

SBAR: COVID-19 Research Project Recovery Plan



Situation

Following on from the COVID-19 pandemic announcement in March 2020, recruitment and face to face follow-up to all research projects hosted by the Golden Jubilee was suspended. As the hospital enters the recovery phase, this paper details a phased recovery plan for the suspended activities.

Background

Recruitment and face to face follow-up was suspended on the 16th March 2020. A letter¹ was sent to the research support group (research nurses, physiologists etc.) and Principal Investigators (PI) confirming the suspension and detailing the reasons behind this course of action.

Subsequent to the above, a COVID 19 Clinical Research Plan and Guidance document² was circulated to the same group. This document provided information on how essential patient safety related activity would be dealt with during the suspension period.

This document details a process for the gradual re-introduction of recruitment and face to face follow up which is in line with local requirements and national advice. The CSO statement on the NIHR Restart Framework can be found at: <https://www.cso.scot.nhs.uk/news/> and the framework itself can be found at: <https://www.nihr.ac.uk/documents/restart-framework/24886>.

Assessment

The NIHR restart advice lists three prioritisation levels. At the Golden Jubilee, the relevant COVID-19 Urgent Public Health studies (Level 1) have been, or are being, reviewed and approved. All other studies are likely to fall into Level 3 which has been further divided into three categories which relate to the relative risk to the patient.

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). At the Jubilee, studies are further divided as follows:

 COVID 19
1 suspension of recru

 GJRI COVID 19
2 Clinical Research Pla

Research & Development Steering Group

Paper Ref: RDSG/110620/07a

Level 3a: Studies where the patient attends the Golden Jubilee for a clinically required intervention **and** is eligible to be consented to the project **and** where there is either no follow up or all follow up can be done remotely (i.e. by telephone or postal questionnaires).

Level 3b: Studies where the patient attends the Golden Jubilee for a clinically required intervention **and** is eligible to be consented to the project **and** where follow up requires the patient to attend the Golden Jubilee for a visit on one or more occasions.

Level 3c: Studies where patient lists are screened to assess eligibility for a project that requires a non-standard of care intervention that the patient would otherwise not have.

PI's will be asked to determine which category their study falls into. Recruitment and face to face follow up for Level 3a studies will be the first category to be submitted to Gold command for restart. Once there is confidence that these studies are progressing, Gold command approval will be sought for Level 3b and then Level 3c projects.

Once the appropriate prioritisation level has been established, PI's and support staff will be asked to complete a checklist with Level 3a studies completed first and as follows:

1. Confirmation is required that the study sponsor has agreed that recruitment and follow-up should restart. This relates to study viability and it is acknowledged that some studies may no longer be viable. If the study is sponsored by the Golden Jubilee, such queries should be sent to the representative of the sponsor (Catherine.sinclair@goldenjubilee.scot.nhs.uk).
2. Sections **1, 2 and 8** must be completed for all projects. The remaining section should be completed if they apply to the project.
3. If the project requires input from the pharmacy department, re-starting must be discussed with the Clinical Trials Pharmacist (Victoria.McNulty@gjnh.scot.nhs.uk) who will sign and date the relevant section.
4. For any other resource, including imaging, cath lab, labs etc., a section should be completed and signed by the relevant Head of Service.
5. Completed checklists should be scanned and emailed to research@goldenjubilee.scot.nhs.uk.
6. The checklist will be reviewed in line with the events table for each project. Any queries will be sent to the study PI as soon as possible.
7. A restart letter will be issued to the study PI.
8. The status of the projects will be changed on the research governance database and the checklist and restart letter will be uploaded to the CRF Manager database.

Recommendation

The Research & Development Steering Group is asked to review this plan for the reinstatement of recruitment and face to face follow up at the Golden Jubilee Research Institute.

Approval will then be sought from Gold Command that Level 3a studies can be restarted. Approval for transition to Level 3b and Level 3c will be sought as and when appropriate.

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Wednesday, 04 June 2020