Consent for Contact (C4C) – Clinician FAQs & Guidance

WHAT IS C4C?

Consent for Contact (C4C) is SLaM's patient research participation register. C4C provides service users with the opportunity to register their interest in participating in clinical studies and trails across SLaM and our partner, the Institute of Psychiatry, Psychology and Neuroscience (IoPPN).

If they wish to be added to the register, a researcher may contact them in future to discuss a study they may be eligible for and may wish to participate in.

Joining the C4C register is **not** consent to participate in any specific study or trial – all it allows researchers to do is view the service user's records and contact them if they meet the eligibility criteria. Service users can then decline or agree to participate in the specific study with informed consent.

All SLaM clinicians (i.e. doctors, nurses, social workers, psychologists, allied health professionals) are expected to discuss C4C with their patients and record whether or not they consent on ePJS.
C4C is part of everyday clinical activity and consent documentation is embedded within ePJS. The consent form is located under the Core Info tab titled "C4C – Consent for Contact" or via the C4C icon found on the top left of a patient's record.

WHY IS THIS IMPORTANT?

SLaM is a research trust, and the largest mental health research trust in the country. Research is a core part of SLaM's mission, as Clinical research is vital to improving patient care and treatment in the NHS, and is a core part of SLaM's mission.

Traditionally, doctors and healthcare professionals have informed their patients about the benefits of participating in research. It is equally important that patients ask their care team about research directly and SLaM is committed to this empowerment initiative through the Consent for Contact programme.

Research doesn't just include, for example, MRI scans or medication regimens – the majority of research conducted involves speaking about lived experience or your views, for example as part of a focus group, an interview, or by filling in questionnaires or participating in surveys.

HOW DO I START A CONVERSATION ABOUT C4C WITH MY SERVICE USERS?

Asking a service user whether they would like to join the register can take place at any stage in their treatment with your team – at initial assessment, during treatment, or at discharge.

Keep in mind the key objectives of approaching service users about C4C:

- To minimize any distress or confusion which may be experienced by service users, through personalisation of interaction and lack of coercion.
- To recognize that anxiety may be inherently present in any contact with services and to be mindful of this.
- To ensure a balance between the simplification of information provided, and the minimum understanding and information needed for service users to make an informed decision.

EXAMPLE CONVERSATION ABOUT C4C – KEY POINTS HIGHLIGHTED:

I'd like to mention something that might be useful to know about, **SLaM's research register**. Have you heard of this? ***check for understanding***

EXPLAIN: It's called Consent for Contact. We ask everybody who uses our service if they would like to be contacted by researchers about research studies they might be suitable for – does this sound like something you may be interested in?

dependent on reception/response/understanding, would go on to communicate the following points

Show/Provide Leaflet

Whether you sign up to the register or not, you don't have to take part in any actual research studies – all we'd like to know now is whether you'd be happy to be contacted about research that you might be able to help with.

These studies are approved by the Research & Development office at SLaM. **Researchers would be able to see your medical records to work out if you would be suitable for a study** based on information such as particular symptoms you have, medication you have been taking or treatments you may have received.

Optional *Examples* - It could be a simple questionnaire or survey gaining feedback about treatment you have received, completing a computer task or trying a new therapeutic intervention or medication.

After hearing more information, would you like to join the register?

- **Response:** Unsure

"That's fine, you don't have to make a decision right now. Here's a leaflet with some more information and questions you might have. Have a read through that information if you would like to, and we can discuss it at some point soon. Is that ok?" ***On next appointment with service user, you would ask about C4C again once they have had time for consideration****

- **Response:** No

"That's fine, **I'll make a note of that on your records**. I'll give you this leaflet on C4C just for your information. Have a read through that, and if you have any more questions, or you change your mind about participating, please feel free to contact me using the details on the flyer."

- **Response:** Yes

"That's great, **I'll put a note on your record,** and here's a leaflet with some more information. **Would you like to be contacted after you have been discharged?** I'll make a note of that too. Have a read through that, and if you have any more questions please feel free to contact me using the details on the flyer. **You can leave the register at any time** so if you change your mind, please speak with a member of your clinical team or contact the C4C team (details on leaflet) and they can change your C4C record. You can also let me know if you have any preferences for how you are contacted (i.e. phone/email), and whether there are any particular studies you don't wish to hear from or participate in."

