the cost for those departments with a small number of trials. To minimize cost to the departments, please include the COE registration fee and the CTMS set-up fee (\$2,500) in all new industry-sponsored clinical trial budgets.

Beginning September 1, 2022, any new clinical trial registered with the COE for which the above requirements have not been met may be suspended until such time that the trial is compliant.

Information sessions on these changes will be held for investigators. However, if you have inquiries regarding these changes, please contact Shelley Welch at shelley.welch@hsc.wvu.edu.