

(XX) Regional Research Delivery Network (RRDN)

Urgent Public Health Research (UPHR) Delivery Plan

V1.0 (date)

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Executive Summary

An urgent public health issue, such as a new influenza pandemic could emerge at any time. Any pandemic could have the potential to cause widespread illness or increase in deaths and huge societal disruption, concentrated over an initial period of a few weeks and ongoing for many months.

This plan concentrates on the impact a public health emergency could have on the XX Regional Research Delivery Network (RRDN) with respect to the delivery of NIHR RDN Portfolio research studies in the XX region, and the actions necessary to mitigate that impact.

As far as possible, the XX RRDN will focus on supporting Delivery Organisations to sustain NIHR RDN Portfolio research activities while also expediting urgent public health (UPH) studies that are currently hibernated studies/waiting for a pandemic to be announced or any subsequent new pandemic specific studies.

Communication will be a key component throughout any pandemic, both to internal and external stakeholders.

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Distribution List

All XX RRDN Delivery Organisations (DOs)

This plan should be read in conjunction with the XX RRDN DOs emergency planning documents and the current version of XX RRDN Business Continuity and Disaster Recovery Plan. It will be circulated to all DOs to aid in their planning.

[Insert details of key DO contacts, as required]

First Name	Last Name	Job Title	Organisation	Email Address

1. Introduction

1.1 Definition of a pandemic

A pandemic is the worldwide spread of a disease, with outbreaks or epidemics occurring in many countries, and in most regions of the world. Planning for a pandemic presents great challenges, because it is impossible to predict its characteristics in advance, for example, whether it will be mild or severe, and whether it will have the most impact on the young, the elderly, or any other groups.

This document covers the impact of a potential human pandemic on the set-up and delivery of research in the XX RRDN region. Many of the principles contained within this plan could also be applied to other public health emergencies.

This plan is intended to complement XX RRDN DOs policies and procedures for the management of a declared pandemic.

This document should be used in conjunction with the XX RRDN Business Continuity and Disaster Recovery (BCDR) Plan for delivery of NIHR RDN Portfolio research across the region.

Other useful documents include:

- Performance and Operating Framework (POF) Support Pages (PSPs);
 - PSP 091 [NIHR RRDN Urgent Public Health Research Response](#)
- XX RRDN Triage of Urgent Public Health Studies process documents
- NHS Trust Working From Home/ Flexible working or Agile working policies.

The plan will be revised in line with DHSC, NHS England and NIHR plans as required.

1.2 Aims

The aims of this contingency plan are to:

- Provide accurate, timely advice and information to staff
- Support patient safety and supply of medication and related treatment working with DOs for ongoing NIHR RDN Portfolio study delivery
- Ensure processes are in place to expedite actions in response to Government or NIHR RDN priorities e.g. activation of studies
- Minimise the disruption to the delivery of NIHR RDN research studies across the region where possible
- Support sites to expedite the approval of UPH studies through appropriate approvals processes (commercial and non-commercial) as required
- Support impact reduction of a pandemic on XX RRDN
- Manage the impact of core staff sickness and caring responsibilities, as well as redeployment of staff to provide essential care for patients during a pandemic.

1.3 Immediate Action

In the event of an urgent public health outbreak it will be imperative that the NIHR RRDNs are able to respond quickly to initiate, deliver and report on NIHR RDN Portfolio studies related to an outbreak/pandemic.

XX RRDN may be required, if nationally agreed, to have a nominated acting Urgent Public Health Champion identified at all times; (add nominated person & designation) who will work collaboratively with all RDN Urgent Public Health Champions to ensure consistent services and research delivery activities across the country.

Please see Appendix 1: Urgent Public Health Champion Role Outline,

The RDN UPH response will be activated at the request of the Department of Health and Social Care (DHSC). Studies already included in the portfolio may be repurposed to meet the research needs of urgent public health emergencies. Following notification by the UPH Review Group that a study will re-purpose, a meeting should be established as soon as possible with the study team or company contact, Lead RRDN, and NIHR RDNCC Research Delivery colleagues to discuss the changes to the existing study protocol. This guidance should be followed in line with the requirements of the study team or company contact. Such studies should be subject to the same oversight as all new UPH studies.

Please see Appendix 2: XX RRDN Urgent Public Health Advisory Team details.