It is also paramount that clinicians specifically clarify that the patient is/is not consenting to be contacted by researchers after they are discharged from SLaM services. This is now indicated on the C4C ePJS form and should be filled in prior to saving on the patient's electronic record.

WHAT KIND OF STUDIES MIGHT PEOPLE ON THE REGISTER BE ASKED TO PARTICIPATE IN?

A wide variety of studies have utilised the C4C register to recruit participants, across many different areas and seeking participants from different backgrounds.

Research might involve speaking about your experiences to a researcher, perhaps in a group setting, or filling in some questionnaires. It may involve other measures, such as taking medicine, having a scan, or a blood sample – the researcher will inform the service user of their study design and what is expected when they contact them to allow them to decide if they wish to partake or not.

There have, for example, been studies conducted using C4C which have aimed to assess the efficacy of using quetiapine in treating depression; the psychosocial impact of living with diabetes and SMI; genetic markers in Alzheimer's; brain imaging in babies study (BIBs), and in developing a questionnaire to assess anxiety in people with a diagnosis of Autistic Spectrum Disorder (ASD).

WHAT IF THE SERVICE USER IS UNWELL AT THE TIME A RESEARCHER WANTS TO CONTACT THEM ABOUT A STUDY?

If a service user is currently under a team, the researcher is required to contact the care co-ordinator prior to making contact with the service user. Typically, the researcher will e-mail the care co-ordinator as listed on EPJS with a brief summary of the study they are recruiting for, and offer the opportunity for the clinical team to advise if there is any reason the service user should not be contacted at this time (such as following a bereavement or during an acute phase of illness).

They will give a 2 week period for the clinical team to air any objection to contact, and following this period if there is no response, they may contact the service user directly.
Researchers who are running these studies are required to have undertaken training to ensure they are able to take informed consent from participants. If a potential participant lacks capacity to agree to take part in the study, they will generally be excluded as they are unable to give informed consent.

HOW DO YOU KEEP SERVICE USERS' DATA SAFE AND CONFIDENTIAL?

If a client has joined the C4C register, researchers are required to submit an application in order to search de-identified records and screen for eligibility. This application is project specific, and the study will have gained a favourable ethical approval from an ethics board, ensuring they have satisfied GDPR requirements and safeguards for participant data, as well as other considerations such as promoting participant safety & well-being.

Once the application to use the register has been approved by an independent committee and researchers have screened the de-identified records, they may request the EPJS IDs of those who fit the eligibility criteria. These IDs are stored separately to the de-identified records. All confidential information regarding service users' records is kept behind the SLaM firewall at all times.

All researchers who have access to participant records are required to have undertaken data protection training.
Information regarding data protection and confidentiality within each specific study will be shared in more detail with service users when they have been approached regarding their potential participation.

WHAT IF MY CLIENT DOESN'T WANT TO GET INVOLVED?

There is no obligation to join the register, and their usual care will not be compromised. Asking service users about C4C is about offering the information necessary for them to make up their own mind about whether they would like to avail of this opportunity, or not – without coercion.

If they aren't sure, they can take time to discuss this with friends, family or carers, as well as taking a look at the SLaM website (slam.nhs.uk/c4c), reading our leaflet, or contacting the C4C team directly with queries.
Service users are free to change their mind at any time about joining or leaving the register. If a service user has previously said "no" to joining the register, clinicians can ask them again at a later stage.

WHAT IF THE SERVICE USER LACKS CAPACITY?

If a service users lacks capacity in the short term, wait for patient to regain capacity and reassess in the future.

If lack of capacity is long term or permanent, patient's next of kin or closest carer should be consulted to make a decision on behalf of the service user.

This must **not** be someone who is caring for the service user in a paid capacity.

