NYU BLUESTONE
CENTER FOR CLINICAL RESEARCH

Research Subject
Informed Consent Form

Title of Study:	A phase 2, single-center, single-arm, open-label trial of vismodegib in patients with keratocystic odontogenic tumors 15-00254
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called "subjects" or "research subjects". These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to determine how well a daily dose of 150 mg of Erivedge (vismodegib) reduces Keratocystic odontogenic tumor (KCOT) size, and to evaluate the safety of this dose. The keratocystic odontogenic tumor is an aggressive benign developmental tumor.

Erivedge is Food and Drug Administration (FDA)-approved for use in adults with a specific type of skin cancer. However, the drug is experimental for patients with KCOT because it has not been FDA-approved for the treatment of KCOT.

You are being invited to participate in this study because you have KCOT.

3. How long will I be in the study? How many other people will be in the study?

This is a single-site study which will take place at the NYU Bluestone Center for Clinical Research. We expect to screen about 40 subjects in order for 20 subjects to receive the investigational product in this study.

It is expected that your participation in the study will last approximately 3 years. This time includes one year of treatment with Erivedge and two years of follow-up.

4. What will I be asked to do in the study?

This study involves one year of treatment with Erivedge (150 mg/day) plus two years of follow-up. The first study visit may take place all at once or over the course of a few days. At this visit, we will make sure you are eligible to participate in the study and ask you to complete some baseline procedures.

During the second phase of the study (treatment), we will ask you to attend a study visit once a month for a year (12 visits total) while you are taking 150 mg/day of Erivedge. If you are not able to tolerate the drug due to the side effects or if the study investigator thinks it is in your best interest to temporarily stop taking the drug, you will be given a 1-3 month treatment break. If, after 3 months, you are not able to resume taking the study drug, you will be discontinued from the study.

During the third phase of the study (post-treatment), we will ask to you attend study visits at 1, 2, 3, and 7 months, and 1 and 2 years post-treatment.

The procedures which will be performed at each visit are explained in detail below:

Phase 1: Screening

Baseline Visit:

The following procedures may take place all on one day or on separate days. In total, the procedures are expected to take approximately 8 hours.

- You will be asked to read and sign this informed consent form.
- We will collect demographic information, and review your medical and dental history, medications, and medical records.
- We will record your height and weight, and take vital signs (blood pressure, heart rate, and temperature).
- If you are a female of childbearing potential, you will be asked to have a serum pregnancy test. No additional blood will be taken for this test. If there are at least 7 days between the date you sign this informed consent form and the date which you are first given the study drug, the serum pregnancy test will be repeated. If a second test is required, a blood draw of approximately 1.5-2 teaspoons (7-10mL) will be performed.
- A member of the study team will perform an exam of your head, neck, mouth, and teeth.
- A member of the study team will perform a physical exam, including an examination of your cardiovascular (heart and blood circulation), pulmonary (lungs), abdomen and nervous systems.
- Approximately 4 teaspoons (20mL) of blood will be drawn for clinical laboratories. If any abnormal results are found, the study investigator may repeat this procedure for safety reasons.

