

APPENDIX 2: Core Consent Forms **Pre-Enrollment Informed Consent**

Your child has been exposed to a moderate amount of lead. This amount of lead does not make your child sick, but it may be enough to harm your child's development, thinking and learning as the child gets older. Children get exposed to lead mostly from dust and chipped paint in their homes. It is important to keep lead dust and chipped paint away from children. We do not know if giving a child medicine to get rid of some of the lead in their bodies will keep the lead from harming them. We do know that medicines that take lead out of the body have side effects, like all medicines.

Your child may be eligible for our study -- the Treatment of Lead-Exposed Children study. We call it TLC for short. We want to see whether a medicine prevents lead in children's bodies from harming them as they grow older. This medicine is called succimer, and it gets rid of some of the lead in children's bodies. It is now used for children who have more lead in their bodies than your child has.

All children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint, will get vitamins and minerals, will get regular checkups and blood tests from a doctor, and will get tests of their thinking, learning and development. The parent or parents, usually the mother, will also have a short intelligence quotient, or IQ test, which is a test of their thinking and reasoning skills, but will not get check-ups or blood tests.

Half the children in the TLC study will get capsules that have succimer in them. Succimer should remove some of the lead from these children's bodies, but it has some side effects. The other half of the children in the TLC study will get capsules that look the same, but have no succimer in them. These capsules will not remove lead from these children's bodies, and have no side effects.

Children with amounts of lead in their bodies like your child's usually do not get medicine to help them get rid of the lead. Succimer is not recommended for children with amounts of lead in their bodies like your child has unless they are in a study. Succimer has been approved for treating children who have more lead in their bodies than your child does.

We do not know whether it is better for children like yours to get the succimer or not. To help find this out, we will put half of the children in the TLC study into a group that gets succimer and half of the children into a group that gets capsules without succimer. We will decide which group your child will be in at random, like tossing a coin. Every child will be in one group or the other. Unless there is a problem, you and the TLC doctor who takes care of your child will never know which group your child is in. There will be another doctor at the hospital who does know your child's group in case of problems. Children will be in this study for 3 years, but they will not take capsules for longer than one year. There is no charge for the study.

Today, we are asking your permission to find out whether your child is eligible to be in the TLC study. Participation is completely voluntary. If you agree to participate, then this is what will happen:

1. Clinic visits and blood tests

Your child will have a blood test and check up today. You will get another appointment to come back to the clinic in about one month for a second check up and blood test. We will look for several things with the blood tests. We will measure the amount of lead. We will make sure that there is not something about the way that your child's liver or kidneys work that would keep us from giving succimer to them.

We will make sure that the cells in their blood are normal and that they have enough iron. If your child has so little iron that he or she is anemic or has low blood, then we will give you iron for him or her and check him or her again after taking it to see if he or she is eligible.

The blood is usually taken with a needle from the vein in the child's arm, and the amount is between one and three teaspoons. The needle stick usually hurts, and sometimes leaves a bruise. Very rarely, a child gets a blood clot or infection. If anything unexpected happens, a doctor from the study will help take care of any immediate need, but the study can not give you care or pay for care for a problem that takes a long time to resolve.

2. Home visits and Cleanup

We will send someone to your home to see if they can find out where the lead came from, and if it can be cleaned up. If your child spends much time at another home, we will also want to look at it. If we can tell that your child will probably be eligible for the study, then specially trained cleaners, who know about lead, will come to your home and clean up any dust and chipped paint. If there is another home where your child spends much time, then we will clean that home too.

3. Vitamins and minerals

We will give you vitamins with minerals tablets, and ask that you give one to your child every day. We will give you a vitamin diary and ask you to write down the times that you give your child the vitamins.

Even if you agree now to do these things, you can stop anytime for any reason. If you do stop, your child cannot be in the study, but it will not change the regular medical care of your child, or change any other benefits outside the TLC study that your family gets. Regular medical care for children like yours includes blood tests for lead. The xxx city health department is responsible for inspecting homes of children whose blood tests show that they have too much lead exposure. The results of your child's blood lead tests have been/will be reported to them. Whatever the city does will not be changed if your child is eligible for this study, or if you decide to be in the TLC study.

Not every child will be eligible for the TLC study. Most of the time, we can tell if a child is eligible by the second clinic appointment, in about one month, but sometimes it will take longer. If your child is eligible, then we will ask for your consent again before your child is treated. We will give you a copy of the consent form for the treatment part of the study to take home with you today.

