PARTICIPANT INFORMATION SHEET & CONSENT FORM STUDY CMX001-125

A study to examine the safety and tolerability of multiple doses of the trial drug Brincidofovir in healthy adults.

FORMAL TITLE:	**A Phase 1, Randomized, Double-Blind, Placebo-Controlled Multiple Ascending Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Brincidofovir Administered Intravenously in Healthy Adult Subjects**
SPONSOR:	**Chimerix, Inc. 2505 Meridian Pkwy, Suite 100, Durham, NC USA 27713**
STUDY DOCTOR:	**Dr Christopher Wynne**
STUDY SITE:	**Christchurch Clinical Studies Trust (CCST)** **31 Tuam Street, Christchurch, New Zealand** **Telephone 03 372 9477 (24 hours)**

You are being asked to take part in a clinical study of the investigational drug Brincidofovir (BCV, CMX001), developed by Chimerix, Inc. BCV 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 consent form gives you important information about this study to help you decide if you want to take part. It tells you about the purpose of this study, study procedures, possible risks, and gives information about your rights.

Please read this information carefully. You should talk to Dr Wynne or the study staff about this study and ask any questions you have. You can also discuss this study with other people, such as your whanau or your general practitioner (GP). If you decide to take part, you will be asked to sign and date this form. You will be given a copy of the signed form for your records.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Taking part in this study is voluntary. You are free to say yes or no, or to change your mind and pull out of the study at any time. If you decide to leave the study, the study staff will ask you why you want to leave the study. You may leave the study without giving the reason.

You will not get any health benefit from the study drug; but there are risks of you having a drug reaction, injury or illness. If you have medical/health insurance, check with your insurer that taking part in this study will not invalidate or restrict the terms and conditions of your policy.

STUDY FUNDING

Chimerix, Inc., a drug company, is funding this clinical study. Chimerix, Inc. is the "Sponsor" of the study, which means it is responsible for starting, managing, and conducting the study. CCST is paid by Chimerix, Inc. to do this study.

Why is this study being done?

BCV is being developed for the prevention and treatment of clinically significant infection and disease caused by dsDNA viruses with high-unmet need, such as cytomegalovirus and adenovirus in adult and pediatric transplant patients, and as a possible medical countermeasure against smallpox.

Thus far, doses have been given by mouth as a tablet or liquid or as a single dose intravenous (IV) infusion. There is a medical need to develop an IV product, which may reduce the gastrointestinal side effects seen after taking the drug orally.

This study will be the second study where BCV has been given through an intravenous infusion.

How is the study designed?

The study will include approximately 28 healthy adult volunteers.

Every person in the study will take four doses of study drug by intravenous infusion. Your first dose will be on Day 1. This study is a multiple dose escalation study.

This means that the first group of study participants (Cohort 1) will be assigned randomly (by chance) to receive four doses of 10 mg of BCV (the lowest dose of the study drug) or placebo. Placebo is a dummy drug with no active ingredients inside.

In Cohorts 1, three study participants will receive study drug, and one study participant will receive placebo (i.e., you have a three out of four chance of receiving the study drug).

In Cohorts 2a, 2b, and 3, six study participants will receive study drug and two study participants will receive placebo (i.e., you have a three out of four chance of receiving the study drug).

The following doses are planned for participants in this study. The planned doses may be adjusted based on safety results from the previous cohort of participants.

Cohort	Number of Participants	Planned Doses
1	3 study drug 1 placebo	IV BCV 10 mg or IV placebo administered over 2 hours, twice weekly for 4 doses
2a	6 study drug 2 placebo	IV BCV 20 mg or IV placebo administered over 2 hours, once weekly for 4 doses
2b	6 study drug 2 placebo	IV BCV 20 mg or IV placebo administered over 1 hour, once weekly for 4 doses
3	6 study drug 2 placebo	IV BCV 20 mg or IV placebo administered over 1 or 2 hours, twice weekly for 4 doses

Levels of the study drug and its breakdown products will be measured in blood samples collected at specific times after dosing. The effects of the study drug on certain blood markers will be looked at. Any changes in your health during the study will be recorded.

Who can take part in the study?

To take part in this study, you must:

- Be aged 18-70 years old and weigh at least 50 kg
- Women must be of non-childbearing potential
- Men must be vasectomized
- Be willing to stick to the study rules and restrictions, including birth control requirements;
- Pass all the screening assessments.

