NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

Data collected prior to subject withdrawal - To keep or to discard?

Background

Research teams often ask if they can continue to use data of participants who had chosen to withdraw from study participation.

This uncertainty was amplified by the PDPA FAQ[1] that suggests investigator should not continue to analyse data of subjects who wish to completely withdraw all their data from the study.

Human Biomedical Research (HBR) Act (in effect from 21st August 2015)

Under section 4(6)(b) of the PDPA, the HBR Act will prevail over the relevant PDPA provisions should there be any inconsistency on consent.

HBR Act (Section 14) specifies that withdrawal of consent shall not affect the research information obtained before the consent is withdrawn. Such information may be retained and used for the research. This means that any information or data already generated from the research or tissue before the point of withdrawal will remain part of the research.

However, the subject or tissue donor is allowed to withdraw consent to continue participating in the research, or withdraw consent for the further use of his/her tissue/health information in research insofar as the tissue/health information is still individually identifiable, and with the following conditions:

a) Has not been used for the research, or
b) Has been used for the research but it is practicable to discontinue further use of the tissue/health information for the research.

The HBR Act (Section 12(1)(n)) requires that the individual be informed of his right to withdraw consent and the limitations of such rights before his consent is obtained. This requires open and upfront discussion with the individual concerning their rights to withdraw consent.

[1]*The Human Biomedical Research (HBR) Act was passed by Parliament on 21st August 2015.*

Scientific validity of the study protected

In conclusion, the data collected prior to the participant's withdrawal could be retained and used so that the scientific validity of the study would not be affected. DSRB recommends that investigators to inform research participants by mentioning in the Informed Consent Form that:

1) Participant's data would be retained or used even after their withdrawal from this study.

2) Participants have their rights to withdraw his/her consent in circumstances specified in HBR Act and the limitation of such withdrawal.

References:

- ***Human Biomedical Research Act Bill*** ***http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0;whole=yes***
- ***Personal Data Protection Act Guidelines for Healthcare Sector*** ***https://www.pdpc.gov.sg/docs/default-source/public-consultation-4---education-healthcare-social-services-photography-submissions/advisory-guidelines-for-the-healthcare-sector.pdf?sfvrsn=2***
- ***NHG Proper Conduct of Research SOP 501-C01 - Informed Consent Form and Process***

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