Participant Information Sheet: Patient

Study title: Involving Medical Companions in an Explanation about Switching to a Biosimilar.

Locality: Auckland District Health Board

Ethics committee ref.: 19/CEN/163

Lead investigator: Professor Keith Petrie

Contact phone number: (09) 923-6564

You are invited to take part in a study on how we can explain biosimilars to patients and their support person. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study anytime without giving reasons.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form. You will be given a copy of the Participant Information Sheet to keep. This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

You are invited to take part in a study examining how we can explain switching to biosimilars to patients and occasionally also their companions, because you are taking a biologic medicine (such as Humira, Enbrel, infliximab, rituximab or tocilizumab). A biosimilar is an almost identical copy of a biologic medical product that is manufactured by a different company.

This is a study based on a hypothetical situation and does not mean that your doctor is thinking of changing your treatment. The aim of the study is to explore how biosimilars can best be explained to patients who are taking biologics, and their companions.

This research is funded by the Department of Psychological Medicine at the University of Auckland as part of a PhD in Health Psychology. Professor Keith Petrie (contact details above) or Chiara Gasteiger (cgas770@aucklanduni.ac.nz) can be contacted to answer any questions.
**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

You have been invited to participate because you are currently being treated using a biologic. This is a hypothetical study and based on this study there is no intention of changing your treatment. Taking part in this study will involve participating in one 30-40 minute session. This study involves completing a few questionnaires and giving some background information on your treatment.

The researcher will then give you a short verbal explanation on biosimilars and you will be asked to answer some questions about the explanation. If you are hearing the explanation with your companion, you can also discuss the hypothetical decision.

The questions asked are simple and we appreciate your honest answers. There are no right or wrong answers.

Through your involvement in the study you will contribute to our understanding on how doctors can best explain medicines to patients in the future, and how companions can be included in this discussion.

**WHAT ABOUT MY MEDICAL RECORDS?**

If you provide consent, the student researcher and supervisors may access your clinical records, such as to find out the name of your biologic treatment or health condition.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

This intervention is considered low risk so researchers do not expect you to experience any kind of risk.

This study will not change your current medication. However, if you are worried about a change in treatment you can contact the researchers (information is below) or talk to your doctor.

**WHO PAYS FOR THE STUDY?**

You will not incur any financial costs due to participation in this study. As a thank you for your time involved you will receive a $20 voucher.

**WHAT ARE MY RIGHTS?**

Participation in this study is completely voluntary. You are free to decline to participate.

If you choose to take part, you can leave the study at any time (you can also keep the gift-voucher) without giving a reason. Whether or not you participate in this study will not affect your relationship with your healthcare provider or your future health care.

You will be given a copy of this document to keep.

Your data will not affect the decision made in your future healthcare.

The data you provide will not be recorded in or linked to your clinical record.

You can ask questions about the study and can contact the student researcher Chiara Gasteiger or co-researchers of this project through their details at the bottom of this sheet.

All private information will remain strictly confidential and no material that could identify you will be used in any report on this study. Your name will only appear on the consent form, which will be coded with a participant identification number so that your identity is kept private.

Only the student researcher and supervisors will access the data.

Publications and presentations on the study will not contain any information that could identify you.
WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

You can also request that the data you have provided is withdrawn until two weeks after taking part in the study. To withdraw your data, please contact the student researcher (Chiara Gasteiger). A summary of the results of this study will be sent to you if you want. As it takes time to analyse the data, it can take more than a year after participation that the summary of the results will be sent to you.

Questionnaires and consent forms will be kept in a locked filing cabinet in the researcher’s office at the University. The final dataset and some other documents may be shared on an Open Science platform, but it will not include information that can identify you.

When the study is finished, all private data (including computer files) will be kept for 10 years, after this time it will be disposed of.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Professor Keith Petrie, Supervisor/Principal Investigator, Department of Psychological Medicine  
(09) 923-6564  
kj.petrie@auckland.ac.nz

Chiara Gasteiger, PhD candidate in the Department of Psychological Medicine  
021 144 8735  
cgas770@aucklanduni.ac.nz

Professor Nicola Dalbeth, Rheumatologist, Department of Medicine  
(09) 923-2568  
n.dalbeth@auckland.ac.nz

Professor Urte Scholz, Head of Applied Social and Health Psychology Unit, Department of Psychology, University of Zurich  
urte.scholz@psychologie.uzh.ch

Professor Sally N. Merry (Head of Department)  
(09) 923-6564  
s.merry@auckland.ac.nz

If you require Māori cultural support contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 42324

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz
Consent Form

- I have read and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
- I understand that the scenario in the study is hypothetical and will not affect my treatment.
- I understand that I will hear the explanation alone or with my medical companion (support person) and that this decision will be by chance.
- I understand that my choice to/not to take part in this study will not affect my relationship with the researcher or with my healthcare provider.
- I understand that I can withdraw my data until two weeks after I have provided it without giving a reason.
- I understand that the study will take 30-40 minutes.
- I understand that all my information will be kept private and no material that could identify me will be used in any report on this study.
- I understand that the results of the study may be published/presented but will not include information that could identify me.
- I understand that the data will be stored for 10 years after which it will be disposed of.
- I understand that only the researcher and supervisor will access the data.
- I am aware that taking part in this study rewards me with a $20 voucher.
- I know who I can contact if I have any questions about the study.
- I give permission to the researcher and supervisors to access some information recorded in my medical file, such as the name of my treatment or health condition. YES ☐ NO ☐
- I wish to receive a summary of the results from the study. YES ☐ NO ☐

My email is: ________________________________

My address is: ________________________________
Declaration by participant:

I hereby consent to take part in this study.

Participant's name: 

Signature: Date: 

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: 

Signature: Date: