COVID-19 Frequently Asked Questions – Version 4, 30 March 2020

Contact details for advice

Email: COVID19ACCORD@ed.ac.uk

Regular updates to this guidance will be sent by email and made available on
http://www.accord.scot/about-accord/accord-news/covid19-planning-and-guidance-research-0

Obtaining advice

- Any clinical research queries related to the impact of the COVID-19 pandemic should be sent to the specific ACCORD e-mail: COVID19ACCORD@ed.ac.uk. This e-mail must only be used for queries relating to the impact of COVID-19. Before doing so, please check if your query can be resolved by reading the guidance published by ACCORD or by reading the following FAQs:

Area/Question	**Answer**
Monitoring	
Does the suspension of SIVs include remote SIVs, e.g. SIVs conducted via video conferencing where the monitor/trial manager does not travel to the research site?	Yes
Does the suspension of SIVs include SIVs planned for sites within NHS Lothian?	Yes
Risk Assessment	
Should completed COVID-19 risk assessments be returned to the (co-)sponsor?	**Yes** for studies with an ACCORD monitoring plan (i.e. subject to an ACCORD combined risk assessment before the study started), provide completed COVID-19 risk assessment to the study monitor. If you are not sure if this includes your study, please enquire via the email address given. **No** for studies without ACCORD monitoring plans, file in the ISF and TMF if necessary.

Area/Question	Answer
Should the COVID-19 risk assessment be completed on a per-trial or per-site basis?	Per site unless a decision has been made to halt the entire study. If all trial activities (i.e. not just a suspension to recruitment) have been halted across the entire study, only one risk assessment per trial is required, from the CI. If a study has sites where some research activities will continue while other sites will halt all research activity, risk assessment should be completed per site for the active sites whereas, a single risk assessment can be prepared to collectively cover the inactive sites.
Are trial teams responsible for circulating risk assessments to sites?	Yes
Do I need to complete the risk assessment if in follow up only?	Yes if follow up includes face-to-face visits.
Should the risk assessment be completed for scanning visits for existing participants?	Yes
Notifications	
Does a temporary halt, for COVID-19 capacity and capability reasons, require a substantial amendment to be submitted to the MHRA and REC?	**No** for the MHRA and REC for regulated studies (CTIMPs and Clinical Investigations of Medical Devices requiring a letter of no objection from the MHRA - this does not include in vitro diagnostics). Prepare a file note documenting the reason(s) for the halt and file in the TMF. **Yes** for the MHRA and the REC, if a temporary halt is due to a participant safety incident, report as a temporary halt (via substantial amendment) in the usual way. If a temporary halt is due to IMP supply issues, inform the MHRA via the clinical trials helpline email and copy ACCORD. You should contact your sponsor representative for REC notification instructions. If your study has research sites outside the UK, you should contact the Competent Authority in each country and seek specific instructions, in regards for notifications. **No** for other unregulated studies. A suspension to recruitment, without halting other trial activities, requires notification to ACCORD only. To implement a full temporary halt, prepare a non-substantial amendment, inform ACCORD and notify NHS Lothian R&D if single site or NRSPCC if multi-site. There is no need to notify the REC. *This answer in particular is subject to change as updated MHRA and HRA guidance is received.*

Area/Question	Answer
Can you advise on how we deal with a single or several sites halting recruitment in a multicentre study?	ACCORD guidance has been updated and recruitment must be suspended from March 17th, until further notice. This includes all studies sponsored by UoE and/or NHS Lothian and is applicable to research sites worldwide. This also includes all studies hosted by NHS Lothian, regardless of the sponsor.
Does a temporary halt for a medical device study need a substantial amendment to the MHRA?	No. It needs to be recorded in the TMF as described above.
I wish for my study to be exempt from the recruitment suspension, what do I do?	You should submit a proposal, detailing why your study should be exempt, to the COVID-19 email address provided. This should be accompanied by your completed COVID-19 risk assessment. The request will be escalated within ACCORD and a decision will be taken as quickly as possible.
I wish to initiate a new study directly related to COVID-19, what do I do?	You should submit a proposal, including any available draft study documents, to the COVID-19 email address provided. The request will be reviewed within ACCORD (may be escalated further, according to UoE/NHSL processes arising) and feedback will be provided as quickly as possible.
If I submit an amendment, to ACCORD, for review, will it be reviewed now?	Amendments are still being reviewed, although COVID-19 related new projects and amendments are being prioritised. The review of other amendments may be subject to delay.