**APPENDIX 1 – SOP S-1047 UHL**

**UHL Pandemic response: COVID-19**

This appendix clarifies the questions to be considered before re-opening research activity

and should be read alongside the National Institute of Health Research (NIHR) ‘A

framework for restarting research studies funded or supported by NIHR which have

been paused due to COVID-19’ – <https://www.nihr.ac.uk/documents/restartframework/24886>

A conversation between the UHL as Sponsor and the Chief Investigator or their representative must consider the following points:

|  |  |
| --- | --- |
| Consideration points: | Yes/No |
| **Do participants continue to meet the inclusion/exclusion criteria?** – *consider whether they have participated in a COVID-19 study (drug washout requirements/potential drug interactions) / have participants been unwell/ circumstances changed since last visit (potential new health conditions).* |  |
| **Is there a risk of COVID-19 exposure for staff/participants? –** *consider ways of reducing potential for exposure.* |  |
| **Is there a requirement/need for PPE to be utilised?** – *Trust PPE requirements must be adhered to.*  |  |
| **Do you have the appropriate space to allow for social distancing requirements?** *– Consideration will also need to be given to the ability to adequately sanitise any areas used for research visits.* |  |
| **Do you have enough staff to be able to conduct the study safely? -** *consider the wider team.* |  |
| **Are participants willing to attend visits within a hospital setting?** – *consider ways to engage and reassure participants e.g. detailed information for participants on measures you are taking to keep them safe, offering appropriate PPE, access to handwashing/sanitising facilities. Will there be any additional costs incurred due to own transport usage as oppose to public transport.* |  |
| **Is re-opening of the clinical trial compatible with any pandemic-related changes to clinical service provision? -** *consider whether patients are currently attending hospital as normal, and whether screening, recruitment and follow-up can proceed according to protocol.* |  |
| **If visit formats have been changed will there be any additional costs?**- *for example posting/couriering drugs to participants/ home visits etc* |  |
| **Has any pause in recruitment impacted on the planned study time scale?**- *consider whether an extension to the end date needs to be submitted* |  |
| **Are original outcomes/end points still achievable?** *– consider whether you are able/need to re-evaluate outcomes/endpoints to obtain meaningful data.* |  |
| **Is the study funder willing/able to continue to provide financial support?**- *consider factors likely to impact on your resources e.g. time extensions/staffing requirements/ PPE provision/additional expenses.* |  |
| **Are there any contractual implications?** |  |
| **Does support service provision remain in place? –** *this ability may be impacted due to potential back logs in clinical workload* |  |
| **Are there any changes that the CI/PI wants to make prior to restart to enhance the study?**  |  |
| **For multi-centre studies, are all participating sites in a position to continue with study participation?** *– each site will need to provide capacity & capability evidence from their R&I/R&D departments. Again consideration will need to be given to end point data/outcomes if the number of participating sites changes.*  |  |
| **Is there an action plan to cover further pauses if required?**­ *– consider if further amendments would be required*  |  |

Where appropriate, written evidence will be required to support the re-opening e.g. confirmation from funders that they will support the study etc.