

Definition and Examples of Amendments

Amendment – any significant changes that are made to an ERB-approved protocol. These changes may be classified as major or minor.

1. **Major amendments** involve substantial alterations in the study protocol that may affect ethical soundness, scientific validity or alter the risk-benefit profile of the study, such as:

- a. Modifications to the primary hypothesis that is being tested.
- b. Changes in the research design or the methodology.
- c. Addition of outcomes or exposures, which may be unrelated to the main focus.
- d. Changes in the study site(s) and/or modifications in the facilities that support safe conduct of the study.
- e. Changes in the definition of the study population.
- f. Major adjustments in the sample size.
- g. New information on the efficacy or safety profile on an investigational product
- h. Addition of new laboratory/medical procedures
- i. Changes in the duration of the follow-up period
- j. Changes in or addition of data collection methods and tools.
- k. Introduction of new plans involving interactions with health professionals and/or patients and/or prospective or current study participants.
- l. Major revisions in the analysis plan.
- m. Changes in data sharing terms and conditions; addition of linkages with other data bases; addition of or changes in linkages with stored biological material.
- n. Changes in collection, analysis, transport, storage and/or access to biological material, including: changes in or addition of source(s) of biological material; modifications in or addition of biological material collected, analysed, transported and/or stored; modifications in or addition of tests to be conducted; etc.

- o. The introduced amendment(s) to the protocol potentially alters the presumed willingness of current study participants to continue their involvement in the study.
- p. Substantial changes in the qualifications of the research team.
- q. A change in the Principal Investigator.
- r. Considerable changes in collaborating institutions/organizations and/or collaborators.
- s. Other changes which may be deemed as more than minor by the Executive Officer, in concurrence with the Chair or the Vice Chair.

2. Examples of amendments which may be considered as minor include:

- a. Changes in the research staff other than the principal investigator, provided the necessary expertise for the research remains unchanged
- b. Adjustments in the study time schedule brought about by delays in study initiation, provided the reasons for delay are presented.
- c. Limited additional analysis suggested by unexpected findings, provided these are clearly presented as post-hoc.
- d. Additional statistical methods to further control for confounding or sensitivity analysis provided these are to be reported as secondary to the main findings