- If you give us permission to use your blood for future genetic testing related to KCOT, we will draw an additional 1.5-2 teaspoons (7-10mL) of blood. You do not need to give us permission to perform this procedure in order to participate in this study.
- If you did not previously have a biopsy of your tumor, or the tissue is no longer available, one will be performed as part of your standard of care. Biopsy will be done regardless of participation in this study; however, we will use the results of the biopsy for this study as well as ask for your permission to store leftover tissue for optional future genetic analysis. If you have multiple KCOTs, it is possible that more than one biopsy will need to be performed. This tissue sample/biopsy will be used to confirm KCOT diagnosis as well as for a genetic analysis of the tumor.
- You will be asked to have a panoramic radiograph and a volumetric CT scan as part of your regular care (regardless of your participation in this study). We will use and store these images for the purpose of this study. No additional scans will be performed for research purposes.
- If you have nevoid basal cell carcinoma syndrome (NBCCS) associated KCOT, a member of the study team will perform a complete skin examination. NBCCS is a hereditary condition characterized by multiple basal cell skin cancers. Photographs will be taken of any suspicious lesions. Your face will not be visible in any of these photographs. You will be referred to a dermatologist if you have any suspicious lesions as per standard of care.
- After all assessments have been completed and it is confirmed that you are eligible for the study, you will be given the first dose (150 mg) of study drug. You will be asked to stay at the study site for 6 hours for monitoring after taking the drug for the first time. You will then be given enough study drug to last you until the next visit, and be asked to take 150 mg by mouth once a day.
    - The capsule may be taken with or without food, and should be taken whole.
    - Do not open or crush the capsule.
    - If you miss a dose of the study drug, do not make up the missed dose. Resume taking the drug at the next schedule dose.
- You will be given the following reminders:
    - Females will be required to use two forms of contraception (one barrier method and one secondary method) during the entire course of the study and 24 months after discontinuation of study drug. Acceptable forms of barrier contraception are: latex, non-latex or any other male condom used with spermicide; or diaphragm used with spermicide. Acceptable forms of secondary contraception are: combination hormonal contraceptives, hormonal patch, or hormonal intramuscular contraceptives (subcutaneous hormonal implant, medroxyprogesterone acetate depot); or tubal sterilization. Another acceptable form of contraception is a 100% commitment to abstinence from sexual intercourse for the entire duration of the study.
    - Males will be required to use condoms at all times with female partners of reproductive potential during treatment and for 3 months after the last treatment.
    - Do not donate blood or blood products while taking the study drug, or for at least 24 months after stopping the study drug.
    - Notify the study team if you experience any changes in your health or if you or a partner becomes pregnant.

<u>Phase 2: Treatment</u>

1 Month, 3 Months, 6 Months, and 1 Year (+/- 7 days):

Each of these visits is expected to take approximately 2 hours.

- We will review your medical and dental history and medications to make sure you are still eligible to participate in the study. A study investigator will make sure it is safe for you to continue taking the study drug.

- If you are a female of childbearing potential, you will be asked to have a urine pregnancy test. If the urine pregnancy test is positive, you will be required to have a serum pregnancy test to confirm the result. If required, 1.5-2 teaspoons (7-10mL) of blood will be drawn for the serum pregnancy test.
- We will take your vital signs (blood pressure, heart rate, and temperature).
- A member of the study team will perform an exam of your head, neck, mouth, and teeth.
- A member of the study team will perform a physical exam, including an examination of your cardiovascular, pulmonary, abdomen and nervous systems.
- At the 3 month, 6 month and 1 year visits, approximately 4 teaspoons (20mL) of blood will be drawn for clinical laboratories. If any abnormal results are found, the study investigator may repeat this procedure for safety reasons.
- At the one year visit, an optional blood draw during the visit will be used for genetic analysis only if new tumor has been identified.
- At the one year visit, if you are clinically indicated for an additional biopsy of the tumor then leftover tissue from this biopsy of your tumor will be stored for optional future genetic analysis. If you have multiple KCOTs, it is possible that more than one biopsy will need to be performed.
- You will be asked to have a panoramic radiograph.
- At the 6 month and 1 year visits, you will be asked to have a volumetric CT scan.
- At the 6 month and 1 year visits, and if you have NBCCS-associated KCOT, a member of the study team will perform a complete skin examination. Photographs will be taken of any suspicious lesions. Your face will not be visible in any of these photographs. You will be referred to a dermatologist if you have any suspicious lesions as per standard of care.
- A member of the study team will check whether you have taken the study drug according to the instructions you were given.
- You will be given enough study drug to last you until the next visit, and be given the following reminders:
    - The capsule may be taken with or without food, and should be taken whole.
    - Do not open or crush the capsule.
    - If you miss a dose of the study drug, do not make up the missed dose. Resume taking the drug at the next schedule dose.
- You will be given the following reminders:
    - Females will be required to use two forms of contraception (one barrier method and one secondary method) during the entire course of the study and 24 months after discontinuation of study drug. Acceptable forms of barrier contraception are: latex, non-latex or any other male condom used with spermicide; or diaphragm used with spermicide. Acceptable forms of secondary contraception are: combination hormonal contraceptives, hormonal patch, or hormonal intramuscular contraceptives (subcutaneous hormonal implant, medroxyprogesterone acetate depot); or tubal sterilization. Another acceptable form of contraception is a 100% commitment to abstinence from sexual intercourse for the entire duration of the study.
    - Males will be required to use condoms at all times with female partners of reproductive potential during treatment and for 3 months after the last treatment.
    - Do not donate blood or blood products while taking the study drug, or for at least 24 months after stopping the study drug.
    - Notify the study team if you experience any changes in your health or if you or a partner becomes pregnant.

