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Martha Kruhm, MS, RAC
Head, Protocol and Information Office
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Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
Executive Plaza North Room 730
Bethesda, MD 20892

Dear Ms. Kruhm,

Enclosed please find Amendment #8 to protocol APEC1621F, *NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 subprotocol of Ensartinib in patients with tumors harboring ALK or ROS1 genomic alterations*, for CTEP review.

Amendment #8 is in response to a Request for Rapid Amendment (RRA) from Dr. Steven Gore (steven.gore@nih.gov) dated May 21, 2024. The purpose of this requested amendment is to provide new and/or modified risk information for ensartinib. The revised CAEPR for ensartinib (Version 2.4, April 18, 2024) has been inserted in the protocol, and the associated risk information in the informed consent document has been revised. The requested revisions are detailed in the summary of changes below. Please find attached the revised APEC1621F protocol and consent documents.

Sincerely,

Lee Baker, MPH, Protocol Coordinator (for)
Meredith Irwin, MD, APEC1621F Study Chair and
Douglas S. Hawkins, MD, COG Group Chair

SUMMARY OF CHANGES: PROTOCOL DOCUMENT

In accordance with the above discussion, the following specific revisions have been made to the protocol. Additions are in **boldfaced** font and deletions in ~~strikethrough~~ font.

#	Section	Comments
1.	Throughout	The version date has been updated throughout.
2.	Risks of Study	The risk list for ensartinib has been updated to align with the protocol.

This model informed consent form has been reviewed by the DCT/NCI and is the official consent document for this study. Institutions must use the sections of this document that are in bold type in their entirety. Editorial changes to these sections may be made as long as they do not change information or intent. If the local IRB insists on making deletions or more substantive modifications to any of the sections in bold type, they must be justified in writing by the investigator at the time of the institutional audit.

SAMPLE INFORMED CONSENT / PARENTAL PERMISSION FOR PARTICIPATION IN RESEARCH

APEC1621F
NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of Ensartinib in patients with tumors harboring ALK or ROS1 genomic alterations

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

Overview

You are being asked to take part in this research study because your tumor testing results submitted for the NCI-COG Pediatric MATCH screening protocol make you a candidate to receive the study drug called ensartinib that we are testing in this study.

Taking part in this study is voluntary. You may choose not to be in this study. If you decide not to be in this study, you will not be penalized and you will not lose any benefits to which you are entitled. You will still receive medical care.

The overall goal of this study is to test any good and bad effects of the study drug ensartinib on your tumor.

The treatment involves a cancer fighting study drug called ensartinib. The treatment on this study takes about 24 months and is divided into 26 cycles of therapy. A cycle is 28 days (4 weeks).

The dose for the children enrolled on the study will be based on the side effects seen in adults. Between 40 and 98 children will receive ensartinib. Your dose will not be increased. If you have bad side effects, your dose may be decreased.

All people who receive cancer treatment are at risk of having side effects. In addition to killing tumor cells, cancer chemotherapy can damage normal tissue and produce side effects.

Common side effects of this study drug are: nausea, vomiting, tiredness, loss of appetite, itching, rash. The list of risks for study drug ensartinib are available in the section What side effects or risks can I expect from being in the study?

You can ask your study doctor questions about side effects at any time.

The potential benefits to you are that your tumor could stop growing or shrink for a period of time. Potential benefits are described in detail in the section Are there benefits to taking part in the study?

You have a choice between another treatment and this clinical trial.

The rest of this form provides detailed information about the study and what to expect should you decide to participate.

Why am I being invited to take part in this study?

You are being asked to take part in this research study because your tumor results from the NCI-COG Pediatric MATCH screening protocol make you a candidate to receive the study drug called ensartinib that we are testing in this study.

This study is called a clinical trial. A clinical trial is a research study involving treatment of a disease in human patients. This study is organized by Children's Oncology Group (COG). COG is an international research group that conducts clinical trials for children and adolescents with cancer. More than 200 hospitals in North America, Australia, New Zealand, and Europe are members of COG. Only hospitals in the United States, Canada, Australia, and New Zealand will participate in this study.

