ACCORD PANDEMIC CONTINGENCY PLANNING POLICY

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1 INTRODUCTION

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 The Sponsor and Chief Investigator (CI) have legally defined responsibilities during the conduct of clinical trials to ensure patient safety and the integrity of trial data at all times. Responsibilities are maintained through robust documentation, quality assurance and monitoring.

1.3 Throughout a period in time when a disease is classed as a pandemic there will potentially be a serious risk to human health leading to a shortage of staff resources and consequently a major impact on research activity. Organisations managing and sponsoring ongoing research studies may identify certain risks to research activities (for example reduced PI oversight due to clinical pressure / illness or reduced access to outpatient facilities / key support services), requiring contingency planning and implementation of risk mitigating strategies.

1.4 Contingency planning will be implemented as per advice that is consistent with NHSL, other regulatory bodies, and Scottish / UK Government.

2 PURPOSE

2.1 To outline a plan of action to mitigate research activity risks during and following a pandemic, ensuring NHSL and UoE fulfil their legal obligations as Sponsors and host of clinical research.

2.2 To provide clear guidance to ACCORD staff and researchers about how to manage studies and research activity throughout a pandemic.

3 SCOPE

3.1 This policy applies to researchers involved in studies Sponsored by NHSL and / or UoE within the UK or globally, and to researchers involved in research studies hosted in NHSL where sponsorship is fulfilled by another institution / company.

3.2 This policy also applies to ACCORD members of staff involved with the management of studies and research activity.

4 PROCEDURE

4.1 Pandemic Steering Group

4.1.1 Once a pandemic or global health emergency has been declared by the World Health Organisation (WHO) or UK Government, a steering group will be formed and will consist of, although not exclusively; the R&D Director, Deputy R&D Director, Heads of Research Governance (NHSL and UoE) and Principal R&D Manager. Members may also be drawn from the wider ACCORD team or research community across NHSL and UoE, where applicable.

4.1.2 The steering group will be tasked with the following;

- Agreeing a communication plan for the steering group.
- Setting up a dedicated email address relating to the impact of the pandemic on research studies and associated queries.
- Assigning a rota for the monitoring of this dedicated email inbox and escalation channels.
- Creating guidance documentation for the research community including but not limited to; research grant funding, site initiation visit / monitoring visits, amendments, urgent safety measures, safety reporting, trial supplies, recruitment suspension etc. Input may be sought from wider ACCORD staff members.
- Devise a strategic plan for the governance review of new pandemic research opportunities and prioritise activity taking into account for example funding sources, feasibility, logistical issues etc.
- Devise ongoing or new guidance for restarting research projects that may have halted or may have halted recruitment during the peak of a pandemic.
- Produce Health & Safety (H&S) guidance for ACCORD staff returning to the ACCORD office following the peak of a pandemic, aligned to a risk assessment that documents and manages the risk of office working.

4.1.3 The steering group will ask the QA Manager to distribute guidance documents to the research community through the available channels (e.g. distribution lists, social media). The ACCORD website will be updated regularly with new information and guidance as this is developed by ACCORD and UK regulators. The QA Manager will file all documentation on the ACCORD SharePoint site.

4.2 Study Specific Risk Assessments

4.2.1 A study risk assessment checklist (POL009-T01) will be made available to CIs and / or Principal Investigators (PI). Completion of this risk assessment will be mandatory for NHSL and / or UoE sponsored studies with a monitoring

plan in place. The risk assessment checklist enables PIs to assess the potential impact of the pandemic on study activity at their site, whilst taking into account resources and processes required for safe research, and whether it is feasible for their site to continue to support the study. This risk assessment should be filed in the Investigator Site File (ISF). ACCORD will issue specific instructions regarding the completion of POL009-T01.

4.2.2 Where applicable, studies sponsored by NHSL and / or UoE and subject to a combined risk assessment (GS002), the PI, or designee, should send the completed risk assessment checklist (POL009-T01) to the assigned Clinical Trials Monitor for review. The assigned Clinical Trials Monitor will identify any additional study / site specific risks associated with the pandemic and categorise the study as low, medium or high risk. Trials identified as high risk on review of the risk assessment (POL009-T01) will be flagged to the wider ACCORD team for discussion at monthly Sponsorship meetings.

4.2.3 The Clinical Trials Monitor will add the study to the Monitoring Risk Tracker located on the ACCORD SharePoint site. This tracker will be used to identify the higher risk trials and prioritise remote monitoring whilst it is not feasible to conduct on-site visits. Where onsite visits cannot be conducted according to monitoring plans, a monitoring deviation will be recorded. This will be categorised as a pandemic related deviation.