2 Months, 4 months, 5 months, 7 months, 8 months, 9 months, 10 months, 11 months (+/- 7 days):
Each of these visits is expected to take approximately 30 minutes.

- We will review your medical and dental history and medications to make sure you are still eligible to participate in the study. A study investigator will make sure it is safe for you to continue taking the study drug.
- If you are a female of childbearing potential, you will be asked to have a urine pregnancy test. If the urine pregnancy test is positive, you will be required to have a serum pregnancy test to confirm the result. If required, 1.5-2 teaspoons (7-10mL) of blood will be drawn for the serum pregnancy test.
- A member of the study team will check whether you have taken the study drug according to the instructions you were given.
- You will be given enough study drug to last you until the next visit, and be given the following reminders:
    - The capsule may be taken with or without food, and should be taken whole.
    - Do not open or crush the capsule.
    - If you miss a dose of the study drug, do not make up the missed dose. Resume taking the drug at the next schedule dose.
- You will be given the following reminders:
    - Females will be required to use two forms of contraception (one barrier method and one secondary method) during the entire course of the study and 24 months after discontinuation of study drug. Acceptable forms of barrier contraception are: latex, non-latex or any other male condom used with spermicide; or diaphragm used with spermicide. Acceptable forms of secondary contraception are: combination hormonal contraceptives, hormonal patch, or hormonal intramuscular contraceptives (subcutaneous hormonal implant, medroxyprogesterone acetate depot); or tubal sterilization. Another acceptable form of contraception is a 100% commitment to abstinence from sexual intercourse for the entire duration of the study.
    - Males will be required to use condoms at all times with female partners of reproductive potential during treatment and for 3 months after the last treatment.
    - Do not donate blood or blood products while taking the study drug, or for at least 24 months after stopping the study drug.
    - Notify the study team if you experience any changes in your health or if you or a partner becomes pregnant.

<u>Phase 3: Post-Treatment (2 years follow-up)</u>

7 Months, 1 year and 2 years (+/- 7 days) post-treatment:

- We will review your medical and dental history and medications to make sure you are still eligible to participate in the study.
- If you are a female of childbearing potential, you will be asked to have a urine pregnancy test. If the urine pregnancy test is positive, you will be required to have a serum pregnancy test to confirm the result. If required, 1.5-2 teaspoons (7-10mL) of blood will be drawn for the serum pregnancy test.
- We will take your vital signs (blood pressure, heart rate, and temperature).
- A member of the study team will perform an exam of your head, neck, mouth, and teeth.
- A member of the study team will perform a physical exam, including an examination of your cardiovascular, pulmonary, abdomen and nervous systems.
- You will be asked to have a panoramic radiograph.
- <u>At the 1 year and 2 year post-treatment visits</u>, you will be asked to have a volumetric CT scan.
- <u>At the 1 year post-treatment visit</u>, and if you have NBCCS-associated KCOT, a member of the study team will perform a complete skin examination. Photographs will be taken of any suspicious