You can't be in the study if you:

- Have a positive test for drugs of abuse
- Have HIV, Hepatitis C or Hepatitis B
- Have donated more than 500 mL of blood or plasma within 30 days before you are enrolled in the study;
- Have an acute illness (for example a cold, flu or fever) or are taking prescription drugs
- Have a history of heart disease, cancer, or liver disease
- Have had your gallbladder removed
- Have a history of tobacco or nicotine use within 6 months

There are other requirements for taking part in this study. Your study doctor will go over these with you.

Are there any medication restrictions for this study?

- No prescription or over-the-counter medicines are allowed within 14 days of Day 1 until the end of the study, unless cleared by a study doctor.
- No medication or herbal products (for example St John's Wort) known to metabolize in your liver within 30 days of Day 1.

Some other medications are not allowed for at least 30 days before dosing, through until the end of the study. A study doctor will discuss all your recent and current medications with you at your screening visit.

You should check with a study doctor before you take any new medications during the study.

Are there any other study restrictions?

- If you wish to remain in the study, you will not be allowed to leave CCST during your in-house stays.
- During your in-house stays, all your meals will be provided.
- Dr Wynne may request a random check of your bags at admission for prohibited items (including drinks and foods).
- No caffeine containing products are allowed during your in-house stay for 24 hours after dosing.

- No citrus, grapefruit, pomegranate, cranberry, or orange products are allowed, from 3 days before your in-house stays until after all blood samples testing the drug level in your blood after your last dose are collected.
- No food products or dietary supplements containing sesame seeds, sesame oil or sesamin for 3 days prior to Day 1 until the final PK sample is collected.
- Only very mild exercise (such as gentle walking) will be allowed from 7 days prior to Day 1 until the end of the study.
- No alcohol consumption for 3 days prior to Day 1 until the end of the study.
- No drug of abuse while enrolled in the study.

If you decide to take part in the study, following instructions and completing study visits are very important. If you realise you have not followed study instructions, it is important that you tell study staff. Throughout the study, you will need to:

- Give full and accurate health information;
- Report all symptoms;
- Follow the study doctors' instructions regarding medication and study procedures;
- Report any additions or changes to your medication.

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

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

Information and samples collected up until your withdrawal from the study will continue to be used and the results of these assessments 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 your information and samples to be used if 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:

- Dr Wynne believes it is in your best interest for you to stop taking part, or;
- You do not follow study instructions, or;
- The study is stopped for any reason.

If you wish to leave the study early, tell the study doctor or a member of the study staff. You do not need to withdraw from the study in writing, just let your study doctor know. You will be asked questions about your experience while you were in the study, and be asked to have follow-up tests to help you withdraw from the study safely.

How will you check that I can take part?

The first visit to the study site will be your screening visit. Before any of the screening procedures are done, you will be given a chance to ask any questions you may have regarding the study. To enter the study, you must sign and date this consent form. No study-related procedures can start until this is done.

At your screening visit you will have a number of assessments, including a recreational drugs and alcohol test, and tests for Hepatitis B & C, and HIV. Other 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.

CCST staff will also contact your GP about your study participation. We may need to talk to them about any health issues or parts of your medical history that might affect you taking part in the study.

During screening or the study, tests may give an unexpected result that could be important in terms of your health. These results will be discussed with you and your family doctor, and appropriate follow-up will be arranged through your usual doctor. If you return a positive test for HIV or Hepatitis, you will not be able to take part in the study. The study doctor will arrange appropriate follow-up, but is also required by law to report positive hepatitis results to the New Zealand Ministry of Health.

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

You will be given a card stating that you are taking part in a clinical trial. This card should be presented at the time of any medical treatment you receive during the study.

How long will I be in the study for? What will I have to do?

Cohorts 1, 3, and any twice weekly dosing cohort:
You will be in this study for about 3.5 weeks (plus a screening period of up to 28 days). This includes two 2-night stay at the study site.

Cohorts 2a, 2b, and any once weekly dosing cohort:

You will be in this study for about 5 weeks (plus a screening period of up to 28 days). This includes two 2-night stay at the study site.

For all cohorts, 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.

The day you have your first dose of study drug is called Day 1. All other days are counted back or forward from Day 1. You will be monitored throughout the study for any changes in your health (whether or not you think they are related to the study drug), and for any changes to your medications.

