CCST Christchurch Clinical Studies Trust

PARTICIPANT INFORMATION SHEET AND CONSENT FORM STUDY

Short Title	A study assessing the similarity of Actemra®, RoActemra® and the trial drug MSB11456.
Protocol Number	MS200740-0001
Project Sponsor	Merck KGaA Darmstadt, Germany
Principal Investigator	Dr Chris Wynne
Associate Investigator(s)	CCST Study doctors on 03 372 9477
Location	Christchurch Clinical Studies Trust. 31 Tuam St. Christchurch **Ethics Number 17/CEN/183**

You are being asked to take part in a clinical study comparing Actemra®, RoActemra® and the investigational drug MSB11456, under development by Merck KGaA ('Merck'). MSB11456 is experimental, which means it has not been approved by any regulatory agency in New Zealand or overseas. Experimental drugs may only be tested in research studies like this one.

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. We expect this will take about 30-60 minutes. You may also want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. This will not affect your relationship with those treating you or with Christchurch Clinical Studies Trust.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

Why is this study being done?

Tocilizumab is a medicine made by another drug company and sold under the brand names Actemra® or RoActemra®. It is a medicine in the class known as 'Monoclonal Antibodies' which are special proteins and resemble a part of the body's natural immune system. Tocilizumab is able to reduce overactive inflammation in the body by blocking some of the signaling pathways which become active in disease. This medicine is used in many countries as a treatment for a condition causing painful joint inflammation known as Rheumatoid Arthritis.

Merck has developed an investigational drug designed to be similar to Actemra® and RoActemra®, called MSB11456. This study aims to test MSB11456 to make sure that it is similar to Actemra® and RoActemra®, in terms of safety, side effects, levels of the drug in the blood over time and ability to reduce inflammation in the body.

How is the study designed?

This study is being conducted at two clinical trial units in New Zealand, and will compare MSB11456 with Actemra® and RoActemra® in up to 474 healthy adults. The study requires a 4-night stay (may be reduced to 3 nights) at CCST and a number of clinic visits.

Every person in the study will receive one 162mg dose of either MSB11456 OR US-licensed Actemra® OR EU-approved RoActemra®. The dose will be given as an injection under the skin in the lower abdomen.

The study drug you receive will be assigned randomly (by chance). You have a 1-in-3 chance of getting MSB11456, a 1-in-3 chance of getting Actemra® and a 1-in-3 chance of getting RoActemra®. You will not know which drug you get, but your study doctor can find out in an emergency.

As a safety measure, the study drug will be administered to the first 9 subjects in separate staggered groups at Auckland Clinical Studies, starting with an initial group of 3 participants. The second group will comprise another 3 participants, the third group a further 3 participants. Between each of these groups the safety of the study drug will be assessed before proceeding to the next group. After the first 9 participants have been observed a decision will be made if enrollment can proceed. Your study doctor will inform you if you are a part of this group.

Blood samples will be collected at specific times after dosing. The amount of study drug in the blood will be measured, and safety assessments will be done regularly. Any changes in your health during the study will also be recorded.

Study funding

Merck, a drug company, is funding this clinical study. Merck is the "Sponsor" of the study, which means it is responsible for starting, managing, and conducting the study.

By taking part in this research project you agree that samples of your blood (or data generated from analysis of these materials) may be provided to Merck. Merck may benefit financially from this research project or from knowledge acquired through analysis of your samples eg. if the project assists them to obtain approval for a new drug. There will be no financial benefit to you from these discoveries.

Christchurch Clinical Studies Trust. will receive a payment from Merck for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Approval by ethics committee

All research in New Zealand involving humans is reviewed by an independent group of people called a Health and Disability Ethics Committee (HDEC). An HDEC has reviewed and approved this study. This means that the Committee may check that the study is running smoothly and that the study is following appropriate ethical procedures.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What would your participation involve?

You will be in this study for about 7 weeks (plus a screening period of up to 5 weeks). This includes a 4-night stay (may be reduced to 3-night stay) at CCST and 8 clinic visits. If you become unwell, or the study doctor is concerned about any of your blood tests or assessments, you may be asked to schedule extra visits. You will be monitored throughout the study for any changes in health (whether or not you think they are related to the study drug), and for any medication use. The day you have your dose of study drug is called Day 1 and all other study days are named with reference to this dosing day.

