



Clinical Development

TBM100C

Model Patient Information and Informed Consent
for Study No. CTBM100C2302

**A Randomized, Open-label, Multicenter, Phase 3 Trial to
Assess the Safety of Tobramycin Inhalation Powder
Compared to TOBI® in Cystic Fibrosis Subjects**

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Investigator: *Name*
 Address
 Phone

Informed consent

You (or your child) are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish for you (or your child) to take part.

Thank you for reading this document.

Trial purpose and conduct

You (or your child) are being invited to join in a clinical research study to find out if a drug called Tobramycin Inhalation Powder (or TIP for short) is safe and has beneficial effects in people with cystic fibrosis (CF) who have lung infections.

Tobramycin Inhalation Solution (TOBI[®]) is a drug that kills bacteria (known as an antibiotic). It is breathed into the lungs and is approved in Europe and the United States for the treatment of infections caused by a bacterium called *Pseudomonas aeruginosa* in patients with CF. TIP is a new, experimental powder form of tobramycin that is also breathed into the lungs using an inhaler called the T-326 inhaler.

The purpose of this research is to study how breathing in TIP twice a day compares to breathing in TOBI[®] in patients with CF. The study will last for 25 weeks.

In addition, 70 people will be asked to take part in a sub-study where the amount of tobramycin in the blood and sputum will be tested more often. The purpose of this sub-study is to measure the way the body absorbs, distributes and gets rid of the treatment (known as pharmacokinetics). You (or your child) do not have to participate in the sub-study in order to participate in the main study. Only some doctors will be doing this work. However, if you (or your child) are asked and choose to participate, you must read and sign the section "What if I Join the Pharmacokinetic Sub-Study?" at the back of this form.

Why You Have Been Selected

You (or your child) are being asked to take part in this research study because you (or your child) have CF and a lung infection caused by the bacterium, *Pseudomonas aeruginosa*. Lung infections often cause problems for patients with CF. Some patients with CF have a type of *Pseudomonas aeruginosa* in their lungs that can cause infections or make their CF symptoms worse.

In order to be in this study, you (or your child) must be at least 6 years old, have CF and have a lung infection caused by *Pseudomonas aeruginosa*. Some of the things that could prevent you (or your child) from being in this study include using certain medicines, not being able to breath well enough to pass certain breathing tests, having bleeding from the lungs, having kidney problems or having had a previous drug reaction to some medicines similar to the one being tested in this study (known as amino glycosides).

About 500 people at CF Centres in the United States and Europe will take part in this study. 300 people will be chosen by chance (like flipping a coin) to receive TIP treatment and 200 people will be chosen by chance to receive TOBI[®] treatment during the study. You (or your child) will know which treatment you have been given.

Do I Have to Take Part?

It is up to you to decide whether or not you (or your child) will take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide that you (or your child) will take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you (or your child) receive.

What Will Happen to Me if Take Part?

This study has three 56-day (8-week) study drug treatment cycles. During each study drug treatment cycle, you (or your child) will receive either TIP or TOBI[®] twice daily for the first 28 days (4 weeks), followed by 28 days (4 weeks) of no study drug treatment.

There will be a total of 11 visits for this study. You will come in to the study centre for 9 of these visits. You will receive a telephone call or an e-mail from the study staff for the other 2 visits.

The first visit is a screening visit. If you (or your child) qualify for the study and you agree to be in this study, you will return to the study centre for the second visit when you will receive your first dose of study drug. During the first treatment cycle, you will return to the study centre for a visit after 1 week of study drug treatment (Visit 3), and again after 4 weeks of study drug treatment (Visit 5). In between these visits, after 2 weeks of study treatment, you will receive a telephone call or an e-mail from the study staff (Visit 4). You will receive another telephone call 2 weeks after you (or your child) have stopped study drug treatment (Visit 6).

You will return to the study centre for two visits during the second study drug treatment cycle (Visits 7 and 8) and again for two visits during the third and final study drug treatment cycle (Visits 9 and 10). There will be a final, follow-up visit at the end of the third cycle (Visit 11).

You will be asked to complete a daily diary (known as the Subject Dosing Log), come to all scheduled visits and return all used and unused study drug and device(s). You will be asked to bring your study drug to every study visit.

