Appendix 1: Sample Study Information Sheet and Informed Consent form

PARENT INFORMATION SHEET

A Prospective Randomized Controlled Non-inferiority Study to Evaluate the Safety and Effectiveness of Non-operative Management in Children with Acute Uncomplicated Appendicitis

Investigators:

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Introduction

We would like you to consider taking part in a research study that will be conducted in The Department of Paediatric Surgery, Sydney Children's Hospital Network, Randwick and Westmead campuses.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the two treatments being compared and the research involved. Knowing what is involved will help you decide if you want your child to take part in the research.

Please read this information carefully. Please ask your study doctor if there is anything you do not understand or if you would like more information. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish for your child to take part, they do not have to. Your child will receive the best possible care whether or not he/she takes part in the study.

What is Acute Appendicitis?
Appendicitis is an infection of a small blind ending tubular structure (the appendix) that arises from the large bowel. In the earlier stages this infection it is confined to the appendix. This is termed *uncomplicated appendicitis*. If the infection is not treated then it may progress to rupture of the appendix resulting in an abscess, or pus within the abdominal cavity. This is termed *complicated appendicitis.*

What is the study about?

For almost 100 years the accepted treatment of appendicitis has been an operation to remove the appendix. This treatment was developed when no other alternatives were available and predated the development of highly effective antibiotics in use today. We now know from studies in adults and some reports in children, that uncomplicated appendicitis can be successfully treated without the need for an operation. In fact even in *complicated appendicitis*, many surgeons will opt to treat the infection with antibiotics rather than an operation, and this has become a common approach.

Your child is invited to take part in this research project. This study aims to assess if clinically uncomplicated acute appendicitis can be effectively and safely managed without the need for an operation. This will be done by comparing outcomes for children with uncomplicated appendicitis treated with antibiotics alone with those who are treated with an operation. Participants will be assigned randomly to be treated with either antibiotics alone or with appendicectomy.

Who can participate in the study?

Children from age 5-16 with a diagnosis of uncomplicated acute appendicitis will be invited to participate.

What will the study involve? Or what kind of medications will my child receive?

Upon admission to hospital your doctor will decide if your child has appendicitis. At that point you will be invited to take part in this study.

If you decide to take part, your child will be allocated randomly to one of two "arms" or groups of the study.

GROUP 1 Antibiotics alone -Intravenous Tazocin (a type of antibiotic) followed by oral antibiotics
GROUP 2 Appendicectomy

For Group 1, your child will require an IV cannula and be treated with intravenous antibiotics for up to 48 hours. They will be closely monitored. If at any time their condition worsens or if the antibiotic treatment is not successful, they will have their appendix removed as per group 2 (see below). . Blood tests, x-rays and ultrasounds will only be done if the doctor thinks they are required in order to make the diagnosis or monitor treatment as part of routine clinical care. There are no extra investigations or blood tests that are required as part of this study. Pain relief will be provided. Once your child is comfortable, eating and drinking and signs of infection have abated, they will be discharged home on oral antibiotics for a total antibiotic course of 7 days. Following discharge we will telephone you at 1 week and 2

weeks and see you in the clinic at 4 weeks. We will make further contact at 3, 6 and 12 months by telephone to see how your child is. Each telephone conversation should take no more than 10 minutes.

For Group 2, your child will be admitted, have an IV cannula as part of routine care and taken to theatre to have their appendix removed. The operation will be explained by the surgical team and your informed consent for the procedure will be obtained as part of standard care in preparation for theatre. A single dose of antibiotics will be given at the time of the operation as is usual practice. Antibiotics may be continued only if thought necessary for your child's care by the treating surgeon after the operation. Post-operatively, your child will be closely monitored. Pain relief will be provided. Blood tests, x-rays and ultrasounds will only be done if the doctor thinks they are required in order to make the diagnosis or monitor treatment as part of routine clinical care. There are no extra investigations or blood tests that are required as part of this study. Once your child is eating and drinking and signs of infection have abated, they will be discharged home.