The first visit to the study site will be your screening visit. You will go through this information sheet with study staff and be given a chance to ask any questions you may have regarding the study. If you decide to take part, you will be asked to sign and date this form.

Once the consent form is signed you will have a number of assessments. These tests are listed on the next page. If you do not want any of the tests done, you should not take part in this study.

The results of the screening assessments will determine whether or not you can take part in the study. However, depending on the type and objectives of the study, even if all your results are normal, you may not be guaranteed a place. We may screen more participants than we need and so you may be asked to be a reserve. This will mean you will be asked to come to the clinic and undergo the tests and procedures until the point that we have enrolled enough eligible participants. You will then be discharged and where possible we will try to include you in a later group.

You will be told if you can take part when all your screening tests have been checked.

To take part in this study, you must:

- Be aged 18 to 55 years;
- Weigh 60 – 100 kg and be a normal weight for your height;
- Not smoke more than 10 cigarettes per day (if you are a smoker);
- Be willing to stick to the study rules and restrictions, including birth control requirements;
- Be in good health, and pass all the screening assessments.

You can't be in the study if you:

- Have any history of any significant medical problems or mental health problems;
- Have any history of significant asthma, eczema or allergy (including any allergy to latex);
- Have a history of tuberculosis or any significant invasive or opportunistic infections;
- Have a history of diverticulosis (disease of intestine) requiring antibiotic treatment;
- Have any history of alcohol abuse;
- Are pregnant or breastfeeding.

There are other requirements for taking part in this study. CCST staff will discuss these with you.

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	Screen Visit	Treatment Period											End of Treatment Visit [a]	End of Study Assessment
		Day -1	Day 1	Day 2	Day 3	Day 4	Day 5	Day 8	Day 11	Day 15	Day 18	Day 22	Day 29	Day 48
Clinic Visit	X						X	X	X	X	X	X	X	X
Inhouse Stay		←	—	—	—	→								
QuantiFERON-TB test	X													
Informed Consent	X													
Medical history / review	X	X												
Height and weight	X	X												
Physical exam	X	X				X								X
Vital signs [b]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ECG (tracing of the heart's electrical activity)	X	X	X											X
Blood samples[c]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urine tests	X	X						X			X		X	X
Hepatitis B&C, HIV tests	X													
Drug, & alcohol screens	X	X												
Pregnancy Test	X	X											X	X
Hormone Test	X													
Study Drug Dose			X											
Injection site assessment			X	X	X	X	X	X	X	X	X	X	X	X

a. If you leave the study early for any reason, you will be asked to undergo the final visit assessments and injection site check.

b. "Vital Signs" means measurement of your pulse, blood pressure and temperature.

c. You will have 4 sets of blood samples collected on Day 1 including before dosing, then 2 hours, 8 hours and 12 hours after dosing

Are there any medication restrictions for this study?

No prescription medicines, over-the-counter medicines, herbal remedies or vitamin therapies are allowed, from 7 days before your first dose of study drug through until the end of the study. The only exceptions are occasional paracetamol (up to 2g/day) (Panadol), vitamins and minerals (at study doctor discretion) and hormone replacement therapy.

A study doctor will discuss your previous and current medications with you at your screening visit, as there are other medication restrictions for this study.

Please do not take any new medicines during the study until you have talked to a study doctor.