It is common to enroll children and adolescents with cancer in a clinical trial that seeks to improve cancer treatment over time. Clinical trials include only people who choose to take part.

Please take your time to make your decision. You may want to discuss it with your friends and family. We encourage parents to include their child in the discussion and decision to the extent that the child is able to understand and take part. You have a choice between another treatment for your cancer and this clinical trial.

What is the current standard of treatment for this disease?

When a cancer comes back (recurs) or does not respond to therapy (is refractory), your doctor may recommend other anti-cancer drugs (chemotherapy), surgery, or radiation therapy. For certain cancers, a combination of one or more of these approaches is considered standard treatment. However, for other cancers such as cancers that recur, or for cancer for which therapy is no longer working, the best treatment is not known.

You are being asked to participate in this study because you have a recurrent or refractory tumor without a proven treatment strategy for cure.

Why is this study being done?

This is a Phase 2 study of a drug called ensartinib. In a Phase 2 study, the goal is to find out what effects, good and/or bad, a drug has on your tumor or type of cancer. Ensartinib is experimental because it has not been proven to work in a situation like yours.

We are using ensartinib in this study because it has been shown to block the growth of cancer cells with specific genetic changes in ALK or ROS1 pathway genes in test tubes and in animals. Ensartinib is considered a study drug in the treatment of your tumor or type of cancer. You are eligible for this study because your tumor was found to have a specific genetic change in this

pathway. Please know that your eligibility for this trial may have been determined in part on the basis of a laboratory-developed test that has not been reviewed or approved by the FDA.

Although ensartinib has been given to a small number of adults, we do not know if it will work against the type of tumor you have.

A Phase 1 study of ensartinib has been completed in adults with cancer. The goal of Phase 1 studies is to find the highest dose of a study drug that can be given without too many side effects. In the Phase 1 study, researchers determined the dose of ensartinib that can be given without too many side effects. This study will be the first time that ensartinib is given to children. The dose for the children and adolescents enrolled on the study will be based on the side effects seen in adults. If you have bad side effects, your dose may be decreased.

The overall goals of this study are to:

- **The main goal of this study is to test any good and/or bad effects of the ensartinib on your tumor.**
- **A second goal of the study is to evaluate side effects that might be caused by ensartinib, which could shrink your cancer but it could also cause side effects.**
- **Another goal is to learn more about the pharmacology (how your body handles the study drug) of ensartinib**

What will happen on this study that is research?

The treatment involves cancer fighting study drug called ensartinib. The treatment on this study can last up to 24 months.

In this study you will receive ensartinib by mouth once daily with or without food, continuously for 28 days. A cycle is 28 days (4 weeks).The dose for the children enrolled on the study will be based on the side effects seen in adults. Between 40 and 98 children will receive ensartinib. Your dose will not be increased. If you have bad side effects, your dose may be decreased.

Your study doctor will confirm that you are able to swallow intact capsules whole. You will be given specific instructions regarding how to take the study drug. You will also be given a medication diary to fill out at home each time the study drug, ensartinib is taken. Use the diary to record the date and time you take ensartinib, and any side effects that you experience. Also record in the diary other medications and/or supplements you are taking and whether you vomited or missed a dose. This diary should be returned to the clinic, along with the medication bottle (even if it is empty) weekly during Cycle 1 and then at the end of every cycle. This will help us know how much of the study drug you take and how it made you feel.

Diagram of Treatment

This chart shows the treatment on this study and describes one cycle of study therapy:

Study Drug	How the study drug will be given	Days
Ensartinib	By mouth, once a day	1-28

Research Study Tests and Procedures

The following tests will be done because you are part of this study. If you were not in the study you would probably not have these tests. Some of the scans used to diagnose cancer and determine your response to therapy may be performed more often because you are taking part in this study.

Copies of the scans used to determine the response to therapy will be sent to a central review center as part of COG quality control. The results of these reviews will not be returned to you.

