IRB APPROVED
AS MODIFIED
May 18, 2022

RESEARCH SUBJECT CONSENT FORM

TITLE: Delivering Transcutaneous Auricular Neurostimulation as an Adjunct Treatment for Neonatal Opioid Withdrawal Syndrome

PROTOCOL NO.: SBM-NOWS-02
IRB Protocol #20214551
PRO118200

SPONSOR: Spark Biomedical, Inc.

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RESEARCH CONSENT SUMMARY

This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

In this consent form you are being asked as the legally authorized representative, parent, or guardian to permit your child to take part in a research study. A person who takes part in a research study is called a research participant. "Your child" in the rest of this form generally means the research participant.

Taking part in this research is voluntary. Whether your child takes part is up to you.

The purpose of this research is to determine if transcutaneous (through the skin) auricular (ear) neurostimulation (nerve activation, tAN) can lower the amount of morphine given to an infant for treatment of symptoms of opioid withdrawal. This study is a follow-up study to a similar study in a small number of participants that had positive results and is being done to support approval of tAN therapy. In this study we will assign infants to either an active group or inactive tAN group, and neither you nor your child's care providers will know which group they are in. If in the tAN therapy group, a microcurrent will be delivered to nerves around the ear for 30 minutes up to 4 times a day, until morphine is weaned off or up to 20 days total. We will monitor withdrawal scores and wean morphine every 12 hours if scores are low. We will also perform a NICU Neurobehavioral Network Scale (NNNS) assessment before, at 1 & 2 weeks during treatment, and before discharge from the hospital. In the inactive group, no microcurrent will be

delivered, but all other study activities will be the same. Your child will remain in the study for 30 days or until discharged from the hospital. tAN may benefit infants with opioid withdrawal by reducing the symptoms and allowing faster weaning of morphine and discharge from the hospital. Activation of these nerves with microcurrents has been shown to be safe in previous studies in newborns and infants with only redness at the ear site. The alternative is to wean morphine and other medications as needed to for withdrawal symptoms every 24 hours per clinical routine, and to hold and console your child and offer your breast milk.

DETAILED RESEARCH CONSENT

In this consent form you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, "your child" in the rest of this form generally means the research participant.

Your child is being invited to take part in a research study. A person who takes part in a research study is called a research participant.

What should I know about this research?

- Please read this consent form carefully and take your time making your decision.
- As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.
- Taking part in this research is voluntary. Whether your child takes part is up to you.
- You can choose not to have your child take part, or you can agree to take part and later change your mind. There will be no penalty or loss of benefits to which your child is otherwise entitled.

Why is this research being done?

The purpose of this research is to determine if transcutaneous (through the skin) auricular (ear) neurostimulation (nerve activation, tAN) can lower the amount of replacement morphine given to an infant for treatment of symptoms of opioid withdrawal. You are being asked to allow your child to join this study because they have neonatal opioid withdrawal symptoms. This study involves research and is a follow-up study to a previous study in a small number of neonates with opioid withdrawal that had positive results. This study is being done to show the safety and effectiveness of tAN therapy in neonatal opioid withdrawal and support approval of tAN therapy by the U.S. Food and Drug Administration (FDA). Nerve stimulation at the ear has been shown to be safe in newborns and infants in previous studies, and procedures in this study have minimal risk. However, tAN therapy is still being tested, so it is investigational and not yet FDA approved. About 80 subjects will take part in this research, with approximately 40 infants at MUSC. A grant from the National Institutes of Health (NIH) to Spark Biomedical will sponsor this phase II study. Portions of Dr. Jenkins' and his/her research team's salaries will be paid by this grant.

How long will my child be in this research?

We expect that the treatment period will last up to 20 days, and we will continue to follow your child up to 30 days or until your child leaves the hospital.

What happens to my child if I agree to take part in this research?