Study instructions

- During your in-house stay, you will not be allowed to leave the study site if you wish to remain in the study.
- During your in-house stay, you may only have food and drinks provided by CCST. Meals are standardised, which means you do not get to choose what you eat.
- Standardised meals are a crucial element of a clinical trial due to its relationship with metabolism of investigational product. By signing this document, you are agreeing that you will be compliant with all meal requirements on this study. You are acknowledging that you understand you may be withdrawn for non-compliance with meal requirements.
- Vigorous exercise should be avoided from 72 hours prior to study drug dosing and until 8 days postdose. Vigorous exercise should also be avoided for 24 to 48 hours before all study visits. Contact sports should be avoided during the entire study
- Dr Wynne may request a random check of your bags at admission for prohibited items.
- No alcohol is allowed for 48 hours before the dose of study drug until Day 8 post-dose
- After Day 8 you are discouraged to consume alcohol until the completion of the study but may consume no more than 1 unit per day (1 unit = 10g of pure alcohol & is equivalent to 330 ml beer, 100ml wine or 30 ml spirits
- No caffeine or caffeine containing products are allowed within 24 hours of study drug dosing.
- Foods containing poppy seeds should be avoided from 3 days before screening and 3 days before clinic admission.
- You will need to fast (have no food or drink except water) for at least 8 hours before some clinic visits. Study staff will let you know when this is required.
- At each visit, the study staff will ask you questions about your health and the medications you are currently taking. You should always report any changes in your health, unusual feelings or symptoms to the study staff. It is also important that you do not start, stop or make changes to any of the medications you are currently taking without first discussing this with your study doctor.
- You will be given a Subject Identification Card if you participate in this study, stating the name of the study and the study doctor's contact information. This card should be carried with you at all times so that you can contact the study doctor at any time and so you can show it to any other doctor or dentist that you might visit while in this study
- CCST will also contact your GP about your study participation. A study doctor may need to talk to him/her about your medical history to check you are able to take part in the study.

What will happen to my test samples?

At outpatient visits, blood samples are taken by direct vein puncture. During your in-house stay, a cannula (small plastic tube) will be put in a vein in your arm. The cannula will be used to collect blood samples more easily. If that cannula stops working, direct vein punctures will be used.

Blood and urine samples collected during the study will be used:

- To monitor your safety;
- To screen for drugs of abuse / hepatitis and HIV;
- To screen for pregnancy / menopausal status (if applicable);
- To measure study drug levels and the effects of the drug on your body;
- To see your body's immune response against the drug
- To develop the test needed to measure your body's immune response against the drug

It is possible that a test may give an unexpected result that could be important in terms of your health. These tests may be repeated for confirmation. The results will be discussed with you and your GP and appropriate follow-up will be arranged through your GP. If you return a positive test for hepatitis or HIV a study doctor will arrange follow-up, but is also required by law to report the result to the Ministry of Health.

The total amount of blood taken for the study will be approximately 403 mL. As a comparison, a standard blood donation is about 470 mL.

Your safety samples (blood/urine) will be tested at your local sites' laboratory located within New Zealand and destroyed after 3 months by internationally accepted means eg incineration. Other samples will be sent overseas to Sponsor-approved laboratories in Singapore and USA, for testing and storage.

The overall volume of blood collected for other samples at a determined visit can be used interchangeably to ensure all study assessment for this visit can be conducted (in case volume available for a sample is not enough to conduct the analysis)

During the study, your samples will be used to evaluate how safe and well-tolerated the study drug is, how your body reacts to it and how the study drug is processed by your body. Your name will not appear on the samples. Rather, your samples will be identified by your study subject number.

Samples and, if applicable, generated and collected data may be re-analysed in the future by the sponsor or its affiliates, subsidiaries, designees, collaborators, partners, or third parties, potentially using new technology. This applies for any analytes (molecules, for example, proteins) that are measured in the scope of the study. There is no time limit on this. Samples can be reanalysed for a maximum of 10 years after closure of the program. For re-analysis of generated data, no time limit applies. By signing this consent form you give us permission to re-analyse the samples and data.

The Sponsor reserves the right to destroy your sample(s) for any reason during the storage period without further notice.

If you withdraw from the study, any stored samples will be kept for testing, except in cases where you explicitly withdraw your consent also from the further use of your samples as outlined above.

We understand that many Māori consider their blood to be tapu and that participation in this type of study requires careful consideration. Should you have any concerns regarding appropriate practice/ tikanga arising from your participation in the study you may wish to discuss these concerns with a kaumatua or whanau member. CCST respects the importance of these values and beliefs so please inform us is you wish to have whanau support present or perform a karakia when donating this blood sample.

What could happen to me by giving these biological samples?

There is a risk that if people other than the researchers get your medical and genetic information they could misuse it. The investigator has strict privacy and confidentiality protection procedures to prevent this from occurring so the chance of this happening to you is extremely small. To help prevent others from finding out anything about you, your name and other information that directly identifies you will not be included with your sample or your medical and genetic information.

What are the risks of Actemra® / RoActemra® / MSB11456?

In a study like this one, every risk or side effect cannot be predicted. Each person's reaction to a study drug, device or procedure may be different. You may have a side effect or be at risk for symptoms, illnesses and/or complications that could not be predicted by your study doctor or the sponsor of this study. If such side effects occur, you must inform your study doctor immediately.