Optional Research Study Tests

Pharmacokinetics

We would also like to do some tests called pharmacokinetic studies. These tests are important to help us learn more about how much of the ensartinib is in your blood. These studies may help children and young adults who receive this study drug in the future. The information learned would not change the way you are treated, and the results of these tests will not be given to you. You do not have to do these tests if you do not want to. You can still be in the study if you do not want to do these tests. At the end of this consent form, there is a place to record your decision about taking part in each test.

We would like to collect a total of 11 blood samples (about 3 mL or less than ½ teaspoon each sample) to see how much of the ensartinib is in your blood. These samples will be taken during Days 1 and 28 of Cycle 1 before the study drug is given, and at 1, 2, 4 hours and then at 6-8 hours after the study drug is given. Another sample will be obtained on Day 2 of Cycle 1, about 24 hours after your first dose. A maximum volume of 33 mL (a little over 6 teaspoons) will be drawn for pharmacokinetic and pharmacodynamic tests in this study.

Circulating Tumor DNA Studies

As part of the screening study of Pediatric MATCH we collected a blood sample. Now that you will receive ensartinib we would like to collect additional blood samples (10-20 mL, or about 2-4 teaspoons) at Cycle 5 Day 1 and end of protocol therapy (only if you receive 5 or more cycles of therapy), to see if a blood test can show whether or not the tumor DNA has changed from when the tumor was biopsied. These studies may help children and young adults who receive this study drug in the future. The information learned would not change the way you are treated, and the results of these tests will not be given to you.

You do not have to do these tests if you do not want to. You can still be in the study if you do not want to do these tests. At the end of this consent form, there is a place to record your decision about taking part in each test.

What side effects or risks can I expect from being in the study?

Treatment Risks

All people who receive cancer treatment are at risk of having side effects. In addition to killing tumor cells, cancer chemotherapy can damage normal tissue and produce side effects.

Risks of Study

The table below show the most common and the most serious side effects that researchers know about ensartinib. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Risks and side effects related to ensartinib* include those which are:

COMMON, SOME MAY BE SERIOUS In 100 people receiving ensartinib (X-396 hydrochloride), more than 20 and up to 100 may have:
• **Anemia which may require blood transfusion** • **Constipation, nausea, vomiting** • **Tiredness** • **Cold symptoms such as stuffy nose, sneezing, sore throat** • **Cough** • **Itching, rash**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving ensartinib (X-396 hydrochloride), from 4 to 20 may have:
• **Abnormal heartbeat** • **Blurred vision** • **Bloating, diarrhea, heartburn** • **Pain** • **Sores in the mouth which may cause difficulty swallowing** • **Swelling of the body** • **Fever** • **Flu-like symptoms including, chills, body aches, muscle pain** • **Infection, especially when white blood cell count is low** • **Bruising, bleeding** • **Weight gain** • **Weight loss, loss of appetite** • **Dizziness, headache** • **Changes in taste** • **Feeling of "pins and needles" in arms and legs** • **Difficulty sleeping** • **Internal bleeding which may cause coughing up blood, or blood in urine** • **Shortness of breath** • **Fluid around lungs** • **Damage to the lungs which may cause shortness of breath** • **Abnormal breathing** • **Hair loss** • **Dry skin** • **Swelling and redness of the skin**

*One patient receiving ensartinib developed Guillain-Barre Syndrome (GBS), which is a rare disorder in which the body's immune system attacks the nerves and can cause significant weakness, numbness or rarely paralysis and breathing difficulties. Most people recover from GBS but some have long-lasting symptoms.

Some drugs or supplements may interact with your treatment plan. Talk to your doctor, pharmacist, or study team before starting any new prescription or over-the-counter drugs, herbals, or supplements and before making a significant change in your diet. Supplements may come in many forms, such as teas, drinks, juices, liquids, drops, capsules, pills, or dried herbs. All forms should be avoided. Your study doctor will give you a study drug information handout and wallet card that lists possible drug interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

Reproductive risks:

You should not become pregnant or father a baby while on this study and for one week after stopping ensartinib because ensartinib can affect an unborn baby. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. **Women should not breastfeed a baby while on this study.**

The treatment used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

You can ask your study doctor questions about side effects at any time.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.
- The study doctor will provide you with information about other drugs you may need to avoid while receiving the study drugs.

