CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

TITLE: A PHASE II STUDY EVALUATING SAFETY AND EFFICACY OF TELATINIB IN COMBINATION WITH KEYTRUDA IN SUBJECTS WITH ADVANCED STOMACH AND GASTROESOPHAGEAL JUNCTION CANCERS OR HEPATOCELLULAR CARCINOMA

STUDY SUPPORT PROVIDED BY: EOC PHARMA

PRINCIPAL INVESTIGATOR: ANDREW HENDIFAR, MD, MPH

STUDY CONTACT PHONE NUMBER AT CSMC: 310-423-2217

AFTER HOURS CONTACT (24 HOURS): 310-423-2217

This research study is sponsored by EOC Pharma. EOC Pharma only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; EOC Pharma is not providing additional compensation to Cedars Sinai Medical Center or the Principal Investigator for their participation in the study.

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1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to examine the use of telatinib in combination with pembrolizumab (Keytruda) in the treatment of third-line gastric cancer or second-line hepatocellular carcinoma. We want to know if these two drugs work together to:

- Increase the length of time you live with cancer and
- Keep your cancer from getting worse.

You are being asked to take part in this research study because you have locally advanced or metastatic, PD-L1 positive gastric/esophagealgastric adenocarcinoma, or hepatocellular carcinoma, and are planning to start treatment with pembrolizumab (Keytruda).

The study will enroll up to 45 people in total.

This research study is designed to test the investigational use of telatinib in combination with pembrolizumab. Telatinib has not been approved by the U.S. Food and Drug Administration (FDA).

In this study, we want to learn what effects, good or bad, telatinib has on people with your condition when given in combination with pembrolizumab. We will give telatinib to you during your treatment with pembrolizumab and watch carefully for any side effects. We will also evaluate your response to treatment.

In other studies, telatinib was given in combination with chemotherapy. Patients in these studies showed improvement. Early results show that adding telatinib to standard chemotherapy treatment has been well-tolerated. Side effects have been predictable, reversible, and manageable. Based on laboratory studies, telatinib and Keytruda worked better when given together to decrease the size of the tumor and improve treatment effectiveness. In this study, we want to see if this combination will also improve response to treatment in patients with gastric/esophagealgastric adenocarcinoma or hepatocellular carcinoma.

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen in this study. Carefully read the information below along with the flowchart of procedures attached as an Appendix.

The flowchart shows when certain procedures will be done. It also shows which procedures are research related and which are standard. **Research-related procedures** are done only if you are in the study. **Standard of care (routine) procedures** would be performed anyway, even if you were not in the study.

A table describing common medical procedures done more often to monitor your health during this study is at the end of this consent form.

Overview of study:
For this study, you will take telatinib twice a day by mouth while you are on your regular pembrolizumab therapy. We will monitor you for side effects and response to treatment. You will also provide blood and stool (poop) samples for research purposes at different time points throughout the study.

Treatments for your disease can cause side effects like nausea and vomiting. You will be given the usual medications to help deal with these side effects.

How long will you be in the study?
We think you will be in this study for about 14 months. The total time includes 28 days of screening to see if you can join the study, up to about 12 months on treatment, and 30 days of follow-up.

We would like to keep track of your medical condition for the rest of your life. We will check in with you by phone call, in clinic, or by medical record review every 12 weeks to see how you are doing. Keeping in touch with you and checking on your condition helps us look at long-term effects.

3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed more often because of the study are described in a table attached to the end of this consent form. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

Unknown Risks

There may be side effects or risks that we cannot predict. Many side effects may go away shortly after the study medication or procedure is stopped. But in some cases, they can be serious, long-lasting, permanent, and/or fatal.

