NHS Lothian Research Prioritisation Strategy during COVID second wave: key principles

DRAFT: November 1st 2020

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Selection of COVID-related research

- Since May 2020 all proposals for COVID related research have been reviewed by a specifically constituted COVID-19 Clinical Research Oversight Committee with an independent Chair (Prof D Newby). Only research supported by this group has been progressed through R&D and adopted onto the local portfolio.
- The ToR for this group, and membership, were agreed and are included in appendix 1
- A record of all study proposals received, and the decision of the group, are collated
- As the COVID vaccine portfolio developed, it was agreed that a separate group would meet to agree which vaccine trials were feasible and EoI made. Members of this Vaccine Trials Portfolio Oversight Group are included in appendix 2, and represented Lothian on the various CSO COVID vaccine-related groups.

Currently active UPH or CSO eligibly funded COVID portfolio

Acute studies: Recovery; GenOMICC; ISARIC tier 0, 1, 2; DEFINE; REMAP-CAP; REALIST; ICE-CAP; PAN-COVID

Community-based: PRINCIPLE; SPIKE (not currently UPH badged)

Follow-up or specialty based: SIREN; PHOSPH-COVID; MEMORY-COVID; CLARITY

Vaccine trials: Oxford trials: under 55s; over 55s

Screening and tracking of Recruitment to COVID-related research in Lothian

- For acute COVID research (new presentations to hospital, ICU, community-based COVID research) the Emergency Medicine Research Group (EMERGE) leads identification of new cases daily, and manages triage to the various COVID trials and studies. This includes the RIE and St John's sites.
- Acute studies at the WGH site are coordinated by the Infectious Disease research team
- For ICU studies effort is focussed in the RIE site, which is the major regional ICU, for trials. Non-interventional studies recruit across all three regional ICUs. Screening and recruitment is managed by the Edinburgh Critical Care Research Group (ECCRG).
- All vaccine trials are now managed by a dedicated group including PIs (lead Rebecca Sutherland; plus Clifford Lean; Iain Page), the two vaccine research fellows, the lead CRF vaccine study nurse and the senior CRF team.
- Other COVID research is led by relevant PIs and dedicated teams:
    a. SIREN: Respiratory team (PI: Kate Templeton)
    b. PHOSP-COVID: Respiratory team; ICU team (PI: Gourab Choudhury)
    c. DEFINE: Respiratory; ID; CRF teams (PI: Kev Dhaliwal)
    d. CLARTY: GI team (PI: Charlie Lees)
    e. ICE-CAP: Pathology (PI: D Dorwood)

Coordination of Research staff

- Tracking and support for research nurse staff is led by the R&D Clinical Research Nurse Manager (Jean Bruce), supported by the Chief Nurse for R&D (Juliet MacArthur), working closely with the research managers for the key COVID research groups (CRF; EMERGE; ECCRG; ID; Respiratory) and the R&D Senior management Team
- Oversight and support is provided for all NHS employed research nurses (no direct oversight of University employed research nurses)
- Coordination of effort from the RN workforce is managed as pro-actively as feasible, to balance support for COVID research and the re-start non-COVID portfolio

Pharmacy

- Coordination of pharmacy activity is led by R&D lead pharmacist (Hazel Milligan), who joins the R&D Senior Management Meetings regularly
- Pharmacy are represented on the COVID-19 Clinical Research Oversight Committee and the Vaccine Trials Portfolio Oversight Group.

ACCORD COVID/restart guidance

- Prioritisation policy and restart guidance have been provided through a 'living' document which is updated regularly according to changing national and local policy and situation
- This is circulated to all researchers with each update, and is available on the ACCORD website: https://www.accord.scot/researcher-access-important-documents-researchers/guidance
- For regulated and higher risk non-regulated NHSL/UoE sponsored research ACCORD directly oversees restart, and issues Sponsor authorisation to open (SATO).
- For non-regulated and other low risk research, including hosted studies (commercial and non-commercial) a checklist requires completion by the PI. If the PI is satisfied that all relevant issues are satisfied and in place, the study can re-start. No formal approval from ACCORD is required, but the PI is requested to inform the ACCORD office.
- At present around 235 non COVID studies have restarted in Lothian since June.
- **At present Lothian policy is to allow non COVID restart activity to continue based on PI and individual research group capacity. However, in order to maintain COVID research activity this may not be sustainable, specifically in relation to:**
    - **The competing resource within the COVID groups (EMERGE, ECCRG, CRF, Respiratory)**
    - **The need to potentially re-deploy RN and pharmacy staff time from non-COVID research groups to support the COVID research groups**

