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Academic and Clinical Central Office for Research and Development

Guidance for Restarting/Commencing Non-COVID-19 Clinical Research

Purpose

- Provide clear guidance to researchers about how to manage their research following the peak of the COVID-19 pandemic and the lift on the halt to recruitment in NHS Lothian (NHSL).
- Provide researchers with information about how ACCORD will manage research activities in the coming weeks/months.
- Provide guidance on research activity and the required response that is consistent with NHSL, other regulatory bodies, and Scottish/UK government.
- A flow chart has been provided on page 2 which summarises what a Chief Investigator (CI) or Principal Investigator (PI) needs to do to restart/commence depending on whether the study is Sponsored by the University of Edinburgh (UoE) and/or NHSL or another organisation, and depending on the regulatory status of the project. More detailed guidance on each study type is also provided in this document.

Obtaining advice

- Any clinical research queries related to COVID-19 specific research should be sent to COVID19ACCORD@ed.ac.uk. Other non-COVID-19 research related questions should be sent to the study Sponsors Monitor or Sponsor Representative (if known) or to resgov@accord.scot. General enquiries related to NHSL hosted studies should be sent to accord@nhslothian.scot.nhs.uk.

Overview

- **Approval to restart/commence a study is conditional on maintained compliance with prevailing Scottish and UK Government instructions and guidance. Studies taking place out with the UK are expected to comply with local Government instructions and guidance.**
- From 01 June 2020, the halt to **new** recruitment to non-COVID-19 studies in NHSL has been lifted in principle **(Sponsored and hosted studies)**. This includes recruitment to UoE/NHSL Sponsored studies across all sites worldwide (where sites have the capacity and capability to restart) and NHSL hosted studies.
- At this time, research in the UK **must not** involve any patient or person (e.g. healthy volunteer, research staff) involved in the research undertaking an activity that is not consistent with UK Government guidance and the Scottish Government Coronavirus (COVID-19): framework for decision making - Scotland's route map through and out of the crisis; https://www.gov.scot/publications/coronavirus-covid-19-framework-decision-making-scotlands-route-map-through-out-crisis/.
- At this time, a participant (e.g. patient or healthy volunteer) must not be asked to come to the hospital to participate in study specific activities that are not integral to ongoing clinical care. Similarly, no research procedures such as a laboratory tests or investigations should be undertaken for research purposes alone if it is not consistent with Government guidance and the Scottish Government route map.

- **Before any studies taking place in Lothian are re-started and new participants recruited, the CI/PI must complete a Restart Risk Assessment. Exceptions to this are noted in the study specific guidance below.**
- A Restart Risk Assessment Checklist has been provided with this guidance to assist CIs/PIs to assess the ability of their research team and their site to support their project following the peak of the COVID-19 pandemic, taking account of resources and processes required for safe research. This checklist can also be found at www.accord.scot.
- Non-NHSL sites involved in UoE/NHSL Sponsored studies must have Sponsor and/or CI approval to restart and must follow local R&D procedures before restarting a study at their site.
- CIs/PIs should consider whether it is feasible for their site to start recruiting new participants and comply with Government guidance, and whether the research team, support departments and third party suppliers have capacity and are ready to restart/commence their study at this time.
- Safety of the participants should be ensured when restarting/commencing trials.
- **The NHSL Clinical Research Facilities (CRFs) and EMERGE team are unable to support studies before 29 June 2020 due to ongoing COVID-19 research commitments.**
- **Please be aware that other support departments may be unable to support studies or access to University buildings may not be possible until a later date.**
- See Appendix 1 for other considerations before and after restarting the study.

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NHS Lothian

WHAT TO DO TO RESTART THE RESEARCH PROJECT?

Is the study Sponsored by UoE/NHSL?

YES

Is the study a Clinical Trial of an Investigational Product (CTIMP)?

YES

Complete Restart Checklist and seek *Sponsor approval to restart

NO

Does the study have an ACCORD monitoring plan?