The results of the TLC study will help doctors know how to treat other children like yours who have been exposed to lead. Your child will not benefit from the TLC study's results, because the results will not be ready in time to help treat your child. The benefits to your child of letting us find out if they are eligible for the TLC study are that we will look carefully at your home for lead dust and chipped paint and tell you about it, clean-up the lead if it looks like your child is eligible, give you vitamins and minerals for your child, have a doctor examine your child, and check the amount of lead in your child's body carefully. There is no charge to you for any of this. Some of the things, like the check ups and blood tests, are often done anyway to children who have been exposed to lead, and some insurance pays for them. We may ask your insurance to pay, but if they do not pay we will not charge you.

We need your help if your child is going to participate in the TLC study. It is important that you give your child the vitamins and keep the vitamin diary, that you keep the appointment to have your home checked for lead, and that you keep the appointment in the clinic next month. Only families that can keep most appointments and give their children vitamins regularly can be in the study. The TLC study records are confidential, and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study.

Enrollment Informed Consent

Your child has been exposed to a moderate amount of lead. This amount of lead does not make your child sick, but it may be enough to harm your child's development, thinking and learning as they get older. Children get exposed to lead mostly from dust and chipped paint in their homes. It is important to keep lead dust and chipped paint away from children. We do not know if giving a child medicine to get rid of some of the lead in their bodies will keep the lead from harming them. We do know that medicines that take lead out of the body have side effects, like all medicines.

Your child is eligible for our study, which is called the Treatment of Lead-Exposed Children study, or TLC for short. We want to see whether a medicine prevents lead in children's bodies from harming them as they grow older. This medicine is called succimer, and it gets rid of some of the lead in children's bodies. It is now used for children who have more lead in their bodies than your child has.

All children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint, will get vitamins and minerals, will get regular check ups and blood tests, and will get tests of their thinking, learning and development. The parent or parents, usually the mother, will also have a short intelligence quotient, or IQ test, which is a test of their thinking and reasoning skills, but will not get check-ups or blood tests.

Half the children in the TLC study will get capsules that have succimer in them. The other half of the children in this study will get capsules that look the same, but have no succimer in them. Children will be in this study for 3 years, but they will not get study capsules for longer than a year. There is no charge for the study.

Now that we know that your child is eligible, we are asking your permission for them to be in the treatment part of the study. Participation is completely voluntary. If you agree to participate, then this is what will happen:

1. Medicine and medicine diaries

We will give you enough capsules to give to your child for 26 days. Taking capsules for 26 days is called a course of therapy, or just a course. Since the capsules are too big for your child to take, we will show you how to open them and sprinkle the beads of medicine that are inside into some food or drink. We will give you a diary and ask you to write down when you have given the capsule, and whether your child is sick. Some people find the capsules smelly; this does not mean that they are spoiled or that they will make your child sick.

The medicine used in this study, succimer, is now used for children with more lead in their bodies than your child has. In this study, we are giving higher doses of succimer than are used in those children, and we are giving succimer for a week longer than it is given to those children. We are doing this because we have to get enough lead out of your child's body to make a difference. Many children have to take more than one course of succimer to get enough lead out of their bodies, and we think that using the succimer the way we are using it will cut down the number of children who need more than one course.

Half the children in this study will get capsules that have succimer in them. Succimer should remove some of the lead from children's bodies, but has some side effects. Side effects from succimer happen in about 10% to 20% of children. The most common side effects are rashes, upset stomach, changes in blood tests that measure how children's livers are working, lower numbers of white cells (the cells that fight infection) in the children's blood, and lower numbers of platelets (the cells that help blood clot) in the children's blood. So far, there have been very few serious side effects with succimer, and they have gone away when the succimer was stopped. Few children have had to stop succimer because of side effects. If your child has severe or too many side effects, we will stop the medicine. We will ask you about any illness that your child has had when you come to clinic, and we will look for side effects with blood tests.

The other half of the children in this study will get capsules that look exactly the same, including the beads inside, but have no succimer. These capsules will not remove lead from children's bodies, and have no side effects.

Since we do not know whether it is better for children like yours to get succimer or not, we will put the children into these two groups at random, like tossing a coin. You and the TLC doctor who takes care of your child will never know which group your child is in, unless there is a problem. There will be another doctor at the clinic who does know in case of problems.

It is important that you tell us if your child gets sick while taking the capsules, and we will give you phone numbers to use for calling us. We also ask you to write down in a medicine diary if your child gets sick while taking the TLC capsules. It is also important to tell us if your child is taking any other medicines while they are taking

capsules. A doctor from the TLC study will help take care of any immediate need, but the study can not give you care or pay for care for a problem that takes a long time to resolve.