Study Plan

Visit 1 (Screening)

On your first visit, you will come to the study centre and be asked to read and sign this informed consent form before any study-related tests are done. The following tests will be done to see if you (or your child) can take part in the study:

- Review of you (or your child's) current and past health and medications
- A physical examination and vital signs, including height, weight, temperature, heart and breathing rate and blood pressure

- A urine sample to check your (or your child's) kidneys
- A blood sample (about 2 to 4 teaspoons) for laboratory testing, including pregnancy testing for women who are able to become pregnant. You (or your child) cannot be pregnant while taking part in this study.
- A sputum or deep-throat cough sample to test for bacteria
- A lung function test (blow into a tube). If you (or your child) use medication to help ease breathing (known as short-acting bronchodilators, eg, Ventolin), you (or your child) will receive a dose of this medication 15 to 90 minutes before the lung function test.

There is a chance that you may be asked to attend a further Screening Visit before Visit 1 in case any of these tests need to be repeated to confirm that you qualify for the study.

Visit 2 (Start of Cycle 1)

If the screening test results show you (or your child) qualify for the study and you agree to take part, you will return to the study centre for the second visit (Visit 2), when you (or your child) will be given the first dose of study drug. You will be chosen by chance (like flipping a coin) to receive either TIP or TOBI®. You or your child will have a 3 out of 5 chance of receiving TIP or a 2 out of 5 chance of receiving TOBI®.

The following tests will be performed at this visit:

- Review of any changes in your (or your child's) health and any medications that you (or your child) have taken since the last visit
- A physical examination (only if we find something unusual during the Screening Visit physical examination)
- Measurement of height and weight
- Vital signs before and 30 minutes after receiving study drug
- A urine sample to check your (or your child's) kidneys
- Collect 1 blood sample (about 2 to 4 teaspoons) for laboratory testing
- A sputum or deep-throat cough sample to test for bacteria
- A lung function test (blow into a tube) before and 30 minutes after receiving study drug. If you (or your child) use a short-acting bronchodilator, you will receive a dose of this medication 15 to 90 minutes before the lung function test
- A hearing test (at selected study centres either on, or within 3 days of the study visit).

You (or your child) will be taught to take the study treatment and how to complete the Subject Dosing Log by the study staff. You (or your child) will then take your first dose of study drug while study staff watch. If you (or your child) use a short-acting bronchodilator, you (or your child) will use it 15 to 90 minutes before receiving the study drug.

The study staff will give you a supply of the assigned study drug and ask you to bring the study drug kit and Subject Dosing Log with you to your next study visit.

Visit 3 (Week 2 of Cycle 1)

The following tests will be performed at this visit:

- Review of any changes in your (or your child's) health and any medications that you (or your child) have taken since the last visit
- Measurement of height and weight
- Vital signs before and 30 minutes after receiving study drug
- A lung function test (blow into a tube) before and 30 minutes after receiving study drug. If you (or your child) use a short-acting bronchodilator, you will receive a dose of this medication 15 to 90 minutes before the lung function test
- Review of the amount of study drug that you (or your child) used by counting the number of used and unused pills or bottles that you return and reviewing your Subject Dosing Log.

You (or your child) will then take your next dose of study drug while study staff watch. If you (or your child) use a short-acting bronchodilator, you (or your child) will use it 15 to 90 minutes before receiving the study drug.

The study staff will review the instructions for taking care of the study drug and inhaler and ask you to bring the study drug kit and Subject Dosing Log with you to your next study visit.

Visit 4 (Week 3 of Cycle 1) and Visit 6 (Week 7 of Cycle 1)

The study staff will contact you by telephone or e-mail to review your (or your child's) medications and ask you how you (or your child) have been doing since your last visit. The instructions for taking care of the study drug and inhaler will also be reviewed.