It is important that there is awareness amongst DOs, Specialty and Settings Groups and (XX) RRDN staff and the relevant research communities of the UPH studies which currently have RDN Portfolio status in (XX) RRDN sites. During a pandemic further studies will be accepted onto the portfolio and badged as UPH which should be shared with sites rapidly to ensure patients have the opportunity to participate and new treatments are established. There will be opportunities for co-enrolment due to a specific patient group and large number of studies. CIs / Sponsors will provide advice on co-enrolment for their studies and this information should be disseminated to participating sites as appropriate.

2. Expedited Procedures and Contingency Plans for the Rapid Set Up of Research

2.1 Expediting Pandemic Studies

There are no major changes from the standard feasibility and set-up processes and on request study performance service for commercial or non-commercial studies, except that the turnaround time is much shorter. The RDNCC will lead an expedited process and advise on appropriate timelines for individual commercial studies.

The need for rapid turnaround will be clearly communicated to DOs. Research teams should be made aware of the need to carefully consider their capacity to take on pandemic studies at a time of greater clinical pressures.

It must be made clear to research teams that the priority is to ensure that patients enrolled in CTIMPs with regular dosing or scanning visits are able to attend as usual. This may mean delays in the set-up and recruitment for new non-pandemic studies. Please refer to [PSP091](#).

2.2 Study Support

It is important to ensure continued provision of Study Support Services (SSS) during a potential pandemic outbreak. The key priority areas will be:

- i. Support sites to expedite approval and activation of UPH studies by prompt distribution and collation of expressions of interest and coordination of study queries from sites
- ii. Ensuring that UPH studies are prioritised
- iii. Support UPH studies from the region (XX RRDN led studies) to apply for UPH study status and subsequently support the study set-up and coordination nationally. SSS will follow the XX RRDN Triage of Urgent Public Health Studies process.

Where sites have put studies on hold during the pandemic, updated study notes will be made to XX LPMS and CPMS as required. The team will liaise with the Heads of Partner Liaison & Planning and Research Delivery for out of hospital settings with updates as required. The SSS team will provide continuity of SSS services as much as is feasible.

XX RRDN will work in partnership with DOs to support studies set-up / guidance on obtaining relevant approvals if required.

Services can be extended from the XX RRDN office during an outbreak, to support staffing in a particular DO affected by the pandemic. XX RRDN staff must be assessed as having the appropriate competencies for the roles being covered and relevant letters of access. This may include XX RRDN SSS staff supporting vaccine trial delivery or data inputting.

Working with the Health and Care Directors and Regional Specialty and Setting Leads (RSSLs) and within the range of settings where research studies are being delivered XX RRDN will work with

the settings to understand and agree business continuity from a research delivery perspective. This will include, but is not limited to, impact of staff absences on research delivery at any given site, opportunities for sharing of staff resources across sites and utilisation of the XX RRDN Agile Research Delivery Team (ARDT) as available. Consideration will be given to joint working with system partners and any other stakeholders to review alternative spaces where study participants may be recruited (e.g. school halls, community leisure centres etc).

2.3 Studies Requiring Service Support Costs

Applications for Service Support Costs (SSCs) should be made by the usual route to the Network and marked with the following identifier: Subject Header For action Request SSCs Pandemic Study IRAS ID XX. Applicants must ensure they are available to respond to any queries, to ensure that decisions are not delayed.

Requests for SSCs and/or additional infrastructure, where DOs are planning to be participating sites for hibernating studies, should be made well in advance and may change and need reviewing during a pandemic.

2.4 Study Management and Reporting

The (XX) RRDN will provide appropriate study management and recruitment reporting. The objective of the (XX) RRDN during an emergency is to ensure support is available so that urgent research studies are delivered in the required timeframe. The Study Support Service team and the Data and Analytics team will be pivotal in supporting the sponsor with collection of data and reporting.

2.5 Recruitment Reporting and Recruitment Reports

Reporting of recruitment is used to determine if studies are struggling to recruit. Under normal circumstances this is done nationally daily through the Open Data Platform (ODP). Locally activity reports are available, which can be provided more frequently during an urgent public health incident.

2.6 Monitoring Urgent Research Study Progress

Study progress will be monitored to identify challenges to study delivery, track study progress and identify studies that are struggling. (XX) RRDN must ensure processes are in place to track recruitment into any urgent research study, and if required, may need to report recruitment to these studies to the RDNCC. The (XX) RRDN already has Information Management & Information Systems processes in place, which will need to be monitored and data collected more frequently in the event of an urgent public health outbreak.

