

Disclaimer: This consent form was not used in these experiments. What was used did not accurately describe the experiment or comply with the laws regarding protection of human experimental subjects. (GAO/HEHS referenced below)

Proposed accurate INFORMED CONSENT for **New England Children's Amalgam Trial** or **Casa Pia Orphan's School in Lisbon, Portugal**

Parent or Guardian:

By agreeing to have your child participate in the **Children's Mercury Exposure Experiment**, your child will receive several mercury/silver tooth fillings for free. These fillings have been used in dentistry for over 150 years. In order to place them in your child, a large hole must be drilled into each tooth. This requires the removal of a considerable amount of healthy tooth structure, and as a result the drilling alone will weaken the tooth by 75 percent. Placing the new mercury/silver filling will not strengthen this tooth. Alternative materials are available that require only the removal of the decayed part of the tooth, and that both seal and strengthen the remaining tooth structure. If your child is selected for the control group, he or she will receive this type of tooth-colored filling. Unfortunately, once we have drilled away a substantial portion of your child's permanent teeth, they will never hold these white-colored composite fillings nearly as well as they would have if we had not intervened with the mercury/silver filling.

Mercury/silver fillings are an unstable mixture that is about half mercury, with lesser amounts of silver and other metals. When compressed it liberates mercury at the surface. It also expands and contracts with temperature, and where moisture is present, as in the mouth, it corrodes. Corrosion on the surface may be chewed off during mastication and swallowed. In addition, the corrosion products are larger than the original filling and thus both thermal expansion and corrosion will produce lateral forces on your child's weakened tooth. This will lead to cracking and eventual fracture of the permanent tooth structure, which may require crowns, larger fillings, root canals, or tooth extraction later in life. The costs of these repairs will not be covered by this experiment.

Mercury is released in significant quantities during placement of these kinds of fillings. We will take **no** precautions to prevent the release of this mercury. The purpose of this study is to determine how much this powerful heavy metal neurotoxin will impair your child's ability to think and react to stimulate. In addition, the daily brushing and chewing that children do with their teeth will exacerbate and stimulate greater volatilization of mercury from these fillings throughout the child's entire life or the life of the filling, whichever comes first. Hot fluids and even clenching of teeth causes mercury to rise to the surface of the mixture and evaporate into the air in the mouth. From there it can be exhaled, inhaled, or absorbed directly into the blood from the mouth and nasal tissues and transported along the nerve pathways back to the brain. Mercury will also migrate from the filling directly into the jawbone surrounding the teeth, and from there be transported to distant sites in the body.

The World Health Organization in 1991 determined that mercury/silver tooth fillings are the predominant source of human exposure to mercury and that there is no lower

threshold for exposure to mercury where some injury does not occur. In 1997 manufacturers of mercury silver dental fillings altered their Material Safety Data Sheets for Germany and California to include the following adverse health effect from chronic inhalation and/or ingestion: Tremor, fatigue, headaches, irritability, excitability, depression, insomnia, loss of memory, hallucinations, psychiatric disorders, mental deterioration and resentment of criticism, bronchitis, kidney failure, chest pain and palpitations, colitis, dermatitis, blood disorders, infertility and birth defects. This experiment will merely confirm earlier studies demonstrating exposure to mercury from implanting mercury silver dental fillings and add nothing new to the body of evidence. We will periodically monitor the child's urine that will not give us meaningful data on body burden or mercury toxicity. We expect the urine mercury to initially increase with placement of these fillings and gradually decline over time even as exposure increases due to the exhaustion of the kidneys ability to excrete mercury. This will indicate that more mercury is being retained in the child's tissues over the time of this experiment. Since chronic mercury toxicity from mercury silver dental fillings does not generally manifest itself until the fourth to fifth decade of life we do not expect to see this devastating disease to develop until many years after the experiment has concluded.

Subsets of the population are unusually susceptible to the toxic effects of mercury. These include women and their fetuses, people who are homozygous for the APOe4 allele and or APOe 3/4 approximately 22% of the population. The mechanism is not fully understood but it is apparently due to the inability to excrete mercury from the brain. In addition, another genetic predisposition toward injury from mercury exists. The genetic polymorphism of coproporphyrinogen oxidase in exon 4 significantly modifies the effect of mercury exposure on urinary porphyrin. Although the lead researcher, James S. Woods, who has elucidated this common genetic polymorphism is on our team of investigators we will not be trying to determine if your child is one of those susceptible to the toxic effects of mercury at the levels we will be exposing them to through the implanting of numerous mercury silver dental fillings.

Mercury exposure in infancy is now linked to autism. In adulthood, mercury is linked to a host of neurological diseases, including Alzheimer's disease. This program of human experimentation will not pay for medical, convalescent or custodial care should your child later in life succumb to one of these mercury-related neurological disorders. In addition mercury exposure is linked to heart and cardiovascular disease. We will neither look for nor pay for treatment of any of these diseases should they develop.

We will measure your child's brain development. Any injury that might occur from exposure to mercury will most likely be permanent and irreversible. We will not pay compensation for such an injury either.

