(1) **Ethics approval**

Ethical approval for this study was obtained from *NAME OF ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD (APPROVAL NUMBER/ID)*.

Or

Ethical approval for this study was waived by *NAME OF ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD* because *REASON FOR WAIVER*.

Or

Ethical approval was not sought for the present study because *REASON*.

Or

Not applicable.

(2) **Informed consent**

Written informed consent was obtained from all subjects before the study.

Or

Verbal informed consent was obtained from all subjects before the study.

Or

Written informed consent was obtained from legally authorized representatives before the study.

Or

Verbal informed consent was obtained from legally authorized representatives before the study.

Or

Informed consent was not sought for the present study because *REASON*.

Or

*OTHER DETAILS*.

Or

Not applicable.

(3) **Trial registration**

*NAME OF TRIAL REGISTRY: TRIAL REGISTRATION NUMBER*

Or

This randomized clinical trial was not registered because *REASON*.

Or

Not applicable.