SCHEDULE OF ASSESSMENTS for Cohorts 1, 3, and any twice weekly dosing cohort

Assessment	Screen Visit	Study Day																Final Visit[a]
		-1	1	2	3	4	5	7	8	10	11	12	13	14	15	18	21	Day 25
Clinic visit	X				X	X	X	X	X				X	X	X	X	X	X
Inpatient stay[b]		<———---->								<———---->								
Medical History	X	X																
Physical Exam	X			X		X			X			X						X
Weight (& height at screen)	X	X			X			X		X								
Pulse, blood pressure, breathing rate, temperature	X	X	X	X	X	X		X	X	X	X	X						X
Set of ECGs (tracings of the heart's electrical activity)	X	X	X			X			X		X							X
Blood test	X	X	X[c]	X	X	X	X	X	X	X	X[c]	X	X	X	X	X	X	X
Urine test	X	X			X		X	X		X		X			X	X	X	X
Hepatitis B&C / HIV test	X																	
Drug & Alcohol test	X	X				X			X	X								
Pregnancy test (if applicable)	X	X			X			X		X								X
Hormone test (if applicable)	X																	
Dose of study drug			X			X			X		X							
Medication and health check		X	X	X	X	X	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

b. Each in-house stay is from about 4pm the day of admission until mid-morning the day you leave CCST (about 42 hours per stay)

c. You will have 11 sets of blood samples collected on Day 1 and on Day 11, until 16 hours post dose.

SCHEDULE OF ASSESSMENTS for Cohorts 2a, 2b, and any once weekly dosing cohort

Assessment	Screen Visit	Study Day																						Final Visit[a]
		-1	1	2	3	4	5	7	8	10	12	14	15	17	19	21	22	23	24	25	26	29	32	Day 36
Clinic visit	X				X	X	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X
Inpatient stay[b]		←-------→														←--------→								
Medical History	X	X																						
Physical Exam	X			X					X				X					X						
Weight (& height at screen)	X	X						X				X					X							X
Pulse, blood pressure, breathing rate, temperature	X	X	X	X				X	X			X	X			X	X	X						X
Set of ECGs (tracings of the heart's electrical activity)	X	X	X						X				X				X							X
Blood test	X	X	X[c]	X	X	X	X	X	X	X	X	X	X	X	X	X	X[c]	X	X	X	X	X	X	X
Urine test	X	X			X		X	X		X	X	X		X	X	X			X		X	X		X
Hepatitis B&C / HIV test	X																							
Drug & Alcohol test	X	X							X				X			X								
Pregnancy test (if applicable)	X							X				X				X								X
Hormone test (if applicable)	X																							
Dose of study drug			X						X				X				X							
Medication and health check	X	X	X	X	X	X	X	X	X	X	X	X	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

b. Each in-house stay is from about 4pm the day of admission until mid-morning the day you leave CCST (about 42 hours per stay)

c. You will have 11 sets of blood samples collected on Day 1 and on Day 22, until 16 hours post dose.

Blood and Urine Samples

At outpatient clinic visits, blood samples are taken by direct vein puncture. On the day you receive your 1st dose and your 4th dose a cannula (small plastic tube) will be inserted into a vein in your arm, so that blood samples can be collected more easily. If your cannula stops working, it will be replaced or 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 / pregnancy;
- To measure levels of the study drug and its breakdown products;
- To measure the effect of the study drug on certain blood markers, which gives researchers an idea of how well the drug might work.

Cohorts 1, 3, and any twice weekly dosing cohort:

- The total amount of blood taken for the study will be approximately 260mL (about 1 cup). As a comparison, a standard blood donation is about 470 mL.

Cohorts 2a, 2b, and any once weekly dosing cohort:

- The total amount of blood taken for the study will be approximately 310 mL (about 1.25 cups). As a comparison, a standard blood donation is about 470 mL.

Testing and storage of samples

Your safety samples (blood/urine) will be tested at Canterbury Health Laboratory in Christchurch.

Other samples for testing will be sent overseas to the following Sponsor-approved laboratories

- PPD® Laboratories in Middleton, WI USA
- Pyxant Laboratories in Colorado Springs, CO USA
- Covance Labs in Durham, NC USA
- Myriad RBM, Inc., in Austin, TX USA

Samples will be used only for the purposes of this study. Your safety samples will be destroyed once they have been tested. Samples sent overseas for analysis will be destroyed at the end of the study. Samples used for study drug metabolites analysis will be conducted at a later time, and therefore, may not be completed by the time you finish the study. After analysis is complete, all samples will be destroyed by internationally accepted means (e.g. burning at very high temperatures). Because samples are sent overseas, there is no opportunity for karakia at the time of sample destruction.