Mercury is found in the umbilical cord blood of newborn infants at such high levels today that 1 out of 16 will be impaired by this exposure. We do not know what the umbilical mercury blood level of your child was. The source of the umbilical cord blood is primarily from the amalgams in the mother's teeth. Should your child someday wish to have a healthy child herself, then you might want to consider having these amalgam removed and replaced with some non-mercury-leaking material. This will be very expensive, and even if meticulous patient protection protocols are followed, should be done at least 214

days before conception to minimize the risk to her unborn baby. We will not pay to have these mercury-leaking fillings removed.

Your child will be tested annually for several broad signs of neurological harm from mercury including memory, IQ and comprehension. We will also periodically sample urine, blood. These experiences would be what one usually expects when visiting a doctor including taking of blood and a physical examination. When receiving dental treatment the child will be given a local anesthetic (shot) to numb the area where we intend to drill away the decay and healthy tooth to prepare a cavity in the tooth to receive the mixture of 50 percent mercury (approximately 750 mg) and the remainder is silver copper zinc and tin. Some people do not like the experience of being numbed up and others do not like the feeling of having their tooth drilled away. It is not necessary to drill away a substantial portion of anyone's tooth unless mercury silver dental fillings are used. Alternative materials such as composite can be bonded to the surface of the tooth and thus only the immediate area around the cavity needs to be disturbed. In addition the composite can be used to seal up the vulnerable groves so that the rest of the tooth is protected from recurrent decay in that grove. When we place the mercury silver dental fillings we drill away all the groves we can and extend the area of the filling to approximately the middle third of the tooth.

Your child's records will be kept in the strictest confidentiality and we will resist to the fullest extent to our ability any effort by outside scientists to review our data findings.

When we sample the urine we will measure mercury, albumin and creatinine. When we sample the blood we will measure mercury and lead. We will try to see if these fillings are causing any kind of kidney problem with a simple measure of urine albumin. We may sample for porphyrins as well. Subsets of the population who are exceptionally vulnerable to mercury often form abnormal porphyrins. We know from other experiments that the child's urine and blood mercury will increase dramatically upon placement of the mercury dental filling.

As we noted earlier we will not compensate you or your child for any permanent neurological injury that they may suffer as a result of this experiment.

Your child's participation is entirely voluntary and the financial compensation given you or the school is merely a token of our generosity and should not be construed as coercive or as a bribe. No punishment of any kind will be received for failure to participate. In addition you or your child may choose to discontinue the trial at anytime.

For more information in the New England trials you may contact David Bellinger at the Children's Hospital of Boston Department of Neurology or Timothy DeRouen at the Washington School of Dentistry in Seattle (derouen@u.washington.edu)

Please sign and return this informed consent form to the **New England Children's Amalgam Trial** or **Casa Pia Orphan's School in Lisbon, Portugal** to allow your child to participate in this medical experiment.

Signature Parent or Guardian _____ Date _____

The above consent form is based upon the Code of Conduct:
From GAO/HEHS-96-72 Protecting Human Research Subjects pp 4-5

From 1962 through 1991 the Health and Human Services system for protecting human research subjects was created piece by piece, largely in response to disclosures of dangerous or controversial biomedical and behavioral research. The tragic consequences of thalidomide use in the United States and revelation of the Tuskegee syphilis study shocked the public and convinced national policymakers that unregulated biomedical research represented a clear threat to research subjects. Two expressions of this concern were the passage of the National Research Act and the promulgation of human subject protection regulations by the Department of Health, Education, and Welfare (HEW) in 1974. The act also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to guide federal human subject protection policy. When the core of the human subject protection regulations was adopted by 15 other departments and agencies in 1991, it became known as the Common Rule.

The Common Rule requires research institutions receiving federal support and federal agencies conducting research to establish committees to review research proposals for risk of harm to human subjects and to perform other duties to protect human research subjects. It also stipulates requirements related to informed consent – how researchers must inform potential subjects of the risks to which they, as study participants, agree to be exposed. HHS regulations contain additional protections not included in the Common Rule for research involving vulnerable populations - namely , pregnant women, fetuses, subjects of in vitro fertilization research, prisoners, and children. In the late 1970's and early 1980's, HHS considered but did not adopt recommendations by two national commissions specific regulations to protect institutionalized mentally disabled subjects.

Basic elements of Informed Consent

- A statement stipulating that research is involved, what the purpose of the research is, what the duration of the subjects involvement will be, and what procedures the subject will undergo.
- A description of foreseeable risks or discomforts to the subject
- A description of expected benefits, if any, to the subject and others.
- The disclosure of alternative procedures or courses of treatment
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- For research that poses more than minimal risk to subjects, an explanation of the availability and nature of any compensation of medical treatment in injury occurs.
- Names of people to contact for further information about the research, the subject' rights, and notification of research related injury.
- A statement stipulating that participation is voluntary and no penalties will be imposed for refusal to participate in research; subject can choose to discontinue participation at any time.