In the lists below, "**Serious**," refers to side effects that might:

- require hospitalization
- cannot be reversed or fixed
- last a long time
- be life-threatening or fatal

Risks of Telatinib

Likely, Some May Be Serious (Out of 100 people**,** occurs in between 10 to 100 people**)**

- High blood pressure
- Voice changes (hoarseness/dysphonia)
- Lack of appetite (anorexia)
- Tiredness (fatigue/asthenia)
- Diarrhea
- Nausea
- Constipation
- Muscle pain
- Dry skin
- Rash
- Skin redness (erythema)
- Vomiting
- Increase in liver enzymes, which may indicate a problem with your liver
- Headache
- Mouth sores (inflammation of oral and gastrointestinal mucosa)
- Bleeding (hemorrhage)
- Abdominal pain (stomach pain)
- Weight loss
- Dizziness
- Low sodium in your blood (hyponatremia), which may cause nausea and vomiting, headache, confusion, loss of energy, restlessness and irritability, muscle weakness, spasms, or cramps, seizures, or coma
- Neutropenia/leukopenia, a decrease in your white blood cell count, which may increase your susceptibility to infection
- Hand-foot syndrome (redness, rash on hands and feet)
- Blood clotting
- ECG abnormalities (a change in heart rhythm)
- Pain
- Protein in urine

- Not enough thyroid hormone, so you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)
- Low platelet count, which may cause bleeding
- Low level of potassium, which may cause muscle weakness, cramping, twitching, paralysis or abnormal heart rhythms (hypokalemia)
- Increased levels of blood lactate dehydrogenase, which may indicate tissue damage
- Increased levels of blood fibrinogen, which may indicate inflammation or injury
- Decrease in amount of blood pumped out of the heart (decreased ejection fraction), which may indicate a problem with the heart
- Blood in the urine, which may indicate a problem with your kidneys or urinary tract
- Reduction in blood flow to your heart, which may indicate a problem with your heart (myocardial ischemia)

Less Likely, Some May Be Serious (Out of 100 people, occurs in between 1 to 10 people)
- Decrease in the amount of time it takes for your blood to clot (activated partial thromboplastin time shortened)
- White blood cells in the urine, which may indicate a urinary tract infection
- Decrease in red blood cell count, which may cause fatigue and weakness
- Increase in urobilinogen level in urine, which may indicate a problem with your liver or red blood cells
- Decrease in hemoglobin level, so you may feel weak, have shortness of breath, dizziness, irregular heartbeat, pounding in the ears, headache, cold hands and feet, pale or yellow skin
- Blood creatinine increased, which may indicate a problem with your kidneys
- Dry mouth
- Abdominal discomfort
- Mouth ulceration (mouth sores)
- Abdominal distension (bloating)

Rare AND <u>Serious</u> (Out of 100 people, occurs in about 1 person. These are serious.**)**
- Elevated liver enzymes (transaminitis), which may indicate a problem with your liver
- Cholangitis (inflammation of the bile duct system), which may cause abdominal pain, fever, chills, yellowing of the skin and eyes, nausea and vomiting, clay-colored stools, dark urine, low blood pressure, fatigue, changes in alertness
- Sepsis (a life-threatening response to serious infection) or multiorgan failure
- Dehydration
- Drug induced pneumonitis (inflammation of the lung)
- Febrile neutropenia (a fever and low white blood cells)
- Bowel perforation (a hole in the bowel)
- Atrial flutter (abnormal heart rhythm)
- Pulmonary hypertension (increase in blood pressure in the lung)
- Syncope (fainting)
- Sudden death
- Myocardial infarction (heart attack)
- Impaired wound healing
- Hemorrhage (bleeding), including in the lung or brain

- Clotting (thromboembolic events), including in the lungs

Risks of Pembrolizumab (Keytruda)

Pembrolizumab, which is approved in the USA and some other countries, is available by prescription to treat several different cancers but may not be approved to treat your type of cancer.

Pembrolizumab works by helping your immune system to fight your cancer.

