Weill Cornell Medicine

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Re: SARS-CoV-2 vaccination considerations for clinical research studies

To Weill Cornell Investigators:

With the widening availability of SARS-CoV-2 vaccines authorized under the Emergency Use Authorization (EUA), investigators may face situations where SARS-CoV-2 vaccination may be considered an exclusion for trial participation or a prohibited concomitant therapy during study participation. While EUA is not considered a full approval by the Food and Drug Administration, it is the position of the WMC Human Research Protections Program that vaccines authorized under the EUA should not be considered an experiemental therapy for the purposes of study entry criteria or study follow-up. If specific trials require exclusion of these vaccines (e.g. clinical trials of SARS-CoV-2 vaccine or COVID therapeutic studies), this should be stated explicitly in the protocol. Receipt of these vaccines do not need to be reported to the WMC IRB for as exception requests or protocol deviations.

I encourage investigators to discuss this issue with study sponsors. For studies that utilize a non-WCM IRB as the IRB of record, this should be discussed with the IRB of record.

Best regards,

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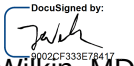
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