**Participant Information Sheet**

**Study Title**: Relationships and unusual experiences in psychosis

**Researcher**: Jacqui Tiller, Trainee Clinical Psychologist

**Chief Investigator:** Dr Katherine Newman-Taylor, Consultant Clinical Psychologist

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

Thank you for considering taking part in this research project. I am a Trainee Clinical Psychologist at the University of Southampton and this project will be my Doctorate thesis. The Chief Investigator of this study is a Consultant Clinical Psychologist. The aim of this study is to investigate relationships and unusual experiences in psychosis. This study is sponsored by the University of Southampton.

**Why have I been asked to participate?**

You have been considered as a candidate to take part in this study as you are receiving input from an Early Intervention Psychosis Team or a Community based service for people who have unusual experiences.

**What will happen to me if I take part?**

If you consent to take part in this project, you will have contact with a researcher in line with current guidelines (either face-to-face, via a virtual appointment or over the phone). The researcher will explain the study and give you the opportunity to ask any questions. If you meet the inclusion criteria and you are happy to proceed, you will be asked to complete a demographic sheet and a series of short questionnaires, which should take no more than 30 minutes. You will be reimbursed with £10 which includes payment for your time and any travel expenses you may have incurred. You will be invited to repeat these questionnaires 6 and 12 months later and will be reimbursed with £10 on each of these occasions.

As part of your participation you will also be asked if you would feel comfortable for a key worker within your care team to complete a questionnaire (the Service Engagement Scale) about how your treatment is currently going. This is done as it is important to understand staff as well a service users’ perspectives of how care and treatment is currently being provided. This is entirely voluntary and you have the right to decline if you do not want a member of staff to complete a questionnaire about your treatment. Declining for a staff member to complete this questionnaire will not impact your ability to take part in the study in any way and it will not affect your current care or treatment.

**Are there any benefits in my taking part?**

There would be no direct benefit for you although some people find it interesting to complete questionnaires about their experiences. You will also be contributing to the evidence base exploring relationships and unusual experiences in psychosis.

**Are there any risks involved?**

The questionnaires have the potential to touch on sensitive topics including relationships with others and how you are feeling currently. However, these are standardised measures and there are no known adverse effects of completing them. If completing these questionnaires causes any distress and you require further support, please contact your GP, the community mental health team or early intervention team you are receiving support from, or Samaritans (116 123). The number of questionnaires has been kept to a minimum to reduce the length of time required from participants.

**What data will be collected?**

The demographic sheet will ask for your gender, age, ethnicity, nationality, time since you began receiving support from the EIP or community team, time since onset of any symptoms of psychosis and whether you have received a formal mental health diagnosis. This will help us describe in general terms who took part in the study and understand the scope of the study’s findings. This information will not be shared with anyone outside the research team. The questionnaires will ask about your thinking (e.g. I often heard people referring to me), how you manage emotions (e.g. I keep my emotions to myself) and relationships (e.g. I try and cope with stressful situations on my own) and how you are currently feeling (e.g. I’ve been feeling optimistic about the future).

**Will my participation be confidential?**

Your participation and the information we collect about you during the research will be kept strictly confidential. Personal identifiable data gathered relating to your name, address and contact number will only be kept for the purposes of future data collection for this study. This information will be kept separate to the consent form you signed. Questionnaire data will be moved to a computer which will be password protected. Any paper forms will be kept in locked cabinets. Please note, the research team will not access your personal medical notes.

Confidentiality will only be broken if you disclose information that indicates you or someone else are at risk of harm. In such instances, this information will be shared with the appropriate agencies (e.g. your GP, care coordinator, social services, police, as necessary). We will aim to involve you as much as possible in this process. This process is important to safeguard both you and the people around you.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to participate.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time prior to data anonymisation without giving a reason and without your participant rights (or routine care as a patient) being affected.

Participants are able to withdraw their consent during the two weeks following the completion of their questionnaire at each time point, this is because data analysis will begin two weeks following completion of a questionnaire. This will be reiterated to participants during the debrief process and on the debrief form.

If for any reason you decide that you no longer want to take part in the study, all you need to do is let me know. You do not have to provide me with a reason and this will not impact your ability to access support from the team. If you withdraw from the study, we will keep anonymised information about you that we have already obtained for the purposes of achieving the objectives of the study only.

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you. The results of this study will be part of a Doctorate thesis and submitted to the University of Southampton and, if appropriate, in a peer-reviewed journal.

If you would like to receive the results of the study, please let the researcher know and you will receive a letter or email summarising the findings.

**Where can I get more information?**

If you have any further questions, please contact Jacqui Tiller via email jlt1n20@soton.ac.uk, or one of her supervisors, Dr Katherine Newman-Taylor at [k.newman-taylor@soton.ac.uk] or Dr Tess Maguire at [t.l.maguire@soton.ac.uk]. The lead researchers can also be reached via telephone on 02380 591930.

Please note: these email addresses and telephone number are not to be used in the case of an emergency. If you are worried about immediate risk of harm to self or others, please contact your care coordinator or local crisis team.

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

**Who has reviewed this study?**

The Social Care Research Ethics committee has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from University of Southampton and Southern Health NHS Foundation Trust, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. These people have a duty to keep your information strictly confidential.

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies (Research Data Management Policy & Data Protection Policy) in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you (consent forms) for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

**Thank you for taking the time to read the information sheet and considering taking part in the research.**