YES

Complete Restart Checklist and seek *Sponsor approval to restart

NO

Complete Restart Checklist and CI approves restart

NO

Complete Restart Checklist and speak to the study Sponsor about restarting in NHS Lothian

*To obtain Sponsor (UoE and/or NHSL) approval to restart, e-mail your completed and CI/PI signed Restart Risk Assessment Checklist to Monitors@accord.scot.

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Restarting CTIMPs & Non-CTIMPs with an ACCORD Monitoring Plan

- Completion of the Restart Risk Assessment Checklist (Part A-H) is mandatory for CIs running existing UoE/NHSL Sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs) and studies with an ACCORD monitoring plan in place (see exception to this below for studies in follow up).
- The study Restart Risk Assessment Checklist must be submitted to ACCORD (Monitors@accord.scot) to obtain Sponsor approval to restart the study.
- The study Restart Risk Assessment Checklist can cover the NHSL site (Part E-H) as well as the study as a whole (Part A-D).
- CIs/PIs **must** contact the relevant NHS support departments (e.g. labs), service providers and essential collaborators (e.g. database providers) before they restart the project.
- In Lothian, where the study involves Edinburgh Imaging facilities, you must contact Dawn Cardy (dawn.cardy@ed.ac.uk) to establish capacity.
- In Lothian where restarting the study means that you will require access to a UoE laboratory/building, approval by the Sponsor/CI to restart cannot be given until the UoE has approved access for the study to the UoE laboratory/building. It should be noted that based on Government guidance it may not be possible to access University laboratories at this time. To confirm whether this approval is in place, please contact:
    - Edinburgh BioQuarter: Sharon Hannah (sharon.hannah@ed.ac.uk)
    - IGMM / WGH: Angela Ingram (angela.ingram@igmm.ed.ac.uk)
    - Easter Bush: Val Hughes-White (val.hughes-white@ed.ac.uk)
    - Central Area (Biomedical Sciences) Janet Philp (j.philp@ed.ac.uk)
    - Central Area (Usher) Vivien Smith (vivien.smith@ed.ac.uk)
- On receipt of a valid Restart Risk Assessment Checklist from the CI, the Sponsor will approve restart of the study. The Sponsor will copy NHSL R&D (accord@nhslothian.scot.nhs.uk) when the approval is issued.
- CIs for multicentre studies Sponsored by UoE and/or NHSL must provide clear instructions about the resumption of new recruitment to all participating sites based on the guidance in this document. The CI is responsible for informing PIs of the Sponsors approval to restart. The Sponsor will provide a letter to be disseminated to sites by the CI/Trial Manager.
- For multi-centre studies, non-NHSL sites must follow local R&D procedures to restart the study, obtaining R&D approval where this is required. PIs from non-NHSL sites need only complete the ACCORD Restart Risk Assessment Checklist where there are no local R&D procedures in place to restart the study to ensure that they have all the resource required to deliver the project and ensure participant safety. Exceptions to this are detailed below (i.e. the MATCH and SNAP-It trials).
- The Sponsor (UoE/NHSL) is delegating approval to restart at other NHS Boards/Trusts/Sites to the local PI, assuming that all local R&D procedures have been followed.
- It is acknowledged that not all sites will be able to restart at the same time and that this will be based on resource/approval at site.
- The CI or Trial Manager is responsible for confirming that each site PI has confirmed capacity to restart and for obtaining a copy of a local R&D risk assessment/checklist or the ACCORD Restart Risk Assessment Checklist (if used). There is no requirement for the CI or Trial

Manager to obtain evidence of local support department or R&D sign off to restart at each site.