Actemra® or RoActemra® are used in many countries around the world, including New Zealand. We do not yet know what side effects MSB11456 has, but it is expected that they will be similar to the side effects seen with Actemra®/ RoActemra®.

Common side effects (reported in 1% – 10% of people taking the drug) include:

- Abdominal pain/ Stomach inflammation;
- Redness or pain at the drug injection site (see 'Injection Site Reactions' below);
- Headache;
- Upper respiratory tract infections
- Nasopharyngitis (common cold)
- Mild to moderate changes in some blood tests, that went away when the drug was stopped and were not associated with any symptoms;
- Inflammation of the front part of the eye (conjunctivitis)
- High blood pressure
- Mouth ulcers
- Infections
- Cough/ Shortness of breath

Because of the way Actemra®/ RoActemra® works, some people are at risk of opportunistic infections or reactivation of latent viral infections which can cause cold sores (Herpes simplex), Shingles (Varicella zoster), Liver inflammation (Hepatitis B) or Tuberculosis. If you have a history of any of these infections or test positive for evidence of infection at screening, you will not be able to take part in this study. Your health will be monitored closely throughout the study for any infections.

Some rare / very rare but serious side effects have also been reported. These include:

- Inflammation of the large intestine (diverticulitis)
- Serious infections
- Formation of small stones in the kidney which may cause pain and blood in the urine
- Reduced function of the thyroid gland which regulates body metabolism
- Formation of a hole in the stomach or intestines which can lead to serious infection

Some medications which interact with the immune system can increase the risk of serious side effects occurring. The risk, including the long-term risk of these side effects is not known for Actemra®/ RoActemra® or MSB11456.

- Some types of malignancy (cancer) occur more commonly in people with Rheumatoid Arthritis, however it is not known if patients being treated with Actemra®/ RoActemra® are at any higher risk.
- Some monoclonal antibodies have a small risk of a serious side effect on the nerve cells in the brain and spinal cord. This can affect how well the nerve cells are able to transmit messages to other nerves and muscles.
- It is not known if certain types of vaccine are safe to give with tocilizumab. If you have received a vaccine of any kind within 12 weeks of the screening visit you must tell the Study Doctor. You will not be able to participate in the study if you have had a vaccine, or plan to have one during the follow up period.

Occasionally, people have allergic reactions (including serious life-threatening reactions) to medications. Allergic reactions, including serious reactions, have been reported rarely with Actemra®/ RoActemra®. Symptoms of an allergic reaction may include:

- Rash, hives, or itchy skin;
- Shortness of breath or wheezing;
- Sudden drop in blood pressure;
- Swelling around mouth, throat, or eyes;
- Fast heartbeat;
- Sweating.

What are the risks or side effects of study procedures?

Blood Sample Collection & Cannulas. Risks include bruises, swelling with itching, and slight bleeding. The area may become inflamed. In rare cases, it may result in a blood clot or an infection. As needles can cause pain, you may feel weak or faint.

In rare cases, inserting the needle can cause injury to a nerve. Normally these problems clear up after a while. You are closely monitored and checked for these or other symptoms and we will take appropriate measures if they occur.

ECG Tests. Sometimes the sticky pads used to attach the ECG leads can cause skin irritation (redness / itchiness).

Injection Site Reactions. Injection site reactions can occur when a drug is administered as an injection under the skin in the lower abdomen. This reaction is typically a bruise or reddened area and normally disappears within a week. You may also experience mild pain or swelling at the injection site. In some cases, more

significant skin reactions have occurred at the injection site including skin lesions with redness and thickening. Those effects could last a few weeks or longer.

Does the study drug affect fertility or unborn children?

For women: The risks to a pregnant woman, an unborn baby or a nursing child from the study drug are not known and may be hazardous. If you are a woman who is pregnant or intend to become pregnant, or if you are currently nursing (breastfeeding) a child, you cannot be in this study.

If you are able to have children you will be asked to take several pregnancy tests before and during the study. You must also be using one of the following forms of birth control, starting at least 4 weeks before your first dose of study drug. You must continue to use one of these methods of birth control until at least 3 months after your last dose of study drug.

