Non-Interventional Study Informed Consent Form

SAMPLE: SITE 222-GUARDIAN

Sponsor:	KURA Oncology, Inc.
Protocol No:	KO-TIP-006
Protocol Title:	An HRAS Mutation Screening and Case-Control Study to Determine the Treatment Outcomes of Patients with Recurrent or Metastatic Squamous Cell Head and Neck Cancer with HRAS Mutations
Investigator:	<Investigator Name>
Address:	<Address>
Phone:	<Phone>

mas of the Head and Neck (HNSCC), which is a specific type of cancer. The decision of your doctor to prescribe any medication is separate from you taking part in this study and your medical care and treatment will not be influenced by whether you decide to participate in this study or not. This form will provide you with essential information about this study and your rights as a participant so that you can make an informed decision about having information collected related to the routine treatment of your HNSCC.

The Sponsor, KURA Oncology, is funding this research. KURA Oncology is also paying your doctor for his/her participation in this study to compensate him for the time needed to collect and document information for this study.

Please read this form carefully and discuss any questions with your doctor. If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should discuss your participation with anyone you choose in order to better understand this study and your options. Do not sign this form unless the study doctor or study staff has answered your questions and you decide that you want to be part of this study.

If you want to participate in this study, you will be asked to sign this consent form to verify that your responsibilities (as listed in this form) have been explained to you, all your questions have been answered, and you give your permission to participate.

When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to a parent or guardian or legally authorized representative who might sign this form on behalf of the person in the study.

2.0 Purpose

The purpose of this study is to assess the effect of DNA/gene issues known as an HRAS mutation on how long patients survive/live after their first treatment for their disease of Head and Neck Squamous cell cancer that has returned or spread through their body. . Additionally, patients without the HRAS mutation will be enrolled in the study to compare their length of survival to patients with the HRAS mutation. Also, potential patients with the HRAS mutation will be contacted regarding future clinical research studies that are

available to participate in for their disease. This study will help to gain more understanding of patients with Head and Neck Squamous cell cancer that has the HRAS mutation and to look at the difference on how each patient responds to treatment/medications for the disease.

3.0 Study Activities

This study is being conducted at several clinical center(s) in the United States (U.S.), European Union (E.U.), Asia and other countries and approximately 150 people with Head and Neck Squamous cell cancer will participate for up to 1 year.

KURA Oncology will not provide (pay for) any medication for this study as there is no medication required to be taken for participation in the study. Prescribed medications will be made available to you by prescription through your doctor. The costs for your routine care (tests and procedures that are required by the study protocol but your study or regular doctor would perform even if you were not taking part in this study) will be charged in the same manner as your regular medical care is charged. These are charges that you would have whether or not you were participating in the study.

After you sign this form, your personal medical history, vital status, date of birth, gender, HPV status, relevant carcinogen exposure, stage/location of disease, information regarding tumors and treatment of disease, outcome of treatment , surgery/radiation treatment (if applicable) and HRAS mutation test result will be reviewed. You will be asked questions about information such as your age and race/ethnicity; and y may r

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mutation test. You will also be asked to provide the treatment and treatment outcome of your disease, which is listed in the previous paragraph if you have not received or completed treatment at the time of joining the study. Your care for your disease won't change based on the results of the test for the HRAS mutation.

You will be asked to provide a blood sample at the time you join the study for the testing of your HRAS mutation status. Also, at screening if you are found not to have an HRAS mutation, you will be asked to provide a second blood sample between weeks 16 and 24, which is about 4 – 6 months after joining the study or at progression of your cancer depending on which occurs first for testing of your HRAS mutation status during your standard treatment of care.

After you join the study, your doctor might decide not to participate in the study any longer. You will be notified if your doctor decides not to participate any longer and you will be informed of another study doctor you can contact with study-related questions for the duration of your participation (if you choose to continue your participation). If your doctor changes, you will be notified but you will not have to sign a new consent form.

4.0 Patient Requirements

After you are enrolled in the study, your doctor will enter information from your regularly scheduled visits into the study database. There are no required visits, tests, or treatments in this study. At your regularly scheduled hospital or practice visits, you will be asked to provide information regarding symptoms for your HNSCC and other relevant information about your health and medications. Information will also be collected from you in person or via telephone to occur every 2 months. Follow-up contact by your physician and/or staff at your physician's office will occur from the time you enroll in the study until 12 months after the last patient is enrolled in the study. The information collected for the follow-up contact will include your status of disease, performance status, dates of your treatment for your disease, the outcome of your treatment and date of progression to first line systemic therapy for your Head and Neck Squamous cell cancer. If you have the HRAS mutation for your disease and have an increase of symptoms or your disease state worsens, you will be offered an opportunity to consider participation in future studies.

Your involvement in this study may last for up to 1 year following the last patient enrolled in this study..

