	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 1 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

This is a Clinical Research Study: Dr. {insert PI name} wants to find out if a new medicine called PF-06252616 is safe and if it can help children with Duchenne muscular dystrophy (DMD). This is called a “research study” or “study”. You have DMD and the doctor wants to know if you want to be in the research study.

The Purpose of the Study: The study will test whether a new medicine helps children with DMD, and whether the medicine causes any problems. PF-06252616 is humanized anti-myostatin (GDF-8) monoclonal antibody. It has been tested in adults, but it has not been tested in children yet. PF-06252616 is not for sale and is only approved for testing in this type of research study.


The doctors and nurses will explain the study and answer any questions that you have. If you agree to be in this study, they will ask you to sign this form. Your parent(s) or legal guardian will sign another form. You can talk to your parents and ask to read the information the doctor gives them.

You do not have to be in this research study. It is up to you and your parent(s) or legal guardians to decide. If you do not want to take part in the study, you do not have to, even if your parent(s) or legal guardian say(s) yes.

You may talk to your parents or legal guardians or friends or anyone else you want to, about the information in this paper. You can decide if you want to take part or not after you have talked it over. You do not have to decide right away.

What will happen to you if you go into the study? The study starts with a visit to your doctor and he/she will do a check-up to see if it is safe for you to be in the study. If it is okay for you to be in the study, you will visit your study doctor about once a month for up to 2 years. Sometimes you may have to visit the study doctor for two days in a row. During the visits, some or all of the following tests will be done:

**Physical examination:** The study doctor will give you a physical examination, and see how tall you are and how much you weigh.

	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 2 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

**Feces and urine samples:** You will need to give urine (pee) samples for some tests. You will be asked to urinate (pee) into a cup for these tests. You will also be given kits to collect feces (poo) samples at home, which your parent / legal guardian will need to bring to your next visits. The study staff can explain to you what you need to do.

**Blood samples:** You will need to give blood samples for some safety tests. Blood samples will also be taken to see how much of the study medicine is in your blood, and what effects it has on your body. Blood samples are taken with a needle from your arm and may hurt or feel uncomfortable.


**Vital signs measurements:** The doctor will listen to your heart beat (heart rate), check your blood pressure, and measure your breathing rate and temperature.

**Side effects and other medicines:** The doctor and study staff will check how you are feeling and what other medicines you are taking during the study. Some other medicines may not be allowed.

**Electrocardiogram (ECG):** Your heart function will be checked using an ECG machine. For this test, you will have wires taped to your chest while you're lying down. The machine will record your heart beats to see how well it is working. This recording does not hurt.

**Magnetic Resonance Imaging (MRI):** While you are lying on a table, a machine creates an image of your body. For this test, you must lie inside the machine, which looks like a tunnel. This machine can make loud noises but it does not hurt. The MRI will be used to look at your liver and your thigh. The MRI may also be used to look at your heart with the help of a dye (gadolinium) given to you through a needle.

**Echocardiogram (ECHO):** This is a test that takes pictures of your heart beats. It uses your heart's sound waves to create a picture of your heart. This test does not hurt.

	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 3 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

**Dual-energy X-ray absorptiometry (DXA):** While you are lying still on a table, a bone scan will be taken of your body. This test does not hurt.

**X-ray:** You will be asked to keep your arm still on a table while pictures are taken of the bones in your hand and wrist. This test does not hurt.

**Tanner staging and testicular volume:** Tanner staging and testicular volume is a way of looking at the changes of a person's body as she or he is growing up. When you have reached a certain stage on this scale, you will no longer need this test or the X-ray described above.


**Functional tests:** You will have tests to see how your muscles are working. You will also include have breathing tests.

**Questionnaires:** You or your parent(s) or legal guardian will be asked to answer questions about your disease and how you are feeling. Some of these questions will be answered using a tablet computer.

You will be given either PF-06252616 or a pretend medicine called placebo about every month for up to 2 years. You will not know which medicine you are getting, but you will be given PF-06252616 for at least half the time you are in the study. These medicines are liquids that will be given to you as an intravenous (IV) infusion. IV infusion means you will have a plastic needle in your arm and the medicine will slowly drip through a tube into your arm.

Restrictions / things you need to do during the study:


- You may need to fast (not eat any food) for 8 hours before some blood tests.
- You will be asked not to eat certain foods for 2 days before collecting bowel samples.
- You should not eat a large meal for 2 hours before DXA scans. You will be allowed to have juice, water and small snacks.

	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 4 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

- You should not take any calcium supplements for 24 hours before DXA (bone) scans.
- If you normally do physical therapy / exercises for your DMD, you should continue doing these.
- You should not do things that are not part of your normal daily routine; like doing more exercise than usual or eating strange foods the day before X-rays, DXA scans, blood tests or functional tests.
- You will not be allowed to take certain medicines during the study; the study doctor will explain these to you and your parent or legal guardians.
- If you and your partner (e.g., girlfriend) are physically able to have children and you are sexually active, you must use birth control correctly during the entire study.
- If you think that you may have gotten a girl pregnant, you must tell your doctor immediately. The doctor may ask for information about the pregnancy and the birth of the baby. The doctor may share this information with the sponsor and {insert IRB/IEC name}.

