Responsible Conduct of Research - Protection of Human Subject

Research involving the use of human subjects has benefited the society by contributing to the medical advancement and development of new drugs and treatment. However, these may imposed unacceptable risks on research subjects. Therefore, all individuals involved in human subject research have the onus to ensure that the rights, safety and the well-being of research subjects are protected by complying with ethical boards' guidance as well as any applicable regulations related to the protection of human subject.

The example below illustrates some RCR concepts.

Case Study

Based on DSRB's requirements, clinical trials are considered to be "greater than minimal risk" studies. As such, PI requirements for such studies are more stringent than that for minimal risk studies. To qualify as a PI for a more than minimal risk study that does not require a Clinical Trial Certificate (CTC) from HSA, the individual should be:

- Dr V has no prior research experience; however, he is interested in carrying out a research on an experimental new drug which has claimed to be effective in lowering the HIV (viral) load in HIV positive individuals thus lowering of their incidence of contracting secondary infections.
- An advertisement for the recruitment of five participants; promising free physical examination, free health care for three months and $1000 compensation was placed at the hospital's communicable disease centre's (CDC) outpatient clinic.
- Upon expressing interest in the research, Dr V will hand the participant an informed consent document and obtain their consent at the clinic's general waiting area immediately. .
- As only five participants will be recruited for the research, Dr V decided that data and safety monitoring for this research would not be required.
- To test the efficacy of the experimental new drug, blood samples will be taken for the entire duration of the research (12 months) from the participants. At each blood taking, 20mls of blood will be taken and an additional of 15mls of blood will be taken and stored for "future research".
- This research was not submitted to the institutional review board (IRB)/institutional ethics board (IEC) for approval as Dr V thought that it was unnecessary.

What should Dr V do prior to conducting the research? (Please select the best answer.)

a. As Dr V is inexperienced in research, he should approach his Head of Department/ a respectable researcher (with track record in research) in his institution and discuss his research proposal and seek guidance on how to carry out his research. After discussion, he should write up a protocol specifying the details of his research (i.e. supporting literature for the new experimental drug, informed consent process, the study team members, inclusion and exclusion criteria, stopping criteria, etc.) and submit his research application to the IRB and local regulatory authority (if applicable) for approval.

b. Dr V should approach the CDC pharmacists as the research involves an experimental new drug. Submission to IRB and local regulatory authority (if applicable) is not necessary as only five participants will be recruited.

c. As Dr V is inexperienced in research, he should approach a pharmaceutical agency to conduct this research on his behalf.

d. Nothing, Dr V is doing everything right.

As there are no safeguards (i.e. the research was not submitted and approved by IRB, there is no data and safety monitoring etc.) in place to protect these participants. Which component or RCR would the above case study be categorized under?

a. Improper conduct of research

b. Protection of Human Subject

c. Mentor & Trainee Relationship

d. Research Misconduct

Useful pointers before starting a research:

- Is the study design scientifically and ethically sound?
- Are processes in place to ensure that subjects are informed of the study and are able to exercise their rights (i.e. subjects may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled)?
- Are mechanisms in place to ensure subjects' safety during participation?
- Are safeguards in place to ensure the well-being of the subjects?
- Has the research application received approval from the ethics board and regulatory authority, if applicable?

To find out more about the RCR unit, please visit: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/responsibleconductofresearch

To find out more about the RCR components, please visit: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/corecomponentsofrcr

References

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Correct Answers for Case Studies
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