Please ensure you read the Notes for C4C Researchers below and refer to them throughout the duration of using CRIS for recruitment.

The following action points detail your remit of responsibility as a researcher on any Consent for Contact (C4C) project. These apply subject to approval of your project by the CRIS Oversight Committee and South London and Maudsley NHS Foundation Trust (SLAM) Research and Development (R&D) team.

If you have any queries in relation to these points or your responsibilities as a researcher using C4C, please contact the NIHR Maudsley Biomedical Research Centre (BRC) Consent for Contact (C4C) team (c4c@slam.nhs.uk).

If you have any queries regarding whether you are covered by your research ethics and R&D approval for recruiting via C4C, please contact the R&D office (slam-ioppn.research@kcl.ac.uk).

1. Participant Selection

Once your CRIS application has been approved, please contact Amelia Jewell, Research Informatics and Governance Lead (amelia.jewell@slam.nhs.uk), who will arrange for you to meet with a member of the CRIS Extraction Team to discuss your search strategy.

The CRIS Extraction Team will work with you to define your inclusion and exclusion criteria. The team will then extract a list of potentially eligible participants based on these criteria, along with any additional output information needed to help you shortlist which participants to contact. These data will remain deidentified and will be saved in an Excel file on the BRC_CRIS shared network drive within SLAM.

Once you have reviewed the deidentified data and selected clients who you would like to contact, you will request their Trust IDs from the CRIS team. To do this, please save a list of the BRCIDs for patients that you would like to contact in an excel file in your folder on the BRC_CRIS shared drive. Please do not save any other data. Then email the member of the CRIS Extraction Team allocated to your project to request the Trust IDs, informing them of the location of your shortlisted BRCIDs file. **Do not email any service user information, even if it is deidentified**.

When shortlisting potential participants please ensure that you check the C4C comments which will be included as an output in your data. The C4C comments will include specific requests from service users, including potential reasons for exclusion from your study. **It is your responsibility as the researcher to ensure that service user comments are respected.**

Upon receipt of the Trust IDs, you will have 3 months from the date they were handed to you to contact the individuals. If recruitment is ongoing after 3 months, you must request an updated data extraction from the CRIS Extraction Team.

2. Data Storage

All data will be saved in the CRIS shared drive (BRC_CRIS) and you cannot move this file to your personal drive or outside the SLAM IT network.

If you request Trust IDs, they will be saved separately from the BRCIDs you have provided, in an Excel spread sheet under password protection which will be sent to you in a separate email. **DO NOT remove password protection from the document.**

The Trust IDs and BRCIDs **must not** be linked together in order to protect the integrity of CRIS as an anonymised database. All information for recruitment from ePJS or from CRIS used must remain within the SLAM firewall until a service user has provided informed consent for your study.

3. Contacting Service Users

Please note, the CRIS Team cannot arrange access to ePJS for researchers conducting C4C projects. Access to ePJS should be arranged by your project supervisor or an appropriate SLAM colleague within your CAG.

Prior to contacting individuals, please check again whether the status on their C4C form or Rescon form on ePJS (within core info tab) has been updated or changed; to ensure that they are still eligible for participation. This means checking both the "Response" and "Comments" fields within the form.

Please also confirm via ePJS that they have not died and what the preferred method of contact is. Check for any "Alerts" on the individuals ePJS to ensure there is not a current reason/risk why you should not contact them, e.g. they are missing and their current whereabouts unknown.

SLaM approval for C4C requires a researcher to contact the clinical team to check that it isn't inappropriate to contact a service user at that time. In line with this, care co-ordinators should always be emailed prior to contacting a service user.

We suggest that you send an email to the care co-ordinator based on one of the templates below (please adapt as necessary for your study), with a study information sheet attached.

To help you decide:

1. If your approved recruitment method requires input or assistance from the care co-ordinator or clinical team (for example in assessing capacity) then details of this should be included on the email to the care co-ordinator and a response from the care co-ordinator will be needed before the service user is contacted. If ongoing support from the clinical team is likely to be needed, we suggest discussing with the care co-ordinator or team involved the most appropriate way to manage this as recruitment continues.

2. For all other cases, the researcher should email the care co-ordinator to notify them of their intention to contact the consenting service user. This notification should include a request to let the research team know within a set period of time if there is any reason why it is not appropriate to contact the service user at this time. If no response is received from the care co-ordinator within this time, the researcher can go ahead and contact the service user.

NB. The care co-ordinator is the most appropriate person to contact, even if the original consent for contact was undertaken by someone else.

<u>Template 1 – Team Input Required</u>

Dear (care co-ordinator)

I am contacting you as we have identified the following service user(s) under your care via the Trust Consent for Contact mechanism and would like to contact them to see if they would be interested in a specific research project.

Name of service user

Name of service user

We need the input/ guidance of the care team (give details) and I would be grateful if I could discuss this with you before contacting the service user(s). Please Let me know a convenient time to contact you

<u>Template 2 – Notification Only</u>

Dear (care co-ordinator)

I am contacting you as we have identified the following service user(s) under your care via the Trust Consent for Contact mechanism and would like to contact them to see if they would be interested in a specific research project.

Name of service user

Name of service user

If you know of any reason why it would not be appropriate to contact this person at this time, please could you let me know within 14 days as I intend to contact NAME(S) the week beginning DATE. Any contact made by our study team will be documented in the new research consent form on ePJS along with the service user's response.

If there is no care co-ordinator listed to contact, then you should in the first instance contact the clinical team lead for the team the individual is under. There may be a psychiatrist or other named professional listed on ePJS and it would also be appropriate to contact them.

When contacting individuals, check within ePJS for a preferred method of contact within the comments section of C4C. It may be the individual wants to be emailed first about potential studies or would like to have a member of their family phoned first. Where possible these preferences should always be respected.

4. Documenting Contacts Made

Every contact with the patient (regardless of patient response) has to be recorded promptly in the C4C or Rescon form under 'Approaches and Participation'. It is best practice to record an event (a clinical note) about your interaction with the patient, providing brief details (e.g., if the patient was distressed

or if you had an introductory call and sent further information). This note will be visible to the clinical team and everyone who accesses the patient's ePJS records.

This is a requirement of your R&D approval. It helps in the audit process of this particular project and also in case the participant has changed their mind or expressed concerns after you have approached them.

It is your responsibility, as the researcher, to update the Research Consent form on ePJS as and when you contact the clients. **The R&D office may remove your project R&D approval if this is not completed.**

If you contact an individual and they advise they do not want to take part in this study, **and** also want to be taken off the C4C register than you can do this by overwriting the C4C form on ePJS with new information (Response and Contact = No). This will remove them from the C4C register and will stop them being contacted about any potential studies.

5. C4C Researcher Training

The NIHR BRC C4C team have developed a course for researchers who have minimal to no experience with using the C4C research register for mental health research in South London and Maudsley NHS Foundation Trust (SLaM).

This course is aimed at researchers at King's and SLaM who already have Research Ethics Committee (REC) and R&D approval to use C4C for their research and need training on approaching service users and navigating C4C forms in ePJS. After attending this course, researchers will be able to access ePJS safely and professionally in accordance with information governance and data protection laws and principles and will have learnt the skills to safely and professionally upload and amend C4C forms on ePJS.

The course can be signed up to via the Health Sciences DTC on SkillsForge. For any enquiries, please contact hs-dtc@kcl.ac.uk.

If you have any questions about the course, please contact the BRC C4C team directly at c4c@slam.nhs.uk.