Effective birth control methods acceptable for this study include:

- Hormonal birth control (e.g. pills or injections);
- IUD (intra-uterine device, including hormone releasing devices such as the Mirena);
- Bilateral tubal ligation (both tubes tied);
- Partner with a vasectomy that has been confirmed to be successful;
- Abstinence (not having sex at all).

For men: We do not know if the study drug will affect sperm or semen so you should not father a child during this study or for 3 months after treatment. If your partner is able to become pregnant, you must use condoms and have your partner use an effective birth control method during the study and for 3 months after your last dose of study drug. Effective birth control methods acceptable for this study are listed above.

For men and women: If you or your partner becomes pregnant during the study, you should immediately report the pregnancy to the study doctor. A study doctor will refer you to seek obstetric care, and will request to track you / your partner's pregnancy and report the outcome, including that of your infant, to the Sponsor and the Ethics Committee.

Are there any benefits in taking part in this study?

There are no direct health benefits to you in taking part in this study. Information from this study may be used to further develop MSB11456.

Reimbursement for participation.

A payment of $3,800 less tax will be made after you complete the study, to cover your time and inconvenience. This amount is based on you completing all study visits as scheduled. You will be reimbursed for reasonable travel, parking and other expenses associated with the clinical research study visits (any unapproved travel costs will be deducted from your final study payment unless by prior arrangement with CCST management).

If you are receiving a benefit or allowance from a government agency, your usual payments may be affected. Your tax statement will state that you were paid from your dosing day through to your final study visit.

If you are withdrawn from the study for medical reasons, having received trial medication, you will receive payment in full. If you leave the study of your own choice, or are released from the study for non-medical reasons, you will be paid according to how far you contributed to the study. If you complete all of the screening visit assessments and are not found eligible for the study, you will not receive any payment.

What happens if I have any ill effects from the study?

If you were injured as a result of treatment given as part of this study, which is unlikely, you **won't** be eligible for compensation from ACC. However, compensation would be available from the Sponsor in line with Medicines New Zealand industry guidelines. We can give you a copy of these guidelines if you wish.

You would be able to take action through the courts if you disagreed with the amount of compensation provided.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What will happen to my information?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your name, address or phone number will not be on the study forms; instead you will be identified by a unique study number, date of birth and initials. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project may be shared during the study and after the end of the study, with the relevant authorities (such as the Ethics Committee that has reviewed and approved this study, government or regulatory health authorities, including the US Food and Drug Administration (FDA), auditors) Sponsor (Merck), its affiliates, representatives assisting with the study research, third parties working with the Sponsor on the development of the compound including the central laboratory, study monitors, Christchurch Clinical Studies Trust or as required by law. All personnel reviewing your medical records will be required to keep the information confidential in accordance with law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. The information from the study may also be sent to regulatory authorities or health insurers in your country or other countries where regulatory approval or payment for the medication is required. In any publication and/or disclosure, information will be provided in such a way that you cannot be identified, except with your permission, unless necessary for the vital interests of your safety.

Data generated in this study may be made available for use in future research. This data would not identify you.

In accordance with the European Federation of Pharmaceutical Industries and Associations and the Pharmaceutical Research and Manufacturers of America's "Principles for Responsible Clinical Trial Data Sharing", the Sponsor will provide qualified researchers on their request with data from this study. Your data will be coded to adequately protect your identity. Sponsor will require the researchers to take adequate measures to protect your data from unauthorized use, disclosure, and access, as well as requiring researchers to promise not to transfer the data to third parties and not attempt to re-identify you.

Information about your participation in this research project may be recorded in your health records.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored using measures which follow the requirements applicable in your country for the protection of your personal information. It will be disclosed only with your permission, or as required by law.

In accordance with relevant New Zealand privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Results from studying samples in this study may lead to discoveries and inventions or other benefits (eg. patents). The rights to these will all belong to Merck.

For safety reasons, to ensure you have not participated in another recent early phase clinical trial we will be sharing limited demographic data (your initials and date of birth) with other research facilities in New Zealand, including Auckland Clinical Studies LTD (ACS)

What do I do if I want to pull out of the study?

Taking part in this study is entirely your choice. If you do take part, you are free to withdraw at any time without having to give a reason.

Please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing, such as follow up visits.

Information and samples collected up until your withdrawal from the study will continue to be used and the results will be included in the study. This is to protect the quality of the study, and to make sure the safety of the study drug is properly assessed. If you do not wish for your information and samples to be used once you withdraw, you should not take part in this study.

