**NIHR Framework for Restart**

***Information Sheet for GPs***

**Background**

Most research, apart from national priority COVID-19 studies was either paused or delayed in light of the COVID-19 pandemic in line with the suspension of many routine NHS services. As the pressure on the system has begun to ease, researchers, Sponsors and the NIHR have started looking at how studies can be reinitiated, and a framework for restarting research was published on 21 May 2020. The [RESTART Framework](https://www.nihr.ac.uk/documents/restart-framework/24886) sets out the basis for prioritisation and decision making.

Each sponsor will be assessing the status of their study based on the RESTART Framework. **The second part of this assessment is to understand the capacity in GP practices and any new arrangements that may be necessary for safety reasons.** There is an expectation that sites start to assess their capability to restart research within a month (roughly) of the Framework’s publication (i.e. by end June 2020).

Many investigators are working to ensure that studies are safe and able to work more remotely in the context of COVID. Some of these studies help mitigate health challenges which may be particularly pertinent to COVID-19 e.g. Obesity, Type2 Diabetes and risk of Stroke.

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| Guiding Principles of Restart |
| 1. Only research that is **still viable** should restart/start |
| 1. Research should only restart/start **when safe to do so**. |
| 1. Safety of research participants and personnel is of paramount importance |
| 1. The **pace of restart** and the commencement of new studies should be **commensurate with capacity and readiness** in local health and care services and the NIHR |

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| Prioritisation for NIHR study support |
| **Level 1** – National Priority Urgent Public Health Studies (UPHS) |
| **Level 2** – Studies where the protocol includes an urgent treatment or intervention without which patients could come to harm (e.g. where potentially life preserving or life extending treatment may not otherwise be available outside the trial) |
| **Level 3** – All other studies (including COVID19 studies not badged as UPHS) |

**What does the Practice need to do?**

The individual study design informs what types of activities will be required, and the practice needs to determine whether they have the capacity and capability to undertake these activities, as well as considering the broader COVID-19 context. Please note the final decision whether to support a study always sits with the practice.

To assist you in decision making you will need to consider the following:

* **What types of studies you can support?** For example, simple survey studies, those with a remote intervention, those requiring face to face contact or participant identification for another site elsewhere.
* **Can you identify and contact patients about research?** The CRNE team will look at the potential to use alternative means to contact patients (such as text messages), but it is likely that for many studies you will still need the capacity to undertake searches and exclude unsuitable patients.
* **Do you have the capacity for collection of data from participant notes?** This may include collection of follow-up data for patients taking part in research who have been discharged from acute care.
* **Do you have the capacity to undertake follow-up visits?** These may include patients recruited into research studies by local Trusts and may be remote or face to face.
* **Can you accommodate** **face to face contact?** Would you need CRNE nurse support? Please consider:
  + Current arrangement for managing COVID and non-COVID patients (hot and cold sites).
  + Ability and extra time required to undertake home visits if required.
  + PPE supplies and equipment.
  + Arrangements for study visits for any vulnerable or shielded patients if required.
  + Equipment requirements and cleaning or disinfecting needs.

See Appendix 1 for a template risk assessment that may be used to undertake the practice’s assessment of each study for restart/start viability and safety.

**Support to GP Practices**

CRNE will work with study teams to identify where amendments can be made to studies to minimise patient contact where possible (such as use of telephone and video consultations).

A local panel has been set up with members from CRNE, GP representatives and the Research Offices to discuss the Restart Framework guidance and its implementation across Eastern primary care research sites. The local panel will provide information and support to practices as required.

To inform the panel decisions on restart, it would be helpful to understand what concerns you have about restarting the paused research, what challenges you foresee and also to ascertain if there are any additional measures that need to be considered.

**Summary of local activities required** (table adapted from Local Level Roles[NIHR Framework for Restart Paper](https://www.nihr.ac.uk/documents/restart-framework/24886))

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| --- | --- | --- |
| What |  | Who |
| Study decision | Decision about which studies open, when and where (see Appendix 1) | General Practice to look at each study restart/start requirements to decide on which studies to open in liaison with Site Principal Investigator (PI), Study Sponsor, Research Office and CRNE team |
| Assessment | Local assessment of whether a study should open/re-open at an individual site (example checklist is available [here](https://www.nihr.ac.uk/documents/restart-framework/24886), see Annex A) | General Practice to determine viability, safety, site capacity, prioritisation in liaison with Research Office,  Site PI and CRNE team |
| Confirmation | Reconfirmation of capacity and capability to restart or open at site | Research Office to confirm any regional support requirements are in place and  General Practice to confirm their capacity and capability to restart/start the study |
| Prioritisation | If there are limitations in availability of resource, capacity or other constraints affecting NIHR-funded support – prioritisation is given based on study urgency (see levels 1-3 above) | Lead Local CRN |

