

**(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.