North Bristol NHS Trust

Standard Operating Procedure

Process to open / re-open for Research during Urgent Public Health Emergencies

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Document Version History

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1.0	11-06-20	N/A

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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1. PURPOSE AND SCOPE

This Standard Operating Procedure (SOP) describes the process required to open or reopen research activity at North Bristol NHS Trust during an Urgent Public Health Emergency (UPHE) or World Health Organisation (WHO) categorised pandemic.

All non-essential research studies will have been suspended or closed and/or set up delayed due to an UPHE or pandemic having been declared. To increase capacity within the clinical health service, and to be able to prioritise urgent and essential studies, research staff will be redeployed.

As some clinical services begin to be re-instated, after the peak incidence and/or as services are re-configured to meet the new clinical pathways, research, as a core function of the NHS, need to be similarly reinstated. This process will be called 'RESTART' for the purpose of this SOP.

It is likely many studies will need to adopt new delivery pathways that map on to the clinical service and protect patients, participants and healthcare professionals.

In assessing study RESTART NBT must maintain flexibility to meet further clinical demand caused by the UPHE / WHO Categorised Pandemic and prioritise the delivery of studies identified by the Department of Health & Social Care (DHSC) and National Institute for Health Research (NIHR) as Urgent Public Health Research Projects.

This SOP clarifies the prioritisation to enable the trust to reopen 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' – www.nihr.ac.uk/documents/restart-framework/24886?pr=

This SOP applies to all staff and external individuals involved in research activity during a WHO categorised pandemic that is **HOSTED** by NBT or where NBT is a research **SITE**.

The prioritisation criteria levels for RESTART of all research studies has been ratified by the Research & Innovation Group

2. DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
DHSC	Department of Health & Social Care
NBT	North Bristol NHS Trust
PI	Principal Investigator
RIG	Research & Innovation Group
R&I	NBT Research & Innovation Office
R&I SMT	R&I Senior Management Team
SOP	Standard Operating Procedure
WHO	World Health Organisation
UPHE	Urgent Public Health Emergency

3. WHO SHOULD USE THIS SOP

This SOP is applicable to:

- All Research & Innovation (R&I) staff who are involved in writing, reviewing, approving and implementing SOPs relating to NBT trust-wide systems and processes for research.
- Chief Investigators and trial managers/trial management responsible for the oversight of NBT sponsored studies.
- Principal Investigators and all staff working on research studies hosted by NBT who are required to be fully aware and compliant with the Trust's research SOPs issued by R&I.

All members of research staff have a responsibility to identify changes in policy, legislation and procedures that affect R&I SOPs and for bringing this to the attention of R&I. Any issues with a SOP should be notified directly to R&I who will decide whether a formal immediate review is required. Any user may choose to review a SOP at any time.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be referred to during the 'RESTART' programme of work

5. PROCEDURE

5.1 *Categorisation of Research*

Prior to, and during, the initial and developing stages of the pandemic all research activity at NBT was categorised as follows:

The categories are:

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).

Level 1 and 2 category research has continued.

This SOP is predominantly targeted at Level 3 studies where recruitment and/or follow up was suspended due to an UPHE.

All studies where recruitment, follow up activities or study set up have been suspended due to a

UPHE / Pandemic will be subject to review before the suspended research activity can be re-initiated.

For studies where NBT is a site R&I will distribute a RESTART data collection form to all PIs and study teams. The data collection form is designed to assess the viability, potential risk mitigations and capacity demands of the studies individually and collectively.

The data collection form will also ask for PIs and team to prioritise the order within which they would like studies to open with an explanation / justification, how it will be delivered and a preferential start date. Submission of this form does not guarantee when, or if, the study will restart but will help co-ordinate planning across teams.

For studies where NBT is a sponsor the CI and trial management the team will also be asked for information on a study wide perspective

All forms must be completed and returned within 7 calendar days to researchsponsor@nbt.nhs.uk with the subject heading “RESTART”.

5.2 *Process:*

Study teams will be asked to complete a data collection form. For sponsored studies the focus is on study wide implications, for hosted studies the focus is on delivery of the study(ies) at NBT.

Teams must:

1. Assess the safety and appropriate mitigation plans
2. Assess the viability of the study with the mitigation plans in place
3. Assess the staff capacity to undertake the research with safety and data integrity mitigations in place
4. Consider the order in which the team would like to open studies and why
5. Categorise the studies against the priority categorisation criteria

Safety Considerations

- Whether the patient population or required staff are, or are potentially, shielding
- Requires the participant to attend the hospital for non-standard visits or where their normal clinic visits are protracted by virtue of the study
- Where study procedure pose a potential specific COVID-19 risk (eg aerosolising procedures) to participants/patients or staff

Where reopening a study would pose a risk to the participant or staff that cannot be mitigated the study will not re-open.