2.7 Non-Commercial Studies

Study sponsor will be responsible for identifying delivery issues and requesting support from the lead RRDN as required. SSS to support requests in a timely manner.

2.8 Commercial Studies

The national RRDN Representative will be responsible for liaising with the company and (XX) RRDN Life Science Key Account Manager (or those with this responsibility) to identify issues related to ongoing delivery of studies. All participating sites involved in industry-led UPH research studies will be required to nominate a representative (e.g. the (XX) RRDN Life Science Key Account and/or Trust Research Lead Representative) to join regular meetings depending on the severity of the incident, but a minimum of weekly to monitor and manage the progress of study site setup and recruitment.

2.9 Suspension of open studies

Recruitment to some NIHR RDN Portfolio open studies may need to be put on hold due to lack of nursing or clinical support service staffing. Priority will be given to CTIMPs with time-critical dosing or scanning visits and new pandemic studies. Decisions on the suspension of open studies must be taken by the Principal Investigator at the site in discussion with the Sponsor and the R&D Department, and in line with national guidelines.

Decisions about the suspension of studies may be very difficult and must be taken in an open and transparent way. Study suspension must be quickly and clearly communicated to participants as required as well as the RDN for end of year performance reporting.

XX RRDN SSS and Data and Analytics teams will document studies suspended due to the pandemic and document this on CPMS (Local Lead for the RRDN studies). Although this is a sponsor's responsibility XX RRDN staff can support as required.

3. Research Delivery Support

3.1 Staff Absence

A major risk to XX RRDN is significant and ongoing staff absence, both within the RRDN Management team and Agile Research Delivery Team (ARDT) as well as research teams in DOs across the region. Staff may be absent from work if:

- they are ill because of the pandemic
- they need to care for children or other family members
- they have medical problems or shielding
- employers have asked staff to work from home
- transport problems make it impossible for staff to travel to work or staff have been 'locked

- down' as part of government/policy led preventative action
- Host organisations are utilising staff in a clinical capacity.

Staff absence is likely to follow the pandemic profile. In a widespread and severe pandemic, affecting 50% of the population, between 15-20% of staff may be absent on any given day. These levels would likely remain constant for more than three weeks and then decline depending on the length and severity of the pandemic. Teams where staff work in close proximity are likely to suffer from higher absence rates. In a widespread and severe pandemic, 30-35% of staff in smaller teams may be absent on any given day. Additional staff absences will result from the other factors described above, particularly the need to care for family members. Where different waves of disease occur, staff may also have periods where they return to research activities and then need to return to support clinical practice.

In a major pandemic all services are likely to be affected e.g. fuel shortages may make it difficult for staff to travel to work, and public transport provision may also be reduced.

Management of staff absence in these circumstances is essential and should be noted in the XX RRDN Risks and Issues Framework, and in line with XX [Host Organisation] Risk Assessment documents. Please also refer to the XX RRDN BCDR Plan.

3.1.1 Agile Research Delivery Team support requests

Requests for support from the XX RRDN ARDT for pandemic studies should be made via the application process.

Email (insert XX RRDDN email address) with details of the requirements to discuss for a rapid response.

3.1.2 Redeployment of Trust-based research delivery staff to clinical areas

If a pandemic causes sufficient staff absence that there is a shortage of clinical staff to provide essential care for patients, RRDN funded staff, both clinical and non-clinical, will be required to provide cover as required to maintain essential services.

Decisions about the redeployment of Trust-based staff will be made by their line managers and the R&D/I Department, in line with requirements of the clinical service. Provision must be made for those patients who are enrolled in NIHR RDN Portfolio studies with regular dosing or scanning visits and priority UPH studies.

Staff should be provided with appropriate training for the duties they are asked to undertake, and allowed to return to their research duties as soon as possible.

Information on NIHR research nurse deployment to clinical areas in DOs will be captured by the RRDN Management Group and documented. Information may be supplied to the RDNCC as required.

3.1.3 Cross cover across research teams

There should be sufficient flexibility within DO nursing, midwifery and allied health profession (NMAHP) teams to provide cross cover for NIHR RDN Portfolio studies in the event of staff absence. The management of ongoing research studies should be a priority, particularly where research visits are time critical.

3.1.4 Redeployment of (XX) RRDN Core Team staff to clinical areas

If the pandemic reaches maximum severity, any suitably qualified member of XX RRDN staff could be asked to provide support within clinical areas. This is supported by the RRDN providing there remains a cohort of staff to deliver NIHR RDN UPH studies.

