

**Guidance for Health and Care Research Wales Support and Delivery Service
regarding pandemic preparedness and response to COVID-19 outbreak
Updated 17 March 2020 (update from previous version highlighted)**

1. Purpose

- 1.1. This guidance describes the actions Health and Care Research Wales Support and Delivery services should consider to ensure pandemic preparedness and appropriate response to a sustained public health emergency. It is intended to act as guidance for all NHS organisations in Wales to inform their local operational response/plan. It may be updated as UK/Welsh Government guidance changes.
- 1.2. The overall aim of all plans is to ensure the continued safety of staff, patients and the wider population. This guidance will be used to facilitate prioritisation of services which supports NHS front-line but also ensures that research delivery which is essential for the treatment, care and safety of participants is prioritised and sustained.

2. Action required by Health and Care Research Wales Support & Delivery Services

3.1 Protection and management of patients/research participants and staff

- a. All staff should refer to and monitor updates and national guidance related to the status of the COVID-19 response (links provided on the COVID-19 webpage www.healthandcareresearchwales.org/covid-19-updates)
- b. All staff should follow local organisation protocol and policy in relation to COVID-19 when approaching new patients to participate in research and/or managing and treating participants of ongoing studies
- c. All staff should follow local NHS organisation guidance and protocols for personal and public protection actions required e.g. dealing with those who require isolation; the use of appropriate PPE.
- d. Managers should support staff who are required to self-isolate according to NHS policy and Public Health Wales guidance

3.2 Emergency planning and staff management to support the delivery of services

- a. Managers should scope staffing capabilities including identification of minimum staffing levels for current workload; description of current skills according to service and/or clinical area including creating a register of non-clinical postholders that have previous clinical experience/skills and are eligible to practice
- b. Managers should determine, and now implement, a plan for remote working wherever possible
- c. Staff are required to work flexibly within the scope of NHS policy, to accommodate the needs of the services across NHS Wales. This may include being flexible to support undertaking other roles (research or non-research) within the employing organisation or supporting colleagues in other NHS organisations to deliver Support & Delivery services.
- d. Study leave and annual leave restrictions will be implemented according to local NHS protocol and policy
- e. Leave continues to be provided according to NHS policy to staff who are carers for dependants and who are unable to work from home and for staff who are required to self-isolate

3.3 Prioritisation and management of clinical research

- a. All managers and teams should also refer to current HRA², MHRA³ and other guidance for the management of research in response to coronavirus (see Section 4 for links), This will include changes initiated by sponsors and changes initiated by sites in relation to clinical services.
- b. Managers should provide an emergency action plan which identifies how the workload will be reduced and managed when staffing levels are reduced. The plan should include prioritisation of the research workload and identification of minimum staffing levels for the safe continuation of services.
- c. Actions to reduce research (or change) study workload for ongoing studies should be risk assessed in discussion with the principal/chief investigator and Sponsor to ensure patient safety, ongoing patient clinical care, and integrity of research projects is maintained.
- d. Should additional funding be required to enable studies to continue but be delivered in different ways, this can be requested e.g. courier delivery of IMPs to patients
- e. Prioritisation of studies to reduce workload should focus on the safe care and treatment of patients and participants, particularly those who are receiving essential clinical care as part of a study. This local action plan will need to be responsive to the direction given by Sponsors, but also by changes in local context
- f. Managers should notify Sponsors, and others involved in the study (e.g. Clinical Trials Units) immediately of any changes in local context that impact on study delivery.
- g. Managers should prioritise studies where participants are receiving essential clinical care as part of a study
- h. Managers should prioritise portfolio COVID-19 studies and/or identified as priority in this emergency by UK/Welsh Government in all aspects of Health and Care Research Wales services including study set-up and delivery
- i. Emergency planning prioritisation should account for staff reductions associated with deployment of Support & Delivery staff to NHS services in emergency need or due to requirements to isolate or remain at home with dependants due to school closures.
- j. Emergency planning prioritisation to reduce and prioritise workload should include cancellation of annual leave and study leave according to local NHS policy; postponement or cancellation of meetings and events; delaying or halting study set up; stopping study recruitment; delaying study follow up.
- k. All portfolio COVID-19 studies will be set up and delivered through the principles of a One Wales approach
- l. Managers should communicate emergency plans regularly with all staff and according to local NHS protocol
- m. Managers should update emergency plans as frequently as required and at least weekly to ensure alignment to national and local organisation updates

