CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

California law requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedure to be followed in the medical experiment and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

For questions about patient rights, contact the office of the Institutional Review Board at Community Health System at (559) 499-6553.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

Signature (Patient)	Printed Name	Date and Time
Signature (Legally Authorized Representative)	Printed Name	Date and Time

_____
If signed by other than patient, indicate relationship

Witness Signature	Printed Name	Date and Time

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO – FRESNO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A Phase II Study, Evaluating the Efficacy of Montelukast (Singulair) in Reducing the Incidence and Severity of Monoclonal Antibodies Associated Infusion Reactions

Principal Investigator: Mohammed Sani Bukari, M.D.
Community Cancer Institute
ATTN: Research Department
785 North Medical Center Drive West
Clovis, CA 93611
559-387-1600

Study Coordinators:

Kelly Meehan	559-387-1829
Alexa Lopez	559-387-1826
Allie Valencia	559-387-1824
Joseph Mosholder	559-387-1825

_____ _____
Patient Name **Medical Record Number**

This is a clinical trial, a type of research study. The study doctor, Mohammed Sani Bukari, M.D. from the University of California, San Francisco-Fresno Department of Hematology & Oncology, or a member of the study staff (Sub-Investigators or Study Coordinators) will explain the clinical trial to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Mohammed Sani Bukari, M.D. and conducted at Community Health System's Infusion Centers located at East Medical Plaza, Community Cancer Institute, and Clovis Community Hospital.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of the study: The researchers want to find out if adding Singulair to the standard premedication regimen (normally some combination of a corticosteroid, acetaminophen, and antihistamine) will further decrease the incidences of infusion-related reactions, make infusion time shorter, and prevent the need to give patients more premedication during or after infusions. Singular (also known as Montelukast) is an already Food and Drug Administration (FDA) approved drug used either alone or in combination with other medications to treat allergies including exercise-induced Asthma. Singular is an experimental drug since it is not FDA approved for its use in this study.

Study Procedures: If you choose to be in this study, you will orally take a Singulair tablet at least 1 hour before the start of each of your treatment infusions. You will also get a 5-10 minute phone call, approximately 24 hours after the end of your infusion, to ask you about any medication reactions you may have experienced and what was done about those reactions.

Singulair dosing will be repeated anytime you are getting your infusion for at most 6 infusions or up to the last therapy cycle if you completed your treatment before the 6th time. However, if your treatment infusion is given more than 3 times a week, Singular will be given daily from your 1st infusion until your 6th infusion.

Certain therapy cycles vary in duration. Some regimens give treatment every day while others are once a week or even once a month. Since Singulair dosing is based on your therapy cycle, your duration on this study can vary from one week to six months.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of Singulair include:

- Upper respiratory infection
- Fever
- Headache
- Inflammation of the back of the throat
- Cough

There are also very rare but serious risks of Singulair, like:

- Neuropsychiatric events such as agitation, anxiety, and abnormal dreams
- Increase in eosinophils, a type of disease-fighting white blood cell

We'll tell you about the other risks later in this consent form.

Possible Benefits: You may benefit from participating in the study, but this cannot be guaranteed.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study.
- Taking part in another study.
- Getting no treatment or receiving comfort care to relieve your symptoms and discomfort.

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

As mentioned above, research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have a hematologic disorder or malignancy and will be starting a treatment regimen that includes monoclonal antibodies (treatments used to stimulate or restore the ability of the immune system to fight cancer) either alone or in combination with chemotherapy. With your treatment regimen comes a standard premedication regimen (normally some combination of a corticosteroid, acetaminophen, and antihistamine). The premedication is given to minimize or prevent infusion-related reactions from the monoclonal antibody treatment and/or chemotherapy treatment. If infusion-related reactions do occur, more premedications may be given during or after the treatment infusions, and the treatment infusion could be held, postponed, or the administration rate could be lowered (increasing infusion time).

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if adding Singulair to the standard premedication regimen will further decrease the incidences of monoclonal antibody associated infusion-related reactions, make infusion time shorter, and prevent the need to give patients more premedication during or after infusions.

WHO PAYS FOR THIS STUDY?

