NHG RESEARCH EDUCATION

Qualité

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Serious Non-Compliance: Collection & Use of Data Without IRB's Approval

Case study

In 2016, study PI submitted a DSRB amendment to increase sample size from 100 to 500 subjects. As this is a retrospective medical records review study, the change infers an increase in an additional 400 sets of subject data.

The DSRB needed some clarifications on the revision to sample size. However, the study team did not respond to DSRB's queries. The submission was subsequently withdrawn due to non-response. This meant that DSRB approval was not given on the amendment.

In 2017, Study PI submitted a Status Report Form (SRF) to renew the study. The DSRB again sought clarifications on the increase in the sample size. Again, the study PI did not respond and the revision to the sample size was not approved.

In 2018, the DSRB noted that study PI had published a journal article based on the consolidated data of 500 subjects. The DSRB determined the collection, use and publishing of data for the additional 400 subjects to be a serious violation of the protocol.

Outcome

A warning notification has been sent to the PI. Follow-up actions to address the non-compliance are requested.

What the PI should have done

1. The PI should address outstanding questions specific to the study amendment and obtain DSRB approval before any additional data extraction and collection is done.

Lessons to learn

1. Access and use of Personal Data

"Personal data" means data, whether true or not, about an individual who can be identified (a) from that data; or (b) from that data and other information to which the organization has or is likely to have access. [3]

For this study, DSRB had granted a waiver of consent and for the collection of personal data for 100 subjects. However DSRB, had not approved an increase in subject samples. Therefore, personal data of additional subjects should not be accessed and collected for research.

Study teams must know of the regulatory requirements and respect subject's individual rights of their data to be used in research, especially sensitive health and/or clinical information.

2. Responsibilities of the Research Team

The PI is responsible for promoting the proper conduct of research by assuring adherence to protocol requirements, protecting the rights and welfare of participants, assuring the integrity of data generated at the site and directing the conduct of the research according to applicable regulations and guidance.[5]

The research team must not implement any protocol deviation or changes prior to review and approval by the DSRB.

Deviations from the research proposal may constitute a HBRA contravention and liable to be convicted.

References

1. NHG Proper Conduct of Research Standard Operating Procedures *501-A02: Responsibilities of the Research Tea, Section 4.4(f)*
2. NHG Proper Conduct of Research Standard Operating Procedures *501-A02: Responsibilities of the Research Tea, Section 4.5(f)*
3. Personal Data Protection Act 2012 – Part I (Preliminary)
4. Personal Data Protection Commission, Advisory Guidelines on the PDPA *For Selected Topics (revised 28 March 2017), Section 2.1 >*
5. NHG Proper Conduct of Research Standard Operating Procedures *501-A02, Section 4 and 4.7d*

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