Diabetes research nursing

In this regular column, Shona Brearley discusses diabetes research nursing from a practical perspective, with the aim of sharing best practice ideas and giving readers the chance to ask for advice about their particular study. If you have any queries, or would like to contribute to this column, contact jdn@sbcommunicationsgroup.com.

The importance of informed consent in diabetes research

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Over the last few months, I have discussed the regulations covering clinical research and the recruitment of people with diabetes to trials, so it makes sense that I should now look at the issues surrounding informed consent in research. The Declaration of Helsinki states that after ensuring the research participant has understood the information about the research, the physician or another appropriately qualified individual must then seek the participant's freely-given informed consent, preferably in writing (World Medical Association, 2000). The International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use guidelines (ICH Good Clinical Practice, 2002) state that:

> *"Freely-given consent should be obtained from every subject prior to clinical trial participation and each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s)."*

Both these agencies make it very clear that the person who conducts the informed consent discussion and witnesses the participant's signature should be someone who is part of the study team and knows the protocol explicitly. This means that it is often more relevant for the research nurse to take informed consent than a doctor, who may be much less involved with the study. However, for most studies sponsored by pharmaceutical companies, their company standard operating procedures (SOPs) state that it must be a physician who takes consent at the screening visit. If the research nurse or a sub-investigator is taking consent, it is crucial that it is recorded on the "Delegation of Responsibilities" log within the study Master file.

For many studies, however, it is the research nurse who takes consent and the nurse must be competent to explain everything about the study to the person with diabetes. There are a few courses available in taking informed consent but these tend to be run by local research units rather than a national standardised course.

For many research nurses, skills in taking informed consent are developed in the practical setting as they gain experience from consenting hundreds (or sometimes thousands) of people for studies.

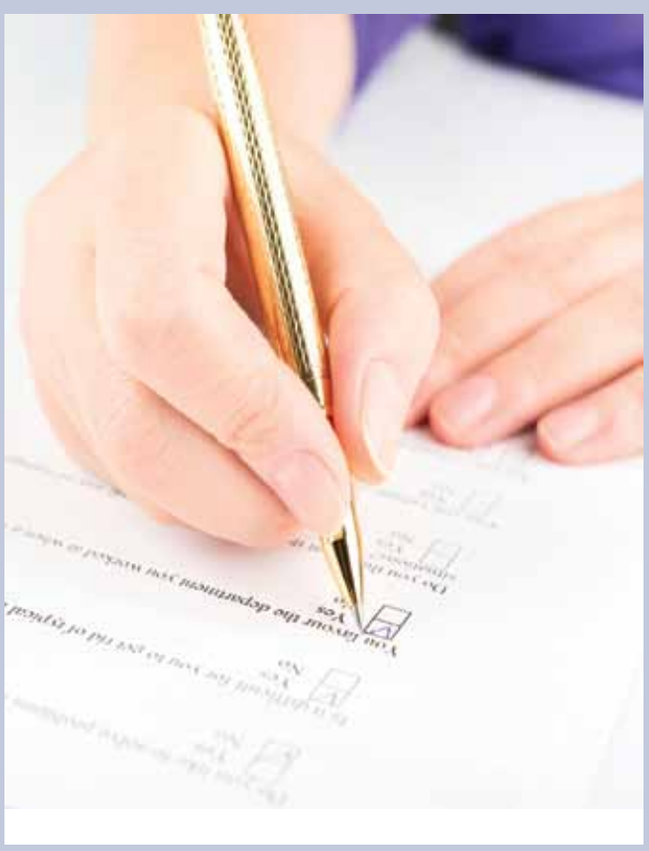
Informed consent as an ongoing process

Often informed consent is seen as a one-off event and only involves a piece of paper that is signed when the participant arrives for a screening visit. However, I think informed consent should be seen as ongoing dialogue between the study team and the participant throughout the study. As a nurse, I feel it is really important for the person with diabetes to know why you are doing each test and the significance of the test. For example, when taking a blood sample, the person should be told that you are testing U&Es, liver function, kidney function, thyroid function tests and so on, and that this is being done to look at how the drug is being excreted from the body and any other systems that it may affect. Explaining why you are doing regular ECGs in a cardiovascular outcomes trial can reassure the participant that they are getting the best possible monitoring and care, especially when the "Patient Information Sheet" told them that they had been recruited to the trial because they are at high risk of a cardiovascular event.

When we audited people with diabetes at the end of one trial, they reported that the most important factor for them throughout the trial was the trusting relationship they developed with the study team and they all commented how they felt that they had been well informed about all aspects of the study.

After the Northwick Park incident (where an early phase trial caused extreme side effects in healthy volunteers), a waiting room full of trial participants in our clinic in Dundee were overheard talking about informed consent the following morning. One person commented that the participants in the trial must have known what they were getting into as it will all have been explained fully and they will have signed a consent form. This was very reassuring for our research nurses and clearly demonstrates that our participants do know exactly what we are asking them to do and are truly providing informed consent.

Maintaining ongoing informed consent is particularly challenging when new information about the drug emerges in the middle of a trial. Obviously, the new information about the drug results in a substantial amendment to the ethics submission and approval, and will mean that a new patient information sheet and consent form will need to be developed. All ongoing participants will need to provide consent to remain on the trial and will need to sign a new consent form. Often the new information can be that the drug has caused side-effects in animal models but the ethics committees have deemed it not significant enough to stop the study. In this instance, it is the responsibility of the study team to discuss the new information with each participant and it is the participant's decision as to whether to remain on the trial or withdraw.



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However, there are some instances when a small change to the study results in major administrative work. For example, in one study that I was involved in, we were required 75 existing participants to give their consent again just because the company had added Croatia to a list of ten other countries participating in the study. We were also required to update the patient information sheet. I am not convinced that these sorts of administrative changes are essential for the participants to be aware of and justify all the extra work. It is my belief that Ethics Committees should look carefully at the changes before deciding that all patients must be re-consented. Hopefully, as this situation arose several years ago, re-consenting of patients has become more pragmatic in recent times.

Accurate records

It is essential that accurate records of the consent process are kept in the source documentation, as well as copies of the patient information sheet and consent form. Any subsequent consent forms must also be kept. Clinical research associates from companies, auditors from the NHS or Medicine and Healthcare Products Regulatory Agency will pay great attention to both the consent process and the associated paperwork should your research site be inspected. Ideally, you should have an SOP which describes the process for taking consent. In the last few years, it has also been required to record the time that informed consent was taken. By recording time, you can show that no study procedures were conducted before time of consent. For example, blood pressure recordings and time of blood sampling are recorded so you can demonstrate that these were taken after informed consent was obtained. As an aside, one Scottish research nurse team was recently asked by an auditor if they all synchronised their watches at the beginning of a shift so that there were no anomalies with the timings that recordings were done! Maybe we will need to do this in future ?

Informed consent is a critical part of medical research and if we are to keep participants safe throughout the study, it is essential that it is carried out to the highest standards. This allows the participant to assess the risk:benefit ratio and make a fully informed decision. Research nurses, who know the study in-depth, are expertly placed to discuss studies with the participants and help them make these decisions. ■

International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use guidelines (2002) *Guideline for good clinical practice*. ICH GCP. Available at: http://www.ichgcp.net (accessed 17.07.13)

World Medical Association (2000) Declaration of Helsinki: Ethical principles for medical research involving human subjects. WMA, Ferney-Voltaire, France. Available at: http://bit.ly/pigNFH (accessed 17.07.13)