However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

Likely, Some May Be Serious (Out of 100 people**,** occurs in between 20 to 100 people**)**

- Fatigue
- Pain in the muscles, bones, or joints
- Decreased appetite
- Itching
- Diarrhea
- Nausea
- Rash
- Fever
- Cough
- Shortness of breath
- Constipation
- Pain
- Abdominal pain
- Loss of skin color
- Not enough thyroid hormone, so you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)
- Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps, and/or feel sick to your stomach (hyponatremia)

Rare AND Serious (Out of 100 people, occurs in about 1 person. These are serious.**)**

- Inflammation of the lungs, so you may have shortness of breath or a cough (pneumonitis)
- Too much thyroid hormone, so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure at the time of receiving your infusion (IV) or just after, or have pain at the site of infusion

- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucous (colitis)
- Inflammation of the skin so you may have peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e., peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body which can cause severe infection (Severe skin reactions, including Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Inflammation of the nerves that may cause pain, weakness, or tingling in your hands and feet, and may spread to your legs, arms, and upper body, leading to severe muscle weakness and possible temporary paralysis (Guillain-Barré syndrome)
- Inflammation of the muscles, so you may feel weak or have pain in your muscles (myositis)
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels), so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye, so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters, or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, a pain in the right side of your belly, yellow eyes and skin, and dark urine (hepatitis)
- Inflammation of the pituitary gland (a gland in the head), which may cause you to feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness, or fainting (hypophysitis)
- Adrenal glands (glands on top of the kidneys) that may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, having joint, muscle, and bellyaches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)
- Type 1 diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination, and weight loss. You are likely to need regular insulin shots
- Inflammation of the kidney, so you may pass less urine or have cloudy or blood urine, swelling, and low back pain (nephritis)
- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting (myocarditis)
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy (thyroiditis)
- A condition that may make you feel weak and tired and may cause drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs (sarcoidosis)
- Inflammation of the brain with confusion and fever. This may also include: disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking,

weakness or loss of movement in some parts of your body, and loss of consciousness (encephalitis)
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation (myelitis)
- Inflammation of the blood vessels (vasculitis). Symptoms will depend on the particular blood vessels that are involved in the inflammatory process, for example; if it is your skin, you may get a rash. If your nerves are not getting enough blood, you could have numbness and weakness. You may also experience fever, weight loss, and fatigue.

Additionally, since pembrolizumab was approved in September 2014, the following side effects have been reported by people receiving pembrolizumab. These side effects were voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of these side effect:

- Inflammation of the joints which may include joint pain, stiffness and/or swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis)
- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This can cause symptoms similar to those seen with inflammation of the liver (hepatitis) such as pain in right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- If you have had a solid organ transplant (for example, if you have received a kidney or heart transplant), you may experience rejection of the transplanted organ.
- If you have had an allogeneic stem cell transplant (a procedure in which a person receives blood-forming stem cells from a donor), you may experience graft versus host disease (GvHD), which may include diarrhea, skin rashes, and liver damage. Sometimes this condition can lead to death.

Risks of Drug Combinations

Using telatinib together with pembrolizumab may cause side effects that are not seen when each is given alone. The drug combination may also increase how common or severe the side effects are. It is unknown whether the combination causes any additional side effects. This combination has not yet been tested in humans.

Reproductive and Lactation Risks

Taking part in this research study can affect an unborn baby. You should not become pregnant or father a baby while on this study. If you or your partner could become pregnant you will need to use birth control. Check with the researcher about approved birth control methods to use while participating in this study.

Women should not breastfeed a baby while on this study.

If applicable - if required for research purposes only:

CT scan with/without contrast
This research study involves exposure to radiation from computed tomography (CT) scans with/without contrast of the locations listed in the table below. This radiation exposure is not necessary for your medical care and is for research purposes only. The approximate amounts of radiation you will receive in this study is provided in Table 1 (rem is a unit of radiation dose) for each CT scan. This is within the typical range for radiation exposure from similar diagnostic x-ray procedures. This use involves minimal risk and is necessary to obtain the research information desired.

Table 1: CT Radiation Dose of Various Locations Without or With Contrast

Location	Without Contrast	With Contrast
Chest, Abdomen and Pelvis	1-2 rem	2-4 rem

Questionnaires
You will be asked to complete brief questionnaires regarding your dietary intake and bowel habits at two timepoints. If you feel uncomfortable or embarrassed answering any of the questions, you may choose to skip the question(s).