This study is paid for by a pilot research grant from the Central California Faculty Medical Group (CCFMG). The study doctors and the study staff do not have any financial or non-financial conflicts of interest regarding this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 80 people will take part in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the main part of the study:

- The study coordinator/investigator will speak to you and/or review your medical record to determine whether you meet the eligibility criteria

During the main part of the study:

If the study coordinator/investigator's review finds that you can be in the main part of the study, and you choose to take part, then you will do the following:

- You will orally take a Singulair tablet at least 1 hour before the start of each of your treatment infusions for up to 6 treatment infusions.

- If your treatment infusion is given more than 3 times a week, Singular will be given daily from your 1st treatment infusion until your 6th treatment infusion.
- Extra clinic visits or blood draws are not required for this study but any notes or lab results gathered as part of your standard of care will be reviewed for any side effects.
- 24 hours after each treatment infusion, you will receive a 5-10 minute phone call to ask you about any medication reactions you may have experienced and what was done about those reactions.
- The final assessment will occur as a phone call 24 hours after your 6th treatment infusion (or final treatment infusion if less than 6). You will be asked about any medication reactions you may have experienced and what was done about those reactions.

HOW LONG WILL I BE IN THE STUDY?
You will be asked to take Singulair for up to 6 treatment infusions. Certain therapy cycles vary in duration. Some regimens give treatment every day while others are once a week or even once a month. Since Singulair dosing is based on your therapy cycle, your duration on this study can vary from one week to six months.

CAN I STOP BEING IN THE STUDY?
Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the drugs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to Singulair include those which are:
Likely adverse reactions (above 5%):

- Upper respiratory infection
- Fever
- Headache
- Inflammation of the back of the throat
- Cough
- Abdominal pain
- Diarrhea

- Middle ear infection
- Influenza
- Runny nose
- Inflammation or swelling of the tissue lining the sinuses
- Ear infection

Less Likely adverse reactions (more than 1% to 5%):

- Fatigue
- Indigestion
- Dental pain
- Stomach flu
- Dizziness
- Rash
- Increase in blood tests evaluating your liver
- Increase in number of white blood cells in the urine

Very Rare but serious adverse reactions (less than 1%):

- Neuropsychiatric events (see below)
- Increase in eosinophils, a type of disease-fighting white blood cell

Neuropsychiatric events: Neuropsychiatric events that have been reported with Singulair use include, but are not limited to, agitation, aggressive behavior or hostility, anxiety, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive compulsive symptoms, restlessness, sleepwalking, suicidal thinking and behavior (including suicide), tic, and tremor.

Other precautions:

- Aspirin sensitivity: Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents (ibuprofen such as Motrin or Advil, Celebrex, Aleve, etc.) while taking Singulair. Although Singulair is effective in improving airway function in asthmatics with documented aspirin sensitivity, it has not been shown to slow nor stop the response of airway closure to aspirin and other non-steroidal anti-inflammatory drugs in aspirin-sensitive asthmatic patients.
- Phenylketonuria (an inherited genetic disorder): Phenylketonuric patients should be informed that the 4-mg and 5-mg chewable tablets contain phenylalanine (a component of aspartame), 0.674 and 0.842 mg per 4-mg and 5-mg chewable tablet, respectively. If uncontrolled, a buildup of phenylalanine can develop resulting in damage to nerve cells in the brain.

Reproductive risks: Available data from published prospective and retrospective cohort studies over decades with Singulair use in pregnant women have not established a drug-associated risk of major birth defects. A published clinical lactation study reports the presence of Singulair in human milk. Data available on the effects of the drug on infants, either directly or through breast milk, do not suggest a significant risk of adverse events from exposure to Singulair. The effects of the drug on milk production are unknown.

If you are pregnant, you cannot take part in this study. Women must take precautions to avoid exposing an unborn child to study drug:

- If you can become pregnant, you must use a reliable birth control method during the study and for at least 28 days after your final dose of Singulair. Talk with your study doctor about what method may be best for you. You must not donate eggs during this same period. Tell your study doctor right away if you get pregnant.

