

For these study designs:	<p align="center">Is the specific research visit "essential to the health and/or well-being" of the participant, thus supporting in-person visits?</p> <p align="center">Note: contractual and grant obligations should not be considered as a factor.</p> <p align="center">If in-person visits (essential or non-essential) can be substituted with remote visits, they may proceed per IRB's guidance on protocol deviations/modifications.</p>		
	<p align="center">These visit types are <u>LIKELY</u> "essential" (Supports an in-person visit)</p>	<p align="center">These visit types may or may not be "essential" (Support for in-person visit depends on specifics of the study)</p>	<p align="center">These visit types are <u>LIKELY not</u> "essential" (Does not support an in-person visit)</p>
Randomized controlled efficacy trial (e.g., phase IIb or III) of a therapeutic drug or device or other intervention	<ul style="list-style-type: none"> • New enrollments (for drugs and devices critical for the health of the patient) • Follow ups 		
Post-approval trial (e.g., phase IV) of a therapeutic drug, device, or other intervention to assess tolerability and/or long-term benefit	<ul style="list-style-type: none"> • Follow ups that are clinically driven 	<ul style="list-style-type: none"> • New enrollments 	<ul style="list-style-type: none"> • Follow-up visits that are research-only and not clinically driven
Early phase (e.g., phase I or IIa) pharmacodynamic, safety, tolerability or feasibility trial a potential drug or device or other intervention	<ul style="list-style-type: none"> • Follow ups 	<ul style="list-style-type: none"> • New enrollments 	
Non-randomized interventional trial of a drug, device, or other intervention requiring safety monitoring	<ul style="list-style-type: none"> • Follow ups 	<ul style="list-style-type: none"> • New enrollments, if intervention is only provided in the context of the research study 	
Non-randomized interventional trial of a drug, device, or other intervention <u>not</u> requiring safety monitoring		<ul style="list-style-type: none"> • New enrollments, if one can only receive the intervention in context of research • Research-only follow ups 	

Comparative effectiveness studies or other study types describing the natural history of disease or other clinical outcomes, requiring safety monitoring	<ul style="list-style-type: none"> • Follow ups involving safety monitoring 	<ul style="list-style-type: none"> • Other follow-ups 	<ul style="list-style-type: none"> • New enrollments
Non-interventional qualitative study			<ul style="list-style-type: none"> • New enrollments • Follow ups
Non-interventional study with collection of clinical data and/or biological specimens for future research			<ul style="list-style-type: none"> • New enrollments • Follow ups

Note: If you feel your study qualifies for essential in-person visits (new enrollment or follow-up), please contact Meredith Capasse (Meredith.capasse@choa.org) for concurrence.