- Trial Managers must follow up with sites to confirm if any retraining is required at site and to ensure that any deviations/violations and Adverse Events (AEs) which occurred during periods of low resource are now recorded and reported as required.
- The CI or Trial Manager must inform ACCORD when a site has restarted (Monitors@accord.scot). Non-NHSL site PIs do not need to submit site specific checklists to ACCORD (with the exception of the studies mentioned in the next bullet point).
- **The exception to this are the MATCH and SNAP-IT trials which are categorised as 'C' under the ACCORD Combined Risk Assessment procedure (GS002) and will require Sponsor approval to restart per site. The CI or Trial Managers for these studies should ensure that the completed site specific Restart Risk Assessment Checklists are submitted to ACCORD (Monitors@accord.scot) for each site.**
- CTIMPs and non-CTIMPs with an ACCORD monitoring plan that are in follow up, and have not halted follow up activities, **do not** need to complete the Restart Risk Assessment Checklist.
- CTIMPs and non-CTIMPs with an ACCORD monitoring plan that are in follow up, and did halt follow up activities, **do not** need to complete Part A-D of the Restart Risk Assessment Checklist. However, for trials in follow up in NHSL, that are restarting previously suspended follow up procedures, Part E-H of the Restart Risk Assessment Checklist should be completed and NHSL R&D notified of the restart (accord@nhslothian.scot.nhs.uk). The PI must send this communication to R&D clearly stating in the e-mail ***'As the Principal Investigator of 'STUDY TITLE', I confirm that I have completed the ACCORD Restart Risk Assessment Checklist and all necessary resources to restart this study have been verified by me. On this basis, I plan to restart this study on DD/MMM/YYYY'***. The NHSL R&D team will acknowledge these e-mails and this acknowledgment should be filed in the study Investigator Site File (ISF). These risk assessments **do not** need to be submitted to the ACCORD Monitoring team for approval. However, please note that the Sponsor may request to see the completed Restart Risk Assessment Checklist should the research team raise any queries regarding restart.
- For trials in follow up at non-NHSL sites, that are restarting previously suspended follow up procedures, site PIs should follow local R&D processes for restarting study specific procedures where these may have been halted and ensure any changes to the COVID-19 Study Specific Risk Assessment (ACCORD COVID-19 Clinical Research Plan and Guidance) are updated and submitted to ACCORD where required.
- Documentation associated with local R&D procedures to restart and the Sponsor's approval to restart should be filed in the Investigator Site File (ISF).
- The Restart Risk Assessment Checklist and the Sponsor approval to restart should be filed in the Trial Master File (TMF).
- **For UoE/NHSL sponsored studies, CIs do not have Sponsor approval to restart CTIMPs & studies with an ACCORD Monitoring Plan without submitting the Restart Risk Assessment Checklist to ACCORD for review (Part A-D).**
- CIs/PIs should re-visit the risk assessments based on local or national changes in guidance and local resource issues (for example further COVID-19 waves).
- Studies that received ACCORD approval for an exemption to the recruitment halt during the height of the COVID-19 pandemic, where circumstances have not changed since the initial

exemption request, need **not** complete the Restart Risk Assessment Checklist or follow local R&D procedures to restart.

- For UoE and/or NHSL Sponsored studies, the halt on remote Site Initiation Visits (SIVs) and Sponsor Authorisation to Open Sites (SATOs) has been lifted as of 01 June 2020. Please be aware that at this time the monitoring team will prioritise restart of already active studies before new studies.
- On-site monitoring visits are still on hold at this time. This is likely to change with evolving Scottish/UK Government guidance.

