

APPENDIX I: CONSENT FORM

Introduction: We are consultants in the Department of Obstetrics & Gynecology of this hospital. We are conducting a study with the title “Effect of intravenous tranexamic acid on blood loss during and after elective Caesarean section”. Tranexamic Acid is a drug that prevents women from bleeding too much after giving birth. It works by preventing blood clots formed from breaking down. This stops bleeding following delivery of a baby especially during Caesarean section. Bleeding during Caesarean section is a leading cause of maternal death and serious complications in our environment. This study when completed may provide evidence for the usefulness of tranexamic acid in women who are planned for Caesarean section in our environment.

Voluntary nature of participation: Participation in the study is absolutely voluntary. You also reserve the right to withdraw from the study at any time without any consequence to you.

Study procedure: A questionnaire will also be administered to you during the course of study and it shall be seeking information on your personal data excluding your name. In the course of the study, tranexamic acid or inactive substance called placebo will be administered to prevent excessive bleeding during or after child birth. The Ethical Committee of University of Abuja Teaching Hospital has approved the study.

Potential risks and anticipated benefits to individual participants

Participants in this study will be subjected to the same standard of care as non-participants. Some side effects which includes nausea, dizziness, hypotension has been noted but this can be minimized by giving the drug slowly. There has not been any

documented long term side effect on babies exposed to tranexamic acid. The research constitutes no added risk to the participants.

Confidentiality: Your name is not required for this study and any information given here will strictly be used for research purposes and kept in confidence. All information gathered as well as the outcome of the procedure will be treated with utmost confidentiality, and will not be used against you in any form. Data generated from this study will be used purely for publication and will not reveal the identity of the individual participants in any way.

You can also reach the researchers on 08066914483 or at the Department of Obstetrics and Gynaecology, UATH, Abuja.

Thank you very much for agreeing to participate in this clinical trial.

I, ----- have been informed about and understood the study on the effect of intravenous tranexamic acid on blood loss during and after elective Caesarean section. I have agreed to participate in the study with the right to opt out any time.

Signature/thumb print.....

Date.....

Hospital number

WITNESS:

Signature/Date.....

Name.....