Visit 5 (End of Cycle 1) and Visit 10 (End of Cycle 3)

The following tests will be performed at these visits:

- Review of any changes in your health and any medications that you have taken since the last visit
- Measurement of height and weight
- Vital signs before and 30 minutes after receiving study drug
- A urine sample to check your (or your child's) kidneys
- Collect 1 blood sample (about 2 to 4 teaspoons) for laboratory testing
- A sputum or deep-throat cough sample to test for bacteria
- A lung function test (blow into a tube) before and 30 minutes after receiving study drug. If you (or your child) use a short-acting bronchodilator, you will receive a dose of this medication 15 to 90 minutes before the lung function test
- Review of the amount of study drug that you (or your child) used by counting the number of used and unused pills or bottles that you return and by reviewing your Subject Dosing Log
- You will be asked to answer some questions about your (or your child's) satisfaction with the study drug treatment

- A hearing test (at selected study centres either on, or within 3 days of the study visit).

You (or your child) will then take your next dose of study drug while study staff watch. If you (or your child) use a short-acting bronchodilator, you (or your child) will use it 15 to 90 minutes before receiving the study drug).

Visit 7 (Start Cycle 2)

The following tests will be performed at this visit:

- Review of any changes in your (or your child's) health and any medications that you have taken since the last visit
- Measurement of height and weight
- A physical examination
- Vital signs before and 30 minutes after receiving study drug
- A urine sample to check your (or your child's) kidneys and for pregnancy testing for women who are able to become pregnant. Results of the pregnancy test must be negative for to continue in this study.
- One blood sample (about 2 to 4 teaspoons) for laboratory testing
- A sputum or deep-throat cough sample for bacterial culture
- A lung function test (blow into a tube) before and 30 minutes after receiving study drug. If you (or your child) use a short-acting bronchodilator, you will receive a dose of this medication 15 to 90 minutes before the lung function test.

You (or your child) will then take your next dose of study drug while study staff watch. If you (or your child) use a short-acting bronchodilator, you (or your child) will use it 15 to 90 minutes before receiving the study drug).

The study staff will give you a supply of study drug and a new Subject Dosing Log and ask you to bring the study drug kit and Subject Dosing Log with you to your next study visit.

Visit 8 (End of Cycle 2)

The following tests will be performed at this visit:

- Review of any changes in your health and any medications that you have taken since the last visit
- Measurement of height and weight
- Vital signs before and 30 minutes after receiving study drug
- A urine sample to check your (or your child's) kidneys
- A blood sample (about 2 to 4 teaspoons) for laboratory testing
- A sputum or deep-throat cough sample for bacterial culture
- A lung function test (blow into a tube) before and 30 minutes after receiving study drug. If you (or your child) use a short-acting bronchodilator, you will receive a dose of this medication 15 to 90 minutes before the lung function test

- Review the amount of study drug that you used by counting the number of used and unused pills and bottles that you return and reviewing your Subject Dosing Log
- Answer questions regarding your satisfaction with the study drug treatment
- A hearing test will be performed (at selected study centres either on, or within 3 days of the study visit).

You (or your child) will then take your next dose of study drug while study staff watch. If you (or your child) use a short-acting bronchodilator, you (or your child) will use it 15 to 90 minutes before receiving the study drug).

Visit 9 (Start of Cycle 3)

The following tests will be performed at this visit:

- Review any changes in your health and any medications that you have taken since the last visit
- Measurement of height and weight
- Vital signs before and 30 minutes after receiving study drug
- A urine sample to check your (or your child's) kidneys and for pregnancy testing for women who are able to become pregnant. Results of the pregnancy test must be negative to continue in this study.
- Collect 1 blood sample (about 2 to 4 teaspoons) for laboratory testing
- A sputum or deep-throat cough sample to test for bacteria
- A lung function test (blow into a tube) before and 30 minutes after receiving study drug. If you (or your child) use a short-acting bronchodilator, you will receive a dose of this medication 15 to 90 minutes before the lung function test.

You (or your child) will then take your next dose of study drug while study staff watch. If you (or your child) use a short-acting bronchodilator, you (or your child) will use it 15 to 90 minutes before receiving the study drug).

The study staff will give you a supply of study drug and a new Subject Dosing Log and ask you to bring the study drug kit and Subject Dosing Log with you to your next study visit.

