NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

Informed Consent Fundamentals – Handling Subjects' Personal Information

Introduction

Informed Consent is a vital element in research. The Informed Consent Form conveys all significant research information, such as risks and benefits, to the subject, allowing him or her to make an informed decision regarding their participation in the study. It is a legal and ethical concept that has become a cornerstone in the field of medical research and bioethics and is fundamentally based on the idea of trust and respect towards the subject.

It is important for investigators to know how to manage their studies in a manner that does not breach this trust. This is vital for both the participants of the study and the validity of the study. There are many ethical issues that may arise during the informed consent process and even the most qualified of investigators can make mistakes. Hence, it is essential to think carefully and take the appropriate steps to ensure and take care of the interests of the subjects who have given their informed consent to participate in a research study.

Handling of Subjects' Contact Information

An aspect of paramount importance in ethics is the strict adherence to the terms of consent set out in the informed consent form. The NHG Research Ethics Committee (REC) recently deliberated over a serious non-compliance whereby the study team did not abide by the terms and conditions set out in the informed consent form.

In this study, subjects were explicitly informed that their personal contact information such as their phone numbers would be destroyed at the end of their participation. However, the study team did not abide to this and used this information to contact these subjects to participate in other studies. This represented a significant breach of the terms of consent for the study.

The REC concluded that investigators must strictly abide by the terms set out in the informed consent form. When subjects agree to these terms, it is essential that investigators conduct the study within those boundaries.

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Subjects expect the study team to uphold high ethical standards and this includes the proper handling of subjects' contact information.

Any deviation from the terms of consent will result in a serious non-compliance that may compromise the conduct and legitimacy of the study as well as future studies conducted by that Principal Investigator. Therefore, investigators must remind themselves to observe strict compliance to these terms set out in the informed consent form especially with regards to subjects' privacy and contact information.

In conclusion, as scientific research advances, it is important to remember to respect the right of the research subject to his or her privacy. Deceiving the subjects endangers the reliability of the informed consent process and could harm subjects, as well as create mistrust between the public and researchers. Protecting the privacy of subjects is and always has been an absolute necessity in bioethics.

References:

- *Escobedo et.al (2007) Ethical Issues with Informed Consent*
- *Erika Church Hayden (2012) Informed Consent: A Broken Contract*
- *Guidelines for the Retention Process of Signed Informed Consent Forms* *http://www.research.psu.edu/orp/humans/conducting-study/closing-study/record-retention/signed-icf-retention*
- *Unite for Sight: Module 4 – Consent, Privacy and Confidentiality* *http://www.uniteforsight.org/research-course/module4*
- *NHG PCR Standard Operating Procedure 501-C01 Informed Consent Form and Process*

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