Following discharge we will telephone you at 1 week and 2 weeks and see your child in the clinic at 4 weeks. We will make further contact at 3, 6 and 12 months by telephone to see how your child is. Each telephone conversation should take no more than 10 minutes.

As part of routine clinical care, your child will be seen by the routine treating doctors every day.

The attached flow diagram explains the decision making processes during the study

Information collected during the study period would include:
Data of birth
Age at presentation
Allergies
Weight
Past medical history
Symptoms and their duration
Physical examination findings
Results of any investigations
Result of randomisation

Group 1

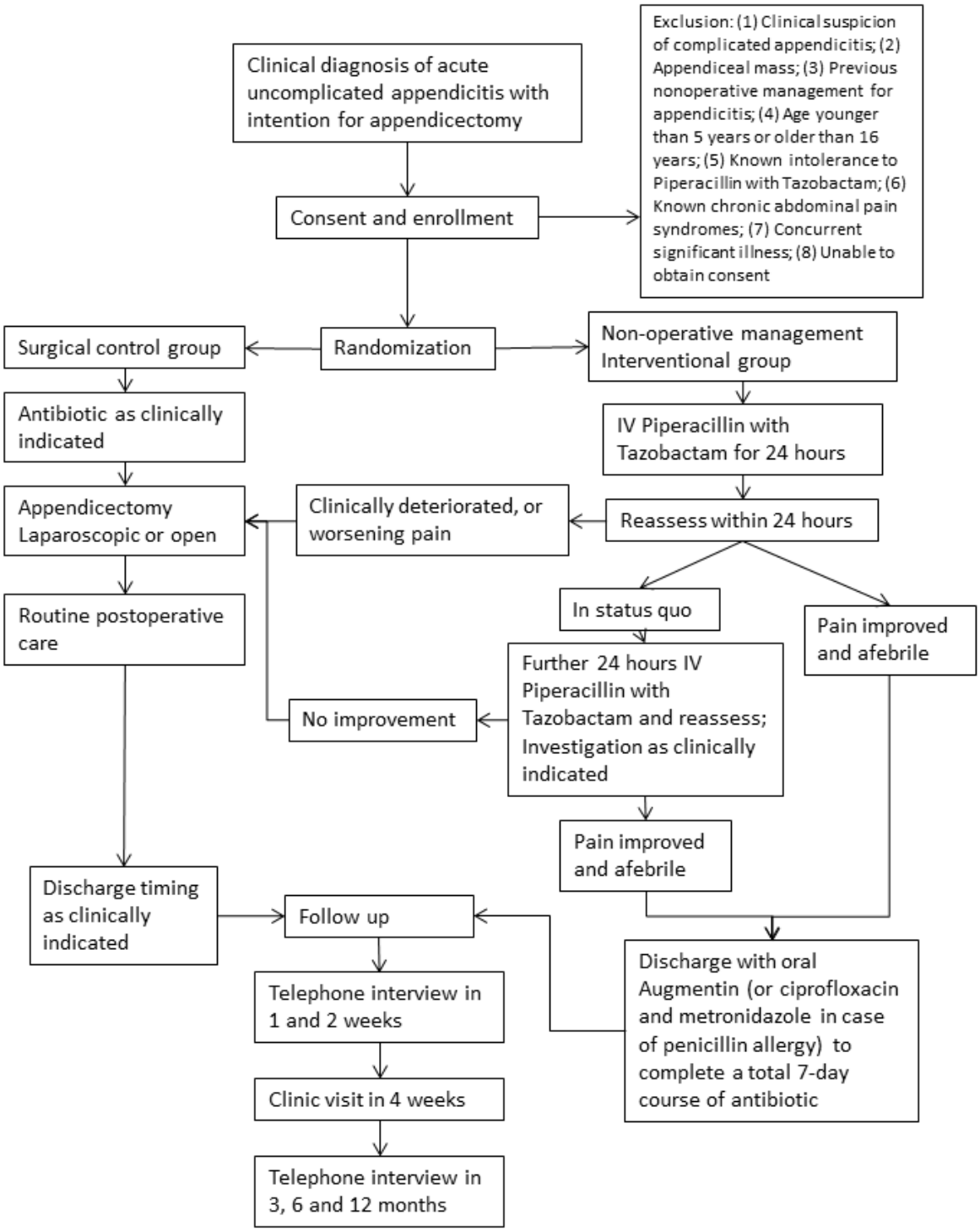
- Antibiotic dose and duration
- Temperature pulse and blood pressure observations as well as pain assessment
- Results of any tests done as part of routine clinical care
- Other medications required including pain killers
- Whether the child proceeded to have their appendix removed
- Dietary intake
- Duration of hospitalisation
- Progress at 1 week, 2 weeks, 4 weeks, 3 months, 6 months and 12 months