Visit 11 (Follow-up/Termination)

The following tests will be performed at this visit:

- Review of any changes in your (or your child's) health and any medications that you have taken since the last visit
- A physical examination and vital signs including measurement of height and weight
- A urine sample to check your (or your child's) kidneys
- A blood sample (about 2 to 4 teaspoons) for laboratory testing, including pregnancy testing for women who are able to become pregnant.
- A sputum or deep-throat sample to test for bacteria
- A lung function test (blow into a tube). If you use a short-acting bronchodilator, you

will receive a dose of this medication 15 to 90 minutes before the lung function test.

In addition, you (or your child) may or may not have the following test performed at this visit:

- A hearing test (at selected study centres either on, or within 3 days of the study visit)
- Review of the amount of study drug that you used by counting the number of used and unused pills and bottles that you return and reviewing your Subject Dosing Log
- You will be asked to answer some questions about your satisfaction with the study drug treatment.

What Do I Have to Do?

If you (or your child) choose to take part in this study, you have to agree to take the study treatment as directed by your study doctor, attend the scheduled study visits and complete the Subject Dosing Log.

It is very important that you (or your child) take the medicine given to you (or your child) just as the doctor tells you to. Do not miss any doses of the medication.

You (or your child) must also tell the study staff about any medications you (or your child) are taking during the study. This includes prescriptions drugs, over-the-counter medicines and vitamins. This is very important.

Please tell your study doctor or study staff if you (or your child) have any unusual symptoms during the study.

You (or your child) may continue all regularly scheduled medicines and treatments except for TOBI[®], certain antibiotics (amino glycosides) and some diuretics (known as water pills), which are not allowed until you are (or your child) is finished with the study.

In particular, you (or your child) may continue to take your (or your child's) regularly scheduled inhaled hypertonic saline at the usual time either at home or in the clinic; however, you (or your child) may not take inhaled hypertonic saline within 30 minutes of a study lung function test (blow into a tube).

You (or your child) may also continue to take your (or your child's) regularly scheduled, long-acting bronchodilators (eg, Serevent[®]) as prescribed within the preceding 24 hours. If you have not taken this long-acting bronchodilator in the 12 hours before your study visit, your doctor may decide that you should take a short-acting bronchodilator at the study visit.

If you (or your child) become pregnant during the study, your (or your child's) study doctor will remove you (or your child) from the study and will ask permission to follow the pregnancy to check that everything is OK.

What are the Alternatives for Treatment?

You (or your child) do not have to take part in this study to receive treatment for your (or your child's) lung infection. If you (or your child) choose not to take part, you (or your child) will continue to receive standard treatment for CF, which may include airway clearance, vitamins and nutritional supplementation, pancreatic enzymes and, when needed, antibiotics. You (or your child) do not need to participate in this study to receive TOBI[®]. The study doctor will discuss with you the risk and benefits of other treatments.

What are the Possible Side Effects of any Treatment Received When Taking Part?

Only one study using TIP in 60 people with CF has been completed. The side effects in this study were cough or cough that got worse, bad taste, sore throat, coughing up blood, runny nose, increased sputum (phlegm), crackling sounds in the lungs, watery eyes, abdominal pain, dizziness and headache. Only one person quit the study due to these side effects.

Tobramycin (the antibiotic contained in TIP and TOBI®) can cause kidney and hearing problems when found at high levels in the blood. Previous studies on people who inhaled TOBI® and TIP found only low levels of study drug in their blood. However, some people who took other drugs like tobramycin for injection, either before or at the same time as TOBI®, had hearing loss. Other people had ringing in the ears and hoarseness. No one who had ringing in the ears had any loss of hearing. The ringing stopped after the end of the study treatment period. People who got hoarse found that they became less hoarse as they continued to take TOBI®.

Allergic reactions can occur with any drug. Common symptoms of an allergic reaction may include rash, itching or skin problems. Symptoms of a severe reaction include swelling of the face, difficulty breathing, and a sudden drop in blood pressure that may cause dizziness. If you have any of these symptoms, call your doctor right away.

An independent, external Data Monitoring Committee (DMC) has been set up by Novartis to monitor safety data, including any serious adverse events, during the study. The DMC includes experienced cystic fibrosis clinicians and statisticians.

