Pursuant to 2 CFR 200.332 and 45 CFR 75.201, we are writing to request prior approval to enter into clinical trial subawards in a fixed price manner. Subaward payments will be made when the subrecipient meets the enrollment milestone as outlined in the subaward as required by the regulations. We request that prior approval be granted as a universal approval to cover any clinical trial subawards we enter into during the duration of the project in order to expedite clinical site activation, provided that such subawards based on fixed amounts (as defined in 45 CFR Part 75.2) satisfy the conditions for such subawards cited in Section 8.1.2.11 (1) through (5). We also request that the universal approval be provided by issuance of a revised Notice of Award.

(Remove if not necessary)
Additionally, we are seeking prior approval to exceed the Simplified Acquisition Threshold for this project. Under the Uniform Guidance (200.332 Fixed amount subawards), a PTE may enter into fixed price subaward "up to the Simplified Acquisition Threshold". The NIH GPS 8.1.2.11 references 45 CFR Part 75.2, but neither speak directly to the SAT limit. However, the FAQs published by the COFAR and OMB makes it clear that agencies may modify the threshold when necessary to minimize administrative burden (please see full text below):

https://cfo.gov/wp-content/uploads/2014/08/2014-08-29-Frequently-Asked-Questions.pdf

"200.332 .332-1 Fixed Amount Subawards - My institution has a fixed amount subaward issued on an active Federal award and it is over the $150,000 Simplified Acquisition Threshold; it will continue to be active after 12/26/14. Instead of modifying the subaward, can I give my subrecipient a new fixed amount subaward to cover just this year's funding so I can stay below the threshold?

It is acceptable to have more than one fixed amount subaward with the same subrecipient if necessary to complete work contemplated under a Federal award. It is expected, however, that each fixed amount subaward will have its own distinct statement of work and be priced for the work and deliverables that will be due under that subaward, and that prior approval of the Federal awarding agency is required for each subaward issued under funding received on or after 12/26/14, as outlined in 200.332. Non-Federal entities having special circumstances, including an unanticipated need to increase a fixed price subaward above the threshold, should consult with their Federal awarding agency for guidance on how to complete the planned scope of work with the least amount of administrative burden."

In the case of clinical trials, our position is that it would be highly burdensome to limit these clinical sites to the SAT for the following reasons:

(List specific reasons here)