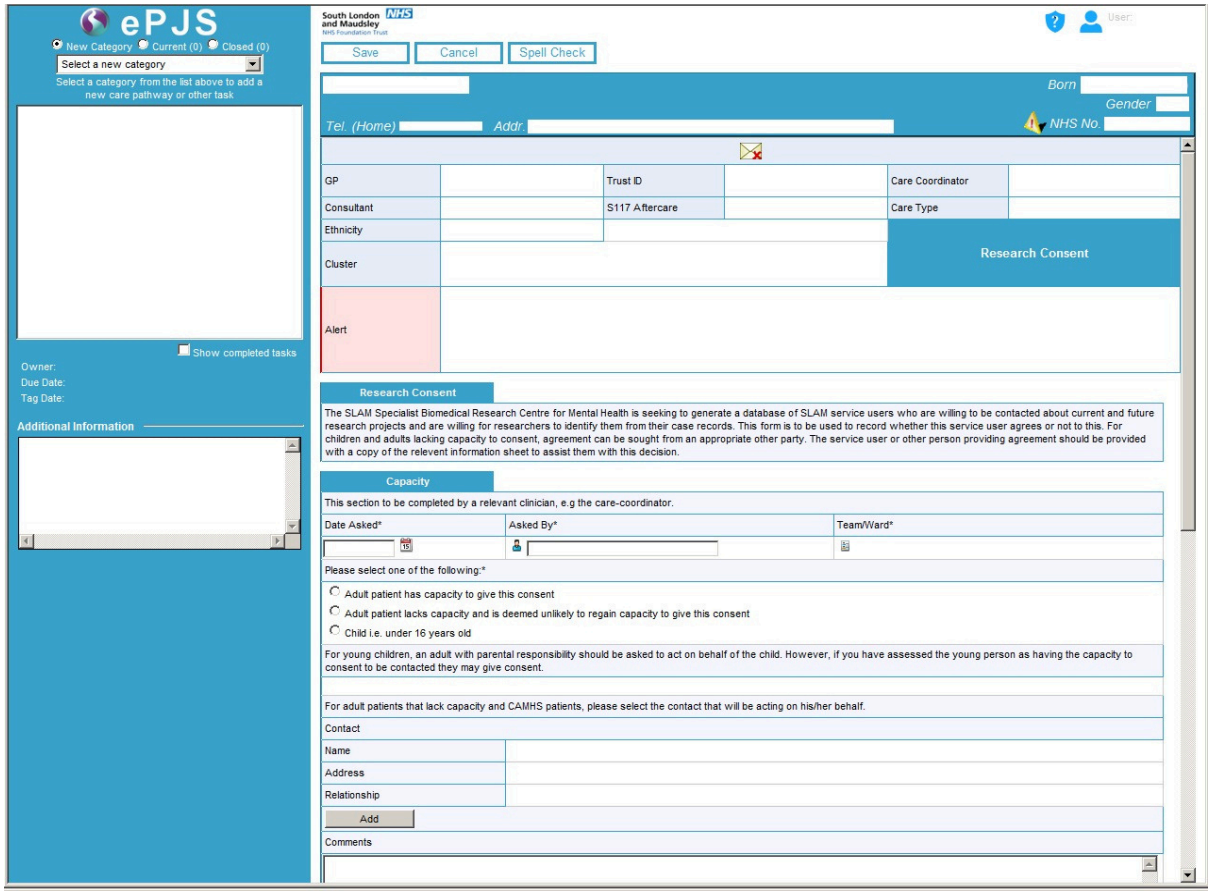
HOW DO I RECORD A RESPONSE ON EPJS?

The C4C icon on a patient's EPJS front page will indicate whether their consent has been requested.

Blue icons mean the patient's response has been recorded. A grey icon means they have not yet been asked if they would like to join the C4C register.

Click on the icon to complete or view the C4C EPJS form via Core Info tab.

Step 1 – Capacity (see below)



1) Fill in date, name of clinician, and team/ward. You can type "D" to fill today's date automatically.