3.4 Supporting front line services

- a. Managers should communicate emergency plans promptly to NHS service managers and release available Support & Delivery staff to clinical services when requested.
- b. Costs associated with Health and Care Research Wales staff and other relevant resources being made available to NHS Wales organisations will not be recovered due to the emergency nature of the situation. The usual process for recovering Support & Delivery (S&D) funding against staff time when S&D funded staff are used for non-research activities will not apply

3.5 Reporting the impact of the emergency on NHS R&D services

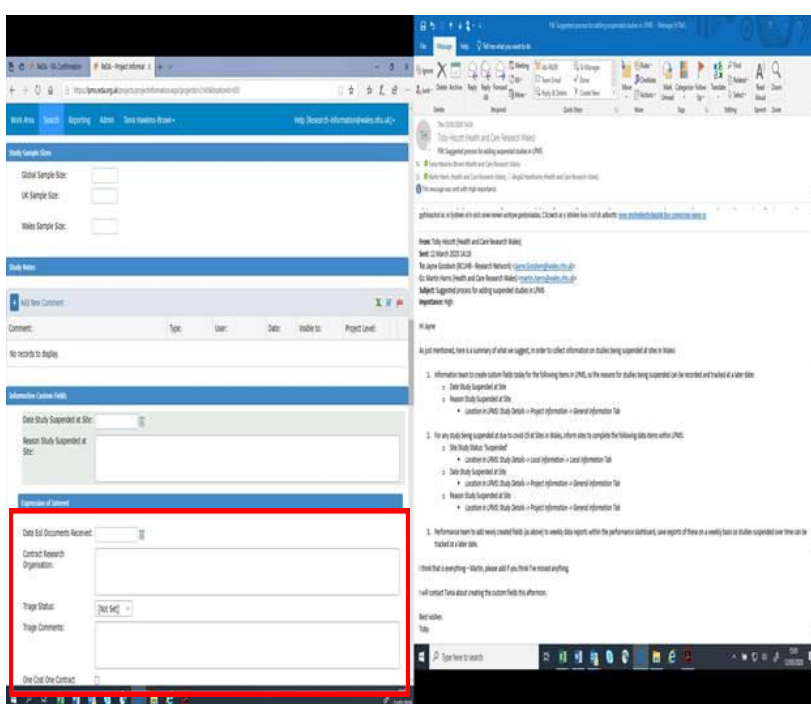
- a. Managers MUST document and report the impact on NHS R&D services, for example suspension of studies or changes in roles of staff. Guidance for reporting on changes to study status are provided in Appendix 3. It is crucial that organisations provide timely updates so that information can be collated nationally immediately, as required. This will evolve as UK discussions continue on tracking impact.

- b. All NHS Delivery Framework Key Indicators will be impacted for reasons outside of the NHS organisation's control during this period and this will be taken into account.

Appendix: Reporting requirement to update on study status

For any study being suspended due to COVID-19 at Sites in Wales, sites must complete the following data items within LPMS **as soon as possible**:

- o Site Study Status: 'Suspended'
 - Location in LPMS: Study Details -> Local Information -> Local Information Tab
- o Date Study Suspended at Site
 - Location in LPMS: Study Details -> Project Information -> Information Custom Fields Tab
- o Reason Study Suspended at Site
 - Location in LPMS: Study Details -> Project Information -> Information Custom Fields



This information will be used to provide live information on the impact of COVID-19 to studies in Wales, and enable reports to Welsh Government to be provided regularly. It is essential this data is accurate and updated as soon as possible a decision is made.

The Performance Team will add the new fields (as above) to weekly data reports within the performance dashboard, and save exports of this data on a weekly basis so studies suspended over time can be tracked during the outbreak.