Group 2

- Operative findings
- Dose and duration of any antibiotics
- Temperature pulse and blood pressure observations as well, as pain assessment

- Results of any tests done as part of routine clinical care
- Other medications required including pain killers
- Any complications
- Dietary intake
- Duration of hospitalisation
- Progress at 1 week, 2 weeks, 4 weeks, 3 months, 6 months and 12 months

FLOW DIAGRAM EXPLAINING THE STUDY



Are there any benefits for my child participating in the study?

Depending on the randomisation process, your child may avoid having an operation for their appendicitis. The potential advantage of this is a faster recovery, less pain and no complications from having an operation or anaesthetic.
We hope that the results from this study will help confirm that children with uncomplicated appendicitis can be safely managed without the need for an operation.
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Are there any side-effects and risk associated with this study?

In prior studies up to 10% of children who initially have antibiotic treatment, subsequently need to have their appendix removed. This is usually clear during the first 24 -48 hours and almost always by 30 days. There is no evidence that children who are treated initially without an operation, have an increased risk of complicated appendicitis should the antibiotic treatment not work.

What will happen to information collected about your child's treatment?

This study will involve the collection and processing of treatment data. By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project that can identify you/your child will remain confidential. Your child's information will only be used for the purpose of this research project and will only be disclosed with your permission. Information about your child may be obtained from his/her health records held at this and other health services for the purpose of this research. By signing the consent form you also agree to the research team accessing health records if they are relevant to your child's participation in this research project. We will also keep your child's files in locked storage areas, and use password-protected computer files. All paper copies of data collected will be stored for a minimum of 15 years - or for those under 18 years of age; it will be stored for 7 years after the date of their 18th birthday

What happens if I choose to withdraw from this study?

Participation in this project is voluntary and if you decide not to take part or decide to withdraw at any time this will not otherwise affect your child's care at the Hospital. Data collected on your child will not be stored or utilised for analysis.

If you have any questions about the conduct of this study, please do not hesitate to discuss them with

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This project has been approved by the Sydney Children's Hospitals Network Human Research Ethics Committee. If you have any concerns about the conduct of this study, please do not hesitate to contact the Executive Officer of the Ethics Committee (02 9845 3066) and quote approval number HREC/15/SCHN/266.

This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.

Parent Consent Form

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Declaration by Parent

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 my child participating in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

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

I give permission for the child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Sydney Children's Hospital Network concerning my child's condition and treatment for the purposes of this project. I understand that such information will remain confidential.

NAME OF PARENT: _____ (Please print)

SIGNATURE OF PARENT: _____ Date: _____

NAME OF PERSON WHO OBTAINED CONSENT: _____
(Please print)

SIGNATURE OF PERSON WHO OBTAINED CONSENT: _____ Date: _____

Declaration by Study Doctor

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

NAME OF STUDY DOCTOR: _____
(Please print)

SIGNATURE OF STUDY DOCTOR: _____ Date: _____