Restarting Non-CTIMP Studies Sponsored by UoE and/or NHSL

- This applies to non-CTIMPs without an ACCORD monitoring plan only. If the study is a non-CTIMP Sponsored by UoE/NHSL and has a monitoring plan, see guidance for restarting above.
- The study Restart Risk Assessment Checklist can cover the NHSL site (Part E-H) as well as the study as a whole (Part A-D).
- CIs/PIs must contact the relevant NHS support departments (e.g. labs), service providers and essential collaborators (e.g. database providers) before they restart the project.
- In Lothian, where the study involves Edinburgh Imaging facilities, you must contact Dawn Cardy (dawn.cardy@ed.ac.uk) to establish capacity.
- In Lothian, where restarting the study means that you will require access to a UoE laboratory/building, approval by the Sponsor/CI/PI cannot be given until the UoE has approved access for the study to the UoE laboratory/building. It should be noted that based on Government guidance it may not be possible to access University laboratories at this time. To confirm whether this approval is in place, please contact:
    - Edinburgh BioQuarter: Sharon Hannah (sharon.hannah@ed.ac.uk)
    - IGMM / WGH: Angela Ingram (angela.ingram@igmm.ed.ac.uk)
    - Easter Bush: Val Hughes-White (val.hughes-white@ed.ac.uk)
    - Central Area (Biomedical Sciences) Janet Philp (j.philp@ed.ac.uk)
    - Central Area (Usher) Vivien Smith (vivien.smith@ed.ac.uk)
- Completion of the Restart Risk Assessment Checklist (Part A-H) is required for CIs running UoE/NHSL Sponsored non-CTIMP studies that involve NHSL support departments and/or UoE labs. These risk assessments **do not** need to be submitted to ACCORD for approval. However, please note that the Sponsor may request to see the completed Restart Risk Assessment Checklist should the research team raise any queries regarding restart.
- CIs/PIs **must** inform the NHSL R&D department that the study has restarted (accord@nhslothian.scot.nhs.uk). The PI must send this communication to R&D clearly stating in the e-mail ***'As the Principal Investigator of 'STUDY TITLE', I confirm that I have completed the ACCORD Restart Risk Assessment Checklist and all necessary resources to restart this study have been verified by me. On this basis, I plan to restart this study on DD/MMM/YYYY'***. The NHSL R&D team will acknowledge these e-mails and this acknowledgment should be filed in the study Investigator Site File (ISF).
- CIs for multicentre non-CTIMP studies (without a monitoring plan) Sponsored by UoE and/or NHSL must provide clear instructions about the resumption of new recruitment to all

participating sites based on the guidance in this document. The CI is responsible for informing PIs of the approval to restart.

- For multi-centre studies, non-NHSL sites must follow local R&D procedures to restart the study, obtaining R&D approval where this is required. Non-NHSL PIs need only complete the ACCORD Restart Risk Assessment Checklist where there are no local R&D procedures in place to restart the study. The Sponsor (UoE/NHSL) is delegating approval to restart at other NHS Boards/Trusts/Sites to the local PI, assuming that all local R&D procedures have been followed to ensure that they have all the resource required to deliver the project and ensure participant safety.
- It is acknowledged that not all sites will be able to restart at the same time and that this will be based on resource/approval at site.
- There is no requirement for the CI to obtain evidence of local support department or R&D sign off to restart at each site.
- CIs must follow up with sites to confirm if any retraining is required at site and to ensure that any deviations/violations and Adverse Events (AEs) which occurred during periods of low resource are now recorded and reported as required.
- Non-CTIMPs without an ACCORD monitoring plan, and have not halted follow up activities, **do not** need to complete the Restart Risk Assessment Checklist.
- Non-CTIMPs without an ACCORD monitoring plan that are in follow up, and did halt follow up activities, **do not** need to complete the Restart Risk Assessment Checklist (Part A-D). However, for trials in follow up in NHSL that are re-starting suspended follow up procedures, Part E-H of the Restart Risk Assessment Checklist should be completed and NHSL R&D notified as above (accord@nhslothian.scot.nhs.uk). The completed checklists **do not** need to be submitted with this notification to R&D. However, please note that the Sponsor may request to see the completed Restart Risk Assessment Checklist (Part E-H) should the research team raise any queries regarding restart.
- For trials in follow up at non-NHSL sites, that are restarting previously suspended follow up procedures, site PIs should follow local R&D processes for restarting study specific procedures where these may have been halted and ensure any changes to the COVID-19 Study Specific Risk Assessment (ACCORD COVID-19 Clinical Research Plan and Guidance) are updated and submitted to ACCORD where required.
- Documentation associated with local R&D procedures to restart and the Sponsor approval to restart should be filed in the Investigator Site File (ISF). These checklists **do not** need to be submitted to ACCORD.
- The overall study Restart Risk Assessment Checklist and the CIs approval to restart should be filed in the Trial Master File (TMF).
- CIs/PIs should re-visit the risk assessment based on local or national changes in guidance and local resource issues (for example further COVID waves).
- Studies that received ACCORD approval for an exemption to the recruitment halt during the height of the COVID-19 pandemic, where circumstances have not changed since the initial exemption request, need **not** complete this risk assessment.

