THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Phase I Clinical Trial Evaluating the Safety and Response with PF-05082566, Cetuximab and Irinotecan in Patients with Advanced Colorectal Cancer
2017-0180

Study Chair: David S. Hong

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

The goal of this clinical research study is to find the highest tolerable dose of irinotecan that can be given in combination with PF-05082566 and cetuximab to patients with advanced colorectal cancer. Researchers also want to learn about possible side effects of the study drugs and if the study drug can help to control the disease.

This is an investigational study. PF-05082566 is not FDA approved or commercially available. It is currently being used for research purposes only. Cetuximab and irinotecan are FDA approved and commercially available to treat several types of cancers, including colorectal cancer. Their use in combination with PF-05082566 is investigational.

The study doctor can describe how the drugs are designed to work.

The study drugs may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side

effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects, some of which may be severe or fatal. You may choose not to take part in this study because of a prolonged stay out of town.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may continue receiving the study drugs for as long as your study doctor thinks it is in your best interest.

PF-05082566 will be provided at no cost to you while you are on study. You and/or your insurance provider will be responsible for the costs of cetuximab and irinotecan.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard therapy for the disease. You may choose to receive cetuximab and irinotecan without taking part in this study. Depending on the type of disease that you have, therapies based on either 5-FU or PD-1 may be standard treatments for you. The study doctor will discuss these options with you. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help your doctor decide if you are eligible:

- You will have a physical exam.
- You will have an EKG to check your heart function.
- Blood (about 1-2 tablespoons) will be drawn for routine tests and biomarker testing, including genetic biomarkers. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. If you can become pregnant, part of this sample will be used for a pregnancy test. To take part in this study, you must not be pregnant, since the effects of the drugs on an unborn baby are unknown.
- Urine will be collected for routine tests. If you can become pregnant, this sample will also be used for a pregnancy test.
- You will have CT scans, MRIs, and/or PET-CT scans to check the status of the disease.
- Most participants in the first phase of the study (before the highest tolerable dose of irinotecan is found) will have a biopsy at screening. This biopsy is needed to study how the drugs you will be given may affect the disease and your immune cells. The type of biopsy you have will depend on the location of the disease. The study doctor will describe this procedure to you in more detail, including its risks. You will be told if you are one of these participants.
- If you are in the second phase of the study (after the highest tolerable dose of irinotecan is found), you will have a biopsy at screening.

You will also receive a consent form for protocol LAB10-0982. On this LAB study, leftover tissue will be used for the analysis of biomarkers and left over tissue will be stored.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a dose level of irinotecan based on when you join this study. Up to 3 dose levels of irinotecan will be tested. Up to 6 participants will be enrolled at each dose level. The first group of participants will receive the lowest dose level. Each new group will receive a higher dose than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of Irinotecan is found.

After the highest tolerable dose level of irinotecan is found, an additional 20 participants will be enrolled on the study and will receive this dose.

All participants will receive the same dose of cetuximab and PF-05082566.

Up to 34 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

You will receive irinotecan and cetuximab by vein on Days 1 and 15 of each 28-day cycle. The first time you receive cetuximab, it will be given over about 2 hours. If you tolerate it well, you will receive it over about 1 hour each time after that. Irinotecan will be given over about 90 minutes.

On Day 2 of each cycle, you will receive PF-05082566 by vein over about 1 hour.

You will also be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

You will no longer be able to take the study drugs if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on the study will be over after the end-of-study visit.

Study Visits

On **Day 1 of each Cycle:**

- You will have a physical exam.
- Blood (about 1-2 tablespoons) will be drawn for routine tests and biomarker testing. If you can become pregnant, part of this sample will also be used for a pregnancy test. If you miss a period or pregnancy is suspected at any other point in this study, the pregnancy test will be repeated.
- Urine will be collected for routine tests.

On **Day 2 of each Cycle:**

- Blood (about 1-2 tablespoons) will be drawn for pharmacodynamic (PD) testing. PD testing measures how the level of study drug in your body may affect the disease. At Cycle 1, this will be done before and 3 times over the 6 hours after the dose. At Cycles 2 and beyond, this will only be done before the dose.
- You will have an EKG before you receive the study drug.

On **Day 15 of each cycle**, blood (about 1-2 tablespoons) will be drawn for routine tests and PD testing.

