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Informed Consent Elements for Pharmacogenetic Research: An Overview

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Introduction

Participant enrollment and retention are meant to be the biggest challenges to successful project completion in clinical trials. This might be because of the nature of clinical research that requires a very small number of participants to shoulder the risks caused due to unproven or unapproved medical products. Informed consent (IC) process is one of the methods used by the researchers to responsibly inform the subjects of these risks and to protect their rights and welfare. So, informed consent is the process of giving potential research participants appropriate information and allowing them to make a voluntary and informed decision about their participation in the study.

Informed consent is meant to be a very critical part of clinical trials as history provides many instances in which the investigations were done without informed consent. One of such instances is about the yellow fever that happened in 1800s. Self-limiting bouts of fever to severe hepatitis and hemorrhagic fever were the symptoms of yellow fever. An Italian scientist, Giuceppe Sanarelli who was working in South America, claimed that he discovered the cause of yellow fever to be a bacterium named "Bacillus icteroids". He injected patients with the cultures of bacillus without their permission. As a result of which 3 out of 5 people died. Later on, a Cuban physician, Carlos Juan Finlay, confirmed that yellow fever was infact caused due to the bites of mosquitoes infected with virus.

Due to incidences like these, informed consent process became a very vital part of clinical studies, worldwide. The three basic components of IC are:-

- Giving information about the proposed research study.
- Ensuring comprehension of the given information.
- Requesting voluntary participation of the subjects. This means, the potential subjects must be informed that they could choose to decline to participate in the study without any fear of repercussions, guilt or ill will on the part of investigators, and at any time or stage of the clinical trial.

Totality of evidence

There's a rigorous approval process in the U.S. for new drugs or devices to provide opportunity for a careful and thorough evaluation of the product under investigation. When new compounds show potential in laboratory tests, studies are designed to evaluate these compounds for pharmacological use. These studies of a new compound/device performed in animals, are referred to as "pre-clinical studies". Pre-cinical studies help in sketching the boundaries for the safe use of the treatment when any clinical trial begins.

Pharmacogenetic Research

A new era of pharmacogenetic research has been triggered as a blast of new human genetic data and highly increased awareness on the fact that genetic variations influence drug responsiveness to a great extent. As a result of this knowledge, the pharmacogentic investigations provide important advances in the design, development and delivery of safe and efficacious pharmaceuticals, which could provide customized drugs for specific populations, defined by their unique genotypes.

Informed Consent Process in Pharmacogenetic Research

There are special considerations and disclosures in the informed consent process involved in pharmacogenetic research. These disclosures are like incorporating genetic objectives into clinical studies; in terms of implying the genetic data to be derived from such studies, including the potential risks for genetic discrimination. Obtaining consent for pharmacogenetic research is a challenging process because of the genetic terminologies used and the concepts may be fundamentally difficult to understand for the subjects. The subjects should always be encouraged to ask questions to understand their purpose of participation in the study. The subjects must be provided the consent material beforehand so that they have sufficient time to understand. It's imperative for the researchers to assure that the language is understandable and that the risks and benefits are very well explained.

Key Elements in the Informed Consents in Pharmacogenetic Research

The key elements of Pharmacogenetic Informed Consents are:-

- Purpose and intent: subjects must be given some background information about the biological function of the genes and how could the particular study help scientists and clinicians learn more about the disease and the treatment.
- Procedures involved in collecting, handling and processing the samples must be clearly described.
- Voluntary participation is required in pharmacogenetic studies like any clinical research protocol. Separate IC documents are utilized for pharmacogenetic trials for allowing the subjects to make a decision independent of their decision to participate in the drug research protocol.
- Sample collection procedures for routine clinical care and the ones particulary applied to the pharmacogenetic research must be explained well in the IC.
- Withdrawal options and timelines from a pharmacogenetic study should also be explained.
- Contact information of the researcher must be indicated in the IC for the subjects.
- Any plans for the communication between the subjects and the researchers must be clearly described.

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- Sharing of the sensitive unintended genetic results must be explained.
- The risks and benefits associated with the pharmacogentic studies must be considered and explained at the time of obtaining the IC.
- Confidentiality of the genetic information from such trials must be appropriately protected, disclosed and utilized. The processes used for confidentiality must be described in an understandable language. Researchers, sponsors, IRBs and regulatory authorities across national and international boundaries must consider all these steps diligently and ensure that the clinical research is valuable and the subjects are adequately informed about the purpose of the study and their roles in it.