There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

The use of ensartinib instead of another treatment may cause more side effects.

The ensartinib treatment that is being studied could be less effective than another treatment.

In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

If you have a drop in your red blood cell count, the cells that carry oxygen around the body you may feel tired. If your red blood cell count drops very low you may need a blood transfusion.

You may lose time at school, work or home and spend more time in the hospital or doctor's office than usual. You may be asked sensitive or private questions which you normally do not discuss.

Are there benefits to taking part in the study?

The potential benefit of the treatment with ensartinib is that it may cause your cancer to stop growing or to shrink for a period of time. It may lessen the symptoms, such as pain, that are caused by the cancer. However, we do not know if you will benefit from taking part in this study. Information learned from this study may help future patients with cancer.

What other options are there?

Instead of being in this study, you have these options:

- **Getting treatment for your cancer without being in a study**
- **Taking part in another study**
- **Getting comfort care also called palliative care.** This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

How many people will take part in the study?

The total number of people enrolled in the study is expected to between 40 and 98.

How long is the study?

Although it is difficult to predict whom, if any child, may benefit, it is possible that people in this clinical trial may receive treatment on this study for up to 24 months.

We would like to continue to find out about your health for about 30 days after your last dose of ensartinib. By keeping in touch with you for a while after you complete treatment, we can better understand the long-term effects of the study treatments.

You can stop taking part in the study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular doctor first. They will help you stop safely.

Your doctor may decide to take you off this study:

- If your disease does not respond to treatment or gets worse
- If you experience side effects of from the treatment that are considered too severe
- You need a treatment that is not allowed on this study
- You are not able to follow study-related treatment instructions
- If new information becomes available that shows another treatment would be better for you
- If he/she believes that this study is not in your best interest
- The study is stopped
- If you are female and pregnant

What about privacy?

We will do our best to make sure that the personal information in your medical record will be kept private. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Children's Oncology Group has a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the Children's Oncology Group will do their best to make sure that any information that goes out to others will not identify who you are. Information about this Certificate of Confidentiality is included in Attachment 1

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include groups such as:

- **Children's Oncology Group and research partners**
- **Representatives of the National Cancer Institute (NCI), Food and Drug Administration (FDA), and other U.S. and international governmental regulatory agencies involved in overseeing research**
- **The Institutional Review Board (IRB) of this hospital**
- **Pediatric Central Institutional Review Board (CIRB) of the National Cancer Institute**
- **The study sponsor and any drug company supporting the study or their designated reviewers.**

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

What are the costs?

Taking part in this study may lead to added costs to you or your insurance company. There are no plans for the study to pay for medical treatment. Please ask about any expected added costs or insurance problems. Staff will be able to assist you with this.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury. However by signing this form, you are not giving up any legal rights to seek to obtain compensation for injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

The NCI will provide ensartinib at no charge while you take part in the study. The NCI does not cover the cost of getting ensartinib ready and giving it to you, so you or your insurance company may have to pay for this.

Even though it probably won't happen, it is possible that the manufacturer may not be able to continue to provide the ensartinib to the NCI for some reason. If this does happen, other possible options are:

- You might be able to get the ensartinib from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
- If there is no ensartinib available at all, no one will be able to get more and the study would close.

If a problem with getting ensartinib occurs, your study doctor will talk to you about these options.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://www.cancer.gov/clinicaltrials/learningabout.

You will not be charged for the costs of the special blood studies that are being done for research purposes only, such as the tumor DNA analysis or pharmacokinetic studies.

Funding support

If you choose to enroll on this study, this institution will receive some money from the Children's Oncology Group to do the research. There are no plans to pay you for taking part in this study.

This study includes providing specimens to the researcher, there are no plans for you to profit from any new product developed from research done on your specimens

What are my rights as a participant?

Taking part in this study is voluntary. You may choose not to be in this study. If you decide not to be in this study, you will not be penalized and you will not lose any benefits to which you are entitled. You will still receive medical care.

You can decide to stop being in the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your doctor will still take care of you.

