MARCH 2019

MANAGING CONFLICT OF INTEREST (RESPONSIBLE CONDUCT OF RESEARCH)

Scenario

Dr Emma is the Co-Investigator (Co-I) for an ongoing study which seeks to recruit patients with chronic skin disorders (e.g. bullous pemphigoid). Informed consent would be required from participants prior to blood samples collection. It was stated in the protocol that participants with diminished cognitive response would be excluded from the study.

Madam Aw, a 70 year old patient, who had been diagnosed with bullous pemphigoid came for her routine follow up visit and was accompanied by her grand-daughter. At this follow up visit, Dr Emma found Madam Aw to be eligible and asked her to participate in the study. The clinical research coordinator (CRC) proceeded to obtain consent from Madam Aw. However, prior to the blood taking for the research study, Madam Aw appeared confused, fearful and was unable to recall if she had signed the informed consent form. She refused all blood taking.

The CRC reported the situation back to Dr Emma and expressed concerns about Madam Aw's behaviour. Upon speaking with Madam Aw's grand-daughter, Dr Emma found out that there had been some behavior changes (i.e. unable to remember recent events, reduced concentration, behaviour changes etc.).

The CRC expressed her concerns to Dr Emma that Madam Aw could be demonstrating early symptoms of dementia and therefore, she should be withdrawn from the research study. However, due to low recruitment Dr Emma felt that Madam Aw should continue participation in the research study. The CRC was concerned with Dr Emma's decision and felt that she might be in the position of a conflict of interest. How could the CRC help manage the situation?

1. The CRC should speak with Dr Emma in private and reminded her of the exclusion criteria of the research study. Madam Aw should not be recruited as she might meet the exclusion criteria.
2. The CRC should ask Dr Emma to consult an independent physician to assess Madam Aw's capacity and document the assessment in the medical records.
3. The CRC should also inform the Principal Investigator (PI) on the situation.

After the PI had discussed with Dr Emma, it was decided that Madam Aw would be withdrawn from the research study. The CRC assisted Dr Emma to withdraw Madam Aw from the research study. Dr Emma also documented in Madam Aw's medical records, the rationale for withdrawal from the research study.

It is encouraged for study team members to take the Collaborative Institutional Training Initiative (CITI) Modules on Responsible Conduct of Research (RCR). It is important to be familiar on the responsible conduct of research in biomedical sciences. With the knowledge gained from the course, the study team will be equipped with research best practices, so as to guide them in making the right decision for the integrity of the research, especially in instances that may challenge individual values and integrity.

References:
- NHG Responsible Conduct of Research (RCR) Manual – Chapter 6: Conflict of Interest
- Responsible Conduct of Research 2nd Edition, Adil E. Shamoo and David B. Resnik, 2009, Oxford University Press

Additional readings:
- NHG investigator's Manual 3rd Edition, Chapter 6.3: Research Involving Cognitively Impaired Persons
- NHG Proper Conduct of Research SOP, 501-C01: Informed Consent Form and Process
- NHG DSRB Sample Language for Documentation of Capacity (www.research.nhg.com.sg > Home > Resources > Ethics Forms and Templates)

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