



KENYATTA UNIVERSITY

UNIVERSITY EXAMINATIONS 2011/2012

FIRST SEMESTER EXAMINATION FOR THE DEGREE OF MASTER OF SCIENCE IN BIOSTATISTICS

SMA 676: CLINICAL TRIALS

DATE: TUESDAY, 6TH DECEMBER 2011

TIME: 5.30 P.M. – 8.30 P.M.

INSTRUCTIONS: Answer questions ONE and any other TWO.

1.
 - i) Define clinical trials. (4 marks)
 - ii) Discuss the phases of clinical trials. (16 marks)
 - iii) Define randomisation. (4 marks)
 - iv) What are the advantages of randomisation? (3 marks)
 - v) Outline the methods of randomisation. (3 marks)

2.
 - i) Define protocol violation. (2 marks)
 - ii) Differentiate protocol violation from protocol deviation. (3 marks)
 - iii) Discuss the types of protocol violations. (15 marks)

3.
 - i) Define compliance. (2 marks)
 - ii) What problems are associated with poor compliance? (2 marks)
 - iii) Discuss the strategies for enhancing compliance. (10 marks)
 - iv) What methods are used to assess compliance? (6 marks)

4.
 - i) With illustration discuss the core designs of clinical trials. (10 marks)
 - ii) Define factorial designs? What are their advantages? (5 marks)
 - iii) Differentiate between multicentre and single centre clinical trials. What are the advantages of each? (5 marks)
