Informed Consent for Clinical Studies on Adults

Ethics Review Committee
Department of Medical Research
Ministry of Health and Sports
Republic of the Union of Myanmar
Informed Consent Form for Clinical Studies on Adults

This informed consent form is for patients with acute/pediatric/surgical wounds who attend Yankin Children Hospital, Yangon Children Hospital and Mandalay General Hospital, and who we are inviting to participate in this research study.

Name of Principal Investigator	: Dr Thet Naing Tun
Name of Organization	: Chemistry Department, University of Bath, UK.
Name of Funding Organization	: Global Challenge Research Fund
Title of the Study	: Testing of a near to patient infection sensor for patients with acute wounds in Myanmar.

PART I: Information Sheet

Introduction

My name is Thet Naing Tun and I'm a senior research scientist working at the Chemistry Department, University of Bath, United Kingdom. My research includes the development of sensor for the early detection of wound infection by bacteria and fungi. Wound infection is common in South East Asian countries including Myanmar, and there are high incident rates. I'm collaborating with medical professors from hospitals in Yangon and Mandalay to start a clinical study of wounds. I'd like to invite you to participate in this clinical study if you have wound that requires to be treated in Yangon Children's Hospital, Yankin Children Hospital and Mandalay General Hospital. I'll give you all the necessary information regarding this study and your participation is much appreciated.

Purpose

Wound infection can potentially occur in any patients with wounds. Underage children with wound are at higher risk of infection due to under-developed immune system and age related factors. Extreme case of wound infection, if missed, can lead to the whole body inflammation and bloodstream poisoning called sepsis, which can be fatal. Wound infection also delays wound healing and can ultimately lead to loss of limbs (by amputation) if it happens in patients with diabetes and underlying medical conditions. Early diagnosis of wound infection is difficult but the timely treatment of infection can reduce the cost, reduce unnecessary use of antibiotics, free hospital beds, and ultimately save the life of patients involved. There is a simple and cost effective way of diagnosing early onset of infection in wound by simply swabbing and testing it in a control medium. If this research is successful, it will greatly benefit to patients and wound care community in Myanmar and South East Asian countries.

Type of Research Intervention

The patients who take part in this research study will get their wound swabbed for once or twice aseptically. Clinical management of patient's wound as per standard care is to be done by hospital staffs such as, clinicians or wound care nurses.

Participant selection

We invite all adult (age 16 to 100 years) with acute/burn/surgical wounds to participate voluntarily in this clinical research study. You can decide to participate or not in this study. With or without participating in this study, the treatment you receive at this hospital will continue as usual.

Procedures and Protocol

If you decide to participate in this study,

- The photograph of your wound will be taken.
- Your wound will be clinically assessed by a clinician or a wound care nurse from the hospital.
- Your wound will be swabbed (up to twice aseptically) using a cotton swab pre-moistened in saline.
- Your wound will be cleaned as per standard procedure and routine wound management will be done by a clinician or a wound care nurse from the hospital.
- The swab from your wound will be tested for bacteria that may be related to early onset of wound infection.
- The swab from your wound will then be disposed according to the clinical waste management procedure of the hospital within two hours after swabbing.

Example for studies that need follow up visits

This study does not require the participating patients to follow up unless they are unwell and require medical treatment at hospital due to possible post infection of wound.

Duration

This research study will take up to 7 months and this study will include only the patients with wounds visiting the participating hospitals for diagnosis and treatment.

Risks and discomfort

There are no known risks for participating in this study. A slight discomfort is expected when the wound is swabbed but other than that, there is no discomfort likely to be experienced by the participating patients.

Benefits

There may not be any direct benefit for you but your participation is likely to help us to find a cost effective method of early detection of wound infection. In the longer term, this research finding will develop the cost effective and health economic benefits to both patients and the clinical staffs working at wound care.

Incentives

There are no incentives provided and the participating in this study is on voluntary basis.

Confidentiality

The information that we collect from this research project will be kept confidential and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will keep it safely. It will not be shared with or given to anyone except your clinician.