Current Key System-level Pressures

Research nurse workforce

Current increased COVID activity, combined with re-start of non COVID research especially in the EMERGE, CRF, and ECCRG portfolios, are placing high pressure on these teams to recruit and support COVID acute research. There are also pressures because posts remain unfilled, notably in the CRF but also in other groups. Solutions include:

- Decreasing or stopping non-COVID research activity within these groups

- Offering overtime to the staff within these groups
- Employing bank staff to support the groups
- Diverting RNs from other groups not undertaking COVID research to support COVID research:
    - NHS based staff already funded by R&D
    - NHS based staff funded from other sources such as grants or commercial income, where funding could be re-charged to R&D while working on COVID research
    - UoE based staff where the UoE could be reimbursed from R&D. This model could also work for staff at risk of redundancy, where R&D could extend salary support and they be seconded to COVID research groups.
- Employing other staff roles, notably administrative staff who could relieve pressure on the research teams (eg data entry; data extraction from TrakCare etc)

Pharmacy

Pharmacy is under pressure from a combination of: COVID work, supporting re-start work, and progressing new study set-up. This is a potentially activity-limiting factor, especially when the vaccine trials are in set-up or active. Potential solutions are:

- Employ new staff (unlikely to have interest)
- Offer bank and overtime work (limited impact)
- Pro-actively decide to pause set-up of time-consuming non COVID studies in lower priority areas
- Pause non COVID studies in low priority areas that utilise significant pharmacy support.

ACCORD

There is a very large backlog of NHS R&D governance work, including review of amendments, new approvals etc. This represents many weeks of work. COVID research always takes priority over non-COVID activity, and is problematic as some studies have had very high amendment numbers (eg Oxford vaccine trial). This could delay the start of new research in set-up for many weeks. Other than COVID research, prioritising this large backlog is very challenging and a strategy is needed to support staff. The situation is further complicated by the fact that staff have been working from home since March (in UoE building) so training etc is very difficult. We have several staff on sick leave and/or on phased return.

Possible solutions are:

- Employ more staff or offer overtime (unlikely to be helpful; recruitment and training very challenging with remote working)
- Agree not to progress new non COVID research until the pandemic pressures are decreased, or actively select which studies to progress
- Agree to pause or withdraw some active non-COVID studies and remove these from prioritisation within governance team.

Financial pressures and risk

- R&D have underwritten and funded a range of COVID-related posts and other work from commercial reserves in order to meet the increased staffing needs. These include vaccine

research fellows and nursing staff, staff overtime to support vaccine trial recruitment, and additional staff to support 'acute' COVID research such as the Recovery and ISARIC studies.

- The support from each COVID study does not fully meet the true costs of these studies. The CSO did not fully meet the NHSL request for additional research staff to support COVID research from the NRS emergency support fund (in June 2020), but have opted mainly for a per patient recruited funding model, to be paid in allocations in 2021/22. Our modelling shows that this will result in a significant shortfall in funding for work already undertaken.
- The agreement to a recruitment fee from CSO for key studies such as ISARIC, Recovery, REMAP-CAP, GenOMICC, PHOSP-COVID, PRINCIPLE, and SIREN is welcome, but creates uncertainty about whether the income from these activities will cover the substantial investment in staff. It is widely acknowledged across the UK that most UPH-badged studies have been under- or un-funded for research costs with expectation this is met within LCRNs or BRCs (in England) or through existing R&D allocations (in Scotland)
- The funding agreed on grants for recruitment to some of the studies (eg ISARIC tier1/2; PHOSP-COVID) has not yet been paid, with no certainty of when this will occur.
- Uncertainty about which vaccine trials will be offered to each Board creates a major financial risk. NHSL have invested heavily in staff to support vaccine trial research, and are exploring renting additional space to conduct work over the next 12 months. However, the Board currently has no guarantee of a pipeline of studies, and the remuneration/ income is impossible to estimate.
- The support from NIHR for vaccine trial infrastructure is welcome, but none has yet been confirmed or seen via CSO.
- The massive decrease in non-COVID commercial trial activity will substantially decrease income over the next 2-3 years. Loss of commercial income that supports a high proportion of R&D core/infrastructure staff could result in a substantial shortfall which could result in redundancies and decreased research capacity during post COVID recovery. This situation is exacerbated by the need to use commercial reserves to support COVID research (as above).