If you decide that your child will take part in this research study, the following study procedures will be performed:

- The study will take place when the participant is in the hospital and receiving morphine for opioid withdrawal.
- Information will be collected from the participant's records during a baseline visit to find out if they meet the conditions to be in the study. Information to be collected will include demographics, weight, heart rate, medical history, and concomitant medications the participant is currently taking. Drug testing will not be done for this study.
- All participants will be examined for symptoms of opioid withdrawal using the Finnegan Neonatal Abstinence Scoring System (FNASS). The FNASS is a common way to measure the signs of withdrawal in infants and is standard of care in many nurseries. The FNASS takes about 10 minutes to complete.
- The participant will be put into a study group by chance (like a coin toss). They have a one out of two chance of being placed in each group. You cannot choose their study group.
- tAN will be started for those placed in one group by placing the device earpiece on the left or right ear and adjusting the stimulation to just below what the infant detects. Therapy will be delivered up to four times per day for thirty minutes approximately one hour before each scheduled morphine dose. tAN therapy is experimental.
- Those placed in the other group will have the device earpiece applied at the same timepoint and for the same duration, but stimulation will not be turned on.
- The amount of morphine given to the participant will be lowered every 12 hours if the participant is experiencing only a few signs of opioid withdrawal (low FNASS). If they have a number of withdrawal symptoms (higher FNASS), such as continuous crying, not being able to sleep, poor feeding, fever, or sweating, and being difficult to console, the dose will be increased or a rescue dose will be given as needed.
- The participant will have their heart rate monitored for signs of slow heartbeat and will be examined for signs of pain using the Neonatal Infant Pain Scale (NIPS) before, during, and after the time when therapy is given. The NIPS is a common way to measure pain in infants. It looks at facial expression, crying, breathing patterns, arm and leg movements, and state of arousal. The NIPS takes about 5 minutes to complete. If the participant looks like they are in pain, tAN therapy will be adjusted or stopped.
- A NICU Neurobehavioral Network Scale (NNNS) assessment will be performed before, at 1 and 2 weeks during tAN, and at 30 days or before discharge by trained licensed occupational therapists.
- All participants will be watched for 48 hours after stopping morphine treatment and 24 hours after stopping tAN therapy for signs of withdrawal.
- Participation in the study will continue until the infant is off morphine or after a total of 20 days of treatment. tAN treatment will still stop at 20 days, even if your child is not yet off morphine.

- You, the care providers, and study doctor will not know which group your child is in. Your study doctor can find out in case of an emergency.

tAN and the device used to deliver the therapy are investigational, which means that they are not approved by the Food and Drug Administration (FDA). tAN therapy will not be available to the participant once they are no longer in the study.

Can my child be removed from this research without my approval?

The person in charge of this research can remove your child from this research without your approval. Possible reasons for removal include:

- It is in your child's best interest
- Your child has a side effect that requires stopping the research
- Your child needs a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor
- Your child is unable to take the research therapy

We will tell you about any new information that may affect your child's health and welfare, or your choice to continue in this research.

What happens if I agree for my child to be in this research, but I change my mind later?

You can decide to not have your child participate in this study. You can decide for them to participate and then change your mind. Your decision will not result in any penalty or loss of benefits to which your child is otherwise entitled. Your child may need more morphine treatment if they are receiving active tAN and are withdrawn from the study.

Could being in this research hurt my child?

tAN is considered minimal risk for adults, and we have observed no significant side effects with nerve stimulation at the ear in preterm and term infants in previous studies. The most important risks or discomforts your child may face from taking part in this research include:

- Dermal (skin) irritation
- Erythema (redness where device is touching the skin)
- Paresthesia (tingling, prickling or numbness)
- Allergic contact dermatitis (red, itchy rash due to allergy)
- Transient (temporary) pain or discomfort due to stimulation
- Transient pain or discomfort due to device malfunction
- Otalgia/otodynia (earache)
- Unresolved muscle twitching due to stimulation
- Failure of a device component resulting in loss or decrease of therapeutic effect

In previous studies of ear nerve stimulation, there was only skin redness, and this occurred in only a few infants and less than 5 in 100 sessions. One infant had redness at the stimulation site

which went away after 12 hours on two separate occasions. Redness occurred after removing the hydrogel in most infants, but there was no sign of irritation before the next treatment 3 hours later, or after completion of tAN therapy in any infant. The other potential side effects listed above were not seen in this study or others using nerve stimulation at the ear in infants.

The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

- There is a risk of a loss of confidentiality of your child's personal information as a result of participation in this study. To minimize this risk, we assign a study number and data will be sent to the sponsor or regulatory bodies under the study number. The file linking your child's name and study number will be password protected behind MUSC's firewall, and only study personnel will have access to this file.

