

Exhibit 11

Form C (Revised 6/93)

CLINICAL INVESTIGATION CONSENT FORM

The Johns Hopkins Medical Institutions
(The Johns Hopkins Hospital
The Francis Scott Key Medical Center, etc.)

<p>0537 V2</p> <p>Featherstone, Kenna</p> <p>Patient I.D. Plate</p>

Title of Research Project: Treatment of Lead-Exposed Children
(TLC) Trial Enrollment

Explanation of Research Project to Subject:

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 her/his body will keep the lead from harming her/him. 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. Children will be in this study for 3 years. There is no charge for the study. 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 repaired and/or 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 (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.

Now that we know that your child is eligible, we are asking your permission for her/him 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 or someone else (relative or babysitter) to write down each day 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.

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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 a higher total dose of succimer than is used in treating children with higher blood lead levels because we are giving succimer for a week longer than it is given to such 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. We think that using succimer the way we are using it will cut down the number of children who need more than one course. Children will not get study capsules for longer than three courses.

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 may have some side effects. Side effects from succimer happen in about 5% to 10% 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. At every visit, we will be checking your child for these side effects. 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. So far, there have been very few 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 side effects, we will stop the medicine.

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. In case of problems, there will be another doctor at the clinic who does know what group your child is in and will take the necessary actions.

It is important that you tell us if your child gets sick with a cold or other illness 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 with a cold or other illness 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.

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

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amount is between one and three teaspoons. The needle stick usually hurts, and sometimes leaves a bruise. To minimize this only experienced personnel will draw blood. 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. **Followup 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 he/she begins taking the 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.

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After one year in the study, 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 as 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 blood has gone up too much, we may want to come and inspect or clean your home again. Very rarely, a child's blood lead level might go up so high during the study that they might receive additional treatment outside of the study. If this happens, the child will get the usual care for children with higher lead levels, which may include succimer. We will refer your child for proper care. 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 Baltimore 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.

The results of the study will help other children because better decisions will be made about their treatment. Your child will not benefit directly 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:

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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 given medicine. 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 directly 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:

- o We will look carefully at your home to identify lead hazards and tell you about it.
- o If your house doesn't qualify, we will offer you any information we have about ways to relocate your family to housing that is known to be lead safe
- o We will clean-up the lead if it looks like your child and house are eligible.
- o We will give you vitamins and minerals for your child.
- o We will have a doctor examine your child.
- o We will check the amount of lead in your child's body carefully.

If you sign this form, you are willing to join the research project described to you on the other side of this page. Your doctors, or the investigators, did explain the other kinds of treatment that are available to you and to others. You should ask the principal investigator listed below any questions you may have about this research study. You may ask him/her questions in the future if you do not understand something that is being done. The investigators (or doctors) will share with you any new findings that may develop while you are participating in this study.

The records from this research study will be kept confidential and will not be given to anyone who is not helping on this study, unless you agree to have the records given out. If the study uses a new drug or device that is under the jurisdiction of the Food and Drug Administration (FDA), the FDA government officials may look at the relevant part of your medical records as part of their job to review new drug and device studies.

If you want to talk to anyone about this research study because you think you have not been treated fairly, or think you have been hurt by joining the study, or you have any other questions about the study, you should call the principal investigator, Dr. J. Julian Chisolm, at 550 9035, or call the Office of the Joint Committee on Clinical Investigation at 955-3008 or call The Francis Scott Key Medical Center Institutional Review Board for Human Research at 550-1853. Either the investigator or the people in the Committee office or IRB office will answer your questions and/or help you to find medical care for an injury you feel you have suffered. The Johns Hopkins University, The Johns Hopkins Hospital, The Francis Scott Key Medical Center, Kennedy Krieger Institute and the Federal Government do not have any program to provide compensation to you if you experience injury or other bad effects which are not the fault of the investigators.

You may withdraw from the research study at any time. Even if you do not want to join the study, or if you withdraw from it, you will still have the same quality of medical care available to you at Johns Hopkins or the Francis Scott Key Medical Center.

If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE
COMMITTEE OR IRB STAMP
OF CERTIFICATION



VOID ONE YEAR FROM ABOVE DATE
RPN NO. 92-11-19-01

Subject's signature
(including children, when applicable)

Sharon Jackson
Signature of Parent or Guardian (when applicable)

Maie W. Kirkland R.N. MS
Witness to Consent Procedures

Janet Lewont MD
Signature of Investigator

June 21, 1995
Date

*Optional unless subject is illiterate, or unable to sign.