3.1.5 Workers at direct risk

Pregnant women and staff with compromised immune systems should be considered for work duties away from direct patient care for the duration of the pandemic. This must be agreed by the line manager and staff member, with Occupational Health involvement as appropriate and in line with local employer policies and procedures.

It may be that an antibody test becomes available before a vaccine and healthcare workers should be prioritised to receive this to allow those with immunity to return to or be at work safely.

3.2 (XX) RRDN Central Teams

3.2.1 Sickness Absence

XX RRDN staff should report sickness absence following their Employing Organisation's policy, contacting their line manager by telephone. It should be clear to staff who they can contact if their line manager is also off sick.

Line managers should be flexible in managing ongoing workload around sickness absence. Regular Managers' & Team Meetings should take place throughout a pandemic outbreak to manage the ongoing situation. There may be pandemic specific procedures to follow at different organisations.

3.2.2 Office Closure

The aim of the XX RRDN Management Team and ARDT during a pandemic will be to:

- Support rapid feasibility and set-up of pandemic studies
- Provide cross-cover to maintain business as usual
- Provide support and advice to Trust-based research staff and staff based in other settings.

If there is significant sickness absence, a decision may be made to close some of the XX RRDN offices. It should be made clear by line managers which members of staff are expected to be able

to work from home, maintaining contact by email and phone.

A minimum of weekly updates will be provided by line managers until the office can be reopened.

The following members of staff are empowered to make a decision on the closure and re-opening of the XX RRDN Office/s:

1. Network Director
2. Operations Director
3. Strategic Development Director

Personal contact details for all Management Team and ARDT members are held in their personal files in the XX RRDN Network office and should be kept up to date. A master list of personal contact numbers is held by the Network Director / Operations Director and Corporate Services Manager in case of emergency.

Please see Appendix 4 for XX RRDN Managers and named Deputies.

If line managers are off sick, staff should either refer to the most senior manager in their team, or if they are also unavailable, to any other manager.

4. Communications

During a pandemic outbreak, communication will be a key component, both to internal and external stakeholders.

Nationally the RDN will need to work closely together to ensure communications strategies and plans are revised, as needed, to ensure timely communications are delivered, tailored to the relevant audiences. As part of this, agreement should be reached on who and how the messages should be developed and delivered by the RDN communications function and delivered in regions as well as other key stakeholders.

The XX RRDN Strategic Development Director, working closely with the Communications Manager will play a key role in ensuring relevant communications are delivered regularly to DOs and wider stakeholders in regions.

The RRDN supported workforce will be notified of this strategy via appropriate management structures locally and plans should be established to enable staff to engage in supporting delivery of UPH studies if the need arises. It will be emphasised that there may be a need for cross DO working.

Efforts will also be made to engage with public health directorates within local authorities, and any other stakeholders, to ensure collaborative cross organisational working.

A key contact list will be agreed and maintained by the XX RRDN in collaboration with all DOs. This will identify individuals within each DO who have a working knowledge of UPH studies currently on the NIHR RDN Portfolio and understand their role in the effective delivery of these studies locally.

A XX RRDN working group will be established in the case of an UPH outbreak. This small internal

XX RRDN group should meet regularly, depending on the nature and extent of the pandemic. The aim is to address any immediate UPH issues, management of relevant regional services and monitoring of studies against national / regional performance measures and metrics. Led by the XX RRDN XX Director, attendees cover all RRDN services and include RSSLs, as appropriate.

A wider stakeholder group will also be established, as required, to ensure regional DOs are working to national / regional strategies and priorities, facilitate collaborative working and support timely communications.

5. Study Participation Inclusion

During any UPH outbreak, ensuring diversity of participants in UPH studies is essential to ensuring validity of research findings. To support the [NIHR Research Inclusion Strategy](#) and RDN strategic aims and objectives, the RDN Study Participation Inclusion function will have an essential role to play to support initiatives to reach and engage under-served populations in NIHR RDN Portfolio studies. This may include cross NIHR activities, regional and local initiatives in collaboration with DOs and wider system partners and stakeholders.

Nationally the RDN will need to work closely together to ensure public and community engagement activities and plans are revised, that existing initiatives to reach under-served populations are mobilised and new initiatives to reach priority groups are developed promptly. An RDN Under-served Communities working group will be established in the case of an UPH outbreak. The group will have a membership which is representative of all RRDN Study Participation and Inclusion Teams alongside RDNCC Research Inclusion and Public Partnership Teams. The aim of this group will be to define and implement a national approach to engaging with priority under-served groups. Led by the National Head of Public Partnerships, this internal group will establish a shared work plan and oversee and advise all UPH community engagement and public engagement activities.

