THE OKLAHOMA STATE UNIVERSITY COLLEGE OF OSTEOPATHIC MEDICINE
INFORMED CONSENT

Title of Project: The Contribution of Osteopathic Cranial Manipulation to the Management of Recurrent Otitis Media.

Investigator(s):
Miriam Mills, M.D., FAAP
Clinical Associate Professor of Osteopathic Family Medicine
1111 West 17th Street, Tulsa, OK 74107

Charles Henley, D.O., M.P.H.
Chairman of Osteopathic Family Medicine
1111 West 17th Street, Tulsa, OK 74107

Teri Bycroft, RN, MSN
Clinical Research Coordinator
1111 West 17th Street, Tulsa, OK 74107

This is to certify that I, ________________________________________________, hereby give permission to have my child or legal ward participate as a volunteer in a scientific investigation as part of an authorized research program of [The Oklahoma State University College of Osteopathic Medicine] under the supervision of [Miriam Mills, M.D.] This research is sponsored by the American Academy of Osteopathic Medicine.

Background: Ninety percent of all children under three years of age have at least one episode of otitis media (ear infection)) and seventy five percent have more than three. Osteopathic physicians find that osteopathic manipulation therapy (OMT) in conjunction with conventional medical treatment will reduce the frequency and severity of recurrent otitis media. These manipulative techniques are not new but have not been well studied in relation to recurrent otitis media. It is believed that the manipulation will improve drainage of the eustachian tube (which normally balances air pressure between the middle ear and the outside air). Drainage of fluid from the middle ear should shorten the length of symptoms and reduce the discomfort that goes with these illnesses.

Purpose of the Study: The purpose of this research is to establish the value of osteopathic manipulative treatment in the management of children with recurrent otitis media.
OMT for ROM
[Drs. Cyrus and Grogg]

**Description of the Study:** After the initial evaluation visit, all participants (Both OMT and control group) will be seen at a minimum on the following schedule:
- 3 visits in 1 week intervals during the first month (includes the first visit), followed by
- 3 visits biweekly, followed by
- 3 visits monthly which includes the final visit

Both groups will receive a behavior rating questionnaire administered by the site coordinator at these visits, and will receive monthly tympanograms. Audiograms will be administered at 0, and 6 months.

The child’s regular primary care physician will give standard care for these ear problems but about half of the children will also be given some manipulative treatments. The manipulative treatment will be given by [Miriam Mills, M.D.] and will consist of some gentle manipulations of the head and neck of the child. The child will have extra visits to the doctor’s office in addition to those required for her/his standard treatment by the regular primary care physician. The site coordinator will interview the mother and/or child to get some additional medical history. The total time over which the child will be seen will be about 10 extra visits to the physician’s office over 6 months. These visits are free of charge.

**Risks and Discomforts:** Generally these techniques are well received and painless to the child. It is possible that an uncooperative child may not like having the doctor touch her/his head and neck and while trying to move away may suffer some discomfort. A visit to the doctor is frequently an unhappy occasion to the small child but it is expected that the experienced physician who will give the treatments will give no more discomfort than any other visit to the doctor’s office. There are no specific physical risks other than those associated with any pediatrician visit which would include squirming loose and/or falling on the floor.

**Benefits:** There is no guarantee that I or my child will directly benefit from these procedures. The research may result in the following benefits: the child may have less discomfort over the course of her/his illness. The time course of the child’s illness may be shortened.

**Alternative to Participation:** If I or my child do not take part in this study, my child will be treated with the conventional medical treatment for this condition.

**Confidentiality:** I understand that the information obtained from or about me or my child will be kept confidential to the following extent. Only authorized personnel will have access to records which could identify me or my child by name. The study doctor and the research staff or representative of the study sponsor may need to be allowed access to my child’s medical record to verify information collected during the study. The information gained will be given to the regular primary care physician at the close of the project. Summary data without patient identification may be published in scientific journals.
I understand that the research investigator(s) named above will answer any of my questions about the research procedures, my rights as a subject, and research-related injuries at any time. I understand that, for any physical injury I or my child may suffer as a result of and during the course of this research investigation, [OSU COM] will not provide compensation. If I have any questions about my rights as a research subject, I may take them to the [Director of the Office of Research and Sponsored Programs at OSU-COM, (918) 561-8241.]

**Voluntary Participation:** I hereby agree to participate and give permission for my child to participate as a volunteer in the above named research project, which has been fully explained to me.

I understand that I or my child is free to refuse to participate in any procedure or to refuse to answer any question at any time without prejudice to me or my child. I understand that I am free to withdraw my consent and to withdraw from the research at any time without prejudice to me or my child.

I understand that by agreeing to participate in this research and signing this form I do not waive any of my legal rights.

I have read this consent form. The study, including its risks and benefits, has been explained to me to my satisfaction. My questions have been answered. I have been provided a copy of this form and by signing this form, I do not lose any rights to which I am otherwise entitled. I am signing this form freely and voluntarily consent to participate.

______________________________  ____________________
Parent or Legal Guardian          Date

______________________________  ____________________
Witness                          Date

______________________________  ____________________
Site Physician                    Date

**FAX COMPLETED FORMS TO (918) 747-9778**