PARTICIPANT CONSENT FORM

DICKENS – A randomised controlled trial of diacerein to treat knee osteoarthritis with effusion-synovitis

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1. I acknowledge that the nature, purpose and contemplated effects of the project so far as it affects me, have been fully explained to my satisfaction by the research staff and my consent is given voluntarily.

2. The details of the procedure proposed have also been explained to me, including the anticipated length of time it will take, the frequency with which procedures will be performed, and an indication of any discomfort, which may be expected.

3. I understand that my involvement includes the following compulsory components:

   a. Providing researchers with my sex, date of birth and Medicare number.

   b. Having a assessment by a study doctor during screening to confirm I have clinically diagnosed osteoarthritis.

   c. Having a knee x-ray and MRI scan at screening and a repeat MRI scan at 24 weeks.

   d. Collection of a small amount of blood at screening, week 12 and 24 by a qualified venepuncturist to monitor my liver and kidney function.

   e. Measurement of height, weight and leg strength at baseline, 12 and 24 weeks if I attend these study visits in person. If I have a Telehealth appointment at these timepoints, I will be asked to self-report my height and weight.

f. Questionnaires about my knee symptoms, medical history, osteoarthritis treatments used, and medication usage at screening, baseline, weeks 4, 8, 12, 16, 20 and 24.

g. Questionnaires about treatment side-effects and overall satisfaction with the study treatment at weeks 4, 8, 12, 16, 20 and 24.

h. Questionnaires about my general well-being, how my symptoms impact on my life, quality of life, occupation, and depressive and anxiety symptoms at baseline, weeks 12 and 24.

i. Questionnaires about my employment, use of health services and the costs I have incurred due to medications, medical appointments, scans, transport, and specialised equipment purchased for my knee pain, and my concession/health care card and private health insurance status at baseline and week 24.

j. I understand I will need to take a capsule (that will contain either diacerein or placebo) daily for 24 weeks.

k. If I am woman of childbearing age and there is a possibility that I may be pregnant, I will need to do a urine test before I can start in the study.

4. Please tick the boxes below to indicate you agree to the following <u>optional</u> components:

a. I give consent for my medical records to be made available to study researchers from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) for the purpose of checking on any knee joint replacement surgery following study completion. YES ☐

b. I agree to have my blood samples stored for future testing which will help to determine if the study treatment is working. I have been informed that my blood samples and associated data may be distributed to other researchers, including researchers outside Australia, for this testing. I understand that I have a right to withdraw consent for the continued use of my blood samples (and data) at any time. YES ☐

5. I understand that there are the following risks or possible discomfort:

   a. I understand that a small amount of radiation exposure is associated with a knee x-ray; and that this amount of radiation is unlikely to be associated with increased risk of disease and is much less than the current National Health and Medical Research Council guidelines.

   b. Having blood taken causes minimal risk, but there may be a chance of discomfort, feeling faint and bruising.

   c. I understand that MRI scans may be claustrophobic, but are otherwise considered safe.

   d. I understand that diacerein treatment has side effects; and that serious side effects are rare.

   e. I understand that the study medication may cause a harmless change in my urine colour.

   f. I understand that caution must be taken when taking the study medication with drugs that modify intestinal transit (e.g. laxatives, excess fibres), certain antacids, and antibiotic and chemotherapy treatment.

   g. I understand that the study medication contains lactose.

   h. I understand that I should not donate blood while participating in this trial.

   i. I understand that the effect of the study medication on an unborn or breast fed baby is unknown and women who are pregnant or breastfeeding will not be able to take part in this study.

6. I have been informed that if my MRI scan shows joint inflammation I will be asked to continue in the study. If my MRI scan is normal I will not be asked to continue with the study.

7. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

8. I understand that the research gathered in this study may be published. I am informed that no 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.

9. 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 if I stop taking the study medication or need to withdraw from the study for any reason, I will be asked if I am willing to continue to attend the planned visits, tests and questionnaires up until the 24-week mark. I also understand I can decline to do this and that I am free to withdraw from the project at any stage and any of my data, blood samples and scans that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.

10. I understand that I will be given a signed copy of this participant information sheet and consent form. I am not giving up my legal rights by signing this consent form.

11. 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 _____

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

Name of investigator _____

Signature of investigator _____ Date _____

PARTICIPANT WITHDRAWAL FORM

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Declaration by Participant:

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with DICKENS staff.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher†
(please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing must date their own signature.

OPTIONAL FURTHER DATA COLLECTION

Participants who have been enrolled in the study for more than 4 weeks and who wish to withdraw from the study are requested to consider completing remaining study assessments.

Your enrolment date was _____, which means that you have been enrolled in the study for _____ weeks.

Please tick the boxes below to indicate IF you agree to the following optional components:

1. I am willing to complete the second MRI as soon after my withdrawal as is feasible. YES ☐
2. I am willing to complete the Week 24 online surveys when they become due YES ☐
3. I am willing to complete the other Week 24 Visit items, excluding the blood collection. This includes measuring my height and weight and my leg strength. YES ☐
4. I am willing to complete ALL remaining study assessments when they become due, which may involve answering multiple online surveys AND clinic visits, depending on the timing of my withdrawal. YES ☐

Name of Participant (please print) _____

Signature _____ Date _____

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____