**Research Study Roles**

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| --- | --- |
| Who | What |
| Sponsor | Assesses viability of study  Liaises with the funder, sites and CRN about adapting and reopening studies  Green lighting of sites |
| CRN | Prioritises CRN resources and puts regional arrangements in place  Approaches practices to take part in new studies / restart paused studies |
| Research Office | Supports sites confirming capacity and capability if required |
| Practice | Assesses capacity and capability  Assesses safety in the context of COVID-19  Issues final decision on taking part / restarting paused study |

**Appendix 1: Risk Assessment for assessing Study Restart / Start**

1. **Study Viability**

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| --- | --- | --- | --- | --- |
|  | Consideration | Yes / No | Further details | Actions taken to mitigate risk (if required) |
| 1.1 | Can you still recruit to the study?  Consider:   * Can the practice meet the protocol requirements? * Capacity within the practice team?   ***If YES*** *please describe*  ***If NO*** *please describe and go to declaration in* ***Section 4*** | Yes / No |  |  |
| 1.2 | Does the study require the support of CRNE Delivery Team or other services?  ***If YES*** *please describe what support is needed*  ***If NO – go to 1.4*** | Yes / No |  |  |
| 1.3 | Has this been discussed and agreed with the CRNE Delivery Team?  ***If NO*** *please contact your CRNE Locality Manager to discuss* | Yes / No / N/A |  |  |
| 1.4 | Will participant concerns about COVID-19 infection impact viability?  ***If YES*** *please describe, and detail what steps are being taken to provide patients with reassurance that the research process is safe* | Yes / No / N/A |  |  |

1. **Patient Safety**

|  | Consideration | Yes / No | Further details | Actions taken to mitigate risk (if required) |
| --- | --- | --- | --- | --- |
| 2.1 | Are remote visits feasible?  Are remote visits feasible for all participants (if only available for a subset, please answer no)?  Are remote visits feasible for all visits / patient contacts?  *Please describe* | Yes / No  Yes / No  Yes / No |  |  |
| 2.2 | If applicable - Has the protocol been amended by the Sponsor to enable remote visits?  *Please describe*  *If* ***NO –*** *please discuss with CRNE and/or the Study Sponsor* | Yes / No / N/A |  |  |
| 2.3 | If applicable - Have risks of COVID-19 transmission in relation to face to face contact been addressed and mitigated for?  Consider   * Requirement for public transport? * Social Distancing Guidelines * Requirement for PPE (please also see 2.6 below)   ***If YES*** *please describe*  ***If NO*** *please describe why not or what risks need to be addressed and how this will be mitigated for* | Yes / No / N/A |  |  |
| 2.4 | Does the study involve patients that may be shielding[[1]](#footnote-1)?  Have measures been put in place to address the additional risks for this group of patients?  *Please describe* | Yes / No  Yes / No |  |  |
| 2.5 | If applicable - Are measures in place to address potential transmission through transport and use of research equipment and samples?  *Please describe* | Yes / No / N/A |  |  |
| 2.6 | Does the study require the use of PPE?  ***If YES*** *please describe*  Please also detail how guidance on the use of PPE for research staff and participants is being provided (e.g. Sponsor specifying or practice arrangements?) | Yes / No |  |  |
| 2.7 | Are controls on handling of COVID-19 infection aligned with practice clinical governance?  ***If NO*** *please explain why and any mitigations* | Yes / No |  |  |

1. **Other Considerations**

|  | Consideration | Yes / No | Further details | Actions taken to mitigate risk (if required) |
| --- | --- | --- | --- | --- |
| 3.1 | How might safety concerns be addressed if there was a second wave of COVID 19? | - |  |  |
| 3.2 | Is there a requirement for COVID-19 testing?  ***If YES*** *please describe and consider what additional risks this might pose and how these might be addressed* | Yes / No |  |  |
| 3.3 | Will the study require on site visits from monitors?  ***If YES*** *please describe and consider what additional risks this might pose and how these might be addressed* | Yes / No |  |  |
| 3.4 | Are there any other considerations that need addressing not covered above?  ***If YES*** *please describe* | Yes / No |  |  |

1. **Practice Considerations**

|  |  |  |
| --- | --- | --- |
| Practice Assessment |  | Additional Comments |
| Taking all factors into consideration in your opinion is this study viable and safe to proceed? | Yes / No |  |
| In terms of patient safety indicate whether this study is: | Low Risk  Medium Risk  High Risk |  |

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| --- | --- |
| **Risk Assessment Approved by:** | **On:** |
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1. Please highlight where a study has specifically been amended to exclude shielded patients as this may have ethical implications regarding equity of access and may need checking relevant ethics committee approval is in place for this [↑](#footnote-ref-1)