Appendix 2: Participant Information Sheet <u>Phase 1: Focus Groups</u>

Study Title: Culturally-adapted Family Intervention (CaFI) for African and Caribbean people diagnosed with psychosis and their families

We would like to invite you to take part in our research study. Before you decide whether or not to take part, we would like you to understand why the research is being done and what taking part would involve. We have prepared this *'Participant Information Sheet'* to tell you about the purpose of the study and what will happen if you decide to take part. This information sheet also tells you about the purpose of the research study and provides more detailed information about the study and how you can expect to be treated if you agree to take part.

If you wish, one of our team will go through this information sheet with you and answer any questions you have. We think this should take about 15 minutes. You are also free to talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the study?

Decades of research shows that Sub-Saharan African and Caribbean people in the UK are more likely than any other ethnic groups to be diagnosed with schizophrenia and other psychoses. However, their experience of mental health services is generally poorer and they have worse outcomes. Fear of mental health services and stigma in the community cause African and Caribbean people diagnosed with schizophrenia to delay contact with services. Prolonged untreated illness is stressful and increases the 'burden of care' on families. It increases tension in the home and can cause family breakdown. This is important because we know that not being in contact with their families may make service users more socially isolated, resulting in longer hospital stays and increases their risk of having to return to hospital after discharge. There is an urgent need to improve the care of African and Caribbean people and provide better support to their families. We piloted a Culturally-adapted Family Intervention (CaFI) with Caribbean families, and found that it was a treatment that helped service users and their families. Members of the African community told us that they would also like to have access to CaFI.

We therefore plan to find out whether CaFI can help both African *and* Caribbean families. We will work with service users, relatives/carers/guardians and members of the community as well as healthcare professionals to see if it is possible to deliver our Culturally-adapted Family Intervention (CaFI) in acute and rehabilitation inpatient hospital wards, and Community Mental Health Teams in Greater Manchester, Merseyside, London, Southampton, and Midlands. We realise that some people may have lost contact or have difficult relationships with their families. To make it possible for them to take part, we will ask these service users to nominate 'trusted individuals' (such as, but not limited to, support workers, church pastors and family friends), who we will train to act as 'Family Support Members' when service users have no contact with their own families.

How does the CaFI therapy work?

Service users will attend 10 sessions of CaFI with their relative/carer/other trusted individual. Each session is 1 hour long. The therapy lasts for about 20 weeks in total. The pace of the sessions within this time period will depend on the needs of the service user and their families. CaFI sessions could take place in the service user's/family's home, a community centre, or a meeting room on the ward, depending on the family's preference.

CaFI sessions aim to help families cope better by:

- Learning about schizophrenia spectrum disorder, treatments, support services, and different healthcare professionals
- Supporting helpful communication with services and between family members
- Learning how to cope better within the family
- Supporting families to set goals and plan for positive change

Why have I been invited to take part?

We are inviting you to take part in this study because you fall into one of three groups of people:

1) ***Current and former service users*** who regard themselves as being from Sub-Saharan African or Caribbean backgrounds (including people who see themselves as 'Black British' or of 'Mixed' heritage, but who have at least one African or Caribbean parent or grandparent).
2) ***Carers and advocates*** (including paid support workers, family and friends) who have experience of working with African and/or Caribbean people. Unlike service users, carers and advocates need not be African.
3) ***Health Professionals*** from a range of professions and levels of experience/expertise, including: nurses, Occupational Therapists, psychologists, and psychiatrists, social workers.

What will I have to do if I take part?

The study is divided into 3 parts, or 'phases'. **You have been invited to take part in FOCUS GROUPS, which is Phase 1 of the study.** The purpose of Phase 1 is to adapt 'Culturally-adapted Family Intervention' (CaFI) for African service users and families and to ensure its acceptability to both people from Caribbean and Sub-Saharan backgrounds. This is because CaFI was originally developed for Caribbeans specifically. Before we start testing CaFI with Africans, it is important to ensure that African people also find it acceptable.

We want to talk with people like you in discussion (focus groups) to find out about your experiences and what is important to you. We will also ask you to help us review CaFI session content and materials. We will use the information you share with us to make sure that CaFI is workable and likely to be acceptable to service users and their families from both Sub-Saharan African and Caribbean backgrounds. People who agree to take part in **Phase 1** of our study will work in three separate

CaFI Culturally-adapted Family Intervention African & Caribbean people with psychoses

groups: 1) people with a diagnosis of schizophrenia or psychosis 2) families, carers and advocates and 3) healthcare professionals. We will aim to recruit 8-10 people for each group. After completion of these three focus groups, we will form a fourth group of 8-10 people, made up from representatives from each group. We will ask you again if you want to be part of this group, which will be made up of service users, carers and health professionals. The focus groups will last around

60-90 minutes. On occasion, it may be that the groups will run longer if participants feel that they would like to discuss some matters further. You have no obligation to stay for the entire duration of the group. The groups will be led by the Lead Researcher, **Professor Dawn Edge,** of the research site with support from research assistants **Helen Wilson** and/or **Henna Lemetyinen**. This is likely to take place in the **University of Manchester, Greater Manchester Mental Health NHS Foundation Trust** or a community setting. The location will be agreed with members of the Research Advisory Group.

Will my taking part be kept confidential?

Yes. If you agree to take part in the study, any information you give the researcher will be kept strictly confidential. However, we do have a responsibility to disclose information that suggests you or someone else might be harmed. If this is the case and you are currently a service user, we would need to inform the person responsible for your care. This is likely your key worker and/or your GP. If you are a current service user, with your permission, we would like to inform your consultant or GP if you agree to take part in the study.

