Nut-22.1. Ethics: describe the procedure for consent and study approval from ethics committee(s).

Example 1. “Before data collection, written consent was obtained from parent participants in the original data collection for the Early Childhood Longitudinal Programs, Birth Cohort (ECLS-B). The National Center for Education Statistics approved our use of the deidentified and anonymized restricted-use data set for the current analysis. The Johns Hopkins Institutional Review Board deemed that this analysis of deidentified secondary data involved non– human subjects research”.

Explanation.

As stated in the Helsinki Declaration, ethics apply to all types of medical research concerning human subjects that includes research on identifiable human material or data. The Council for International Organizations of Medical Sciences has recently published a new version of its International Ethical Guidelines for Health- Related Research Involving Humans. It is useful to provide details about ethical approval, if it has been granted, and by whom. The need for ethical approval for observational studies, however, varies across countries (see also Nut-22.2).

Regardless of the legislation available in the country of research, all research studies collecting data from human participants impose ethical obligations to participants. Therefore, researchers should ensure clarity and describe how they addressed the ethical issues in their research, including the research risks of harm. In addition, the procedures to guarantee data privacy and confidentiality during the analysis and handling of personal data should be clearly described.