**APPENDIX 14AB: COMMUNITY BASED SURVEY**

**Estimating the prevalence, quality and life, economic and societal impact of arthritis in Tanzania: a mixed methods study**

**COMMUNITY BASED SURVEY**

**PARTICIPANT INFORMATION SHEET**

**Invitation to participate in a study of joint pain**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you decide to take part in this study, you will be given a copy of this Participant Information Sheet and the signed consent form to keep as your copy.

**What is the purpose of the study?**

The purpose of this study is to collect information, from patients admitted to hospital, about different types of joint pain that people experience.

**Who is organising and funding the research?**

The study is organised by the Kilimanjaro Clinical Research Institute (KCRI) under the Kilimanjaro Christian Medical Centre (KCMC) and funded by the UK’s National Institute for Health Research.

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

You have been invited to take part in this study because you are aged 5 years or above and you are a member of the community in Moshi Municipal or Hai where the study is taking place.

**Do I have to take part?**

No, Participation in this research is voluntary and you are not forced to. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

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

You wil be asked to complete a questionnaire and you will undergo a general examination of your joints and walking which will take under 2 minutes. If there are any abnormalities identified then you will undergo a more extensive examination to look at your joints but this will take less than 5 minutes. If there is any evidence that your joints are swollen or abnormal you will be offered the opportunity to have an ultrasound examination of the affected joint(s) to further investigate the problem. This will involve putting jelly on the surface over the affected joint and then rubbing a probe over the surface of the joint to get an internal “picture”. The ultrasound test will take place at the time or within the next 3 months. If this shows evidence of inflammation, with your permission, a blood sample would be taken for later analysis. Anything that is found on examination, ultrasound or blood tests that needs any treatment or advice will be fed back to you and referral will be arranged to appropriate local services if necessary.

**What would I be required to do?**

You would be asked to fill in a questionnaire, with assistance if required. You would also be asked to allow an examination of your joints and to walk a few steps. Some, but not all participants, will be asked to allow a more extensive examination of their joints. Some, but not all participants, will have an ultrasound examination. Of these participants, some but not all, will be asked to give a blood sample. You are free to end participation in the research at any point without having to give a reason and without this affecting your treatment.

**Are there any potential risks to taking part?**

The study poses minimal risks.  The research questionnaire and examination will take up some of your time. The examinations and ultrasound scan should cause little discomfort. If a blood sample is required, there may be a little discomfort and slight bruising. For most people the benefits of participation outweigh this risk.

**What are the possible benefits of taking part?**

You will receive no direct benefit from taking part in this study. However, the information that is collected during this study will give us a better understanding of joint pain in your communities and may help to improve its treatment. Participation also offers the chance to contribute to science and medical knowledge that may help you and others in the future.

**Will my participation be anonymous and confidential?**

We may be collecting and storing identifiable information from you in order to undertake this study. Some of this data will be transferred to the University of Glasgow. This means that the University is responsible for looking after your information and using it properly. We may keep identifiable information about you for 10-15 years after the study has finished and will not pass this information to a third party without your express permission.

Your rights to access, change or move the information we store may be 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 personally-identifiable information possible. You can find out more about how we use your information from the Principal investigator: Prof. Blandina Mmbaga at Kilimanjaro Clinical Research Institute Tel 0768 435 116.

Researchers from the University of Glasgow and KCMC collect, store and process all personal information in accordance with the General Data Protection Regulation (2018).

All study data will be held in accordance with UK The General Data Protection Regulation (2018)

The data will be stored in archiving facilities in line with the University of Glasgow retention policy of 10-15 year years. After this period, further retention may be agreed or your data will be securely destroyed in accordance with the relevant standard procedures.

Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data, including direct quotations from the interview, will form part of the study result that will be published in expert journals, presentations, student dissertations/theses (if applicable) and on the internet for other researchers to use. Your name will not appear in any publication.

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

Results from the study will be published in academic journals and presented at conferences. A summary report will be written and made available to Tanzanian authorities and research participants.

**Who is organising and funding the research?**

The study is funded by the UK’s National Institute for Health Research. The sponsor of the research is KCMC-KCRI.

**Who has reviewed the study?**

The project has been reviewed by the College of Medical, Veterinary & Life Sciences Ethics Committee at the University of Glasgow. It has also been reviewed by KCMUCo Local Ethical Review committee and by The National Institute for Medical Research in Tanzania.

**Questions**

You will have the opportunity to ask any questions in relation to this study before giving consent to participate.

**What should I do if I have concerns about this study?**

If you have and questions or concerns and or need further clarification about your participation, please contact Blandina Theophil Mmbaga +255768435116, email: b.mmbaga@kcri.ac.tz or Elizabeth Msoka +255 788 840 366, Email: e.fbright@kcri.ac.tz

For any ethical related questions please contact the ethical committee which has provided permission for the study; Kilimanjaro Christian Medical University College Ethics Committee Box 2240, Telephone+255-27-275-3909.

**Thank you for taking your time to read this information sheet and considering participating in our study**