Follow-up Visit for Discontinuing Participants
While you are free to stop the study at any time, we want you to complete a Final Study Visit. During this visit, we will conduct tests to collect safety information and discuss any important information to share with your treating physician.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

If you agree to join this research study, there may or may not be direct medical benefit to you. The possible benefits are improvement in your cancer and prolonging your life. No benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

We hope the information learned from this research study will help other individuals with stomach or liver cancer in the future by helping us to learn about improved treatment options.

5. WILL I BE INFORMED OF RESEARCH RESULTS?

Some of the research tests done in this study follow standard clinical procedures and are performed in certified clinical labs. These test results may be shared with you and placed in your Cedars-Sinai medical record. Other research tests done in this study are for research purposes only and are performed in a research only lab where the results are not intended for clinical use. These research-only results will not be shared with you or included in your Cedars-Sinai medical record.

Unanticipated Findings
If, unexpectedly, we find that results of your research procedures could impact your care and/or health, we will contact you using the last contact information provided by you. If necessary, we may recommend additional testing to confirm the research finding. You would need to pay for any additional testing and treatment.

6. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason. These reasons include:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

You may choose (or you may be required) to stop certain parts of the study but continue with other parts. For example, you might stop taking a study drug but continue with follow-up visits or let us keep reviewing your medical records. We will ask you to sign a new consent form if the procedures change.

7. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary. You have the right to stop the study at any time or change your mind. Your choice will not affect the care you receive at Cedars-Sinai Health System.

If you do not join this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach [for example, Keytruda treatment without the study drug telatinib, or supportive care only]
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.
- you may choose to pursue supportive or palliative care for your condition. Such care is focused on reducing suffering and improving the quality of life of individuals with chronic or life-threatening illnesses. The primary intent of palliative care is not to cure a disease or to prolong life. Palliative therapy is focused primarily on managing symptoms.

The researcher will discuss these options and their risks and benefits with you.

8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. 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 identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP),

etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Immediately notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research related illness or injury?
Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Charity Care Policy and Procedure. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

10. FINANCIAL CONSIDERATIONS

Costs of Participation
Please review the flowchart for a listing of items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the study sponsor.

Only items, drugs and services that are reasonable and necessary for your medical care throughout the study will be billed to your insurance. You remain responsible for all deductibles, co-pays, and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. You should check with your health benefit plan if you have questions or concerns about your insurance coverage.

Compensation for Participating
You will not be paid for taking part in this research study.

Financial Interest in the Research
The PI and institution have no potential financial conflict of interest with respect to this study.

11. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact the investigator listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

12. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights;
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and the Experimental Subject's Bill of Rights.

SIGNATURE PAGE

Consent Form for Research and
Authorization for Use and Disclosure of Identifiable Health Information (Research)

SIGNATURE BY THE PARTICIPANT

Main Research Study: *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

Name of Participant (Print)	Signature	Date Signed

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with this "Authorization for Use and Disclosure of Identifiable Health Information (Research)" form.*

Name of Participant (Print)	Signature	Date Signed

SIGNATURE BY THE INVESTIGATOR: *I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

Name of Investigator (Print)	Signature	Date Signed

SIGNATURE BY THE INTERPRETER/WITNESS

(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Name of Witness (Print)	Signature	Date Signed

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APPENDIX: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures 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 to the subject 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 procedure 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 any signed and dated written consent form used in relation to the experiment.

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.

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AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

- **USE AND DISCLOSURE OF HEALTH INFORMATION**

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "**A Phase II Study Evaluating Safety and Efficacy of Telatinib in Combination with Keytruda in Subjects with Advanced Stomach and Gastroesophageal Junction Cancers or Hepatocellular Carcinoma**" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☒ Pathology reports
☒ Imaging reports (e.g., x-rays or scans)
☒ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Mental health records
☐ Billing records
☐ Other tests or other types of medical information: N/A

- **WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?**

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis and use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai is required by law to protect your private information. However, the recipients described above may re-disclose (or share) your information with other parties unless such sharing is prohibited by law.