On **Days 4, 9, and 22 of Cycle 1**, blood (about 1-2 tablespoons) will be drawn for PD testing.

If you had a biopsy at screening, you will have another biopsy about **6-8 weeks** after Cycle 1 Day 1.

Every 8 weeks, you will have the same imaging scan(s) you had at screening.

End-of-Study Visit

After you stop receiving the study drugs:

- You will have a physical exam.
- Blood (about 1-2 tablespoons) will be drawn for routine tests, PD testing, and biomarker testing. If you can become pregnant, part of this sample will also be used for a pregnancy test.
- You will have the same imaging scan(s) you had at screening.

Follow-Up

Every 3 months (+/- 1 month) after the end-of-study visit, you will be called and asked about how you are doing and any other treatments you may be receiving. These calls should last about 10 minutes each time.

Other Instructions

- Visit the study doctor at scheduled visits.
- Tell the study doctor/study staff the names of any drugs you are taking, including vitamins, herbal treatments, and over-the-counter drugs (such as cough or cold medicines). The study doctor will let you know which drugs to avoid during the study

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly

after the study drugs are stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

PF-05082566, irinotecan, and cetuximab may each cause low blood cell counts (red blood cells, platelets, and white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

PF-05082566 Side Effects

This is an early study of PF-05082566, so the side effects are not well known. Based on early human studies, PF-05082566 may cause:

• high blood pressure • fever • headache • chills • fatigue • fever • chills • dizziness • headache • difficulty sleeping • skin rash/itchy skin • skin bumps • low blood levels of sodium (possible headache, confusion, seizures, and/or coma)	• loss of appetite • abdominal pain • nausea • diarrhea • throat pain • inflammation of the intestines • low blood counts (red blood cells, platelets)	• abnormal sensation (such as pins and needles) • painful joint inflammation • muscle spam pain (back/muscle) • ear pain • eye irritation • lung inflammation (possible difficulty breathing) • shortness of breath • flu-like symptoms • vaginal infection

The drug may cause an increased risk of infection, such as pneumonia. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Based on studies in animals and similar drugs, PF-05082566 may cause:

• liver injury	• difficulty breathing	• immune reaction

• vomiting		(possible loss of drug function and/or allergic reaction)

Based on studies in animals and similar drugs, PF-05082566 may cause cytokine release syndrome. This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, flu-like symptoms (nausea, fever, and chills), and/or affect your lung/liver/kidney function. It may also cause certain brain-related symptoms, such as dizziness, weakness, confusion, difficulty speaking, and/or decreased brain function (possible paralysis and/or coma).

All drugs may cause an allergic reaction, which could become life threatening. You should get medical help and contact the study staff right away if you think you have difficulty breathing, rash, hives, blisters, or swelling of the face, mouth, lips, gums, tongue, or neck.

Irinotecan Side Effects

Common (occurring in more than 20% of patients)

• fever • dizziness • sweating • flushing • hair loss • increased saliva • food passing through the intestines quickly and/or cramping • nausea	• diarrhea (possibly severe or life-threatening) • abdominal pain • vomiting • cramps • loss of appetite • constipation • weight loss • jaundice (yellowing and/or darkening of the skin)	• pain • weakness • teary eyes • pupils of the eyes getting smaller • difficulty breathing • inflammation in the nose • inflammation of the mucous membranes

Irinotecan may commonly cause low blood cell counts (red blood cells and platelets). You may become anemic and/or have problems with bleeding, bruising, fatigue, and/or shortness of breath. You may need a blood transfusion.

Occasional (occurring in 3-20% of patients)

• swelling • low blood pressure • blood clot blocking a blood vessel (possible stroke) • difficulty sleeping • chills • drowsiness	• confusion • skin rash • dehydration • gas • sores in the mouth • feeling of fullness • abdominal swelling • upset stomach	• bleeding • abnormal liver test (possible liver damage) • back pain • cough • pneumonia • infection

Rare but serious (occurring in fewer than 3% of patients)