Strategy to manage resource demand balance during the second wave

NHS Research Staff

1. We will seek to appoint to vacant research positions, especially research nurses, as a priority.
2. We will offer existing staff the opportunity to work overtime hours on COVID related research. Funding for this work will be provided through R&D ACCORD, with research managers providing details of hours worked and the projects on which work was undertaken. R&D finance will seek to recover funding for this work from relevant grants and other sources of income for COVID work. (Overtime should not be offered for non-COVID research, unless funding is directly available from the funder, agreed by the local PI, and payment is organised by the PI)
3. We will establish a bank of research staff with the skills and training to contribute to COVID research. These might include University employed staff (with NHS contracts), retired staff, or clinical staff. Interested staff will be offered research work as required to support COVID research within the NHS, with this being organised and coordinated through the major research groups supporting the COVID research programmes (for example EMERGE, CRF, ECCRG, Respiratory research groups). Oversight of this research bank will be by Jean Bruce

(R&D Clinical Research Nurse Manager) in conjunction with the research managers for the research groups supporting COVID. Payment of bank staff will be underwritten by R&D, with all hours approved and justified (in terms of which COVID studies) by research managers. The R&D finance team will seek to recover payments from relevant COVID research income.

4. We will seek to employ 3-4 administrative posts (grade 3/4) as a matter of urgency to support COVID research. These will be for 6 months in the first instance, and will align with current Lothian-wide efforts to recruit additional administrative staff to support the NHS during the pandemic. Posts will be sought where: there is a clearly defined role (eg data entry; database organisation; data extraction from TrakCare etc); there is clear COVID-aligned line management (for example through EMERGE, CRF, Respiratory teams, ECCRG). Funding for these posts will be underwritten from R&D, with work undertaken recovering from relevant COVID-related funding.
5. We will seek to establish new research teams for specific COVID study areas of strategic importance. These include: vaccine trials; and, monoclonal antibody post-exposure prophylaxis trials. We will specifically explore whether University-based research nurses/staff could be seconded rapidly to this work for an agreed period (for example 6 months). We will offer payment to the University to fund or extend University contracts for defined periods, with the intention that the employment remains with the UoE to expedite staff availability and security for the individuals. This offer will proactively be explored for UoE staff who may be at risk of redundancy. These individuals will be line managed by the CRF during their work on COVID research.
6. We will contact groups with significant research portfolios and strong research teams and/or NHS based research groups undertaking non-COVID research where funding for research staff is currently provided by R&D. We will seek support from PIs to provide part or full time deployment of members of their groups to support COVID research, through the major COVID research groupings that are under greatest pressure (CRF, EMERGE, Respiratory, ID). Where R&D already fund posts, these individuals will continue to be funded by R&D. Where posts are funded through grants, commercial, or other income, we will ensure any time provided is re-paid to the PIs.

Space

1. We will explore the use of alternative space at the BioQuarter and WGH sites to conduct vaccine studies and other COID research out with the acute hospital wards. We will specifically work with the University in relation to the use of the Centre for Dementia Prevention for 6-8 months, and any suitable space at the WGH campus.

Research study prioritisation

1. We will work within the framework of guidance from NIHR and CSO in relation to research prioritisation.
2. We will make all UPH badged or CSO funded COVID research approved by the COVID-19 Clinical Research Oversight Committee a priority while NIHR/CSO mandate this as policy.
3. Our highest priorities for patient recruitment will be:
    a. Recovery, PRINCIPLE, REMAP-CAP, GenOMICC, REALIST, DEFINE, ISARIC Tier 0, PHOSP-COVID, SIREN, ICE-CAP, PAN COVID (new studies with UPH badging and/or CSO approval may be added to this list)
    b. Vaccine trials and post-exposure prophylaxis trials approved by UPH
4. For non COVID research, we will prioritise research in which participants receive IMPs or other treatments of high importance to their disease treatment, for example for cancer,

inflammatory disease, or inherited diseases such as CF, where this opportunity only exists through participation in research.