Risks of Morphine

Serious adverse reactions associated with morphine sulfate use include: respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock and cardiac arrest. The common adverse reactions seen on initiation of therapy with morphine sulfate are dose-dependent and are typical opioid-related side effects. The most frequent of these include constipation, nausea, and somnolence.

Other commonly observed adverse reactions include: lightheadedness, dizziness, sedation, vomiting, and sweating.

Other less frequently observed adverse reactions expected from opioid analgesics, including morphine sulfate include:

- Body as a Whole: malaise, withdrawal syndrome
- Cardiovascular System: bradycardia, hypertension, hypotension, palpitations, syncope, tachycardia
- Digestive System: biliary pain, dyspepsia, dysphagia, gastroenteritis, abnormal liver function tests, rectal disorder, thirst
- Hemic and Lymphatic System: anemia, thrombocytopenia
- Metabolic and Nutritional Disorders: edema, weight loss
- Musculoskeletal: skeletal muscle rigidity
- Nervous System: abnormal dreams, agitation, amnesia, anxiety, ataxia, confusion, convulsions, coma,
- delirium, hallucinations, lethargy, nervousness, abnormal thinking, tremor, vasodilation, vertigo, headache
- Respiratory System: hiccup, hypoventilation, voice alteration
- Skin and Appendages: dry skin, urticaria, pruritus
- Special Senses: amblyopia, eye pain, taste perversion
- Urogenital System:, dysuria,, oliguria, urinary retention, anti-diuretic effect

Will being in this research benefit my child?

We cannot promise any benefits to your child or others taking part in this research. The potential benefit to your child and other future children with opioid withdrawal, is that the treatment they receive may prove to be more effective than the than other available treatments, although this cannot be guaranteed.

If your child is in the group that receives tAN therapy and it is successful in treating their opioid withdrawal with faster weaning of morphine, your child could have shorter hospital stay with fewer side effects than the current standard therapy; however, this cannot be guaranteed.

Will it cost me money to take part in this research?

There will be no additional costs to you as a result of being in this study. However, routine medical care for your child's condition (which they would have received whether or not they were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. It is possible that your insurance company will refuse to pay for the costs associated with study participation, in which case you will be held financially responsible. Please ask Dr. Jenkins if you would like to know more about which tests and studies are being done solely for research purposes.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

What other choices do I have besides participation in this research?

Instead of being in this research, the usual care for infants with opioid withdrawal is weaning replacement morphine every 24 hours. Other interventions that do not involve opioids are to hold and console your child and offer your breast milk.

Will I be told about my child's results?

Your child's FNSS scores and neurobehavioral scores will be a part of the medical record, and you will be told about them and how fast the morphine is being weaned.

What happens to the information collected for this research?

As part of this research study, your study doctor and his/her research team will keep records of your child's participation in this study. We assign a study number to your child, and data will be sent to the sponsor or regulatory bodies under the study number. The file linking your child's name and study number will be password protected behind MUSC's firewall, and only study personnel will have access to this file. We protect your child's information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you or your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be

used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if you have consented to the disclosure, including for your child's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about your child's involvement in this research. We will place information about your child's participation in your child's MUSC medical record. Results of research tests or procedures will be included in their MUSC medical record. All information within your child's medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your child's research information will be disclosed.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include child abuse and neglect, or harm to self or others. Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

Authorization To Use and Disclose Information For Research Purposes

The health information MUSC may use or disclose (release) for this research study includes information in your child's medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your child's condition.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with Spark Biomedical, an agent for the study doctor.

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

Your child's study doctor and his/her research team will use and disclose (release) your child's health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this consent form. If you choose not to sign, it will not affect your child's treatment, payment or enrollment in any health plan or affect their eligibility for benefits. However, your child will not be allowed to be a participant in this research study.

What if I decide not to give permission to use and give out their health information?

Then your child will not be able to be in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if your child is participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA, until the company's application to study the drug/device is withdrawn, or until December 31, 2070. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, your child will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your child's health information that is created during your participation in this study. After the study is completed, you may request this information.

Your child's health information will be used or disclosed when required by law. Your child's health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

Information about your child (including their identifiable private information) may have all of their identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if my child is injured because of taking part in this research?