We will ask you to come back to the clinic in one week after your child starts taking capsules and we will check your child and do a blood test for lead and for any side effects. The blood is usually taken with a needle from the vein in the child's arm, and the amount is between one and three teaspoons. The needle stick usually hurts, and sometimes leaves a bruise. Very rarely, a child gets a blood clot or infection. We will look at the medicine diary with you to see how many of the capsules your child took, and we will ask you if your child was sick.

We will ask you to come back to the clinic again one month from now, and have the same things done. If the lead in your child's body has not gone down enough, then we will ask you to come back to clinic and give you enough capsules for another 26 day course to give to your child. We think that about half to three quarters of the children in the study will get a second course. The chance will be the same whether your child got the capsules with succimer or the capsules without. If your child gets a second course, then we will ask you to come in for blood tests and a check up at one week and one month after the course starts, and to keep a medicine diary, the same as the first course. A few children, about 10%, who still have too much lead will get a third course of capsules, which will be the same as the first two courses.

2. Blood lead results

You and the TLC doctor taking care of your child will not know the results of the blood lead tests done during the first six months after your child starts taking capsules, but another doctor will know in case there is a problem. If your child is still taking capsules after six months, then you will not know the results of the blood lead tests done during treatment, and for three months after your child is finished taking capsules. You may have the blood lead results after these treatment periods if you want them.

3. Follow up visits and vitamins

Once your child finishes taking the capsules, we will ask you to come back about every three to four months for a blood lead test until you have been in the study for about three years. We will give you vitamins at these clinic checkup visits, and ask that you give one to your child every day. You will not need to keep a diary anymore, but we think it is important for your child to take the vitamins every day.

4. Thinking, reasoning, and development tests

We will test your child's thinking, reasoning and development three times: at six months, 18 months, and three years after they begin taking capsules. These tests take about 2 hours or less in the younger children, and about 2 hours and 30 minutes in the oldest children. The tests have the child play with toys and mazes and solve simple problems. Most children enjoy these tests, but they have to be feeling well to do them. Sometimes the tests have to be re-scheduled if your child is sick or not feeling well.

When your child is three, we will give a parent, usually the mother, a short version of an IQ test, which involves reading and solving problems and takes about 45 minutes. We will also ask the parent questions about the child's behavior. There are no risks from any of these tests.

5. Damage at home or moving to a different home

It is important for you to tell us if you move, or if a plumbing leak or anything else damages the walls or ceilings in your home, because we will need to come out and inspect and clean up the way we did at the beginning of the study. If the doctor who sees the results of the blood lead tests finds that the amount of lead in your child's body has gone up too much, we may want to come and inspect or clean your home again. Very rarely, a child's lead might go up so high during the study enough so that they are no longer eligible for the TLC study. This usually happens because something happened at their home, such as sanding paint, or they visited a home where there was chipped paint or dust with lead in it. If this happens, the child will get the usual care for children with larger amounts of lead in their bodies, which may include succimer. The TLC study will not pay for or provide that care.

Even if you agree now to do these things, you can stop any time for any reason. If you do stop, it will not change the regular medical care of your child, or change any other benefits outside the TLC study that your family gets. Even if you stop being in the study in the early part, we will still invite you to come in later for the blood tests and the tests of your child's thinking, reasoning and development.

Regular medical care for children like yours includes blood tests for lead. The xxx city health department is responsible for inspecting homes of children whose blood tests show that they have too much lead exposure. The results of your child's blood lead tests have been/will be reported to them. All of the inspections and clean-ups in the study are additions to what the city would do, and the city's actions will not be changed.

Children with amounts of lead in their bodies like your child's usually do not get medicine to help them get rid of the lead. Succimer is not recommended for children with amounts of lead in their bodies like yours unless they are in a study. Succimer has been approved for treating children who have more lead in their bodies than your child does.

If anything unexpected happens, a doctor from the TLC study will help take care of any immediate need, but the study can not give you care or pay for care for a problem that takes a long time to resolve.

The results of the study will help other children because better decisions will be made about their treatment. Your child will not benefit from the study's results, because they will not be ready in time to help us in treating your child. The benefits to your child are:

We will look carefully at your home for lead dust and chipped paint and tell you about it.

We will clean-up the lead dust in your home.

We will give you vitamins and minerals for your child.

A TLC doctor will examine your child regularly.

We will check the amount of lead in your child's body carefully and regularly.

We will regularly test your child's thinking and development.

We believe that children in the study will get equal or better care than children outside the study, and that their homes will have less lead in them sooner than if they were not in the study. There is no charge to you for any of this. Some of the things, like the check ups and blood tests, are often done to children who have been exposed to lead, and some insurance pays for them. We may ask your insurance to pay, but if they do not pay we will not charge you.

The TLC study records are confidential, and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study.