- **WHEN WILL MY AUTHORIZATION EXPIRE?**

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

- **REVOKING AUTHORIZATION**

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

- **NOTICE OF RIGHTS AND OTHER INFORMATION**

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. The Research Team may not condition (withhold or refuse) treating you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

APPENDIX: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Blood draw: A needle is placed in the vein in your arm to draw blood.	Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting.
Electrocardiogram (ECG): abbreviated as EKG or ECG – is a test that measures the electrical activity of the heartbeat using electrodes (disposable adhesive discs placed on the skin).	There's no pain or risk associated with having an electrocardiogram. When the disposable adhesive discs are removed from your skin, there may be some minor skin discomfort or irritation. You may experience temporary discomfort (pulling on the skin/skin hair) during removal of the patches. This hair may be shaved for patch placement.
Infusion Procedure: Infusion is the administration of drugs directly into your bloodstream using intravenous (IV) lines. The risks associated with IV lines are described separately below.	Occasionally, people have allergic reactions (including life-threatening reactions) when taking any medication. Symptoms of any allergic reaction can include a rash, hives, itching, and/or difficulty breathing, closing of the throat, swelling of the lips, tongue or face, and rarely death. If you experience any difficulty breathing, closing of the throat, swelling of the lips, tongue or face, or hives, you should stop taking your study drug and immediately seek emergency medical attention. In general, allergic reactions to medicines are more likely to occur in people who have allergies to other drugs, foods, or things in the environment, such as dust or grass. If you have allergies to other medicines, foods, or other things in the environment, or if you have asthma, you should let your researcher know.
Intravenous (IV) lines: You will receive the study drug or other medications or contrast agent through an intravenous (IV) line. An IV line is a small tube that is attached to a catheter and inserted by needle into a vein usually in your hand or arm. Qualified	IV lines are usually safe and well tolerated and complications are rare, but can include phlebitis (swelling of the vein) and infection. The IV may come out accidentally or blood may leak around the line. If the IV is not in the vein, medication or fluid can enter the surrounding soft tissues, and can be associated with swelling, discomfort,

medical professionals will place IV lines for use in this study.	bruising and irritation. Rarely, a clot can develop in the IV line itself. If this happens, the staff may remove the old IV line and start a new IV line. There is also a small risk of feeling lightheaded and fainting.
Magnetic Resonance Imaging (MRI): An MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. During the procedure you will lie down in a large donut-like looking magnet and we will ask you to lie still on a table for the duration of the procedure (about 2 hours). You will be able to communicate with researchers all the time and you will have a panic button to use if you want to stop the procedure at any time.	You may feel slightly anxious inside the scanner due to a fear of small enclosed spaces (claustrophobia). Also, at times, you may hear very loud noises as the MRI machine is taking pictures of your body. You may be given headphones and may request ear plugs if you feel the noise is too loud. At any time, you may ask the technician to stop the exam if you are unable to complete the exam.
Physical Exam: Includes height, weight, and vital signs (heart rate, blood pressure, respiratory rate, temperature).	There are no physical risks associated with these procedures.
Concomitant Medications: You will be asked about your previous and current medications that you take.	There are no physical risks associated with these procedures.
Medical History Review: You will be asked about your medical and surgical history with attention to your cancer.	There are no physical risks associated with this procedure.
Urine Collection: You will be asked to provide urine samples.	There are no physical risks associated with this procedure.
Stool Collection: You will be asked to provide stool samples.	There are no physical risks associated with this procedure.
Pregnancy Test: If you are a woman who is able to become pregnant, blood and/or urine samples will also be used to do a pregnancy test.	If your test is positive, you will be told and at that point you should discuss options available with your primary physician.
Demographic Information: You will be asked about your age, gender, race, and ethnicity.	There are no physical risks associated with these procedures.