If your child is injured or gets sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your child's underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor. Signing this consent form does not take away your right to pursue a claim through the legal system.

Future Contact

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

☐_ Yes, I agree to be contacted

_☐___No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but your child will not be identified. Information that is obtained concerning this research that can be identified with your child will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will

receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to your child.

Your child's participation in this study is voluntary. Your child may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if your child decides to do this. Your child's decision not to take part in the study will not affect your child's current or future medical care or any benefits to which your child is entitled.

The investigators and/or the sponsor may stop your child's participation in this study at any time if they decide it is in your child's best interest. They may also do this if your child does not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact Dr. Jenkins (843) 792-2112. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792- 4148. This includes any questions about my rights as a research subject in this study.

The permission of one parent is sufficient even if both parents are alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Documentation of assent is not required.

I agree for my child to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____
Signature of Person Obtaining Consent Date *Name of Participant

Participant's Personal Representative (if applicable):

_____
Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian*
____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI
Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES
MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE
We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE
This Notice went into effect on April 14, 2003 and was last revised on August 2018.

IRB APPROVED
AS MODIFIED
May 18, 2022

The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
RESEARCH SUBJECT CONSENT FORM

TITLE: Delivering Transcutaneous Auricular Neurostimulation as an Adjunct Treatment for Neonatal Opioid Withdrawal Syndrome

PROTOCOL NO.: SBM-NOWS-02
IRB Protocol #20214551
STU-2021-1073

SPONSOR: Spark Biomedical, Inc.

CO-INVESTIGATORS: Venkatakrishna Kakkilaya, MD
5323 Harry Hines Boulevard
Dallas, Texas 75390
United States

Lorraine Bautista, MD
5323 Harry Hines Boulevard
Dallas, Texas 75390
United States

STUDY-RELATED PHONE NUMBER(S): 214-648-3906
469-419-3841 (24 hours)

RESEARCH CONSENT SUMMARY

This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

In this consent form "you" generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you

- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that taking part in this research will last approximately 30 days or until you leave the hospital.

Why is this research being done?

The purpose of this research is to determine if transcutaneous (through the skin) auricular (ear) neurostimulation (nerve activation) can lower the amount of replacement morphine given to an infant for treatment of symptoms of opioid withdrawal. This study is a follow-up study to a similar study in a small number of participants and is being done to support approval of tAN therapy. tAN has been shown to be safe in newborns and infants, and procedures in this study have minimal risk.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include the following:

- The study will take place when the participant is in the hospital.
- Information will be collected from the participant during a baseline visit to find out if they meet the conditions to be in the study.
- The participant will be put into a study group by chance (like a coin toss/ like drawing straws). They have a one out of two chance of being placed in each group. You cannot choose their study group.
- All participants will be examined for symptoms of opioid withdrawal using the Finnegan Neonatal Abstinence Scoring System (FNASS).
- tAN Therapy will be started for those placed in one group by placing the device earpiece on the left or right ear and adjusting the stimulation to a level just below what the infant detects. Therapy will be delivered up to four times per day for thirty minutes approximately one hour before each scheduled morphine dose for up to 20 days.
- Those placed in the other group will have the device earpiece applied at the same timepoint and for the same duration, but stimulation will not be turned on.
- The amount of morphine given to the participant will be lowered every 12 hours if the participant is not experiencing signs of opioid withdrawal. If they do have symptoms, the dose will be increased or a rescue dose will be given as needed.
- The participant will have their heart rate monitored for signs of slow heartbeat and will be examined for signs of pain before, during, and after the time when therapy is given. If the participant looks like they are in pain, tAN therapy will be adjusted or stopped.
- A NICU Neurobehavioral Network Scale (NNNS) assessment will be performed before, at one and two weeks during tAN, and at 30 days or before discharge.
- All participants will be watched for 48 hours after stopping morphine treatment and 24 hours after stopping tAN therapy.

