## Accuracy assessment of novel and existing low-cost temperature monitoring tools for neonates

**Background and Purpose**

The purpose of the study is to design a low-cost temperature monitor to provide thermal care to babies in low-resource hospitals. An estimated 15 million babies are born preterm every year, and prematurity at birth is responsible for more than 1 million neonatal deaths. Hypothermia is especially common among premature babies. Close monitoring of temperature is essential to reduce neonatal illnesses and complications.

We wish to evaluate a low-cost infant temperature monitor that was specifically designed for use in low-resource hospitals. This study will test whether this temperature monitor is accurate and easy to use. We will test our new temperature monitor alongside two existing low cost devices. The results of this study will help us know how well these devices work in clinics here in Malawi. This study will also help us decide if any design changes are needed.

**Why are we doing this study?**

We hope to demonstrate that these temperature monitors are accurate for measuring infant's temperatures in different environments. We also want to see if this device is easy for the nurse to use.

**Description of Research**

If you agree for your child to take part in this study:

1. You will review and sign this form.
2. The nurse will attach the temperature sensors to your baby.
    a. Rice University -designed neonatal temperature monitor (NTM): the sensor is a metal piece placed in a stretchy band placed around a baby's belly
    b. Bempu: plastic bracelet worn around the wrist
    c. ThermoSpot: small sticker placed in axilla
    d. Gold Standard patient monitor: metal probe placed on belly with reflective sticker
3. A trained researcher will be present and will help the nurse with attaching the devices if needed. The researcher will routinely monitor the devices and collect signals from the devices using a laptop.
4. The researcher will record the following information about your baby's monitoring:
    a. Date of Study
    b. Date of Birth
    c. Gestational age at birth
    d. Corrected gestational age
    e. Sex
    f. Birth weight
    g. Type of delivery
    h. Current weight
    i. Admission temperature
    j. Temperature measurements taken as standard of care
    k. Other comorbidities
    l. Medications/treatments given
    m. Abdominal circumference

5. Every hour, the temperature from each device will be recorded by the research technician. A temperature measurement at the axilla will also be taken every four hours as part of the standard of care.

Temperature values from the NTM and gold standard will be recorded automatically by the study equipment. Temperatures will also be recorded if any devices sound an alarm. Clinician and researcher observations will also be recorded.

**You may choose to remove your child from the study at any time. Refusing to involve your child in the study will have no effect on the quality of care he or she receives.**

**Duration:** The monitoring period will last for up to three days.

**Location:** Neonatal and KMC wards at Queen Elizabeth Central Hospital

**Participant Requirements:**

1. Parental consent
2. The patient is currently being treated at QECH in the neonatal ward.
3. The study devices and vitals monitor are available for use at the time.

**How many people will this study enroll?**

We plan to enroll up to 30 babies from the neonatal ward, and up to 30 babies from the KMC ward for a possible total enrollment of 60 babies.

**Can I change my mind if I decide that I prefer not to continue in this study?**

Yes, if at any time you decide you do not want your baby to continue with the study, the monitoring by NTM and the commercial devices will be stopped and your baby will receive the standard of care.

**What if I do not wish to enroll in the study?**

Your baby's entry into the study is entirely voluntary. Your baby's monitoring will be conducted in the standard way and your decision will not influence the care you receive.

**Risks of Side Effects and Discomforts to Participants**

The risks and discomfort if your baby participates in this study are the same as during routine pediatric checkup. The trained study nurse will assess the subject for clinical complications before using the test devices. If you, the researcher, or the nurse, indicate concerns during the tests, the use of the devices will be discontinued and your baby will undergo the hospital's standard monitoring by nurses.

**Confidentiality**

There is a small risk of loss of confidentiality in this study. Researchers will take all precautions to ensure your personal information remains protected and confidential. All data sheets related to this study will be given a unique code and not labeled with any identifying information. This informed consent document will be kept in a locked cabinet in the office of the lead researcher of this study.

If you have any questions about the study please ask the nurses or doctors seeing to your care on the

ward please contact Dr. Queen Dube, University of Malawi College of Medicine, Blantyre, Malawi, at 0999981454, or contact the chairman of the College of Medicine Research and Ethics Committee (COMREC) at 01 871 911.

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| Have you understood the study? | Yes | No |
| Are you willing to be enrolled in the study? | Yes | No |
| Have you any questions to ask that we have not answered? | Yes | No |

Name…… Signature……

Name of witness…… Signature……

Date……