Capacity Considerations

The teams will be asked to consider the capability issues related to the study specifically:

- Is the study deliverable when considering the patient pathway and any changes due to COVID- 19
- What logistical challenges will be posed by the new ways of working imposed by the Trusts COVID-19 response (eg PPE; access; patient flow)
- Are staff available to deliver the study
- Are support departments (e.g. pharmacy, radiology or pathology) required to deliver the study, if so have they confirmed they are able to and in what time frame
- What other resource implications for the delivery of the study are there

5.3 *Decision Process*

- Once data is returned from a study team/PI/CI, R&I will confirm if the safety and logistical mitigation plans, if required, are appropriate
- R&I will confirm the study prioritisation categorisation assigned by the team or will seek additional information if required.
- When all preconditions have been met R&I will confirm with the study team when a study can restart, noting their preferred restart date.
- Where a CI/PI / study team disagrees with the timing of a study RESTART they can refer the decision to R&I Senior Team for review, if further adjudication is required the Director of Research will be asked to review the decision.

"RESTART" Sponsored Studies

Studies will be permitted to open when:

- Feasibility data from sites has been received and agreed by R&I confirming the study is deliverable and sufficient staff and resources are available
- All regulatory approvals are in place, any study awaiting a substantial or non-substantial amendment will not RESTART until appropriate HRA / R&I approval are in place
- Appropriate risk assessments for the delivery of the study considering participant exposure has been conducted and mitigated
- Appropriate risk assessments for the delivery of the study considering Health Care Professional exposure has been conducted and mitigated
- Where sought, the funder has confirmed they are satisfied with the viability of the study and support the resumption of the study

"RESTART" Studies where NBT is a Site

Studies will be permitted to open when:

- The sponsor has confirmed they approve the study RESTART
- All regulatory approvals are in place, any study awaiting a substantial or non-substantial amendment will not be RESTART until appropriate HRA / R&I approval are in place
- Appropriate risk assessments for the delivery of the study considering participant exposure has been conducted and mitigated
- Appropriate risk assessments for the delivery of the study considering Health Care Professional exposure has been conducted and mitigated
- The viability of the study has been confirmed at NBT
- Sufficient staff and resources are in place to safely deliver the study

Prioritisation Criteria

Teams and PIs will be asked to prioritise the order they would like studies to re-open based on the following criteria levels:

1. Studies where opening research activities can be managed without input from research delivery teams or support departments. This will include studies where all the activity can be undertaken by Trials units / trial managers or where the study can be managed by the PI / researcher without additional support.

2. Studies where opening research activities can be managed with the current levels of staffing; i.e. while delivery teams are reduced due to redeployment within the clinical or research environment and staff are potentially 'shielding' for health purposes and unable attend work or 'see' patients / participants.

3. Studies where opening research activities can be managed with a partial return to normal levels of staffing, while delivery teams are reduced due to redeployment within the clinical or research environment and staff are potentially 'shielding' for health purposes and unable attend work or 'see' patients / participants.

4. Studies where opening research activities can be managed once pre-UPHE staffing levels have been re-instated.

N.B : It is unlikely all suspended studies will be able to restart simultaneously and the timings will be managed jointly between the study team and R&I senior team, based on the capacity within the study team and wider research infrastructure. No differentiation will be made between RESTART for commercial and non-commercial studies.

5.4 *RESTART Authorisation*

Once a study has been confirmed by R&I senior team for restart the R&I Office will:

1. Complete the RESTART EDGE workflow

2. Issue RESTART confirmation

3. Update the study Status on EDGE

Once the RESTART confirmation has been received by the study team suspended research activity on that study can resume.

Responsibilities

	Responsibility	Undertaken by	Activity
1	Chief Investigator/ Principal Investigator / Study Team	PI/Study Team	Provide all data required by R&I to assist in RESTART prioritisation
2	R&I Office	R&I Office	• Plan RESTART process • Collate data provided by PI / Study team • Issue Confirmation and update EDGE to reflect new status
3	R&I Senior Team	R&I ST	• Ratify RESTART process • Confirm the RESTART prioritization groups • Communicate RESTART prioritisation groups to study teams • Communicate which prioritisation group studies 'sit in' with the PI and study team
4	RIG	RIG UPHE group	• Ratify RESTART process • Confirm the RESTART prioritization groups

6. RELATED SOPS AND DOCUMENTS

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/003	Research Amendments

- Other related documents

RI/QMS/SOP/001a	R&I SOP Template