Unknown Risks: The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may or may not make your health better. While doctors hope Singulair will be more useful against the likelihood of infusion reactions during your treatment infusions, there is no proof of this. We do know that the information from this study will help doctors determine if we should adopt this strategy in the future for patients undergoing immune antibody treatment.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your other choices may include:

- Getting treatment or care for your condition without being in a study
- Taking part in another study
- Getting no treatment
- Getting hospice care or palliative care. Hospice care tries to keep you as comfortable as possible. This type of care focuses on quality of life and keeping you comfortable through pain and symptom management but does not involve active life prolonging treatment. It does not treat the cancer directly, but instead tries to improve how you feel. Palliative care is a type of medical care that focuses on relief from the symptoms and stress of serious illness. Its goal is pain and symptom management but leaves open the options for life prolonging interventions or treatment.

Please talk to your doctor about your choices before deciding if you will take part in this study.

HOW WILL MY INFORMATION BE USED?

Researchers will use your information to conduct this study. Information gathered during this research study will only be used for this study. They will not be shared with other researchers.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that the personal information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a CMC medical record,

one will be created for you. Your signed consent form will be added to your CMC medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data and look at and/or copy your medical records for research, quality assurance, and data analysis for the purpose of monitoring or managing the conduct of this study:

- Representatives of Community Health System
- Representatives of Community Health System Institutional Review Board
- Representatives of the University of California
- The Office for Human Research Protections (OHRP)
- Department Of Health and Human Services (DHHS)

ARE THERE ANY COSTS TO ME FOR TAKING PART IN THIS STUDY?
No. There is no additional cost to you or your insurance provider for taking part in the study. The study medication, Singulair, will be provided free of charge.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
You will not be paid for taking part in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you tell your study doctor, Mohammed Sani Bukari, M.D., if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at (559) 387-1600.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Community Health System IRB at (559) 499-6553.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Mohammed Sani Bukari, M.D., at (559) 387-1600 or the research team at (559) 387-1825.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of Community Health System Institutional Review Board at (559) 499-6553.

ClinicalTrials.gov is a website that provides information about clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

CONSENT
You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign on the next page.

SIGNATURE
I have been given a copy of all pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

I FREELY ACCEPT TO PARTICIPATE IN THIS STUDY
To be signed simultaneously, (i.e. on same date), by all parties:

_____	_____	_____
Printed Name of Patient	Signature of Patient	Date and Time
_____	_____	_____
Print Name of Investigator	Signature of Investigator	Date and Time
_____	_____	_____
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date and Time

In the event that an interpreter is needed:

I have accurately and completely read the foregoing document to: _____
(Patient or Legally Authorized Representative's name)
in _____, the patient's (or legal representative's) primary
(identify language used)

language. He/She understands all terminology/conditions, acknowledges his/her agreement by signing the document in my presence.

_____	_____	_____
Print Name of Interpreter	Signature of Interpreter	Date and Time

AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

Protected Health Information is any personal health information through which you can be identified. A decision to participate in this research means that you agree to the use of your health information for the purposes explained in this consent form. By signing this form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your information will only be used in accordance with the provisions of this consent form and applicable law.

Your health information related to this study, including your past and present medical history, research records, records about phone calls made as part of this research, and records about your study visits may be used or disclosed in connection with this research study. Study records that identify you will be kept confidential as required by law. Except when required by law, you will not be identified by name, Social Security Number, address, phone number, or any other direct personal identifier in study records disclosed outside of the Community Health System (CHS). For records disclosed outside of CHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in the office of the Principal Investigator, Mohammed Sani Bukari, M.D.

Representatives of the following groups are authorized to use and/or disclose your health information in connection with this research study:

- The Principal Investigator, Mohammed Sani Bukari, M.D., and Sub-Investigators
- The Community Health System Institutional Review Board
- The research team (manager, clinical research coordinators/assistants, study staff)
- Community Health System
- The University of California

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections (OHRP)
- Department Of Health and Human Services (DHHS)

EXPIRATION DATE OR EVENT FOR THE RETENTION OF RECORDS

The study results will be retained in your research record for the period of 25 years. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at Community Health System. Any research information in your medical record will be kept indefinitely.

VOLUNTARY PARTICIPATION

Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent or authorization for the use and disclosure of your health information at any time. Your choice will not at any time affect the commitment of your health care providers to administer care and there will be no penalty or loss of benefits to which you are otherwise entitled. If you decide to end your participation in the study, please notify the researcher(s) in writing.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the Privacy Office, at 559-724-4400.

Signature (Patient)	Printed Name	Date and Time

Witness Signature	Printed Name	Date and Time