Sharing the Results

Confidential information will not be shared. The knowledge that we get from doing this research will be published relevant international journals and presented in local/international conferences/seminar to benefit the wound care society involving patients and careers.

Right to Refuse or Withdraw

You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at these hospitals will not be affected in any way.

Who to Contact

If you have any questions, you may ask the following chief clinical leads now or later, even after the study has started. If you wish to ask questions later, you may contact any respective professors from hospitals:

Professor Nyo Nyo Win Senior Consultant Pediatric Surgeon, Yankin Children Hospital Kanbe Road, Yangon 11081 Myanmar Phone: +95 9 5135153 Email: nyo.nge@gmail.com	Professor Angela Tin Hla Professor and Head Plastic-Maxillo-Facial and Burn Unit Mandalay General Hospital 30th St, Bet: 74th & 77th St. Chan Aye Tharsan T/S Mandalay, Myanmar Phone: +95 2 21041 Email: dr.thwet@gmail.com	Professor Aye Aye Head of Dept. Senior Pediatric Surgeon Yangon Children's Hospital Pyidaungzu Yeika St Yangon Myanmar Phone: +95 1 222807 Email: drayeaye2439@gmail.com

PART II: Certificate of Consent

This section can be **written in the first person**. It should include a few **brief statements** (study title, procedure, study site, risk and benefits, incentive etc.) about the research and be followed by a statement similar to the one in italic below. A witness must sign the participant's voluntary consent. A researcher or the person going over the informed consent must sign each consent. The certificate is an integral part of the informed consent.

Example: I have been invited to participate in research of a new malaria drug. I understand that it will involve receiving an injection and five follow-up visits. I have been informed that the risks are minimal and may include only _____. I am aware that there may be no benefit to me personally and that I will not be compensated beyond travel expenses. I have been provided with the name of a researcher who can be easily contacted using the number and address I was given for that person.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

A literate **witness must sign** (if possible, this person **should be selected by the participant** and should have **no connection to the research team**). Participants who are illiterate should include their **thumb-print** as well.

Thumb print of participant

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____

Signature of witness _____
Date _____
Day/month/year

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Researcher_____

Signature of Researcher _____

Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to participant _____(initialed by the researcher/assistant).

Sample Informed Consent Form for Clinical studies on Children

Ethics Review Committee
Department of Medical Research
Ministry of Health
Republic of the Union of Myanmar

Informed Consent Form for Clinical Studies on Children

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

Example This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X

Name of Principal Investigator	: Dr Thet Naing Tun
Name of Organization	: Chemistry Department, University of Bath, UK
Name of Sponsor	: Professor Nyo Nyo Win
Title of the Study	: Testing of a near to patient infection sensor for patients with acute wounds in Myanmar.

PART I: Information Sheet

(1) Introduction

My name is Thet Naing Tun and I'm a senior research scientist working at the Chemistry Department, University of Bath, United Kingdom. My research includes the development of sensor for the early detection of wound infection by bacteria and fungi. Wound infection is common in South East Asian countries including Myanmar, and there are high incident rates. I'm collaborating with medical professors from hospitals in Yangon and Mandalay to start a clinical study of wounds. I'd like to invite you to participate in this clinical study if you have wound that requires to be treated in Yangon Children's Hospital, Yankin Children Hospital and Mandalay General Hospital. I'll give you all the necessary information regarding this study and your participation is much appreciated.

(2) Purpose

Wound infection can potentially occur in any patients with wounds. Underage children with wound are at higher risk of infection due to under-developed immune system and age related factors. Extreme case of wound infection, if missed, can lead to the whole body inflammation and bloodstream poisoning called sepsis, which can be fatal. Wound infection also delays wound healing and can ultimately lead to loss of limbs (by amputation) if it happens in patients with diabetes and underlying medical conditions. Early diagnosis of wound infection is difficult but the timely treatment of infection can reduce the cost, reduce unnecessary use of antibiotics, free hospital beds, and ultimately save the life of patients involved.

There is a simple and cost effective way of diagnosing early onset of infection in wound by simply swabbing and testing it in a control medium. If this research is successful, it will greatly benefit to patients and wound care community in Myanmar and South East Asian countries.

