**Participant Information Sheet**

**Title:** The efficacy of topical preparations in reducing the incidence of P. Acnes in total shoulder arthroplasty

**Short Title:** TSA Skin Prep

**Principal Investigator:**  Dr. Levi Morse, Dr. Matthew Wilkinson

**Associate Investigator:**  Andrea Grant, Dr. Darren Hinton, Dr. Jodie Morris, Tristan Symonds, Dr. Kenji Doma

**Location:** Mater Health Service

**Introduction –**

You are invited to take part in this research project. This is because you are planning to undergo a total shoulder replacement. This research project is testing the effectiveness of a topical skin preparation in preventing the growth of a bacteria commonly identified as a cause of post-op infections. The treatments being tested are Benzoyl Peroxide and Benzoyl Peroxide/Clindamycin.

This participant information sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in this research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is **voluntary**. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide that you want to take part in the research project you will be asked to sign the consent section. **By signing the consent, you are telling us that you:**

Understand what you have read

Consent to take part in the research project

Consent to have the tests and treatments described

Consent to the use of your personal and health information described

**Background –**

Elective total shoulder arthroplasty (TSA) is a common and effective orthopaedic procedure for the treatment of osteoarthritis and rotator cuff injuries. Infection remains a common reason for surgical revision. A common bacteria causing these infection is Propionibacterium Acnes (P. Acnes).

The current method to reduce post op infections is to use skin preparations prior to surgery. This standard surgical prophylaxis does not seem to decrease the bacterial load. This may be a potential source of infection for susceptible patients having procedures with surgical implants.

Benzoyl Peroxide (BPO) and Benzoyl Peroxide/Clindamycin (BPO/C) topical skin preparations have been shown to reduce the superficial skin colonization of P. acnes.This study aims to investigate the use of BPO and BPO/C as a topical skin preparation and to determine the effects it has in reducing positive superficial and deep cultures in patients undergoing TSA.

**What would your participation involve?**

The trial will be a randomised control study. This means that if you choose to participate in the trial you will be allocated to be in one of three groups. One group will receive treatment with benzoyl peroxide, one group will receive benzoyl peroxide/clindamycin and one group will receive a placebo treatment.

At your initial visit, you will need to fill in a participant information document that collects data about your demographics and clinical condition. This will ask if you suffer from any dermatological conditions at your shoulder or have any ongoing shoulder infections. This may mean you do not meet the inclusion criteria for the study.

If you do meet the inclusion criteria you will need to have a skin swab at the site of surgical incision during your consult with the surgeon.

Prior to your surgery you will need to apply the topical skin preparation for two days, once in the morning and once at night before bed as directed. Finally once in the morning the day of your surgery.

***You will be supplied the skin preparation to go home with***

You will undergo four addition swabs during your procedure; one prior to surgical skin preparation, one after the first incision, one upon entry into the shoulder joint and one skin swab at the end of the procedure.

To be included in the study you must meet the following criteria –

* Patients who require a primary TSA for treatment of osteoarthritis or rotator cuff injuries
* Age 28-80
* BMI <40
* Able to provide informed consent
* Able to participate in the physical requirements of the study.

If you fit any of the following criteria you will not be able to take part in the trial –

* Current dermatologic disorders about the shoulder
* Current clinical signs of shoulder infections
* Documented Allergy to any of the skin preparations
* Are of a non-English speaking background
* Breastfeeding
* Pregnant or planning to become pregnant

We are aiming to recruit 35 participants in each arm of this study (105 total). The study will take place at the Mater Hospital. We hope to complete the study over a period of 24 months.

**Do you have to take part in this research project?**

Participation in any research is voluntary. If you do not wish to take part, you don’t have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide to take part, you will be given this patient information consent form to sign and you will be given a copy to keep. Your decision whether to take part or not take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you.

*You don’t have to take part in this research project to receive treatment.*

**What are the risks and disadvantages of taking part in this research?**

*Treatment related risks –*

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects or are worried about them, talk to your study doctor. Your study doctor will be looking out for the side effects. Tell your doctor immediately about any new or unusual symptoms that you get.

*The risk of side effects for this treatment is low.*

Your treating team will look after you in the management and follow-up in the case you suffer from the side effects –

* Mild stinging or burning;
* Itching or tingly feeling;
* Skin dryness, peeling, or flaking
* Redness or other irritation

**What I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that the person or the research supervisor to discuss any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect any additional personal information from you, although personal information already collected will be retained to ensure that results of the research project can be measured properly to comply with the law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must let them know.

*There will be no costs to you to participate in the trial.*

**Complaints and Compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment, if you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Who is organising and funding the research?**

The study is being organised by Orthopaedic Research Institute of Queensland in coordination with James Cook University

**Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called the Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Mater Hospital

The project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**Further information and who to contact**

The person you may need to contact will depend on the nature of your query

If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the you can contact the principal study doctor or any of the following people project (for example, any side effects).

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Andrea Grant* |
| Position | *Research Coordinator* |
| Telephone | *0413 685 331* |
| Email | *Research\_coordinator@oriql.com.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

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**Location:** 7 Turner Street, Pimlico

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  | Signature |  | | | Date |  | |  | |
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|  | | | | | | | | |
|  | Name of Witness\* to Participant’s Signature (please print) | | |  | | |  | |
|  | | | | | | | | |
|  | Signature |  | | | Date |  |  | |
|  | | | | | | | | |

\* Witness is not to be the investigator, a member of the study team or their delegate. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation**

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**Location:** 7 Turner Street, Pimlico

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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Details of verbal withdrawal to be clearly stated hear by the study doctor -

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

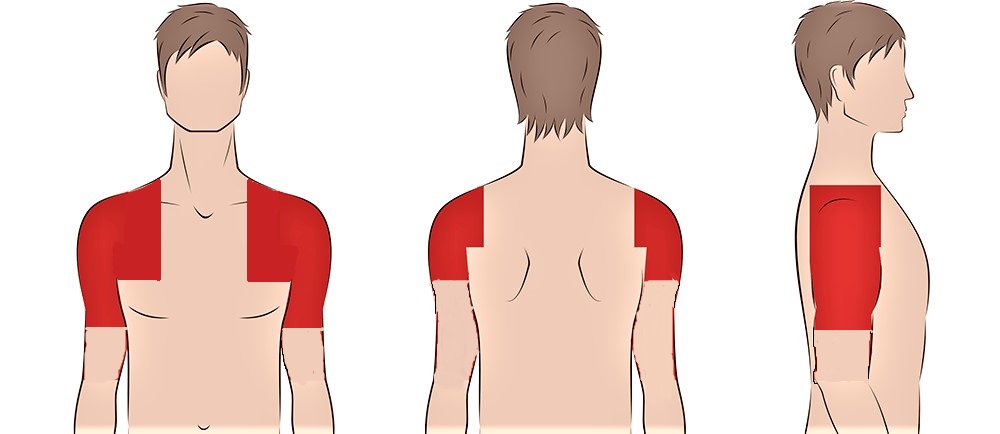
Note: All parties signing the consent section must date their own signature.

**Appendix 1.0: *How to Apply Tropical Treatment cream.***

Prior to your surgery you will need to apply the topical skin preparation for Two days; once in the morning and once at night before bed as directed, finally once more in the morning the day of your surgery.

Application of cream only required on the shoulder undergoing surgery.

The Image below is to assist you in identifying the area of application.

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