

Recommendations for the Management of Clinical Trials during COVID-19 Pandemic

3/18/2020

Rationale: The current COVID-19 pandemic requires extraordinary efforts to limit the spread of this disease. Of paramount importance is the use of *Social Distancing* as a primary intervention. This means minimizing subject visits and associated activities related to clinical investigations. In addition, there are growing shortages of personal protective equipment (PPE) requiring these resources to be conserved. Therefore, it is imperative that starting immediately, we limit in person clinical trial activity to those studies that are essential to the health and/or well-being of the subjects.

Recommendations: Attached is a table providing guidance for investigators to provide assistance in determining the best approach to manage their clinical studies during this critical time. A few general guidelines follow:

- 1) First ask: Is the specific research visit "essential to the health and/or well-being" of the subject, thus supporting in-person visits?
- 2) Use the attached table as a decision support tool to help make this critical decision.
- 3) All investigators are urged to reach out to the study sponsors to communicate their current plans for managing their clinical trials during the COVID-19 pandemic. All contractual and grant obligations will need to be addressed with sponsor.
- 4) If in-person visits can be substituted with remote visits, they may proceed per IRB's guidance on protocol deviations and modifications (see below). Careful documentation of all subject contacts is critical.
- 5) COVID-19 studies may be considered an exception to the approach outlined in the attached table given the high priority of research in this area.
- 6) For NIH studies, please review "Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19" <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>
- 7) As the current situation evolves, there may be changes in the guidance provided in this document.

Specific IRB Guidance:

1) Protocol Deviations and the IRB:

- Sustained changes to your protocol/research procedures, to comply with restrictions, require an amendment with the reviewing IRB (Emory or external).
 - NOTE: Documentation for the modification can be a letter/memo, instead of a formal protocol revision.
- For urgent deviations that cannot wait for IRB approval (we anticipate many): these must be reported according to the reviewing IRB's reporting policy (i.e. promptly, if they impact the rights or welfare of subjects, or the integrity of research data). See [Emory's Reporting Policy](#) or your reviewing IRB's policy or confer with the lead site investigators.
 - Some deviations pose no significant threat to participant safety or scientific integrity. As such, reporting is left to the discretion of the investigator within the context of the IRB's reporting policy.

- Note: COVID-19 screening requirements during study visits are not considered part of the research, thus no modification is required.
- The IRB supports moving to home visits, use of other service providers for standard procedures, and phone calls for participant data collection and monitoring, so long as no procedures would be performed that are unsafe in this setting and liability insurance coverage is adequate.
- **See our more detailed guidance here:** <http://irb.emory.edu/documents/guidance-Covid-19.pdf> or on the attached document.

2) New COVID-19 Research and the IRB:

- The IRB is prioritizing time-sensitive research related to the virus. Please continue to contact the Director, [Rebecca Rousselle](#), or one of the [Assistant Directors](#) to alert us.

Let's all continue to work together to protect our patients, our subjects, our staff and our community during this difficult time. Thank you for your cooperation.

Suggested Approach for Determining the Need for In-Person Visits for Clinical Studies during the COVID-19 Pandemic

For These Study designs	These visit types are LIKELY “essential” (Supports an in-person visit)	These visit types may or may not be “essential” (Support for in-person visit depends on specifics of the study)	These visit types are LIKELY <u>not</u> “essential” (Does not support an in-person visit)
Randomized controlled efficacy trial (e.g., phase IIb or III) of a therapeutic drug or device or other intervention	Follow-ups addressing a time-sensitive clinical or safety-related need	New enrollments if there is a time-sensitive or immediate clinical need	Follow ups that are not time-sensitive and are not clinically driven
Post-approval trial (e.g., phase IV) of a therapeutic drug, device, or other intervention to assess tolerability and/or long-term benefit	Follow ups that are clinically driven	New enrollments	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	Follow ups	New enrollments	
Non-randomized interventional trial of a drug, device, or other intervention requiring safety monitoring	Follow ups	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		New enrollments, if one can only receive the intervention in context of research	
Comparative effectiveness studies or other study types describing the natural history of disease or other clinical outcomes, requiring safety monitoring	Follow ups involving safety monitoring	Other follow-ups	New enrollments
Non-interventional qualitative study			New Enrollments and Follow ups
Non-interventional study with collection of clinical data and/or biological specimens for future research*			New Enrollments and Follow ups

*Non-interventional studies that do not require in person visits may continue, especially when data collection can be performed remotely through web, email, standard mail, telephone, etc.