You may also be withdrawn from the study even if you want to continue. For example, you could be withdrawn from the study because:

- The Principal Investigator believes it is in your best interest for you to stop taking part, or;
- You do not follow study instructions, or;
- Merck stops the study for any reason.

If you wish to leave the study early, please tell a member of the study staff. You may be asked questions about your experience while you were in the study, or be asked to have follow-up tests.

Can I find out the results of the study?

When the research project ends the study data must be analysed, so the results of the study may not be available until about a year after the research finishes. The study doctors and/or Merck may decide to discuss or publish the results of the study. This may include publication in journals, presentation at conferences or

other professional forums. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

Who do I contact if I have a question or complaint?

The Principal Investigator, Dr Chris Wynne or study staff will answer any questions you have about this research or about taking part in the study.

You can ask questions at any time by contacting CCST:

Call 03 372 9477

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

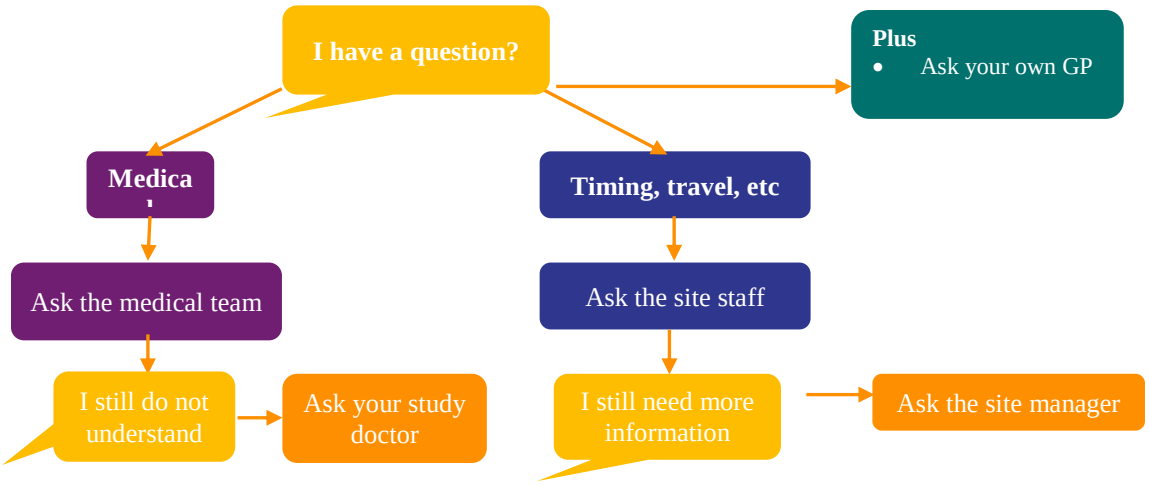
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

Māori cultural support is available through:
Pete Mason, Co-Director, Connections 'Ngà Kete E Rua' Phone 03 358 7990 or 027 4414 312.

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

Phone: 0800 4 ETHICS (438 442)
Email: hdecs@moh.govt.nz

What about any other questions I might have?

