NHS Borders Restart Risk Assessment Guidance

This restart risk assessment guidance has been developed to aid the completion of the restart risk assessment checklist v1.0.

Following the temporary halt of recruitment during the COVID 19 pandemic, the checklist has been developed to assess the potential impact of restarting studies. The aim is identify, document and mitigate the risks before restarting to ensure the safety of participants and staff.

Instructions for Principal Investigator

Please work through the checklist and confirm whether all resources are in place that you require to enable a restart to the study.

It is recognised that services may have had to adapt and may be running differently to previously.

When completing, consideration should be made to the following:

- Are there sufficient staff to enable a restart?
- If you recruit through clinics, how are these currently being run? If they are remote, have the sponsor agreed to changes to the consent process? Discuss with sponsor if unsure and check whether there is an amendment.
- Can medications be sent/ couriered to patients?
- Is sufficient PPE in place to enable staff and patients to mitigate risk of exposure?
- Are support services running as normal? Liaise with appropriate services and R&D
- Are you required to send samples to external laboratories? Are they open/have capacity to receive these samples? The sponsor will be able to advise.
- Is training up to date? Would staff benefit from refresher training? Are there any new staff?

Please provide comments to support statements.

If you are unsure, please contact Joy Dawson, Research Governance manager.

Email :research.governance@borders.scot.nhs.uk Phone: 01896 826717

Once completed, please sign the form and return to the email address above.

R&D will then review and make the final decision as to whether the study can restart. This will be carried out in conjunction with guidance issued by NHS Research Scotland (NRS) and the Chief Scientist Office (CSO). The R&D manager will liaise with the sponsor if necessary and will sign the checklist. The sponsor will confirm the date the site may reopen the study, and this will be added to the checklist. A copy will be sent to the PI to file in the Investigator Site File.