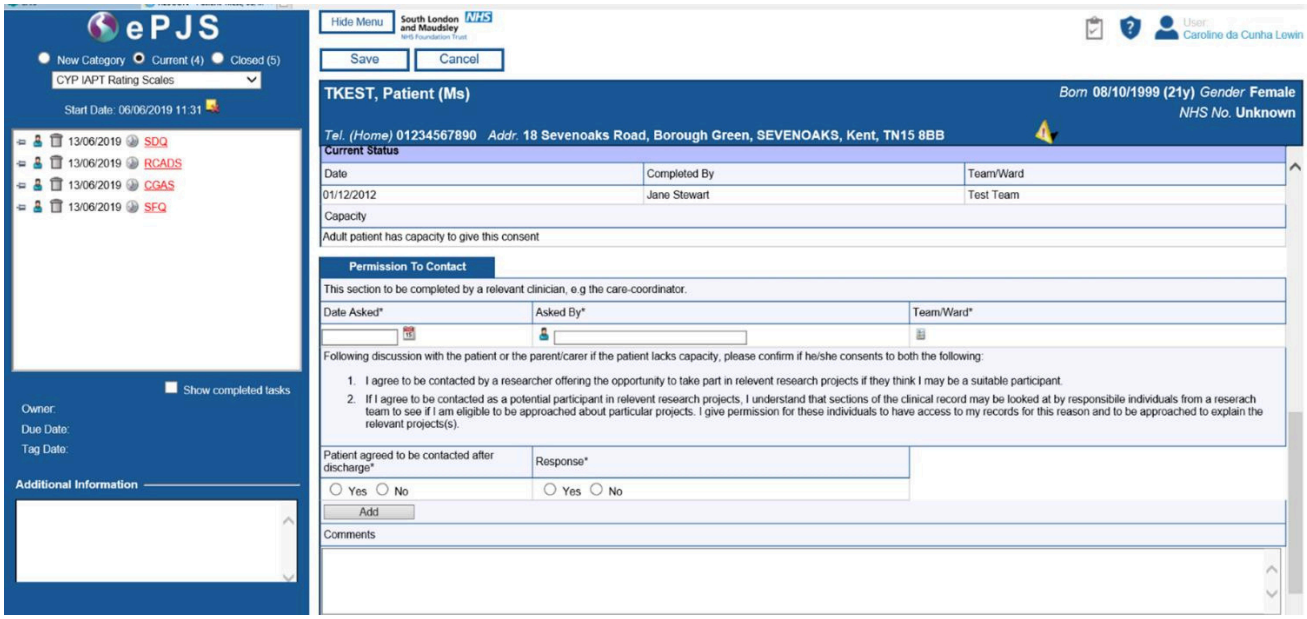
2) Select from the options if the patient has capacity, does not & is unlikely to regain capacity to consent, or is under 16 years of age.

3) If the client **has** capacity, simply click the top option and move on to the next section.

4) For either of the other two options, please fill in the details of the person who will be acting on their behalf.

5) There is a "comments" section for any further information regarding capacity or information about the carer/parent/guardian.

Step 2 – Recording response (see below)



1) Once you've filled in the capacity section, you can record the service user's response (i.e. "yes" or "no" to joining the register). Again, fill out the date, clinician name, team/ward.

2) Response: whether they agree, or not, to join the register.

3) Also, whether they agree to be contacted after discharge.

4) Comments section here is available for any comments the service user or you would like to add – it may be that they work certain hours and wouldn't like to be contacted during those hours; that they only wish to be contacted about paid participation studies; that they would not like to be contacted about studies which investigate trauma. Any and all stipulations should go here so researchers can view this when screening for eligibility.

5) That's all you have to do! Simply click to save and confirm.

Note the final section, approaches/participation, is for researchers to fill in when they contact a client.

WHEN SHOULD I REVISIT C4C?

If a patient has previously said “no” to joining the register, we would recommend offering them the opportunity to change their mind and revisiting this after an appropriate period of time. It’s up to you, who knows the individual, to judge when this may be. It is not unusual for service users to initially say no, but when offered the opportunity again, change their minds! It’s down to us as clinicians to give them that chance.

WHERE CAN I FIND FURTHER INFORMATION?

LEAP training - Available to view at any time which takes approximately ten minutes to complete.

https://slam.nhs.uk/consent-for-contact – Public-facing webpage on the SLaM website with access to our leaflets.

C4C@slam.nhs.uk – Contact the C4C team directly!

We’re always happy to answer queries from service users, clinicians and researchers. We also offer brief bespoke training sessions for clinical teams who wish to improve uptake within their service, and can support you to monitor this progress.