



Participant Consent Form
A randomised trial of *Curcuma Longa* for treating symptoms and effusion-synovitis of knee osteoarthritis (CurKOA trial)

1. I acknowledge that I have received, read and understood the Information Sheet provided that explains this study to me and what is required of me if I choose to participate in this study.
2. The details of the procedure proposed have been explained to me, including how long it will take, how often procedures will be performed, and an indication of any discomfort which may be expected. I understand that my involvement means:
 - The possibility of an X-ray at screening
 - An ultrasound scan at screening and MRI at baseline and month 3;
 - Collection of a small amount of blood (approximately 9 mL) and urine (approximately 25mL) at baseline and at month 3. This is to assess markers of inflammation and cartilage degradation. The samples will be stored for analysis of these biomarkers;
 - Taking *Curcuma Longa* or placebo capsules each day for 3 months;
 - Answering questions about knee pain and function, quality of life, health and wellbeing, medication use and side effects. Some of these questions will be asked only once, and others monthly;
 - Measurement of height, weight and physical function measures (eg. 30s chair stand, 40m fast-paced walk and stair climb tests);
3. I understand that there are the following risks or possible discomfort:
 - Having blood taken causes minimal risk, but there may be a chance of discomfort and bruising;
 - I understand that ultrasound scans may be uncomfortable due to probe pressing on the knee joint, but are otherwise considered safe.
 - I understand that MRI scans may be claustrophobic, but are otherwise considered safe.
 - *Curcuma Longa* is considered a safe treatment, but diarrhoea and gastric irritation may be a possibility.
 - X-rays are associated with a small amount of radiation exposure
 - Although the physical tests will be conducted in a controlled environment to minimise risk there may be the possibility of injury during completion of these tasks.

4. I have been informed that if my ultrasound scan shows effusion or synovitis (fluid in the knee or swelling of the synovial membrane), I will be asked to continue in the study. If my scan does not show this I will not be asked to continue with the study.

By signing this form, I acknowledge that:

- I have received, read and understood the Information Sheet provided that explains this study to me and what is required of me if I choose to participate in this study.
- I understand that the purpose of this research project is to improve the quality of medical care, and that my involvement may not be of any benefit to me.
- I have been given the opportunity to have a member of my family or friend present while the project was explained to me.
- I understand that no identifying information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health.
- I also understand that I am free to withdraw from the project at any stage and any of my data/specimens that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.
- I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.
- I understand that the trial will be conducted in accordance with the latest versions of the *National Statement on Ethical Conduct in Human Research 2007* and applicable privacy laws.



CONSENT

Name of participant _____

Signature of participant _____ Date _____

The following section regarding the witness is not essential but may be appropriate for patients where the research teams feel that the participant should have a witness to the consent procedure or where the protocol insists upon witnesses.

Name of witness (if appropriate) _____

Signature of witness _____ Date _____

I have explained this project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator _____

Signature of investigator _____ Date _____