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Restarting Studies Hosted in NHSL

- CIs/PIs must contact the relevant NHS support departments (e.g. labs), service providers and essential collaborators (e.g. database providers) before they restart their project.
- Where the study involves Edinburgh Imaging facilities, you must contact Dawn Cardy (dawn.cardy@ed.ac.uk) to establish capacity.
- If restarting the study means that you will require access to a UoE laboratory/building, approval by the Sponsor/CI/PI cannot be given until the UoE has approved for the study access to the UoE laboratory/building. It should be noted that based on Government guidance it may not be possible to access University laboratories at this time. To confirm whether this approval is in place, please contact:
    - Edinburgh BioQuarter: Sharon Hannah (sharon.hannah@ed.ac.uk)
    - IGMM / WGH: Angela Ingram (angela.ingram@igmm.ed.ac.uk)
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    - Central Area (Biomedical Sciences) Janet Philp (j.philp@ed.ac.uk)
    - Central Area (Usher) Vivien Smith (vivien.smith@ed.ac.uk)
- Completion of this Restart Risk Assessment Checklist (Part E-H) is required for CIs or PIs running studies hosted in Lothian that involves NHSL support departments and/or UoE labs. These restart risk assessments **do not** need to be submitted to ACCORD for approval i.e. by signature of the risk assessment the CI/PI will approve restart of these projects. The CI/PI must send this communication to R&D clearly stating in the e-mail ***'As the Principal Investigator of 'STUDY TITLE', I confirm that I have completed the ACCORD Restart Risk Assessment Checklist and all necessary resources to restart this study have been verified by me. On this basis, I plan to restart this study on DD/MMM/YYYY'***. The NHSL R&D team will acknowledge these e-mails and this acknowledgment should be filed in the study Investigator Site File (ISF).
- CIs/PIs for hosted research projects need to be mindful of any additional information or advice that they have received from the study Sponsor (e.g. requirement to complete a Sponsor restart specific checklist, commercial Sponsors may want to delay re-starting recruitment to their studies if there are supply issues in relation to IMP) and must seek Sponsor approval to restart.
- All CIs/PIs MUST communicate with support departments when completing the Restart Risk Assessment Checklist to ensure that they have all the resources required to deliver their project and ensure patient safety.
- The completed Restart Risk Assessment Checklist should be filed in the Investigator Site File (ISF). These checklists **do not** need to be submitted to ACCORD.
- CIs/PIs should re-visit risk assessment overall based on local or national changes in guidance and local resource issues (for example further COVID waves).
- Studies that received ACCORD approval for an exemption to the recruitment halt during the height of the COVID-19 pandemic, where circumstances have not changed since the initial exemption request, need **not** complete this risk assessment.
- On-site monitoring visits are still on hold at this time. This is likely to change with evolving Scottish/UK Government guidance.

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New Studies Sponsored by UoE/NHSL