While you are in the study, you must:

- Follow the instructions you are given.
- Complete the follow-up contacts if applicable to you.
- Tell the doctor about any changes in your health or the way you feel.
- Tell the doctor if you want to stop being in the study at any time.

5.0 Potential Risks/Benefits

The collection of your information for this study does not involve any risk for you or give you any direct benefit.

Information from this study might help researchers come up with new tests or medications to help others in the future.

There is a small risk of side effects from drawing blood for the tests that you will have throughout the study. There could be bruising at the site where you will be getting your blood drawn. There may also be an inflammation of the vein, or infection. More than one tube of blood may be taken at each blood draw.

You and your insurance company will be responsible for the cost of any medications (as you would normally).

8.0 Payments

You may receive payment for your travel reimbursement for participation in the study according to your institution's rules. Ask your study doctor or study staff when and how you will receive this payment if allowed by your institution for your participation in the study.

9.0 Alternatives to Being in this Study

This study does not provide treatment for your condition. Your alternative is not to be in this study. Your decision to participate in this study will not change the care you receive from your doctor. Your decision to discontinue participation in this study will not influence the way your doctor will be treating you.

10.0 New Information

You will be informed if new information becomes available that would affect your willingness to continue participation in this study.

11.0 Problems

As this is a screening study, there are no additional medical procedures beyond the provision of blood samples that are required as part of the study. You will be treated according to your doctor's standard of care practices. If you have a physical injury as a result of a blood test required for this study, tell the study doctor right away. Medical care will be offered to you by the [insert Institution] for any injury or illness that happens that is directly caused by your participation in this study. You will be billed for the costs of the care that are not paid by your insurance company or other third-party payer. You should

check with your health benefit plan to find out if the costs of care for treatment of injuries from being in this research study are covered.

You do not give up any of your legal rights by signing this form.

12.0 Contacts

During your participation in this study, you can contact your doctor to ask questions concerning your health or the collection of your medical data.

If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor, or if you have general questions about what it means to be in a research study, you can call <Insert Name of IRB>, the review board that reviewed this study, at <Insert IRB phone number>.

13.0 Termination of Participation

Joining a study is completely voluntary and you can decide to withdraw from the study at any time without penalty or loss of any benefits you are entitled to. Your decision will not affect your care in any way, either now or in the future.

If you decide to withdraw from the study, please notify your doctor Data collected up to the time that you w new i udy.

- You do not follow directions you have received about the study.
- You no longer want to provide information for the study
- KURA Oncology or the US Food and Drug Administration (FDA) stops the study for any reason.

If you stop being in the study early, the doctor may ask you some questions about being in the study.

14.0 Information About Your Personal Data and Your Rights

This section explains who will collect, record, store, use and share your health and other personal data and information if you agree to be in this study. Signing this form is entirely voluntary, but if you do not sign this form, you cannot be in the study.

During the study, the study doctor and study staff will use, collect, record, store and share health and other personal data and information about you (your “records”). Your records will include any information about you that the study doctor needs to accomplish the purpose of the study, including information from your medical records. Your records also will include other identifying information about you, such as your name and address.

There are national and state laws that make the study doctor protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information to accomplish the purpose of the study. After the study doctor shares your records with the Sponsor and others, the laws may no longer protect the privacy of your records. The Sponsor or others may share your records with other people who may not have to protect the privacy of your records.

To protect your privacy, information that discloses your identity will be anonymized by assigning you a numerical identity or “code” against which all of your information will be stored. While your records are located at the study location, the personnel managing the study, the supervisory authorities and the IRB or Ethics Committee, will have access to this uncoded identity information. Otherwise, only coded information will be transmitted outside the study location. Only the study doctor and authorized persons will be able to connect this code to your name, by means of a list that will be kept securely by the study site for 15 years. The results of the study may be published or presented. If that is the case, your identity will remain private

and any such publication or presentation will not identify that you participated in the study. Your records may also be used in future medical and pharmaceutical research activities that are unanticipated.

INFORMATION FOR EU/SWITZERLAND ICFs ONLY: If you are a citizen of the European Union or Switzerland, your records may be transferred to or processed in countries outside the European Union or Switzerland, including the United States, that do not have the same level of data privacy protections as in the European Union or Switzerland. The Sponsor will take appropriate measures to ensure the security and confidentiality of your records transferred outside of the European Union or Switzerland. By taking part in this study, you are giving your express consent and your unconditional and clear permission to have your records given to the Sponsor or to facilities chosen by the Sponsor, that are in countries outside of the European Union or Switzerland, including the U.S., and to have your coded records processed and stored there. Ways in which your health information is secured may include using systems with passwords/encryption and limiting access to only those personnel that need to use your records for the purposes outlined in this form. If you would like more information on the Sponsor's privacy policies, please visit www.kuraoncology.com/privacy-policy.