You can change your mind at any time during the study. If you withdraw your consent for your samples, no further samples will be collected but samples you have already provided will continue to be analysed and the results recorded. This is to protect the quality of the study. You will not be able to have your samples returned to you.

You may wish to consult your whanau or hapu group before entering this study, as some iwi maintain beliefs involving the collective ownership of tissue.

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).

What are the risks of Brincidofovir (BCV, CMX001)?

Oral BCV, in either tablet or liquid form, has been taken by more than 1200 healthy volunteers or patients. IV BCV, in solution for injection form, has been taken by 30 healthy volunteers.

There may be risks to you if you participate in this study. Because this drug is investigational, not all of its side effects may be known. There may be rare and unknown side effects. Some of these may be life-threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

This is the 2nd clinical study of the IV formulation of BCV in humans.

POSSIBLE RISKS AND DISCOMFORTS ASSOCIATED WITH BCV

Some patients have received oral BCV treatment for up to six to nine months, but the average duration of treatment is about 12 weeks. Once swallowed, BCV is converted in the body to an active drug called cidofovir that blocks a virus from multiplying. Cidofovir (brand name Vistide) is an FDA-approved injectable anti-viral medication. One of the more serious side effects of cidofovir is that it can damage the kidneys. Rare events of kidney damage seen in clinical studies of seriously ill patients receiving multiple doses of BCV have not been thought to be due to BCV.

A drug similar to the study drug, called Cidofovir may cause the following side effects:

- headache
- diarrhea
- stomach pain, upset or vomiting
- constipation
- sore mouth or tongue
- joint and muscle pain
- coughing
- fever and chills

In a recently completed study of BCV, multiple oral doses of BCV or placebo were given to patients one or two times per week, just after receiving their bone marrow transplant. The most

frequently reported side effects that were considered to be related to BCV included the following:

Side Effect	Frequency in patients taking oral BCV	Compared to frequency in patients taking placebo after transplant	Difference in Frequency between BCV and placebo patients
Diarrhea	Most likely; 60%	35%	25%
Increased levels of enzymes in the blood that can indicate liver damage	Most Likely; 60% (These test results were rarely associated with symptoms and typically went away when BCV was stopped)	40%	20%
Abdominal Pain	Likely; 35%	15%	20%
Nausea	Less Likely; 30%	20%	10%
Vomiting	Less Likely; 25%	15%	10%
Decreased Appetite	Less Likely; 20%	10%	10%

Some patients required hospitalization for very frequent and severe diarrhea.

The most common side effects seen in healthy volunteer studies with oral tablets or liquid were mild GI-related adverse events (e.g., diarrhea, nausea) experienced by less than 10% of healthy volunteers. Increases in levels of enzymes in the blood that can indicate liver damage were experienced by less than 30% of healthy volunteers. These increases returned to baseline after dosing and were mild to moderate at a maximum. These side effects were observed in healthy volunteers who took up to two doses of 200 mg and in a study with single oral doses of 350 mg and 200 mg of BCV.

Side effects seen in a recent study of 30 healthy volunteers who received single intravenous doses of BCV were similar in nature. The most common were increases in levels of liver enzymes, mild GI-related effects (e.g., diarrhea, nausea), and headache. One healthy volunteer had pain and swelling at the intravenous infusion site. All side effects were more common in volunteers who received a 50 mg dose, which is higher than currently planned in this study.

	BCV 10 mg Given over 2 hours	BCV 25 mg Given over 2 hours	BCV 50 mg Given over 2 hours	BCV 50 mg Given over 4 hours	Placebo
Diarrhea	0	0	11%	33%	0
Nausea	0	0	0	22%	0
Decreased appetite	0	0	0	11%	
Headache	0	0	22%	22%	0
Pain and swelling at intravenous site	0	0	11%	0	0
Increased levels of enzymes in the blood that can indicate liver damage	0	33%	33%	56%	10%

In this study, you will receive four doses of BCV or placebo intravenously dosed either once or twice a week.

