INFORMED CONSENT FORM.

Project title: Combined urethral and suprapubic catheter drainage improves post operative management after open simple prostatectomy.

Principal Investigator.

Dr Obi Anselm Okwudili.
Department of surgery,Faculty of medicine Ebonyi state University Abakaliki.
Tel. 08033464195
Email draoobi@yahoo.com

PART 1: INFORMATION SHEET

1.Introduction.

We would like to invite you to participate in the above study comparing two methods of draining blood and urine from the bladder after open prostatectomy.One method uses only a catheter passed through the penis and the other method uses two catheters;one passed through the penis and the other passed into the bladder through the lower abdomen(suprapubic catheter).

2.Purpose of study.

The purpose of the study is to determine which method of drainage is better.These two methods have been in use for several years,but no one has tried to determine which one is better than the other.

3.Type of research intervention.

You will be selected to be in either the first or second group by a random selection method towards the end of your operation.During the period immediately after your operation someone will check the flow of urine and blood from your bladder,determine how often blood clots are blocking your catheter,the level of your blood(haemoglobin) and assess your requirement for analgaesics.

4.Participant selection.

Your selection will be based on your need for open prostatectomy to solve the problem you have been having with urination because of your enlarged prostate(BPH).You will not be included in this study if we suspect that you have prostate cancer.

5.Voluntary Participation.

Your participation is voluntary from the beginning to the end.You can undergo your prostate surgery without being part of this study.You will not be penalised or victimized.If you accept to participate,you are free to opt out of the study at any point.The entire study will last 18 months but you will be involved once and that is during the period of your prostate surgery.This period will last between 7 to 10 days.

6.Risks.

You will be asked some personal and confidential information and you are free to decline answering any question that you do not want to answer without giving us the reason for doing so. There are no additional risks to you different from the well known risks associated with undergoing prostate surgery.

Your blood will be taken to determine the level of your blood (i.e. hemoglobin estimation).You will be asked how often your catheter gets blocked by blood clots.

7.Benefits.

You will not incur additional surgery fees. Your booking for prostate surgery will be fast tracked without displacing others who are already on the waiting list. In addition the result of this study will improve post operative management after open prostatectomy for benign prostate disease (BPH)in Nigeria and worldwide.

8.Reinbursements.

You will not be provided any monetary incentive for participating in the study. However the cost of the additional catheter or extra medication will be borne by us if you are in the group that will use two catheters.

9.Confidentiality.

The research team will maintain the highest level of confidentiality in the handling of your data. All data will be analyzed and reported in such a way that responses will not be linked to you. The data provided will only be used for the specific research purposes of the study.

10. Contact Person.

If you need further information about the progress and outcome of this research, please feel free to contact:

Dr Obi Anselm Okwudili.
Department of surgery,Faculty of medicine Ebonyi state University Abakaliki.
Tel. 08033464195
Email draoobi@yahoo.com

11. Illiterate Participants

If you do not understand English please kindly let us know. We will provide someone who will translate every information in this document to you in a language that you understand.

This questionnaire has been reviewed by the University research ethics committee of Ebonyi state university, which is supporting this study.

Please feel free to ask any more questions about any part of the research study.

PART 11: CERTIFICATE OF CONSENT.

I have been invited to participate in this research.
I have read the foregoing information. I have had the opportunity to ask questions about it and all questions I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Name of participant………

Signature of participant……………………………………………………………………………………………………….

Date……