- New studies will progress through Sponsor review/approval following the normal process (ACCORD Standard Operating Procedure GS003 Sponsorship Approval). Please be aware that reviews may not progress in the usual 10 working days at this time.
  The NIHR has developed a 'Framework for Restart' to provide guidance on local decision making (https://www.nihr.ac.uk/documents/restart-framework/24886). This Framework and the 3 prioritisation levels is supported by the Chief Scientist Office (CSO) Statement on the Restart Framework; https://www.cso.scot.nhs.uk/cso-statement-on-the-restart-framework/. ACCORD will adopt the NIHR's 3 levels of study prioritisation detailed in their guidance.
  Level 1: Essential studies providing evidence for pandemic management, i.e. nationally prioritised COVID-19 Urgent Public Health (UPH) Research studies.
  Level 2: Studies where the research protocol includes an urgent treatment or intervention without which patients could come to harm. These might be studies that provide access to potentially life preserving or life-extending treatment not otherwise available to the patient.
  Level 3: All other studies (including new COVID-19 studies not in Level 1).
- For all COVID-19 related research, please follow the ACCORD COVID-19 Clinical Research Plan and Guidance for new COVID-19 related research.
- For all other new clinical research, the Sponsors Representative or assigned Clinical Trials Monitor may ask you to verify how risks around participant safety during the COVID-19 pandemic are being managed and mitigated where applicable. We recommend that CIs/PIs review the Restart Risk Assessment Checklist and consider the questions around COVID-19 participant and staff safety which are likely to apply to the study.
- Where the study involves Edinburgh Imaging facilities, you must contact Dawn Cardy (dawn.cardy@ed.ac.uk) to establish capacity.
- If the study means that you will require access to a UoE laboratory/building, you must ensure the UoE has approved access for the study to the UoE laboratory/building. It should be noted that based on Government guidance it may not be possible to access University laboratories at this time. It should be noted that based on Government guidance it may not be possible to access University laboratories at this time. To confirm whether this approval is in place, please contact:
  - Edinburgh BioQuarter: Sharon Hannah (sharon.hannah@ed.ac.uk)
  - IGMM / WGH: Angela Ingram (angela.ingram@igmm.ed.ac.uk)
  - Easter Bush: Val Hughes-White (val.hughes-white@ed.ac.uk)
  - Central Area (Biomedical Sciences) Janet Philp (j.philp@ed.ac.uk)
  - Central Area (Usher) Vivien Smith (vivien.smith@ed.ac.uk)
- For UoE and/or NHSL Sponsored studies, the halt on remote Site Initiation Visits (SIVs) and Sponsor Authorisation to Open Sites (SATOs) has been lifted as of 01 June 2020. Please be aware that at this time the monitoring team will prioritise restart of already active studies before new studies.

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NHSL R&D Management Approval for New Sponsored and Hosted Studies

- During the COVID-19 pandemic, the NHSL R&D governance team continued to progress non-COVID-19 studies but final sign offs by support departments or heads of service have not been requested since 23 March 2020. Therefore, there is a large backlog of new studies and amendments to existing studies that now need these sign offs before they are approved by R&D.
- We will seek sign off from support departments prior to seeking Head of Service approval to ensure that new studies can be supported at this time.
- Please be aware that support departments and Heads of Service will not have the capacity to sign off the large number of studies and amendments currently in our system as well as new studies and amendments received in the coming weeks/months. These processes will take longer than usual.
- R&D governance review of non-COVID-19 studies and amendments (already in the system and new) will be processed in accordance with the NIHR guidance on levels of prioritisation, as detailed above.
- New studies that receive R&D Management Approval following the lift on the recruitment halt 01 June 2020) are **not** required to complete the risk assessment.

NHSL Clinical Research Facilities (CRFs) & EMERGE Team

- The NHSL CRFs and the Emergency Medicine Research Group of Edinburgh (EMERGE) team are unable to support restart/commencement of studies before **29 June 2020** due to ongoing COVID-19 research commitments.
- CIs/PIs can contact these support departments in advance of that date to discuss logistics for restarting studies. Initial contact should be with the assigned study Lead Nurse.
- Research teams are encouraged to complete other aspects of the study Restart Risk Assessment Checklist before approaching the CRF or EMERGE, and ensuring that the study Sponsor has approved restart in NHSL.

