Appendix – Consent Form (English)

Determining the epidemiology and risk factors of surgical site infections in Pakistan - A prospective, multicenter cohort study

INTRODUCTION

I am *[insert your name]* from the Department of Surgery at the *[insert hospital name]*. We are conducting a national clinical research that seeks to assess the rate and risk factors of surgical site infections in patients undergoing surgery. **Clinical research** is a way to find out if healthcare is being provided in line with international standards and identify areas of further improvements. This will allow us to develop strategies to decrease the rates of surgical site infections in patients.

We are going to inform you about the details of this research and invite you to be a part of it. You can take your time to decide whether you want to participate in this research or not. Before you decide, you can talk to anyone you feel comfortable with about this research. There may be some words that you find difficult to understand. In that case, please ask me to stop as I go through the information and I will take out the time to explain.

PURPOSE OF THE RESEARCH STUDY

Surgical site infections are the infections of surgical wounds. These are one of the most common complications after surgery. The purpose of this research is to determine the rate and associated risk factors of surgical site infections in patients undergoing surgery in Pakistan. This will allow us to develop strategies to reduce the rates of surgical site infections and improve outcomes for patients.

PROCEDURES

We will collect details relevant to the study from your hospital records. After your surgery, we will assess your surgical wound within 30 days to see if you have developed surgical site infection or not. These follow-ups may be performed via telephonic interviews after 3, 15, and 30 days of your surgery. Your personal privacy will be respected and maintained while we assess your wounds for any complications.

POSSIBLE RISKS OR DISCOMFORT

There are no known risks to you associated with this research.

POSSIBLE BENEFITS

There are no direct benefits to you that would result from your participation in this research. However, your participation will help us improve the practice of surgery in Pakistan and develop strategies to reduce the rates of surgical site infections in patients. This will benefit future patients undergoing surgery in Pakistan.

FINANCIAL CONSIDERATIONS

There is no financial compensation for your participation in this research.

CONFIDENTIALITY

Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes. However, participant anonymity will be ensured in the resulting publications.

RIGHT TO REFUSE OR WITHDRAW

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. In the event you decide to discontinue your participation in the study:

a). There are no potential consequences that may result.
b). Please notify Dr. *[insert name of institutional supervising consultant]* of your decision so that your participation can be orderly terminated. You can contact him at *[insert contact number]* and *[insert email ID]* or contact *[insert name of secondary contact]* from the research team at *[insert contact number]* and *[insert email ID]*.

AVAILABLE SOURCES OF INFORMATION

Any further questions you have about the study will be answered by the Supervising Consultant:

Name: Dr. *[insert name of institutional supervising consultant]*
Phone Number: *[insert contact number]*
Email ID: *[insert email ID]*

Name: *[insert name of secondary contact]*
Phone Number: *[insert contact number]*
Email ID: *[insert email ID]*

In case of a research-related emergency, call:
Emergency Number: *[insert contact number]*

AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws.

Name of participant: _____
Signature of participant:

Date: _____

Name of witness: _____
Signature of witness:

Date: _____

Signature of Supervising Consultant:

Date: _____

Name of person obtaining consent: _____
Signature of person obtaining consent:

Date: _____