The University of Texas Southwestern Medical Center
Children's Medical Center
Parkland Health and Hospital Systems

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	Effectiveness of Repositioning and Cranial Remolding in Infants with Cranial Deformation
Funding Agency/Sponsor:	UT Southwestern
Study Investigators:	Tiffany Graham MSPO, CPO, LPO, FAAOP(D) Rami Hallac, Ph.D. Susan Simpkins, PT, EdD Caitlin Deville, PT, MPT, DSc Alex Kane, M.D. Jijia Wang, PhD

You may call these study clinicians or research personnel during regular office hours at 214-645-3736. At other times, you may call them at 972-921-7045

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to determine the rate of correction of deformational head shapes using repositioning methods vs cranial remolding orthosis treatment.

Why is this considered research?
This is a research study because repositioning and cranial remolding orthoses have been approved by the FDA to treat deformational head shapes in infants, however success of repositioning is not well documented.

Cranial remolding orthosis treatment is being compared to repositioning which are both standard of care treatments for deformational head shapes. This is research because researchers are observing each of the procedures and are interested in learning which procedure is more effective at treating deformational head shapes.

The following definitions may help you understand this study:

- Cranial Remolding Orthosis: Helmet-like device that aids in correction of deformational head shapes
- Cranial: Head
- Repositioning: Moving an infant's head to try to take pressure off of a flattened spot
- Deformational: positional; the infant's flatness was caused by positioning
- Torticollis: Tightening of the neck muscles

Why am I being asked to take part in this research study?
You are being asked to take part in this study because your infant is the appropriate age and appears to have a normal head shape.

Do I have to take part in this research study?
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?
About 150 people will take part in this study at UT Southwestern, Children's Medical Center or Parkland Health and Hospital Systems

What is involved in the study?
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. These procedures are research procedures which are being done solely for the purpose of this study.

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

- Physical exam and medical history
- Neck range of motion evaluation
  - If clinically indicated possible assignment to torticollis treatment (physical therapy)
- Demographic information (age, sex, ethnic origin).
- 2 types of noninvasive scans
- 3dMD scanner

    - High precision 3D surface image of a subjects face and head
- Orthotist scanner
    - Uses FDA approved methods to create a 3D image (may include white light, photography, or lasers)

When your child is 12 months of age, you will be asked to have a new 3dMD scan and fill out a survey.

Study Medication/Intervention
Your participation in this study will not include any medication or intervention. If your child is identified to possibly need intervention for a cranial shape or physical therapy intervention, this finding will be discussed with you and you may discuss this with your child's physician.

Procedures and Evaluations during the Research
Scans and surveys
You will have the following tests and/or evaluations:
Visit 1 (1-2 hours):
- Consent form
- Evaluation of head shape and neck range of motion
    - If an abnormality is found, this will be discussed with you and you may choose to discuss this with your physician.
- Scan/Measure (at UTSW and at Children's Medical Center)
- Evaluation of developmental milestones
    - If an abnormality is found, this will be discussed with you and you may choose to discuss this with your physician.

Visit 2 (10min at each location):
- Scan/Measure (at UTSW and at Children's Medical Center)

Visit 3 (30min):
- Scan/Measure (at UTSW and at Children's Medical Center)
- Re-evaluation of head shape, neck range of motion, and developmental milestones
    - If an abnormality is found, this will be discussed with you and you may choose to discuss this with your physician.

Surveys may be administered at each visit. Caregivers will be provided with evaluation results and may choose to share them with their pediatrician, if desired.

How long can I expect to be in this study?
You can choose to stop participating for any reason at any time. The expected length of the study will be from age 2 months to 12 months (10 months total). However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?
Study Procedure/Intervention

Participation in this study may involve loss of confidentiality. No additional risks outside of the standard of care exist due to participation in this study.

Loss of Confidentiality
Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What will my responsibilities be during the study?
While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments
- Follow the researchers' instructions
- Let the researchers know if your telephone number or address changes.
- Let the researchers know about any new diagnoses or treatments
- Tell your regular doctor about your participation in this study
- Report to the researchers any injury or illnesses while you are on study even if you do not think it is related

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like an open wound, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area).

What are the possible benefits of this study?
If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with deformational head shapes in the future. Information gained from this research could lead to better head shape corrections in other infants.

What options are available if I decide not to take part in this research study?
You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have the following options:

- No treatment

Please talk to the researchers or your personal doctor about these options.

Will I be paid if I take part in this research study?
Yes. You will be paid $75 to take part in this research study. You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. $25 compensation will be credited to the card after completion of each study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Parking at the School of Health Professions building for the purpose of study visits will be paid via a parking voucher to exit the garage. There are no funds available to pay for transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care outside of this study.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas, Children's Medical Center, or Parkland Health and Hospital Systems

You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.
If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

Your clinician is a research investigator in this study. She is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another clinician who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical condition becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?
Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The UT Southwestern Institutional Review Board.

Are there procedures I should follow after stopping participation in this research?

- No further appointments or change in your activity are expected to be needed.

Whom do I call if I have questions or problems?
For questions about the study, contact Tiffany Graham 214-645-3736 during regular business hours and at 972-921-7045 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.

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Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Legally Authorized Representative's Name (Printed)

_____ _____ _____ AM / PM

Legally Authorized Representative's Signature Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time