The most common side effects seen in animals that received BCV were decreased appetite, diarrhea, and dehydration. In rats given BCV for 13 weeks (about three months), tumors were observed. These BCV-related tumors occurred extremely early compared to the progression of tumor findings that are commonly observed around two years in a lifetime study in rats. Similar tumors were noted in animals given cidofovir, which shares the active form of BCV. The early occurrence of tumors in rats was also noted with cidofovir. No tumors have been seen in monkeys given BCV or cidofovir for 9 months and there have been no increased reports of cancer in people given BCV or cidofovir. **However, based on the findings in rats, BCV is considered a potential carcinogen in humans. A "carcinogen" is a substance capable of causing cancer**.

Animal studies have shown that BCV can cause sterility when given more frequently than is planned for this study. In a study with rats given 2 doses of BCV, the effect on sperm was reversible, however after 1 weeks of dosing in rats sterility was irreversible. Based on these data, it is anticipated that administration of 1-2 doses of BCV to humans presents minimal risk on male fertility. However, the effect of long term BCV dosing is unknown and may result in irreversible effects.

Animal studies have also shown that BCV can hurt or kill embryos or fetuses and may cause birth defects. These effects were shown in animal studies and have not been studied in humans, either in healthy volunteers or in patient studies. (See "RISKS TO THE UNBORN" section of this consent).

UNKNOWN/UNFORESEEABLE RISKS

In addition to the risks listed above, there may be unknown, infrequent, and unforeseeable risks associated with the use of this medication, including severe or life threatening allergic reactions or unexpected interactions with another medication.

ALLERGIC REACTION

Symptoms of an allergic reaction may include rash, flushing, itching, sneezing or runny nose, abdominal pain, diarrhea, swelling of face, tongue or throat, dizziness, lightheaded or fainting, trouble breathing, irregular or racing heart rate, and seizures.

You will be informed in a timely manner, both verbally and in writing, of any new information, findings or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

If you experience an injury, bad effect, or any other unusual health experience during this study, you must immediately contact the study doctor or the study staff.

Does the study drug affect fertility or unborn children?

RISKS TO THE UNBORN

Pregnancy/Fetal Risks: The effects of the study drugs on the unborn child are unknown and may be hazardous. **The Risk section of this form discusses animal studies that have shown that BCV may cause birth defects and sterility.**

- **Male participants must be vasectomized**
- **Female participants must be of non-childbearing potential** (i.e., postmenopausal for 1 year prior to Day 1 with a confirmed blood hormone test; or premenopausal women with documentation of surgical sterility (uterus removed, both ovaries removed, tubal ligation or occlusion, ovarian failure).

Are there any other risks?

BCV may cause other side effects that are not yet known. If any new information is discovered that might affect your decision to continue with the study, you will be told.

Please tell the study doctor or study staff if you feel unwell at any time during the study (whether you think it is related to the study or not). You will be monitored throughout the study in order to minimize risks.

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 (Accident Compensation Corporation). 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. The Sponsor offers no other form of reimbursement for study-related injury or illness. You would be able to take action through the courts if you disagreed with the amount of compensation provided.

You might not receive compensation from the Sponsor if your injury was caused by the investigators, if there is a deviation from the proposed plan of research, or if your injury was caused solely by you. If this is the case, you will **not be covered by** ACC and may have to pursue a civil action against the investigators (or institution). Ethics Committees require that researchers and their institution have indemnity cover for such risk.

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.

Are there any benefits in taking part in this study?

There are no direct health benefits to you in taking part in this study. However, information from this study may be used to further develop BCV.

Genetic Research

No genetic research is involved in this study.

Payment for participation

CCST arrange for taxis or petrol vouchers to assist with transport to and from the unit, if you live in the Christchurch metropolitan area. If you live outside this area, we will discuss your travel costs individually.

For all Cohorts a payment of $4600 less tax will be made after you complete the study, to cover your time and inconvenience.

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.

Are there any alternative treatments?

Your alternative is to not participate in this study.

What will happen to my information?

During this study the study doctors, nurses and other CCST staff will record information about you, your health and your participation in the study on forms provided by Sponsor. These forms are known as case report forms. You will not be able to take part in this study if you do not consent to the collection of this information about you.

The information collected about you will be held by CCST, the Sponsor and Sponsor's authorised representatives. CCST staff and the Sponsor's on-site monitor(s) will see your full name and health information. To make sure that your personal information is kept confidential, however, your name and any other information that allows you to be identified directly will not be entered on the case report forms or included in any records that also leave the study centre for the purposes of medical, laboratory, statistical activities or samples your doctor provides to the Sponsor or the Sponsor's authorised representatives. Instead, you will only be identified by a code. The code is used so that your doctor can identify you if needed.