A wider stakeholder group will also be established, to engage with public engagement and research inclusion leads across the NIHR Coordinating Centre and wider stakeholders including NHSE and the HRA. This group will build a strategic and collaborative approach to engaging communities and the public. As part of this, agreement should be reached on how initiatives to reach and engage under-served populations are developed and delivered nationally to ensure collaborative cross-organisational working.

An Urgent Public Health Public Reviewer Group will be established to embed public voice within the governance and prioritisation of UPH studies. Participants will be recruited to reflect under-served groups and a broad range of relevant lived experiences. The group will include representatives from all RRDN regions and will be supported and managed by the RDNCC Public Partnerships Team.

Appendix 1 Role Outline - Urgent Public Health Champion

The NIHR RDN is preparing systems for rapid set-up for research investigation of unexpected and severe infections that have the potential to cause disease widely amongst the UK population. The likeliest occurrence is a severe acute respiratory infection (SARI) such as MERS, but the network can equally respond to other potentially severe outbreaks such as the recent epidemics of botulism amongst IV drug users. RDN guidance is available on Urgent Public Health.

Each RRDN should ensure they have an active clinical investigator to be the network urgent public health champion. The champions should have experience of recruitment of patients to portfolio studies. The physician must be willing and able to coordinate recruitment of patients from a range of medical settings to Urgent Public Health studies. The person in this role should ensure they link with other relevant Specialties within the RRDN including Respiratory, Injuries and Emergencies, Critical Care, Primary Care and Paediatrics.

Responsibilities

1. The champion will support the development and on-going review of the (XX) RRDN Urgent Public Health Research Delivery plan by providing clinical leadership and oversight.
2. The champion will support activities associated with the development of the (XX) RRDN Urgent Public Health Research Delivery plan including training needs, discussions with local Delivery organisations, and raising awareness amongst local researchers.
3. The champion will respond to national calls for sites to recruit patients to nationally coordinated urgent public health studies. Such studies will likely be organised rapidly in response to an emerging epidemic or pandemic, and will require the champion to work with the (XX) RRDN on feasibility, and preparation of local capacity in the event that cases of the disease in question emerge amongst patients' at all relevant local medical units under the umbrella of the (XX) RRDN.
4. In the event of an urgent public health outbreak with an associated nationally coordinated research programme the champion will familiarise him/herself with emerging investigational protocols coordinated through the (XX) RRDN and support activities associated with rapid set up and delivery.
5. The champion will act as a key link between the RDNCC, (XX) RRDN, research teams and Specialty members feeding back challenges and developing solutions.

Travel and reasonable expenses will be provided by the (XX) RRDN in which the champion is based.

Appendix 2 Urgent Public Health Advisory Team for (XX) RRDN

Role	Name	Email/ Phone	Responsibility
Acting Urgent Public Health Champion			See Appendix 1
Network Director			Executive member
Health and Care Director (Medical)			Executive member
Health and Care Director (NMAP)			
Operations Director			Executive member
Strategic Development Director			Executive member
Heads of Partner Liaison & Planning			Coordinates communications between NIHR RDNCC and DOs Lead on coordination of UPH studies
Head of Research Delivery and Out of Hospital Settings			Coordinates communications between NIHR RDNCC and Public Health team and Out of Hospital Settings

Agile and Direct Delivery Teams			Coordination of the deployment of the ARDT
Regional Specialty Lead for Infection			Specialty Group lead input to prioritise resources and study delivery. Give Specialist advice as required
Data and Analytics Senior Manager			Oversee response of Data Analytics. Maintenance of relevant regional and national databases
Study Support Service (SSS) Senior Managers			Coordinate response of SSS team/assisting DOs with opening new urgent studies if required Support Management Team as required

Appendix 3 (XX) RRDN managers and deputies

Title	Named Person	Deputy 1	Deputy 2
Network Director			
Health and Care Directors			
Operations Director			
Strategic Development Director			
Corporate Services Manager			
Communications and Engagement Officer			
Infection Specialty Lead			
Head of Partner Liaison and Planning			
Head of Research Delivery			
Life Science Key Account Manager			
Workforce and People Senior Manager			
Host Trust Finance Lead			
ARDT Team Leader			
Data and Analytics Senior Manager			
SSS Senior Manager			