lesions. Your face will not be visible in any of these photographs. You will be referred to a dermatologist if you have any suspicious lesions as per standard of care.
- You will be given the following reminders:
  - Females will be required to use two forms of contraception (one barrier method and one secondary method) during the entire course of the study and 24 months after discontinuation of study drug. Acceptable forms of barrier contraception are: latex, non-latex or any other male condom used with spermicide; or diaphragm used with spermicide. Acceptable forms of secondary contraception are: combination hormonal contraceptives, hormonal patch, or hormonal intramuscular contraceptives (subcutaneous hormonal implant, medroxyprogesterone acetate depot); or tubal sterilization. Another acceptable form of contraception is a 100% commitment to abstinence from sexual intercourse for the entire duration of the study.
  - Males will be required to use condoms at all times with female partners of reproductive potential during treatment and for 3 months after the last treatment.
  - Do not donate blood or blood products while taking the study drug, or for at least 24 months after stopping the study drug.
  - Notify the study team if you experience any changes in your health or if you or a partner becomes pregnant.
- At the end of the 2 year post-treatment visit, you will have successfully completed the study.

1 Month, 2 month, and 3 months (+/- 7 days) post-treatment:
- We will review your medical and dental history and medications to make sure you are still eligible to participate in the study.
- If you are a female of childbearing potential, you will be asked to have a urine pregnancy test. If the urine pregnancy test is positive, you will be required to have a serum pregnancy test to confirm the result. If required, 1 tablespoon (7-10mL) of blood will be drawn for the serum pregnancy test.

5. What are the possible risks or discomforts?

Risk of Study Drug

Erivedge is FDA-approved for use in adults with a specific type of skin cancer. However, the drug is experimental for patients with KCOT.

The most common side effects of Erivedge are:
- Muscle spasms
- Alopecia (hair loss)
- Dysgeusia (change in sense of taste)
- Weight loss
- Fatigue
- Nausea
- Diarrhea
- Decreased appetite
- Constipation
- Arthralgias (joint pain)
- Vomiting
- Ageusia (loss of taste)

Other potential side effects of Erivedge are:

- Amenorrhea in pre-menopausal women (loss of menstrual period)
- Hyponatremia (low sodium in the blood)
- Hypokalemia (low potassium in the blood)
- Azotemia (high levels of nitrogen-containing compounds in the blood, such as urea and creatine)

Premature fusion of the epiphyses (the end part of the long bone) has been reported in pediatric patients exposed to vismodegib. In some cases, fusion progressed after drug discontinuation.

Other Risks

Some of the procedures performed in the study carry certain risks, which are listed below.
Oral exam: There is a small risk of minimal pain or discomfort during the oral exam.
Blood draws: Blood draws will be conducted according to standard methods by a trained phlebotomist, nurse, dentist or physician. There may be some discomfort and/or bruising at the site of needle entry. There is a very small risk of fainting. Infection in the area of the needle insertion is rare. Preventive measures will be used during sample collection to reduce the risk of these rare side effects.

It is possible that this research may involve risks which are currently unforeseeable.

Panoramic radiograph and a volumetric CT scan risk: Because these imaging procedures are done as part of your routine care and regardless of your participation in this study, the doctor ordering these images or technologist performing the procedures will explain the risks of these procedures to you.

Genetic testing risk

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

6. Can I be in the study if I am pregnant or breastfeeding?

Because taking part in this study may harm an embryo, fetus, or breastfeeding baby, you should not become pregnant, breastfeed a baby, or father a child while participating in this study and for 24 months after discontinuation of study drug. Other risks may not yet be known.

If you are currently pregnant or breastfeeding, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use two forms of contraception (one barrier method and one secondary method) during the entire course of the study. Acceptable forms of barrier contraception are:

- latex, non-latex or any other male condom used with spermicide
- diaphragm used with spermicide.