Could being in this research hurt me?

tAN is considered minimal risk for adults, and we have observed no significant side effects in preterm and term infants in previous studies. The most important risks or discomforts you may face from taking part in this research include:

- Dermal (skin) irritation
- Erythema (redness where device is touching the skin)
- Paresthesia (tingling, prickling or numbness)
- Allergic contact dermatitis (red, itchy rash due to allergy)
- Transient (temporary) pain or discomfort due to stimulation
- Transient pain or discomfort due to device malfunction
- Otalgia/otodynia (earache)
- Unresolved muscle twitching due to stimulation
- Failure of a device component resulting in loss or decrease of therapeutic effect

In a previous study, tAN therapy did not result in any unanticipated adverse events. One infant had redness at the stimulation site which went away after 12 hours. Redness occurred after removing the hydrogel in most infants, but there was no sign of irritation before the next treatment 3 hours later, or after completion of tAN therapy in any infant.

Will being in this research benefit me?

The most important benefits you may experience from taking part in this research include a decrease in the amount of replacement morphine needed to manage symptoms of opioid withdrawal, potentially resulting in a shorter stay in the hospital. Possible benefits to others include the same.

What other choices do I have besides taking part in this research?

Instead of being in this research, other choices may include use of replacement morphine according to the doctor's standard of care.

DETAILED RESEARCH CONSENT

In this consent form "you" generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to determine if transcutaneous (through the skin) auricular (ear) neurostimulation (nerve activation) can lower the amount of replacement morphine given to an infant for treatment of symptoms of opioid withdrawal. This study is a follow-up study to a similar study in a small number of participants and is being done to support approval of tAN therapy. tAN has been shown to be safe in newborns and infants, and procedures in this study have minimal risk. About 80 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last approximately 30 days or until you leave the hospital.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include the following:

- The study will take place when the participant is in the hospital.
- Information will be collected from the participant during a baseline visit to find out if they meet the conditions to be in the study. Information to be collected will include demographics, weight, heart rate, medical history, and concomitant medications the participant is currently taking.
- The participant will be put into a study group by chance (like a coin toss/ like drawing straws). They have a one out of two chance of being placed in each group. You cannot choose their study group.
- All participants will be examined for symptoms of opioid withdrawal using the Finnegan Neonatal Abstinence Scoring System (FNASS). The FNASS is a common way to

measure the signs of withdrawal in infants. The FNASS takes about 10 minutes to complete.

- tAN Therapy will be started for those placed in one group by placing the device earpiece on the left ear and adjusting the stimulation to an already decided level. Therapy will be given up to four times per day for thirty minutes, approximately one hour before each scheduled morphine dose for up to 20 days.
- Those placed in the other group will have the device earpiece applied at the same timepoint and for the same duration, but stimulation will not be turned on.
- The amount of morphine given to the participant will be lowered every 12 hours if the participant is not experiencing signs of opioid withdrawal. If they do have symptoms, the dose will be increased or a rescue dose will be given as needed.
- The participant will have their heart rate monitored for signs of slow heartbeat and will be examined for signs of pain using the Neonatal Infant Pain Scale (NIPS) before, during, and after the time when therapy is given. The NIPS is a common way to measure pain in infants. It looks at facial expression, crying, breathing patterns, arm and leg movements, and state of arousal. The NIPS takes about 5 minutes to complete. If the participant looks like they are in pain, tAN therapy will be adjusted or stopped.
- A NICU Neurobehavioral Network Scale (NNNS) assessment will be performed before, at one and two weeks during tAN, and at 30 days or before discharge.
- All participants will be watched for 48 hours after stopping morphine treatment and 24 hours after stopping tAN therapy.

During the research, you and the study doctor will not know which group you are in. Your study doctor can find out in case of an emergency.

tAN therapy is investigational, which means that it is not approved by the Food and Drug Administration (FDA). tAN therapy will not be available to the participant once they are no longer in the study.

This study is a follow-up to a smaller study which had positive results.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Promptly report all side effects to the investigator
- Follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.

Could being in this research hurt me?

tAN is considered minimal risk for adults, and we have observed no significant side effects in preterm and term infants in previous studies. The most important risks or discomforts you may face from taking part in this research include:

- Dermal (skin) irritation
- Erythema (redness where device is touching the skin)

- Paresthesia (tingling, prickling or numbness)
- Allergic contact dermatitis (red, itchy rash due to allergy)
- Transient (temporary) pain or discomfort due to stimulation
- Transient pain or discomfort due to device malfunction
- Otalgia/otodynia (earache)
- Unresolved muscle twitching due to stimulation
- Failure of a device component resulting in loss or decrease of therapeutic effect

In addition to these risks, taking part in this research may harm you in unknown ways.