Possible side effects from taking blood samples include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

You (or your child) may have some coughing or shortness of breath after performing lung function testing, but you (or your child) should not feel any pain.

What are the Possible Disadvantages and Risks of Taking Part?

It is possible that if the treatment is given to a pregnant woman, it will harm the unborn child. Pregnant women must not, therefore, take part in this study; neither should women who plan to become pregnant during the study. Women who can become pregnant will be asked to have a pregnancy test before taking part to make sure they are not pregnant. Women who could become pregnant must use a method of birth control (contraceptive) that the study doctor says is ok during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her study doctor.

It is also not known if the antibiotic contained in TIP would be found in breast-milk. So, women who are breast-feeding also cannot take part in this study.

Since TIP is experimental, there may be other risks that we do not know about. Any drug could cause of an allergic reaction, which if not treated promptly, could become life threatening.

What are the Potential Benefits of Taking Part?

You (or your child's) participation in this study may not have any direct benefit to you (or your child). The study treatment may reduce bacteria in your (or your child's) lungs. However, it is not known if you (or your child) will feel better, the same, or worse as a result of taking part in this study.

What if New Information Becomes Available?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If we become aware of new information during the course of the study that may affect you (or your child's) desire to continue in the study, the study staff will share this information with you (or your child).

If, during the study, the sponsor decides to perform any new tests on samples taken from you (or your child), you may be asked to give your consent again and you will again have the right to refuse.

The study doctor or sponsor may remove you (or your child) from the study without your consent for any of the following reasons: if it appears to be medically harmful to you (or your child), if you (or your child) fail to follow directions, if it is discovered that you (or your child) do not meet the study requirements, or if the study is cancelled. Your doctor may also remove you from the study for other reasons.

What if Something Goes Wrong?

If you are (or your child) is injured as a result of taking part in this research study and your doctor believes that the injury is directly related to the use of study medicine, Novartis Pharmaceuticals Corporation (sponsor of this study) will pay for medical care required to treat this injury. Novartis will not be responsible for any other treatment costs for you (or your child's) regular medical care. In the event of an injury, you should contact the study doctor immediately at the telephone number listed on page 2 of this form. You will not lose any of your legal rights by signing this consent form.

Will my Taking Part in this Study be Kept Confidential?

If you consent to take part in this research study, any of your (or your child's) medical records may be inspected by Novartis Pharmaceuticals Corporation (the company sponsoring this study) for purposes of analysing the results. They may also be looked at by people from Novartis and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the study centre.

The records will not be used for any other purposes or disclosed to any other party without your permission. All study records will be coded with an identification number to protect you (or your child's) identity. You (or your child's) privacy and the protection of your (or your child's) personal data will comply with the European Union Data Protection directive; however your (or your child's) study information may also be transferred to countries outside the European Union.

Your (or your child's) study information will be retained for 2 years after either the research drug is approved to treat the health condition named in the study or research on the drug for this treatment has ended.

What will Happen to the Results of the Research Study?

Study data may be published or shared with other researchers, but the identity and medical information of each study participant will remain strictly confidential.

The study results will be reported to regulatory authorities after the end of the study within the time that they request.

The reports and any publications will be sent to your study doctor who will be able to provide you with further information.

Who is Organising and Funding the Research?

This research study is being organised and funded by Novartis Pharmaceuticals Corporation.

You (or your child's) reasonable and necessary expenses relating to the study (eg, travel and parking) will be reimbursed if you can provide receipts for those expenses.

Your study doctor will be paid for including you (or your child) in this study.

Who to Contact for Further Information

If you (or your child) have any questions about the study, or if you (or your child) become injured or have a medical problem at any time during the study, you (or your child, or the child's parent or guardian) should contact the study doctor at the telephone number listed on page 2 of this form.

If you need any further information regarding your (or your child's) rights as a research subject before, during or after this study, you may contact *[add IEC name and phone number]*.

You will be given a copy of this information sheet and signed consent form to keep.

Sample Signature Page

Protocol number: CTBM100C2302

Protocol title: A Randomized, Open-label, Multicenter, Phase 3 Trial to Assess the Safety of Tobramycin Inhalation Powder Compared to TOBI® in Cystic Fibrosis Subjects

Statement of Consent

I confirm that I have read (or someone has read to me) and understood the information sheet dated <<*date and version to be added*>> for the above study and have had the opportunity to ask questions.