We will tell you about new information that may affect your health, welfare, or your willingness to continue in the study. A committee outside of COG closely monitors study reports and notifies COG if changes must be made to the study. Members of COG meet twice a year to discuss results of treatment and to plan new treatments.

During your follow-up visits after treatment, you may ask to be given a summary of the study results, which will only be available after the study is fully completed.

A summary of the study results will also be posted on the Children's Oncology Group website (http://www.childrensoncologygroup.org/). To receive the results, you may either (1) go to the COG website to check if results are available or (2) register your information with the COG on its web site and have an email sent to you when the results are available. Your pediatric oncology team from your hospital can give you additional instructions on how to do this. Please note, that the summary of results may not be available until several years after treatment for all people on the study is completed, and not only when you complete treatment.

Whom do I call if I have questions or problems?

For questions about the study or if you have a research related problem or if you think you have been injured in this study, you may contact Dr. XXXX or your doctor at XXXX.

If you have any questions about your rights as a research participant or any problems that you feel you cannot discuss with the investigators, you may call XXXX Institutional Review Board (IRB) Administrator at XXXX.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Patient Advocate at XXXX.

Where can I get more information?

The **COG Family Handbook for Children with Cancer** has information about specific cancers, tests, treatment side effects and their management, adjusting to cancer, and resources. Your doctor can get you this Handbook, or you can get it at https://www.childrensoncologygroup.org/index.php/cog-family-handbook

Visit the NCI's website at http://cancer.gov/

If you are in the United States, You may call the National Cancer Institute's Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237)

Information about long term follow-up after cancer treatment can be found at: http://www.survivorshipguidelines.org/.

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 web site at any time.

You will get a copy of this form. You may also ask for a copy of the protocol (full study plan).

Specimens for optional research tests

The choice to let us use blood samples for research is up to you. No matter what you decide to do, it will not affect your care. You can still be a part of the main study even if you say 'No' to taking part in any of these optional research studies.

If you decide that your blood can be used for research, some of your health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.

If you decide now that your blood can be used for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then, any specimens that we have will be destroyed.

If you want to learn more about tissue research with specimens, the NCI website has an information sheet called "Providing Your Tissue For Research: What You Need To Know." This sheet can be found at: https://www.cancer.gov/publications/patient-education/providing-tissue.

Please read the information below and think about your choices. After making your decisions, check "Yes" or "No", then add your initials and the date after your answer. If you have any questions, please talk to your doctor or nurse, or call our research review board at the IRB's phone number included in this consent.

1.) *My blood may be collected and sent to a COG laboratory and studied to see how much of the ensartinib is in your blood can be used to predict how a subject will respond to therapy.*

*Yes*_____ *No*_____ _____ / _____
Initials *Date*

2.) *My blood may be collected and sent to a COG laboratory and studied to see if a blood test can show whether or not the tumor DNA has changed from when the tumor was biopsied.*

*Yes*_____ *No*_____ _____ / _____
Initials *Date*

Signature

I have been given a copy of all __ pages of this form. **The form includes two (2) attachments.**

I have reviewed the information and have had my questions answered. I agree to take part in this study.

Participant:_____ Date:_____

Participant / Parent (or Guardian):
_____ Date:_____

Participant / Parent (or Guardian):
_____ Date:_____

Physician or Responsible Investigator:
_____ Date:_____

Physician or NP obtaining consent:
_____ Date:_____

Attachment 1

Procedures Common to all Patients on APEC1621F

Standard Tests and Procedures

The following tests and procedures are part of regular cancer care and may be done even if you do not join the study.

- Physical
- Neurological exam
- Vital signs (blood pressure, pulse, temperature)
- Blood tests- to monitor your blood counts and blood chemistries
- MRI, X-rays, CT scans, or other tests that are needed to check your tumor
- Bone marrow examinations if needed for your type of tumor, to monitor your response to treatment The bone marrow procedure is described in the COG Family Handbook for Children with Cancer.
- Urine tests to measure how your kidneys are functioning.
- Pregnancy test for females of childbearing age before treatment begins.

Attachment 2

Certificate of Confidentiality

The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. The Certificate protects against the involuntary release of information about subjects collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.