NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

Waiver of Documentation of Consent vs Waiver of Consent: The difference and what should be documented?

Background

The ethical principle of "Respect for Persons" as stated in the Belmont Report highlights the need for subject's autonomy to decide on his/her participation in a research study.

The Informed Consent process assists the subject to make a well-informed decision and documentation of the process affirms the subject's willingness to participate. Therefore, the DSRB requires that written informed consent be obtained from all subjects and the process be documented prior to participation in any research.

However, in some instances, the DSRB may consider a waiver for the requirement of documentation of consent or the requirement to obtain informed consent for a research study. Conditions of waiver can be found in the NHG Investigator's Manual for DSRB Biomedical Domains 2nd Edition.

Differentiating Waiver of Documentation of Consent and Waiver of Consent

Waiver of Documentation of Consent

- ✓ Consent to participate in the research study is obtained from subject &
- ✓ Informed Consent Form is not required to be signed by Subject.

Example: A Principal Investigator (PI) would like to conduct a face-to-face interview to investigate the behaviour of subjects involved in shop-theft incidents. Identifiable information of the subject will not be recorded.

In this scenario, the PI may request to obtain consent verbally only, and not requiring the study subjects to sign an Informed Consent Form, since the consent document would be the only record that links and identifies the subject to the study.

The DSRB may grant a **waiver of documentation of consent**, taking into consideration that the principal risk would be potential harm resulting from a breach of confidentiality. DSRB may also request the study team to provide subject(s) with an information sheet similar to a consent form, but without the subject's signature field. This information sheet would need to be reviewed and approved by DSRB prior to use.

Waiver of Informed Consent

- ✓ The research is conducted without obtaining consent from the subject.

Example: A PI would like to review medical records (Period: 2005-2014) and evaluate the prevalence of subjects with liver cirrhosis that leads to liver cancer. It is estimated that 5000 records would be reviewed.

In this scenario, the DSRB may allow a waiver of informed consent as the study involves:

a) Minimal risk &
b) The research could not be practicably carried out without the waiver since it would not be feasible to contact the subjects, who might no longer be following up at the institution or deceased &
c) The results of this research do not impact the current standard of care received by these subjects.

Waiver of Documentation of Consent: Is source documentation of informed consent process still required?

If the DSRB has approved a Waiver of Documentation of Consent, the subject will not be required to sign on an Informed Consent Document. However, the PI should still obtain verbal consent from the subject, and document the informed consent process in the subject's medical records or source documents. Proper documentation of the informed consent process serves as a record to ensure that the subject has been informed and provided with sufficient information to decide on his/her participation in a research study.

At minimum, the following should be recorded:

1. Protocol Reference
2. Date of Informed Consent
3. Description of Informed Consent Process

References:

- ***NHG Investigator's Manual for DSRB Biomedical Domains 2nd Edition Sections 5.9 – 5.11***
- ***PCR SOP 501-C01: Informed Consent Form and Process***

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