Appendix 1: Other Consideration Before & After Restarting

	Considerations and Documentation
Deviations	Please ensure any deviations logged during the peak of the COVID-19 pandemic are reported to the study Sponsor in accordance with your protocol.
Amendments	Where amendments have been made to study documents during the peak of the COVID-19 pandemic, consider whether any further amendments are required to revert any changes made. Also consider if the study protocol needs to be amended in order to restart the project e.g. to accommodate remote visits. Amendments must be discussed with the study Sponsor. Please refer to the ACCORD COVID 19 Clinical Research Plan and Guidance for more information on the amendments during the COVID-19 pandemic.
Safety Reporting	Please ensure that safety reporting has been conducted in accordance with the protocol and that all Serious Adverse Events (SAEs) have been reported to the study Sponsor. If an SAE has not been recorded/reported in accordance with the protocol, record and report as soon as identified and contact the study Sponsor.
Halt to Recruitment	**CTIMPs & Non-CTIMPs**: Prepare a file note documenting the lift of the halt to recruitment and file in the TMF/ISF.
Temporary Halt	**CTIMPs & Non-CTIMPs**: Where a non-substantial amendment was submitted to temporary halt the study, a non-substantial amendment will now be needed to revert this. Amendments should be processed following Sponsor and HRA procedures and guidance.

	Considerations and Documentation
Participants that may be infected with COVID-19	If research involves taking samples (blood, sputum, etc.) it is essential to ask the COVID-19 status of participants. In patients who are symptomatic but not confirmed positive an individual risk assessment should be undertaken. Ensuring the safety of staff processing samples is paramount. Assume that samples should NOT be taken for research purposes from infected or possibly infected patients unless SOPs guaranteeing safety are agreed. For samples used for safety monitoring in NHS local laboratories check with local laboratories to clarify procedures for research participants. **If it is considered necessary to add testing for SARS-CoV-2 to the protocol, follow procedures for an Urgent Safety Measure. The substantial amendment, describing the USM, can be deferred for 28 days after the measures have been taken and email notification.**
Site Initiation Visits (SIVs) and Sponsors Authorisation to Open new sites (UoE/NHSL Sponsored studies)	Consideration must be given with regards to what is possible and this must be discussed with the study Sponsor e.g. Sponsors may be able to conduct SIVs remotely should you have the capacity within the research team to host a remote meeting. If the study is Sponsored by UoE and/or NHSL and you require SATO and/or SIV (i.e. if your study is a CTIMP or has gone through an ACCORD risk assessment, please contact the ACCORD Monitoring team (Monitors@accord.scot) or contact your assigned Clinical Trials Monitor directly. Please be aware that at this time the monitoring team will prioritise restart of already active studies before new studies.
On-site SIVs and monitoring visits.	At this time Lothian will not host or conduct any on-site monitoring visits. This may change in the coming weeks as Scottish Government guidance continues to evolve.
Equipment maintenance & calibration	During the COVID-19 pandemic, it may not be possible to maintain equipment according to a planned schedule. If you intend to use equipment that has fallen out with its calibration/preventative maintenance dates, before doing so you must assess the risk on patient safety and data integrity. Please discuss with the study Sponsor and document rationale and risk mitigation in the Study Specific Risk Assessment. Use of equipment out with calibration/preventative maintenance dates must be recorded as a deviation or violation.
Good Clinical Practice (GCP) Training	CIs/PIs should remind the research team that they should have up to date GCP training if working on the research project. This is mandatory for CTIMPs Sponsored by UoE/NHS Lothian. Please reference ACCORD Policy GCP and SOP Training (POL001) http://www.accord.ed.ac.uk/research-access-resources-researchers/policies

	Considerations and Documentation
	As face to face GCP courses at sites are unlikely to be running at this time, please refer to the NIHR GCP training online if update training is required; https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm
Receiving Consent	It may not be feasible at present to receive written consent on paper forms from a participant. If this is the case, please discuss this with the study Sponsor e.g. alternative approaches to taking consent may be considered, in line with published guidance on proportionate consent and e-consent; https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/ Note that any changes to arrangements for consent should be agreed with the Sponsor and documented e.g. an amendment may be required.
Ongoing Consent	As is standard practice, please ensure existing participants remain content to be part of the study, particularly in light of the ongoing COVID-19 pandemic. This can be done verbally during a study visit or during a phone call (where applicable) and should be documented in the participant's medical notes.