

C-STICH Trial: COVID-19 Guidance for sites

Due to the rapidly changing situation regarding COVID-19, we anticipate difficulties with restricted travel for staff and participants, and redeployment of research staff to NHS frontline roles. We are working under these unprecedented circumstances to ensure participant safety, maintain the integrity of the trial, and collect primary outcome data.

Prioritising Research Activities

- Please refer to the **Site Capacity Pyramid** (page 3) below on how research activities for C-STICH should be prioritised.
- Please then **inform the C-Stich Trials Office** of what 'level' your Trust is currently able to operate (this should also be in accordance with your Trust's guidance).

Open to Recruitment

- As per the **Site Capacity Pyramid** (page 3) below, **C-STICH is currently open to recruitment**, provided your Trust is able to operate at '**Level 2 (Rand)**' or above.

Safety Reporting

- As per the **Site Capacity Pyramid** (page 3) below, safety reporting should continue as per protocol, ie:
 - Please continue to report SAEs as per protocol (ie within 24 hours of awareness).
 - However please **email** SAEs to the cstich@trials.bham.ac.uk mailbox.
 - When emailing SAEs, please ensure the subject title includes 'SAE' and the participant's trial number.

Sending of hard-copy documentation

- For the moment, please retain any hard-copy documentation that you would usually post/fax to the C-STICH Trial Office.
- Unless you are able to **email** it to the cstich@trials.bham.ac.uk mailbox
- Though please remember, if you are **emailing consent forms, these should be sent via encrypted email**. If you are unsure how to send an encrypted email, please contact the Trials Office, as they will be able to provide guidance on this.

Deviations

- Please document all protocol deviations locally. The C-STICH Trial Office will provide guidance on how these should be reported when the COVID-19 crisis is over.

C-STICH Trial Team Contacts

Email: CStich@Trials.bham.ac.uk

Phone: 07866312007 (please only ring between the hours of **9am - 6pm Mon-Fri** (unless urgent), as this is my personal number)

All latest updates could also be found via our website: <https://www.birmingham.ac.uk/research/bctu/trials/womens/C-Stich/index.aspx>

Guidance documents

HRA:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

NIHR:

<https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-on-covid-19-on-research-funded-or-supported-by-nihr/24469>

Please Note:

This document is correct as of 5th May 2020, and further changes may follow in the coming days. We will try to offer as much practical advice as we can to help you with the running of the C-STICH trial under the current circumstances.

Thank you, and all the very best to everyone your end,

C-STICH Trial Management Group

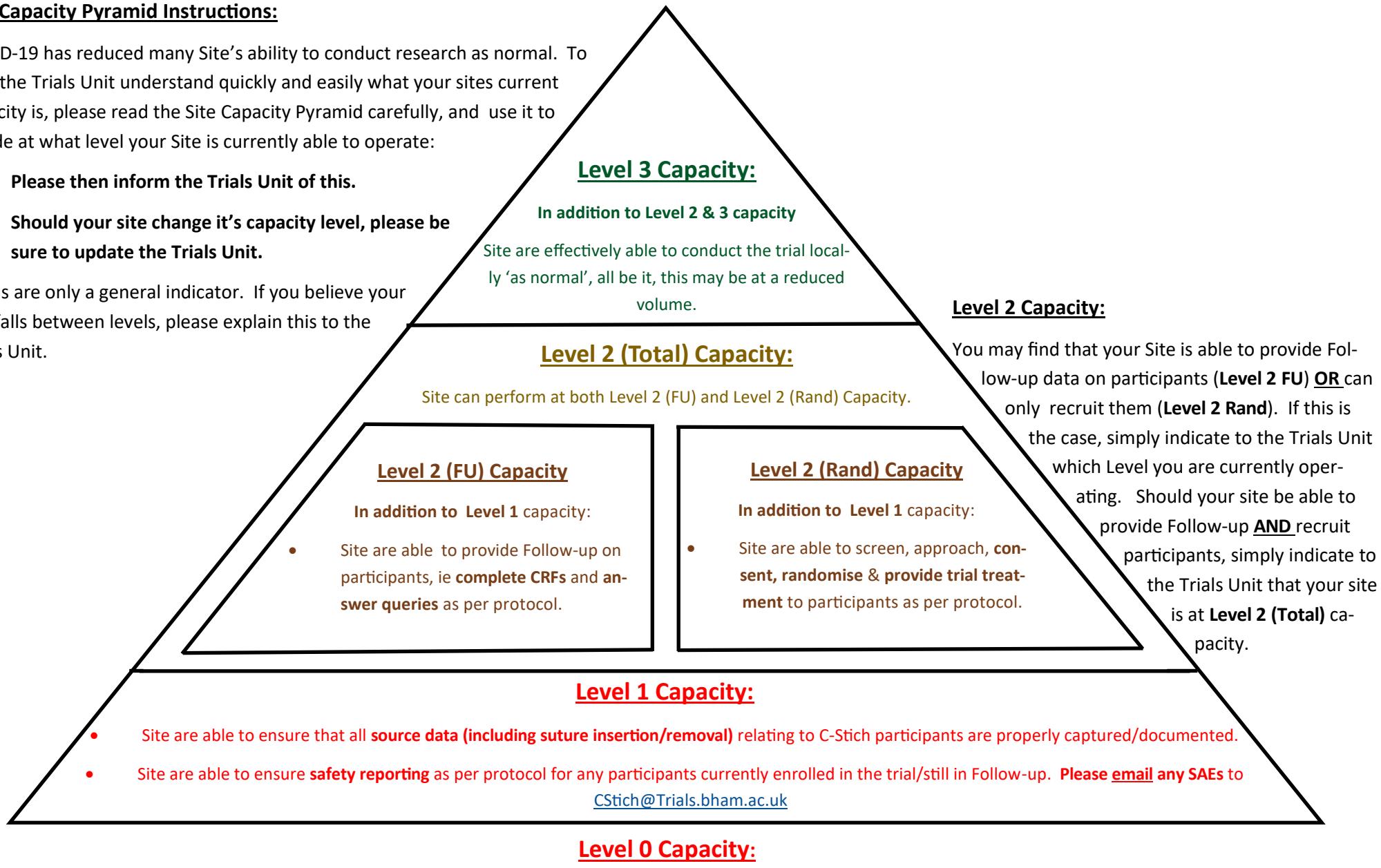
C-STICH COVID-19: Site Capacity Pyramid

Site Capacity Pyramid Instructions:

COVID-19 has reduced many Site's ability to conduct research as normal. To help the Trials Unit understand quickly and easily what your sites current capacity is, please read the Site Capacity Pyramid carefully, and use it to decide at what level your Site is currently able to operate:

- Please then inform the Trials Unit of this.
- Should your site change it's capacity level, please be sure to update the Trials Unit.

Levels are only a general indicator. If you believe your Site falls between levels, please explain this to the Trials Unit.



IMPORTANT: If your site lacks Level 1 capacity, please inform the Trials Unit Immediately.