The legal basis upon which we are using your personal information is “public interest task” and “for research purposes” if sensitive information is collected (Data Protection Act 2018).

Greater Manchester Mental Health NHS Foundation Trust (GMMH) is the sponsor for this study. GMMH is based in England, in the United Kingdom. The research team will be using information from you to undertake this study. GMMH will act as the data controller for this study. This means that she is responsible for looking after your information and using it properly. GMMH and the other research sites will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum amount of information that could identify you – this is known as ‘personally-identifiable information’.

You can find out more about how we use your information at **https://www.gmmh.nhs.uk/gdpr-in-research** or by contacting **Project & Trial Manager Helen Wilson (tel: 0161 276 3312; email: helen.wilson@gmmh.nhs.uk).**

NHS will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from GMMH and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in GMMH who

will have access to information that identifies you will be people who need to contact you to inform you of study findings, other research opportunities, to ask you a clarification about your information, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

NHS will keep personally-identifiable information about you from this study for 10 years after the study has finished.

'Personal identifiable information', such as your name, address or contact number, will be stored securely in a locked filing cabinet separate from any information that you share in the focus groups. Only the site Lead Researcher, Professor Dawn Edge, and the research team will have access to this locked filing cabinet. Your name will not appear on any of the forms we use to collect information, nor in anything we publish about the study. Instead, we will give your information a study number or use a made up name that is nothing like yours. It will not be possible to identify you in anything that we publish.

You will be asked to give consent to having your focus group conversations audio-recorded. This will help us to make sure the information we use is accurate, as it would be difficult to do this from notes alone. The recording will be destroyed after it has been written up and your personal details will never be disclosed. If you are a service user under the care of **Greater Manchester Mental Health NHS Foundation Trust,** a copy of your consent form will be placed in your usual medical notes and this copy may be reviewed by the Trust Clinical Audit Department to confirm that you have given written informed consent to taking part in the study. Responsible individuals from the **University of Manchester** may also look at the research records to audit the conduct of the research. With your permission, we would also like to send information recorded from the focus groups to the UK Data Archive so that other researchers can use it in the future.

What are the possible risks of taking part?

Focus groups are a widely used method for exchanging views and experiences and giving feedback. However, we realise that talking about experiences of mental illness and of mental health services might be upsetting for some people. We will remind you that you do not have to answer any questions you do not want to.

You can leave the focus groups at any point if you feel upset. If you do feel distressed after the focus groups, you can contact the site Lead Researcher, **Professor Dawn Edge (tel: 0161 275 2570)**. If you are a current service user and feel distressed out of office hours, we suggest that you speak to your key worker or other relevant staff. We will also provide a list of organisations that are able to provide support to all participants. These include, for example, the Samaritans (08457 909090), Rethink National Advice Service (020 8974 6814) and SaneLine (0845 767 8000).

Are there any benefits of taking part?

We cannot promise that the study will help you directly, but your participation would possibly help us improve care and support for African service users with schizophrenia and their families. We also

believe that improving health professionals' knowledge and awareness of African and Caribbean communities and African and Caribbean people's knowledge about schizophrenia and understanding of health professional roles will improve relationships between staff and members of these communities. Ultimately, we hope this will lead to better outcomes for service users, reduce family stress and tension, and increase staff confidence.

Do I have to take part?

No. Taking part is entirely voluntary. It is up to you to decide whether or not to join the study. If you agree to take part, we will ask you to sign a consent form. If you are a service user or carer and do not wish to take part, this will not affect the standard of care and treatment that you or the person you care for receives.

What happens if I change my mind?

You are free to withdraw at any time, without giving a reason. If you withdraw, we would like to keep any information you have given up to that point. You can still ask to be updated about the study findings. Changing your mind will not affect the standard of care and treatment that you or the person you care for receives. In the unlikely event that you lose the capacity to give consent during the course of this study, you will be withdrawn from the study, but we will continue to use the information we have already collected. If you recover and wish to take part, we will do our best to make this possible if the study is still running.

Expenses and payments

Reasonable travel expenses will be paid in exchange for travel receipts. Permitted payments for service users, honorarium for carers and volunteers will be paid at £10 per hour (max £50 per session). 'Permitted payments' means that taking part in the study should not impact any benefits you receive.

What do I do now?

A researcher from the study will contact you in a few days. They will go through the information sheet with you and answer any questions you might have. This should take about 15 minutes. You can let them know if you are interested in taking part. They will give you more time to think about being in the study and, if you are interested in taking part, the researcher will ask you to sign a consent form to show that you are willing to take part. They will then explain what will happen next.

What do I do of something goes wrong?

If you have a concern about any aspect of this study, please ask to speak to the site Lead Researcher, **Professor Dawn Edge (tel: 0161 275 2570)**. who will do their best to answer your questions. If **Professor Edge** is unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Trial Manager who will contact the relevant research team or the mental health trust: **Helen Wilson (tel: 0161 276 3312).**

In the event that something goes wrong and you are harmed during the research, then you may have grounds for a legal action for compensation against the Greater Manchester Mental Health NHS Foundation Trust or the University of Manchester, although you may have to pay for your legal costs. The normal National Health Service complaints mechanisms will still be available to you. Please find further information on the NHS website: https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/.

Thank you very much for considering taking part in our research.
Please discuss this information with your family, friends or mental health team if you wish.

Please feel free to contact us should you require further information, clarification or advice on how to take part:

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