The Sponsor and its authorised representatives will analyse and use the coded information they receive for the purposes of this study. If needed for these purposes, the Sponsor may communicate information to affiliates of the Sponsor, people and companies with whom the Sponsor works, and regulatory or other governmental agencies. These people, companies, and agencies may be located overseas.

Some countries may not offer the same level of privacy protection as you are used to in your country. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Your medical information and records may be re-disclosed and no longer protected by applicable privacy law.

The Sponsor, either alone or together with other researchers, may publish or present the results of the study based on your records and the records of all subjects in this study; however, you will not be identified personally in any publication or presentation.

Representatives from government agencies, the local ethics committee, and the Sponsor or its authorised representatives, may also need access to your medical records and study records for the purpose of checking data collected for the study. By signing the consent form, you authorise this access.

Your de-identified study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to BCV (but at all times in compliance with applicable laws and regulation).

A description of this clinical trial will be available on Australian New Zealand Clinical Trials Registry (ANZCTR). This website will not include information that can identify you. At most, the website will include a summary of the results.

As indicated above, taking part in this study is voluntary and you may withdraw from the study at any time by telling your Study Doctor. By signing this consent, you authorise the collection and use of information about you as described in this consent. You may withdraw this authorisation by telling your Study Doctor. If you withdraw your consent, your participation in the study will end and the study team will stop collecting information from you.

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.

This authorisation for the collection and use of information about you has no expiration date, unless and until you withdraw it. If you have any questions about the collection and use of information about you, you should ask your study doctor.

Clinical trial information will be entered into the clinical trial registry databank, maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM).

Can I find out the results of the study?

You can request a letter telling you about the results of this study. The letter will be sent to you once the final study report is available (this can take 1 – 2 years).

What if I need more information or have a question?

Dr 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 calling CCST on 03 372 9477.

If you have any queries or concerns about your rights as a participant in this study**,** or you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act.

- Telephone (NZ wide): 0800 555 050 or Free Fax: 0800 2787 7678 (0800 2 SUPPORT)
- Email (NZ wide): advocacy@hdc.org.nz

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

- Phone: 0800 4 ETHICS (438 442) or email hdecs@moh.govt.nz

For Maori support please contact:

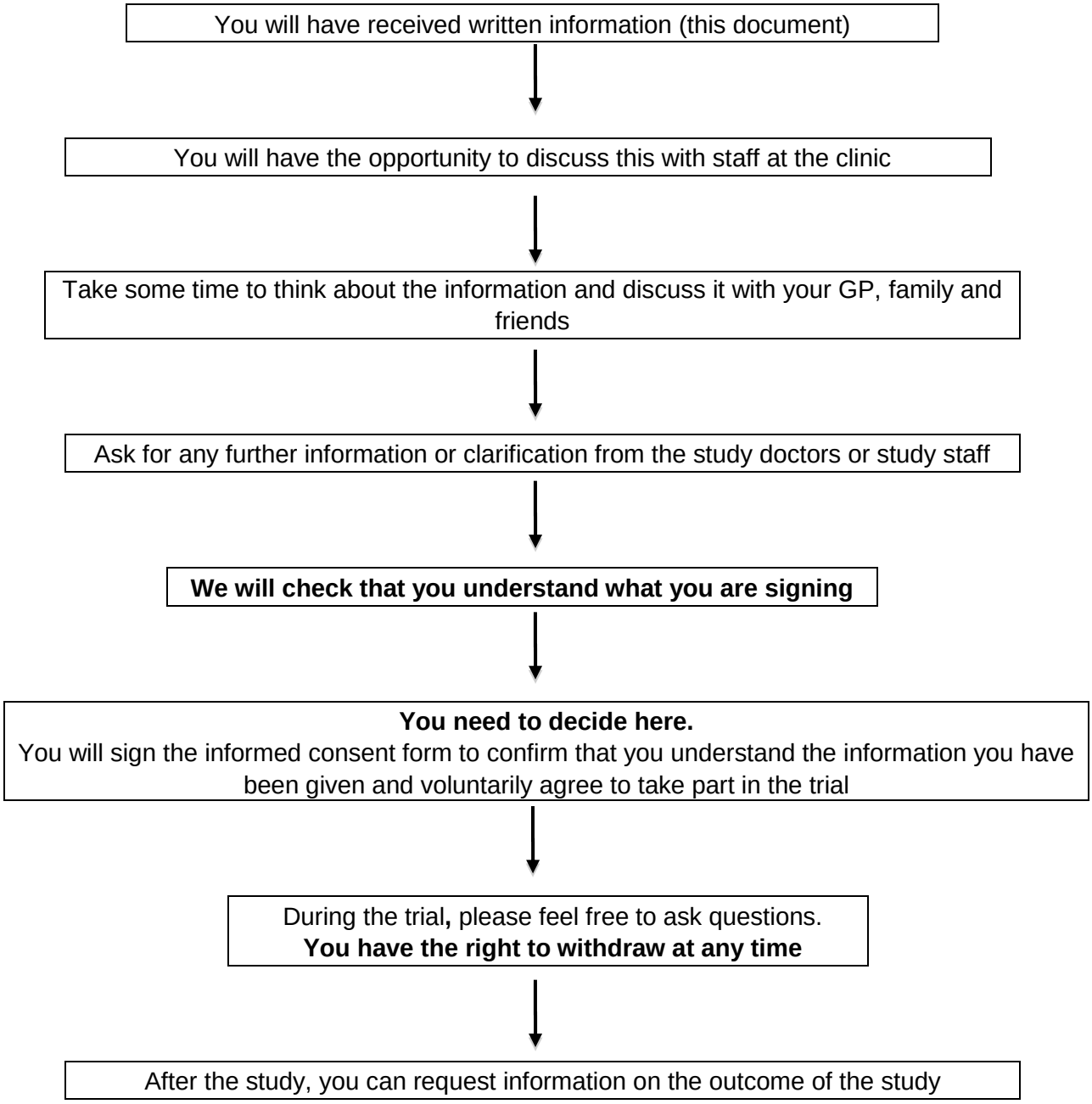
Peter Mason, Co-Director Connections Ngā Kete E Rua

- Phone: 03 358 7990

All research in New Zealand involving humans is reviewed by an independent group of people called a Health and Disability Ethics Committee (HDEC). The Northern B 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.

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: STUDY CMX001-125

A study to examine the safety and tolerability of multiple doses of the trial drug Brincidofovir in healthy adults.

FORMAL TITLE	**A Phase 1, Randomized, Double-Blind, Placebo-Controlled Multiple Ascending Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Brincidofovir Administered Intravenously in Healthy Adult Subjects**
PROTOCOL NUMBER	CMX001-125
PRINCIPAL	Dr Christopher Wynne
STUDY SITE	Christchurch Clinical Studies Trust (CCST)

Participant's Name: _____

- I have read and understand the information sheet for taking part in study **CMX001-125.**
- I have had the opportunity to discuss the nature / purpose / possible risks of this study. I have had sufficient time to ask questions and all of my questions have been answered in a way I understand.
- I understand that taking part in this study is voluntary and that I may refuse to participate or withdraw from the study at any time without giving a reason and this will in no way affect my future health care or result in penalty or loss of benefits to which I am otherwise entitled.
- I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
- I consent to my information being processed by the Sponsor and passed to other companies working with the Sponsor, and I understand that my information may be forwarded to other countries worldwide.
- I understand that some of my samples will be sent overseas for analysis, and that they will be destroyed once the study is completed.
- If I decide to withdraw from the study, I agree that the information and samples collected up to the point when I withdraw may continue to be processed.

- I understand that the study drug or study tests, will be stopped if they appear harmful to me.
- I know whom to contact if I have any side effects.
- I understand that my GP will be informed of my participation in this study.
- I agree to an auditor appointed by the sponsoring company, the Ethics Committee, or health or regulatory agencies reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I give permission to access my relevant medical records.
- I will be given a copy of this information and signed and dated consent form. By signing this consent form, I am not giving up any of my legal rights.
- This trial is being carried out for the principal benefit of Chimerix Inc. I understand that if I suffer any injury as a result of my participation in the trial, Chimerix Inc. has agreed to pay me compensation under the Medicines New Zealand Industry Guidelines.
- I wish to receive a summary of the results of the study YES / NO

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) Time: __ __ **:** __ __hrs

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) Time: __ __ **:** __ __hrs