Good day, my name is Carin Dreijer, I am an Occupational Therapist at Chris Hani Baragwanath Hospital, Occupational Therapy Department. I would like to invite you to consider taking part in a research study, entitled: The effects of a comprehensive Occupational Therapy intervention programme on the Occupational Performance of patients with Rheumatoid arthritis, living in Soweto.

Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions. This information is to help you to decide if you would like to take part. You should fully understand what is involved before you agree to take part in this study.

- If you have any questions, do not hesitate to ask me.
- You should not agree to take part unless you are satisfied about all the procedures involved.
- Please be completely truthful with me regarding your health history, since you may otherwise not benefit from participating in this study.
- If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will be given a copy to keep.

PURPOSE OF THE STUDY:
- You have been diagnosed as suffering from Rheumatoid Arthritis and I would like you to consider taking part in the research of a new programme that will aim to help you cope better with your arthritis at home.
- The purpose of this study is to determine if Occupational Therapy treatment in the hospital and at your house, will help you cope better with your every day tasks.

LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS
- Approximately 60 patients will participate in this study.
- The total amount of time required for your participation in this study will be a maximum of 1 week in hospital and 5 hours afterwards.
- You will be asked to visit me twice during the study. Both times will be on the same day as you come to collect your repeat medication.
- I will visit you once at your home during the study.

PROCEDURES:
At each following visit you will be required to fill out two questionnaires about how you cope with your daily tasks. You will also fill out a pain questionnaire.
- 1 week admission to C H Baragwanath Hospital
- Visit 1 month and 4 months later
You will be expected to
• Attend a group with other patients with similar problems. With your permission, this will be video taped to look at the information again afterwards.
• Have me visit your home to see how you are coping with your everyday tasks. I might need to take photos of your house while I am there.

BENEFITS OF THE STUDY:
• The potential benefit from your participation in this study may be that you will be able to cope better with your every day tasks at home, e.g. washing and cooking.
• However, you may not benefit from this study.

RIGHTS AS A PARTICIPANT IN THIS STUDY:
• Voluntary:
  Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not affect your access to other rehabilitation services.

REIMBURSEMENT FOR STUDY PARTICIPATION:
• You will not be paid to participate in this study but your transport and, when necessary, refreshment costs will be reimbursed adequately.

ETHICAL APPROVAL:
• This study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee.

SOURCE OF ADDITIONAL INFORMATION:
• For the duration of the study, you will be under the care of the rheumatology doctors as usual, but all OT treatment will be provided by myself. If at any time between your visits, you feel that you need to contact me, please do so. You can get hold of me at the C H Bara Hospital OT department: (011) 933 8294 / 933 9113

CONFIDENTIALITY:
• All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Neither your name nor any other identifying information will appear on any study document. You will only be identified by a code.
• Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.
• All group members will be expected to hold all information obtained during the focus group confidential. Group members can choose to use false names if they wish for their true identity not to be revealed.
• This information will be reviewed by authorised representatives of the hospital and University of the Witwatersrand.
• These records will be utilised by them only in connection with carrying out their obligations relating to this clinical study.

Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission.
INFORMED CONSENT:

- I hereby confirm that I have been informed by Carin Dreijer (OT) about the nature, conduct, benefits and risks of clinical study.
- I have also received, read and understood the above written information (Patient Information and Informed Consent) regarding the clinical study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Patient:

Printed Name     Signature or Thumbprint     Date and Time

I, Carin Dreijer (OT), herewith confirm that the above patient has been fully informed about the nature, conduct and risks of the above study.

Printed Name     Signature     Date and Time

Translator /other person explaining Informed Consent (Designation):

Printed Name     Name     Signature     Date and Time