(3) Type of Research Intervention

The patients who take part in this research study will get their wound swabbed for once or twice aseptically. Clinical management of patient's wound as per standard care is to be done by hospital staffs such as, clinicians or wound care nurses.

(4) Participant selection

We invite all children (4 months to 16 years) with acute/burn/pediatric/surgical wounds to participate voluntarily in this clinical research study. You can decide to participate or not in this study. With or without participating in this study, the treatment you receive at this hospital will continue as usual.

(5) Procedure and protocol

If you decide to participate in this study,

- The photograph of your wound will be taken.
- Your wound will be clinically assessed by a clinician or a wound care nurse from the hospital.
- Your wound will be swabbed (up to twice aseptically) using a cotton swab pre-moistened in saline.
- Your wound will be cleaned as per standard procedure and routine wound management will be done by a clinician or a wound care nurse from the hospital.
- The swab from your wound will be tested for bacteria that may be related to early onset of wound infection.
- The swab from your wound will then be disposed according to the clinical waste management procedure of the hospital within two hours after swabbing.

(6) Duration

This research study will take up to 7 months and this study will include only the patients with wounds visiting the participating hospitals for diagnosis and treatment.

(7) Side Effects

There are no known side effects anticipated.

(9) Risks

There are no known risks for participating in this study. A slight discomfort is expected when the wound is swabbed but other than that, there is no discomfort likely to be experienced by the participating patients.

(10) Benefits

There may not be any direct benefit for you but your participation is likely to help us to find a cost effective method of early detection of wound infection. In the longer term, this research finding will

develop the cost effective and health economic benefits to both patients and the clinical staffs working at wound care.

(11) Incentives

There are no incentives provided and the participating in this study is on voluntary basis.

(12) Confidentiality

The information that we collect from this research project will be kept confidential and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will keep it safely. It will not be shared with or given to anyone except your clinician.

(13) Sharing of the results

Confidential information will not be shared. The knowledge that we get from doing this research will be published relevant international journals and presented in local/international conferences/seminar to benefit the wound care society involving patients and careers.

(14) Right to Refuse or Withdraw

You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at these hospitals will not be affected in any way.

(15) Who to Contact

Professor Nyo Nyo Win Senior Consultant Pediatric Surgeon, Yankin Children Hospital Kanbe Road, Yangon 11081 Myanmar Phone: +95 9 5135153 Email: nyo.nge@gmail.com	Professor Angela Tin Hla Professor and Head Plastic-Maxillo-Facial and Burn Unit Mandalay General Hospital 30th St, Bet: 74th & 77th St. Chan Aye Tharsan T/S Mandalay, Myanmar Phone: +95 2 21041 Email: dr.thwet@gmail.com	Professor Aye Aye Head of Dept. Senior Pediatric Surgeon Yangon Children's Hospital Pyidaungzu Yeika St Yangon Myanmar Phone: +95 1 222807 Email: drayeaye2439@gmail.com

PART II: Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the research (study title, procedure, study site, risk and benefits, incentive etc.) and be followed by a statement similar to the one in italic below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.
Example: I have been invited to have my child participate in research of a new malaria vaccine. I understand that it will involve my child receiving an injection and three follow-up visits. I have been informed that the risks are minimal and may include only _____. I am aware that there may be no benefit to either myself or my child personally and that I will not be compensated beyond travel expenses. I have been provided with the name of a researcher who can be easily contacted using the number I was given for that person.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study and understand that I have the right to withdraw my child from the study at any time without in any way affecting either my child's or my own medical care.

Name of Participant_____

Name of Parent or Guardian_____

Signature of Parent or Guardian _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____ and thumb print of parent

Signature of witness _____

Date (Day/month/year) _____

I have accurately read or witnessed the accurate reading of the consent form to the parent or guardian of the potential participant and the individual has had the opportunity to ask questions.

I confirm that the individual has given consent freely.

Name of Researcher_____

Signature of Researcher _____

Date (Day/month/year) _____

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant _____ (initialed by researcher/assistant).