Things that could make you feel bad, afraid or uncomfortable: Remember to tell your parent(s) / caregiver(s) and the doctor what you are feeling while you are in the study especially if something makes you feel bad, afraid or uncomfortable.


- PF-06252616 could cause liver damage from too much build-up of iron in your body. It can also cause sores in your stomach, nose bleeds, skin rashes, or your body to change into an adult (puberty) earlier than expected. During the study, your doctor will be watching carefully for these changes.
- Your condition could get worse if PF-06252616 doesn't work, or if you are given placebo.

	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 5 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

- The needle put into your arm for the blood sample or infusion may hurt when it goes into your arm. You might get an infection at the place where the needle went into your arm. You might also get a red spot or bruise on your arm or your arm might feel sore.
- Blood sample collection and lung function tests may make you feel dizzy.
- Stickers used for the ECG and gel used for the ECHO may cause a rash on your chest, but this should not hurt.
- Both the X-ray and DXA scans expose you to a small amount of radiation, but this is less than 1 year of natural radiation that you receive normally. This radiation should not affect your health.
- You may feel uncomfortable during the MRI, because of the tight space and loud noise of the machine.
- You will have to fast (not eat) for a few hours before some tests. This might cause dizziness, headache, stomach discomfort or fainting.
- You may feel tired or embarrassed by the questions the doctor or nurse asks you or your parent / legal guardian in some of the questionnaires. If some questions in the questionnaire make you feel uncomfortable, you can choose to not answer them.
- You may feel embarrassed or uncomfortable during exam of your body.

You might also feel other things. While you are in the study, you have to tell the doctor or your parents or legal guardian if you feel sick or if you take any new medicines. You or your parent or legal guardian can call the doctor at the telephone number on the first page of this form.

Possible good things from being in this study: You could get better in this study, but you may not. There are no guarantees. This study might not help you with your DMD. The possible benefits associated with taking part may help other children with your condition.

	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 6 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

Participation is voluntary and **you do not have to be in the study if you don't want to.**

It is your choice if you want to be in this study or not. No one will be upset or angry if you choose not to take part.

Your doctors or your parent(s) or legal guardian cannot make you be in the study if you don't want to be in it. If you say okay now to be in the study and you change your mind about it later you can stop being in the study. Just tell the doctor or your parent(s) or legal guardian if you want to stop at any time. If you quit the study, you will be asked to come in for one last visit and may be asked about the reason you no longer wish to take part. Your doctors will still take care of you if you don't want to be in this study.

Privacy: When you visit the clinic, the study doctor will write down information about you so that other people can look at it, too. Any information that is used for this study will have a number on it instead of your name.


Contacts and Questions: You can ask questions about the study any time. You can call the doctor any time. If you want to ask questions about what it means to be in a research study, you or your parents or legal guardian can call {insert IRB/IEC name} at {insert IRB/IEC number}.

Your doctor will talk to you about what it means to be in a research study. He or she will also talk to you about what it means to have DMD. You should ask your doctor all of the questions you have. You should also talk to your parent(s) or legal guardian about the study and DMD.

It is okay to ask questions about what we are telling you. You can circle or highlight things on this paper you want to know more about. If you don't understand something, just ask us. We want you to ask questions now and anytime later that you think of them.

For you to be in this study both you and your parent(s) or legal guardian must agree to you being in it. But it is still up to you if you *want* to do it.

No, I do not want to be in this study

	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 7 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

Yes, I do want to be in this study

Participant -----Date -----Time

Parent(s) or legal representative(s)-----Date-----Time

**CONSENT FOR PARENT/LEGALLY ACCEPTABLE REPRESENTATIVE WHO CANNOT READ**

The study participant’s parent/legally acceptable representative has indicated that he/she is unable to read. One or more members of the study team read the consent document to the study participant’s parent / legally acceptable representative, discussed it with the study participant’s parent / legally acceptable representative, and gave the study participant’s parent/legally acceptable representative an opportunity to ask questions.

Printed name of impartial witness ‡

Signature of impartial witness


Date of signature §

Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the subject or subject's legal representative cannot read.*)

§ Parent / legally acceptable representative / impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject or the subject’s legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.



	<b>PEDIATRIC ASSENT FORM</b> (Recommended for ages 11 years – legal age of adulthood)	Page 8 of 8
<b>Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy</b>		
<b>Protocol Number:</b> B5161002		<b>Version Date:</b> 23/Aug/2016
<input checked="" type="checkbox"/> <b>Study-Level</b> or <input type="checkbox"/> <b>Country</b>	<b>Language:</b> English	<b>Center ID:</b> N/A
<b>Country:</b> N/A		
<b>Assent Derived From:</b> N/A, original version		

**ASSENT SECTION For Subjects:**

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject's decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Initials of Person Obtaining Assent: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

-- Please provide a copy of this assent to the minor, parents or legal representative --