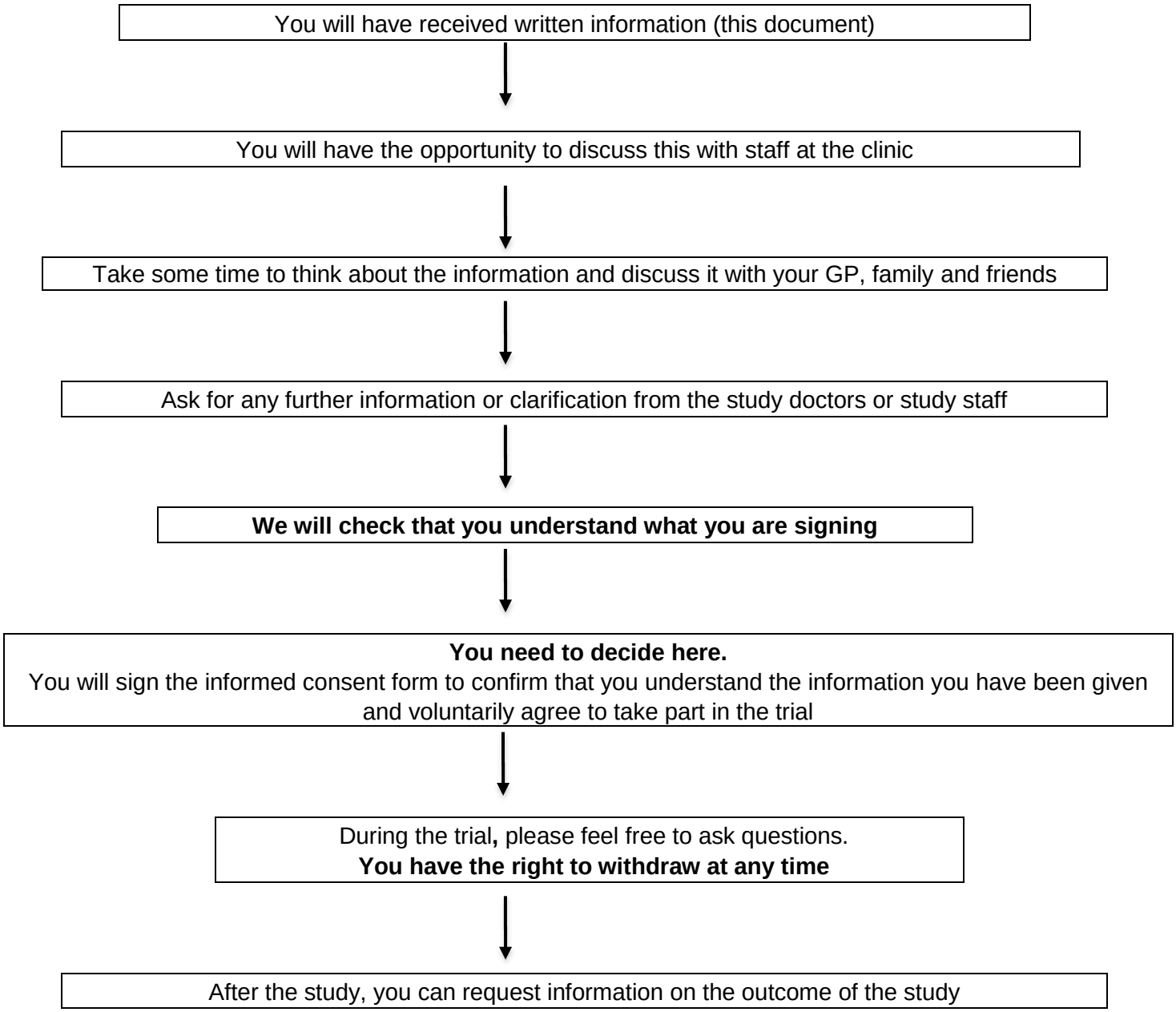


Do I have to decide straight away?

No, you do not have to decide straight away. You should take some time to consider whether or not to participate, we will be in touch in a week or so to discuss your decision**.** The following steps are useful in helping you reach a decision.

DO I HAVE TO DECIDE STRAIGHT AWAY?

No, you do not have to decide straight away. You should take some time to consider whether or not to participate**.** Study staff will let you know when they will need your decision. The following steps are useful in helping you reach a decision.



CONSENT FORM

Short Title	A study assessing the similarity of Actemra®, RoActemra® and the trial drug MSB11456.
Protocol Number	MS200740-0001
Principal Investigator	Dr Chris Wynne

***Please let study staff know if you require an interpreter*.**

Declaration by participant:

- I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study.
- I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the 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 consent to the research staff collecting and processing my information, including information about my health.
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.
- I agree to my samples being sent overseas and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.
- I will receive a summary of the results from the study if I wish.
- I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

Statement by Participant	I hereby consent to take part in this study. I understand that I will receive a signed copy of this consent form for my records. _____ (full name) _____ (signature) __ __ / __ __ __ / __ __ __ __ (**Date DD/MMM/YYYY)** Time 24hr Clock __ __: __ __

Statement by Consenter (Investigator/designee)	I have discussed this study with the above-named participant. The participant appeared to fully understand the information provided about the study. _____ (full name) _____ (signature) _____ (project role) __ __ / __ __ __ / __ __ __ __ (**Date DD/MMM/YYYY)** Time 24hr Clock __ __: __ __