Risks of Morphine

Serious adverse reactions associated with morphine sulfate use include: respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock and cardiac arrest.

The common adverse reactions seen on initiation of therapy with morphine sulfate are dose-dependent and are typical opioid-related side effects. The most frequent of these include constipation, nausea, and somnolence.

Other commonly observed adverse reactions include: lightheadedness, dizziness, sedation, vomiting, and sweating.

Other less frequently observed adverse reactions expected from opioid analgesics, including morphine sulfate include:

- Body as a Whole: malaise, withdrawal syndrome
- Cardiovascular System: bradycardia, hypertension, hypotension, palpitations, syncope, tachycardia
- Digestive System: biliary pain, dyspepsia, dysphagia, gastroenteritis, abnormal liver function tests, rectal disorder, thirst
- Hemic and Lymphatic System: anemia, thrombocytopenia
- Metabolic and Nutritional Disorders: edema, weight loss
- Musculoskeletal: skeletal muscle rigidity
- Nervous System: abnormal dreams, agitation, amnesia, anxiety, ataxia, confusion, convulsions, coma,
- delirium, hallucinations, lethargy, nervousness, abnormal thinking, tremor, vasodilation, vertigo, headache
- Respiratory System: hiccup, hypoventilation, voice alteration
- Skin and Appendages: dry skin, urticaria, pruritus
- Special Senses: amblyopia, eye pain, taste perversion
- Urogenital System:, dysuria,, oliguria, urinary retention, anti-diuretic effect

In a previous study, tAN therapy did not result in any unanticipated adverse events. One infant had redness at the stimulation site which went away after 12 hours on two separate occasions.

Redness occurred after removing the hydrogel in most infants, but there was no sign of irritation before the next treatment 3 hours later, or after completion of tAN therapy in any infant.

Will it cost me money to take part in this research?

Taking part in this research should not lead to any added costs to you. In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include a decrease in the amount of morphine needed to treat opioid withdrawal symptoms and a shorter stay in the hospital. Possible benefits to others include the same.

What other choices do I have besides taking part in this research?

Instead of being in this research, other choices include use of replacement morphine according to the doctor's standard of care.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the

confidentiality of your research records will be protected in this study. 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.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Demographic information
- Medical history prior to enrollment
- Medication exposure while in utero
- Treatment and medication administered to your child while they are enrolled in the trial

We will get this information by asking you, asking your child's doctor, and looking at your medical record.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor, Spark Biomedical, Inc., funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- The following collaborators at other institutions that are involved with the study:
    - Medical University of South Carolina
- The committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- The members of the local research team.
- The Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center and Parkland Health and Hospital System.
- Institutional Review Board.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use a participant identification number instead of your name to identify your health information. This participant identification number will be listed on all study-related documents and in the electronic data capture system. Any study documents containing PHI will be kept in a secure room in a locked file cabinet, safe, or other secure location.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Venkatakrishna Kakkilaya, MD and Lorraine Bautista, MD, 5323 Harry Hines Boulevard, Dallas, Texas 75390. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the device is approved by the FDA, until the company's application to study the drug/device is withdrawn, or until December 31, 2070. This permission to use your personal health information expires on the date noted above.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

OR

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor. Signing this consent form does not take away your right to pursue a claim through the legal system.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

You do not give up any of your legal rights by signing and dating this form.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor
- You are unable to take the research therapy

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

You can decide to not participate in this study. You can decide to participate and then change your mind. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern or Parkland staff or doctors. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you decide to leave this research, contact the research team so that the investigator can make sure that your child continues to get replacement morphine to manage symptoms of opioid withdrawal. We do not expect any potential adverse consequences because of withdrawing from the study.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

Statement of Consent:

The permission of one parent is sufficient even if both parents are alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Documentation of assent is not required.

Assent of children is not required

Your signature documents your permission for you or the individual named below to take part in this research.

Surrogate Signature Section

Printed Name of Participant			AM PM
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was:

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate
was: _____.

			AM PM
Printed Name of Witness	Signature of Witness	Date	Time