In certain circumstances, your records or results may be looked at by the U.S. Food and Drug Administration (FDA) or other governmental regulatory agencies for purposes of analyzing the results, checking data accuracy, or checking that the study is being conducted properly. The study doctor may also share your records with the IRB or Ethics Committee. These agencies, boards and committees may use your records to check the study information, how researchers are performing the study, participants' safety, and the r

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Confidentiality will be maintained in accessing, keeping, processing and publication of information related to your taking part in the study. You have the right to see, copy and correct your information relating to the study for as long as this information is held by the study doctor. However, to make sure that the study is scientifically reliable, you might not be able to review some of your records relating to the study until the study has ended.

By signing this form, you allow the study doctor to collect, record and use your records for the study and to share your records with the Sponsor, Kura Oncology; authorized representatives of the Sponsor; people and organizations who work with or for the Sponsor; and other researchers involved in this study. By signing this form, you allow any of these people or entities to store, share and use your records to monitor the study, review the study, check the accuracy, completeness, safety and results of the study, and perform required scientific analyses for the study.

You can cancel this consent to collect, record, store, use and share your records at any time. If you want to cancel your consent, please contact your study doctor. If you cancel your consent:

- You will not be able to continue in the study.
- The study doctor will not be able to use or share your records unless it is necessary to protect the integrity of the study or as otherwise allowed by law.

Even if you leave the study early or cancel your consent, any personal data collected from you previous to your withdrawal or cancellation may still be shared and processed as described in this form along with other data collected as part of the study. However, no new information will be collected from you.

This consent to collect, record, store, use and share your records expires in 50 years. Remember that you may withdraw your consent at any time by contacting your study doctor.

You will receive a signed copy of this form for your records.

Indicate your agreement to the use and sharing of your records by checking the box below and signing:

End of Section About Information About Your Personal Data and Your Rights

15.0 Consent to Use and Sharing of Personal Records

- I agree to the use and sharing of my records related to this study as described above.

Name of Patient: (Print)	
Signature of Patient/Date:	

16.0 Consent Form

<In EAPA the consent form is typically starting on a separate page. Delete paragraph 15 and add study title in a separate line>

16.1 Participant with Legal Capacity to Consent to Participate

Name of Physician:	<Name of Physician>
Name and Address of institution:	<Name and Address of Institution>

with me about this study. They have answered all my questions and voluntarily agree that I take part in this study.

- I give permission for my medical records to be reviewed by the Sponsor or designee and/or representatives of any drug regulatory authorities and Independent Ethics Committees.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. I agree that the Sponsor can continue to use the information about my health collected during my participation in the study to preserve the integrity of the study, even if I withdraw.
- I agree to the use of my medical data as described in this form. In particular, I agree that my coded personal data may be transferred and processed worldwide and submitted to drug regulatory authorities or be used for legitimate scientific purposes, including usage in future medical and pharmaceutical research.
- I agree for my medical information related to my treatment to be collected in this study.
- I confirm that I have received a copy of the information sheet and my data consent form

Note: Prior to participation in the study, the patient should receive a copy of the information sheet and signed and dated consent form.

Name of Patient:	
Signature of Patient/Date:	

16.2 Participant without Legal Capacity to Consent to Participate:

Name of Physician:	<Name of Physician>

Name and Address of institution:	<Name and Address of Institution>

☑ By signing and dating this document, I declare the following:

- I confirm that I have had time to read carefully and understand the patient informed consent form for this study.
- I have been able to ask questions about this study. The doctor or the staff of the doctor of my relative/friend has talked with me about this study. They have answered all my questions and voluntarily agree that my relative/friend takes part in this study.
- I give permission for the medical records of my relative/friend to be reviewed by the Sponsor or designee and/or representatives of any drug regulatory authorities.
- I understand that the participation of my relative/friend is voluntary and that I am free to withdraw him/her at any time without giving any reason and without the medical care or legal rights being affected. I agree that the Sponsor can continue to use the information about the health collected during the participation of my relative/friend in the study to preserve the integrity of the study, even if I withdraw him/her.
- I agree to the use of the medical data of my relative/friend as described in this form. In particular

- I confirm that I have received a copy of the information sheet and the data consent form

Note: Prior to participation in the study, the patient/guardian should receive a copy of the information sheet and signed and dated consent form.

Name of Patient:	
Signature of Patient/Date:	
I certify that under state law I am the guardian of the participant named above and that I am authorized to sign this consent to his/her participation in the research study described above.	
Name of the Guardian:	test sign
Signature of the Guardian/Date	test sign test sign (Jul 23, 2018) Jul 23, 2018

17.0 Confirmation of Consent

17.1 Confirmation of Person Explaining the Consent

I attest that the participant and/or parent or guardian named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Name of Person Explaining the Consent: (Print)	{{*name_es_:signer2:fullname}
Signature of Person Explaining the Consent: /Date:	

17.2 Confirmation of Principal Investigator or Sub-Investigator

I attest that I or my representative discussed this study with the participant and/or parent or guardian named above.

Investigator: (Print):/Date:	