4.2.4 The study risk assessment and all associated documents will be appended to the Combined Risk Assessment (GS002-T02) and filed in the Trial Master File (TMF) and / or Sponsor File by the Clinical Trials Monitor.

4.2.5 Where a pandemic or global health emergency has resulted in a halt to recruitment for NHSL and/or UoE sponsored studies, the CI and / or PI must complete a study Restart Risk Assessment Checklist (POL009-T03) prior to restarting and recruiting new participants. This checklist enables CIs/PIs to assess the ability of their research team and their site to support their project following the peak of a pandemic, taking account of resources and processes required for safe research. Completion of this risk assessment checklist will be mandatory for actively recruiting NHSL and / or UoE sponsored studies with a monitoring plan in place. ACCORD will issue specific instructions regarding the completion of POL009-T03.

4.2.6 Where mandatory, the study Restart Risk Assessment Checklists must be submitted to ACCORD (Monitors@accord.scot) to obtain Sponsor approval to restart the study. The assigned Clinical Trials Monitor will perform a review of the Restart Risk Assessment in accordance with POL009-T04 (Monitor Review of Restart Risk Assessment Checklist).

4.3 Internal ACCORD Pandemic Contingency Planning Risk Assessment

4.3.1 The QA Manager will coordinate the internal ACCORD pandemic contingency planning risk assessment (POL009-T02) to document business continuity

plans during a pandemic. This will include but is not limited to ACCORD staff resource, monitoring activities, amendment processing, the use of urgent safety measures, reporting of serious breaches, and maintaining an audit trail of decisions as well as issues relating to how to maintain business-critical IT systems and compliance with the ACCORD QMS (where possible). Contingency measures identified at the risk assessment will be linked to current ACCORD SOPs to prevent SOP deviations being required and reported.

4.3.2 The QA Manager will forward the internal ACCORD pandemic contingency planning risk assessment (POL009-T02) to the following team leads; QA, Monitoring, Governance (NHSL & UoE) and Pharmacovigilance. Team leads will be asked to identify risks and mitigation factors. The QA Manager will have the option to coordinate a meeting (in person or virtually e.g. video-conferencing / emails) to follow-up on risk mitigation factors. This can be done individually with the team or as a group. The R&D Director and Deputy R&D Director will be asked to contribute to the review of the internal ACCORD QMS risk assessment.

4.3.3 Once complete, the QA Manager will circulate the risk assessment (POL009-T02) for final review to the Senior Management Team (SMT) and team leads. The QA Manager will coordinate signing of this document by these groups and save a completed copy to the ACCORD QA Files.

4.4 ACCORD Office Health & Safety (H&S) Risk Assessment

4.4.1 The Steering Committee, with input from the wider ACCORD team, will produce H&S guidance to help the ACCORD team work safely when they are able to return to the ACCORD office following the peak of a pandemic. This H&S guidance will be based on a risk assessment (POL009-T02) where risks will be identified and removed or reduced, with any mitigation strategies documented. This will include but not be limited to practical measures to be taken should social distancing be required in a closed office environment, provision of additional handwashing facilities and/or hand sanitiser and/or Personal Protection Equipment (PPE), where considered appropriate.

5 REFERENCES AND RELATED DOCUMENTS

- Impacted SOPs; See ACCORD Quality Management System.
- POL009-T01 Study Risk Assessment
- POL009-T02 ACCORD Pandemic Contingency Planning Risk Assessment
- POL009-T03 ACCORD Restart Risk Assessment Checklist
- POL009-T04 Monitor Review of Restart Risk Assessment Checklist
- GS002 Combined Risk Assessment

6 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	17-Apr-20	New procedure drafted in response to the COVID-19 pandemic
2.0	10 JUN 2020	Addition of Restart Risk Assessment Checklist (POL009-T03) and Monitor Review of Restart Risk Assessment Checklist (POL009-T04). Management of the COVID-19 Mailbox Work Instruction (POL009-WI01) made obsolete.

7 APPROVALS

Sign	Date
AUTHOR: Lorn Mackenzie, QA Manager, NHSL, ACCORD	
APPROVED: Heather Charles, Head of Research Governance, NHSL, ACCORD	
AUTHORISED: Fiona McArdle, Deputy R&D Director, NHSL, ACCORD	