Acceptable forms of secondary contraception are:

- combination hormonal contraceptives,
- hormonal patch
- or hormonal intramuscular contraceptives (subcutaneous hormonal implant, medroxyprogesterone acetate depot)
- tubal sterilization.

Another acceptable form of contraception is a 100% commitment to abstinence from sexual intercourse for the entire duration of the study.

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

Note to Men

Because the effect of participating in this study on sperm are unknown, you will be required to use a condom (even if you have had a vasectomy) with spermicide during sexual intercourse with female partners of reproductive potential throughout the study and for 3 months after the end of study treatment.

If your partner becomes or thinks she may have become pregnant during the time you are in the study, you must tell the principal investigator right away. The principal investigator may ask for your partner's permission to collect information about the outcome of her pregnancy and the health of her baby. You will be given a contact form to share with your partner so that she can reach out to the study team if she is interested in providing information about her pregnancy and the health of her baby. By sharing the contact form with your partner, your partner will become aware of your participation in this study. If your partner chooses to provide her and her baby's health information, she will be asked to sign a consent form before this information is collected.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

It is possible that some study subjects who receive Erivedge may experience an improvement in their KCOT while taking Erivedge during the study. However, if you receive such benefit, because Erivedge is not FDA-approved for KCOT, your doctor cannot prescribe it after you finish the study. Also, you may not get any benefit from being in this research study. Others with KCOT may benefit in the future from what we learn in this study.

9. What other choices do I have if I do not participate?

You do not have to participate in this study to receive care for your condition. The standard treatment for patients with this condition is surgery. Before deciding whether or not to participate in this study, you may discuss other potential therapies with the Principal Investigator or your personal physician.

10. Will I be paid for being in this study?

You will not be compensated for participating in this study.

11. Will I have to pay for anything?

You will not be billed for any procedures which take place as part of the research study. The study drug, Erivedge, will be provided to study participants free of charge. You and/or your health insurance company will be responsible for the costs of your normal care (*i.e.,* care that you receive outside of study procedures).

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU College of Dentistry to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions. The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will my information be protected?

NYU College of Dentistry, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

What information about me may be used or shared with others?
The following information may be used or shared in connection with this research:

- Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, CT Scans, panoramic radiographs, biopsies, and diaries.

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU College of Dentistry policies and applicable law.

Why is my information being used?
Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

Who may use and share information about me?
The following individuals may use, share or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: Genentech
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

15. Optional permission for samples for future genetic testing

This optional study involves the collection of additional blood samples and leftover tissue from the biopsy of the tumor to store for future genetic testing. The purpose of this optional study is to understand the genetics of KCOT. Optional means that you may refuse to take part in this optional study and still participate in the main study. This study is voluntary and will include only people who choose to take part. Please take your time to make your decision.

Samples will be stored at Bluestone Center for Clinical Research for up to 10 years to be used for future genetic studies. The genetic testing will not include tests that can identify your risks for other conditions and results will not be shared with you. Only users authorized by the Bluestone Center for Clinical Research and Genentech would have access to the samples.

The stored samples will be labeled with the subject code, diagnosis and/or location of the sample. The linking key between subject code and your identity will be maintained by the Principal Investigator. You may withdraw your samples from storage and future use by providing a written request to the Principal Investigator.

If you agree to take part, about 1.5-2 tablespoon of blood will be taken with a needle from a vein in your arm. Blood samples will be taken at the baseline visit and also at one year visit if you have a new tumor. If clinically indicated, an additional biopsy of the tumor will be done and the leftover tissue from the tumor will be stored for future genetic analysis.

Please initial your answer: I choose to provide additional specimen samples for the optional future genetic testing:

Yes______ **No______**

16. Optional permission for future use

NYU College of Dentistry would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYU College of Dentistry or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYU College of Dentistry will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYU College of Dentistry or its research partners. ______________ Subject Initials

17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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 website at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date