It has been explained to me that I (or my child) do not have to take part in this study and I understand that my (or my child's) participation is voluntary. If I (or my child) do take part, I (or my child) can change my (his or her) mind or withdraw from the study at any time without giving any reason. There will be no penalty if I (or my child) do not take part in the study or if I (or my child) withdraw from the study and my medical care will not be affected.

By signing this document, I am not giving up any of my legal rights.

I understand that sections of any of my medical notes may be looked at by responsible individuals from Novartis Pharmaceuticals Corporation or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

_____ Name of subject	_____ Date	_____ Signature
_____ Name of parent or legally authorised representative*	_____ Date	_____ Signature
_____ Name of person taking consent (if different from investigator)	_____ Date	_____ Signature
_____ Investigator	_____ Date	_____ Signature

*By signing this consent form, I verify that I have the legal authority (legal custody) to give permission for this child to take part in this study. I have provided copies of guardianship to the study doctor, or designee, which show that I have the above described legal authority (please attach)

What if I Join the Pharmacokinetic Sub-Study?

**I am participating (I allow my child to participate) in the pharmacokinetic sub-study:

☐ Yes ☐ No

If you (or your child) are one of the people who agree to join the pharmacokinetic portion of the study, the following tests will be performed at Visit 2 (Start of Cycle 1), Visit 5 (End of Cycle 1), Visit 9 (Start of Cycle 3) and Visit 10 (End of Cycle 3).

- 4 additional blood samples (about 2 teaspoons each) will be collected to measure the amount of tobramycin in your (or your child's) blood: one sample before receiving study drug, one sample between 0 to 2 hours after receiving study drug and 2 samples between 2 to 5 hours after receiving the study drug
- Three additional sputum samples or deep-throat sample will be taken to measure the amount of tobramycin in your sputum between 30 minutes to 2 hours after receiving study drug
- If you decide to stop the study early, on your last visit you will be asked to give one additional blood sample (about 2 teaspoons) to measure the amount of tobramycin in your (or your child's) blood.

These blood and sputum samples will be sent to Novartis Pharmaceutical Corporation and will be analysed so that more can be learned about tobramycin in the bloodstream and sputum.

Possible side effects from taking the blood samples include dizziness, faintness, inflammation (redness and swelling) of the vein, pain, bruising or bleeding at the site of puncture. There is also a slight possibility of infection.

**I agree (I agree my child) to take part in this pharmacokinetic sub-study.

Name of subject

Date

Signature

Name of parent or legally
authorised representative*

Date

Signature

*By signing this consent form, I verify that I have the legal authority (legal custody) to give permission for this child to take part in this study. I have provided copies of guardianship to the study doctor, or designee, which show that I have the above described legal authority (please attach).

Addendum to Informed Consent to Take Part in a Clinical Research Study

Protocol number: CTBM100C2302

Protocol title: A Randomized, Open-label, Multicenter, Phase 3 Trial to Assess the Safety of Tobramycin Inhalation Powder Compared to TOBI® in Cystic Fibrosis Subjects

Sponsor: Novartis Pharmaceuticals Corporation

Investigator: *Name*

Patients who have been randomized to TOBI have the option to retain the compressor at the end of the study under no attached conditions. The compressor used in this study, PARI Boy Compressor, is valued at approximately €105, respectively. Patients (their parent or legally authorised representative) will be required to sign an IEC-approved informed consent addendum prior to receiving the compressor. If the patient decides to retain the compressor at the end of the study, he/she (or their parent or legally authorised representative) will be responsible for maintenance of the compressor. Please contact the device manufacturer for further information.

Consent

By signing this form I have not waived any of the legal rights which I otherwise would have as a participant in a research study.

I voluntarily consent to participate/continue/conclude my participation in this study.

_____ Name of subject	_____ Date	_____ Signature
_____ Name of parent or legally authorised representative*	_____ Date	_____ Signature
_____ Name of person taking consent (if different from investigator)	_____ Date	_____ Signature
_____ Investigator	_____ Date	_____ Signature