FROM: UNC Office of the Vice Chancellor for Research and the Office of Clinical Trials

DATE: May 21, 2021

SUBJECT: Administrative Fee for Interventional **Industry** Sponsored Clinical Trials

One of the strategic research goals of the University is to grow clinical research. To that end, the University is focused on expanding the infrastructure essential to achieving this goal while improving quality, efficiency and compliance.

Beginning July 1, 2021, the fee structure applied to industry-sponsored clinical trials will change for all newly proposed and budgeted studies. This new fee structure will replace the current fees required by the University (IRB, contracting, billing compliance and quality assurance fees) and is being modified to provide for a simpler, more efficient fee model compared to the current model.

For all studies with contract/budget negotiations beginning on/after July 1 (leading to a fully executed agreement, IRB approval, completed BCA, and final congruency confirmation) a one-time $3,500 fee will be applied to all **industry-**sponsored clinical trials that are interventional and include two or more study visits per participant. Studies that are purely observational, include only surveys or registries, or are not industry-funded will not be subject to this fee.

The $3,500 fee is exempt from F&A and will be charged to the study-specific Peoplesoft Project ID (account code 558893) immediately upon creation of the Project ID.

In addition, a fee of $100 per study subject enrolled will be charged to the study Project ID and will be calculated based on IRB renewal data and confirmed through OnCore and/or CRMS. This fee will be calculated and assessed annually (but charged only once per enrolled subject) and is also exempt from F&A. This fee will not be charged for subjects enrolled and who do begin active study treatment, screen fails will not be included.

Study teams should budget for these fees while developing and negotiating study budgets with the sponsor. While the fee will be charged to each study as described above, study teams are free (and encouraged) to negotiate higher amounts if the sponsor will permit, and the difference may be retained by administering department.

The new fee model will be used to expand and improve the infrastructure critical to supporting the University’s clinical research.