5. For other non-COVID research, we will support continuation of research where a full risk assessment has been undertaken following the NHSL restart guidance and all relevant research and clinical service facilities have agreed that restart and/or continuation is feasible AND support from research nurses, pharmacy, or other support services remains feasible and will not compromise prioritised COVID research
6. Research studies that do not fall into a priority group, and where the study utilises significant pharmacy resource, research nurse staff that could be deployed to support COVID research, or key space/facilities required to deliver the COVID portfolio may be asked to pause or limit recruitment. This decision will be led by ACCORD, and follow discussion with the relevant PI, and the COVID-19 Clinical Research Oversight Committee. Decisions will be based on system pressures, and may change as the second wave evolves.

ACCORD approval of new research

Sponsor review and set-up

1. All grant applications, whether for COVID or non-COVID related research, will be progressed and supported by ACCORD as usual within the capacity available within the University ACCORD governance team. The ERO is implementing a policy to provide adequate notice to ACCORD for approval and NHS costing of grants, which should be respected by applicants and the ERO team.
2. Studies that have been funded, whether relating to COVID or non COVID research, will undergo UoE/NHSL sponsor review for ethics, MHRA, and other relevant non NHS approvals as usual within the capacity of the ACCORD UoE team.

NHS R&D approvals

COVID research

1. All eligibly funded COVID research (UPH and/or CSO supported) that has received support from the COVID-19 Clinical Research Oversight Committee will be expedited for NHS R&D approval to start, and be prioritised over any non COVID work.
2. COVID research that is not UPH badged/CSO supported (therefore eligibly funded) will not be prioritised

Non-COVID research in set-up

- For non COVID studies currently in set up for NHS R&D approval:
    a. Where there is evidence from the sponsor (commercial or non-commercial) that sponsor set-up is ongoing and progressing AND it is considered feasible that the study could commence recruitment during the pandemic, every effort will be made to progress local NHS R&D approval
    b. Where local records indicate that the sponsor (commercial or non-commercial) is NOT currently progressing local R&D approvals, the study will be withdrawn until the sponsor contacts ACCORD. We will take lack of communication or progress from the sponsor since 1st May 2020 as indicative of lack of progress. These studies will not be further progressed until January 5th 2021 at the earliest.
- **ACCORD will not accept any new applications to set-up and give local R&D approval for non-COVID hosted research (commercial and non-commercial) in NHSL before January 1st 2021. Capacity will be reviewed after that date.**

- New locally sponsored eligibly funded non COVID research will be supported whenever possible for NHS R&D approval if it is feasible for the study to commence during the COVID pandemic. If it is not feasible for the project to start (for example lack of staff or access to facilities), NHS R&D approval will not be progressed until these issues have resolved.
- Although NHS R&D approval may not be possible, sponsor review can be progressed during this period as far as possible, prior to R&D submission and with due consideration of clinical and pharmacy capacity to provide input to sponsor review processes
- For new studies that are not locally sponsored (commercial or non-commercial), but the PI considers there is a strong case to progress local NHS R&D set-up prior to January 5th 2021, an exemption request can be submitted. This will be reviewed by the COVID-19 Clinical Research Oversight Committee.
- Any requests for exemption should be submitted to the following e-mails:
    a. Heather.Charles@nhslothian.scot.nhs.uk
    b. Fiona.McArdle@nhslothian.scot.nhs.uk
- The decision of the COVID-19 Clinical Research Oversight Committee in relation to exemptions will be final. Of note, this committee includes senior members of the ACCORD management team, pharmacy, the CRF, the key research groups delivering COVID research, and several senior independent clinical researchers.

Amendments

1. UPH badged COVID studies will receive highest priority in relation to reviewing and approving amendments. These will be expedited as quickly as possible.
2. Until January 5th 2021, amendments for non COVID research will only be reviewed by the ACCORD NHS governance team if the study is known to have re-started since June, and ACCORD notified of completion of the re-start checklist (as per ACCORD guidance).
3. Amendments for other studies will not be reviewed or approved before 5th January 2021.
4. For locally sponsored research, the UoE governance team will continue to receive and progress amendment proposals for sponsor review and progress those without allowing R&D submission or seeking clinical/pharmacy input where resources may be stretched