• chest pain due to heart trouble • slow heartbeat • heart attack • stroke • inflammation of deep veins (possible blood clots) • abnormal heart rhythm • decreased blood supply to the heart • change of blood flow through blood vessels (possible circulation problems) • blockage of an artery in the lungs • fainting	• tickling/tingling sensation • high blood sugar (possible diabetes) • increase in the digestive enzyme that breaks down fat (possible kidney failure) • inflammation of the pancreas (possible abdominal pain) • inflammation of the intestines (possibly with sores and/or lowered blood supply) • blockage in the stomach and/or intestines • abnormally enlarged colon	• decreased intestinal function (possible vomiting, swelling, and/or pain) • hole in the intestines, which may cause the contents to leak • low blood level of sodium (possible headache, confusion, seizures, and/or coma) • enlarged liver • kidney problems • kidney failure • hiccups • lung problems • lung disease • nodules in the lungs • severe allergic reaction

<u>Cetuximab Side Effects</u>

Common (occurring in more than 20% of patients)

• heart attack • fatigue/lack of energy • headache • difficulty sleeping • fever • skin rash (possibly acne-like), peeling, and/or itching • dry skin	• weight loss • dehydration • abdominal pain • constipation • diarrhea • mouth blisters/sores (possible difficulty swallowing) • vomiting	• abnormal liver tests (possible liver damage) • weakness • pain • nerve damage (loss of sensory function) • difficulty breathing • cough • sore throat

• nail changes • low blood levels of magnesium (possible weakness and/or seizures)	• nausea • loss of appetite • low white blood cell count	• infection • severe rash at the site of previous radiation • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Cetuximab may commonly cause a low white blood cell count. A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Occasional (occurring in 3-20% of patients)

• confusion • depression • anxiety • chills/shivering • skin sores • hair loss (partial or total) • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering)	• low blood levels of calcium and/or potassium (possible weakness and/or cramping) • dry mouth • abnormal taste • upset stomach	• painful red eyes • immune reaction • infusion reaction (possible chills and/or hives) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Frequency unknown but occurring in 1-10% of patients

• hair growth

Rare but serious (occurring in fewer than 3% of patients)

• heart attack • stoppage of heart and lung function • decreased blood supply to the heart • low blood pressure (possible dizziness/fainting) • irregular heartbeat • inflammation of the membranes around the	• shock • loss of consciousness • large skin blisters • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • changes in body salts	• eye ulcer • kidney failure • lung inflammation (possible difficulty breathing) • difficulty breathing due to narrowing of the airways • blockage in the lung (possible pain, shortness of breath,

spinal cord and brain (possible headache and/or coma)	such as sodium and/or potassium (possible fatigue and/or weakness)	and/or failure to breathe)

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: If you can become pregnant or father a child, you must use 2 highly effective methods of birth control while you are on study and for at least 90 days after your last dose of study drug. Highly effective methods of birth control are those that, alone or in combination, result in a failure rate of less than 1% per year when used consistently and correctly and include:

- Established use of birth control pills, insertions, injections or implants, as long as you remain on the same treatment throughout the entire study and have been using this method for enough period of time to ensure it is effective
- Copper-containing intrauterine device (IUD)
- Male condom or female condom used with a spermicide (foam, gel, film, cream, or suppository)
- Male sterilization with confirmed absence of sperm in the post-vasectomy ejaculate
- Bilateral tubal ligation ("tubes tied") or bilateral salpingectomy (removal of both Fallopian tubes)

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Pfizer, Inc. for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. David S. Hong, at 713-563-1930) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from

participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Pfizer, Inc., the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: Pfizer, Inc.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

Conflict of Interest

Dr. David Hong (Study Chair) has received compensation from Pfizer Inc. as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Pfizer, Inc., who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

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

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2017-0180**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

__**X**__ The IRB has determined that the signature of both parents is NOT required.

WITNESS TO PARENTAL/GUARDIAN PERMISSION

I was present during the explanation of the research to be performed under Protocol **2017-0180**. The child participant was also present. In my opinion, the parent(s)/guardian provided permission for the child to participate in the research.

_____ _____
SIGNATURE OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR

WITNESS TO ASSENT

I was present during the explanation of the research to be performed under Protocol **2017-0180**. The child participant was also present. In my opinion, the child assented to participate in the research. (Note: If obtaining assent, a witness signature is required.)

_____ _____
SIGNATURE OF WITNESS TO THE ASSENT (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE ASSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____	_____	_____
NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____	_____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION