5 Common Challenges When Obtaining Informed Consent in Clinical Research

Do you consider participating in a clinical study? You have talked about it with people whose opinion matters to you. You have clarified your decision to your family and friends. But do you know whether or not this is really the right thing to do? Are you familiar with all the details about the goal of the study? Do you have an idea how long it is going to be? Do you know what possible risks and benefits to expect? Can you firmly say you understand it all so your participation in the trial is absolutely voluntarily? Well, in order to guarantee that potential clinical trial subjects are well-informed about what they are going to undertake, clinicians need to obtain informed consent from their patients as part of the research process.

So what exactly does informed consent represent?

In brief, informed consent is an important ethical and legal requirement when it comes to clinical research that involves human beings. Conventionally, it is the process where a clinical trial volunteer is introduced to the specifics and aspects of the trial. The main purpose is to provide the necessary information to the volunteer in a digestible language and easy to understand manner. This way, based on the given details, he or she can make the final decision as to whether to take part in the trial or not.

As mentioned before, the informed consent underlines the rights of the person, the objectives of the study, its advantages, risks, procedures to be taken, anticipated duration, and other important information necessary to enable participants to draw their own conclusions and reach to a decision in the end. In this sense, participants are asked to read the whole Informed Consent Form (ICF) thoroughly and carefully first. After that, they can discuss it with the team of researchers, ask questions and receive answers. Only when everything is crystalized, can participants sign the ICF and move forward with the next study-related process or terminate their clinical trial journey.

It is important to note that apart from clinical trials, informed consent is a vital prerequisite before enrolling applicants in other types of research that involves humans. This includes: domestic researches, studies performed abroad, social, behavioral, diagnostic, therapeutic, interventional trials and others.

Unfortunately, even though informed consent may sound simple enough, things are not always that easy and straightforward. There are some challenges that keep popping up every now and pose certain barriers in the process of obtaining informed consent.

What are the issues then?

1. Ambiguity

Confusions surrounding the trial are often confusions surrounding the consent as well. In this regard, some research projects may be too complex. Explaining the specifics, respectively, and slicing the whole information bit by bit becomes more difficult to be done, compared to a trail that is less complicated and with crystal clear tasks. For adequate understanding to take place, there's a need of adequately prepared research procedures and papers which are later presented to volunteers.

2. Patients perceptions

One thing for someone may have an entirely different meaning to someone else. It is almost impossible to assess people's standpoint regarding a particular study because there are no proven ways to evaluate their understanding in terms of the information that has been provided. And this is something that researchers are tackling when obtaining informed consent from their patients before the start of the trial. In order to cope with this, experts suggest the use of shorter sentences and a language style that does not exceed the average level of people's literacy. Otherwise, that may lead to misconceptions, wrong assumptions and incorrectly interpreted information. In case something is unclear, it is recommended that people should avoid jumping to conclusions on their own. Ask the experts themselves. They are there to explain.

3. Language barriers

Mobile devices and other technologies allow for remote recruitment of people from different parts of the world. However, this poses certain risks related to the language that is being spoken and used. Some essentials may be translated in the wrong way or incompletely. Other times, they may simply be omitted. And this affects not only how future participants consume the whole information but also what decision they are going to make.

4. Predetermination

In some cases, obtaining informed consent from volunteers is prevented by human's pre-set thoughts and conceptions. When they are being approached about a trial, some people tend to see it as too dangerous, compared to traditional treatments. Worried about the unknown side effects, possible risks or definite ineffectiveness, they chose to rely on conventional cures and methods. Sometimes, this is because the information delivered to them is way too detailed or it is simply presented in the wrong way. Which scares people away and makes them think traditional techniques are better, reliable and more efficient.

5. Children

Where given studies require the participation of children who are under 18, informed consent must be obtained from their parents. The major challenge that arises here is when parents give their permission and agree to everything that is being outlined in the ICF, but the child refuses to participate. In this sense, it is not the parent who withhold consent, but the child.

In conclusion, despite the fact that there is a number of challenges that accompany the process of obtaining informed consent, no research activity which includes human subjects can be initiated without such consent from potential participants. Everyone should know their place and should know their responsibilities. People involved in research processes should never exceed the power given to them for personal benefits and reasons. Well-being of patients, their rights and safety must always be taken into account. No human subject must be deceived or misguided in any situation. These are the things that should come before any other interest of science.

Should you need any further information regarding informed consent, its specifics, significance, relevant regulations, requirements and more, you can sign for our **Good Clinical Practice** here:

https://crotraining.co.uk/online-training/good-clinical-practice-gcp-training-international-edition/

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