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Informed Consent in Pharmacogenomics

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Informed consent (IC) is a crucial issue in pharmacogenomics. IC is defined both as the printed signed document that is kept on record as well as the process of informing subjects about their participation in research. The Pharmacogenomics Working Group (PWG) published an important 'points to consider' article in our previous issue,¹ which provides comprehensive coverage on this area. Some of the points raised by that group are highlighted in this editorial.

A key factor to consider in the IC process is that in large-scale studies it is difficult both in terms of logistics and likelihood to re-consent subjects. IC should therefore be adequately obtained the first time around. For that to occur, it is necessary to identify *a priori* all future uses related to the samples and tackle them upfront in the IC process. These are summarized in Table 1.

We now have the technology to make substantial advances in pharmacogenomics. The availability of properly consented samples is a limiting factor for progress in many areas of pharmacogenomics research. We hope that these guidelines from the PWG, summarized in Table 1, will be considered by those developing IC procedures and documents in pharmacogenomics research. This

Table 1 Key issues in IC for pharmacogenomics research

- Early availability of the consent document permitting subjects to read it ahead of time, so that they can reflect and formulate questions prior to meeting for IC signature.
- Trained staff, fluent in the patients' language, who are available at the time of IC document signing AND afterwards for answering questions.
- Description of sample collection.
- Is the same IC document used for the drug trial and for the pharmacogenomic study?
- Nature of association with drug trial: can one participate in the drug trial without donating DNA for the related pharmacogenomic study?
- Archiving DNA.
- Creation and immortalization of cell lines.
- Description of sample storage.
- Procedures for assurance of confidentiality.
- Description of the level of sample anonymity (samples can be identified, coded, double-coded/de-identified, anonymized, or anonymous).
- Availability of procedures for withdrawing subjects' data and samples if they so desire at a later date and a clear description of the limitation to this approach, including timeline (eg, once samples are anonymized it is no longer possible to retrieve them; once data are pooled, analyzed and presented or published it is no longer possible to retrieve them).
- Scientific use of the sample: can the sample be used only for the testing of a specific target/hypothesis, or can it be used for any type of genetic or pharmacogenetic research?
- Ownership of the sample.
- Commercial uses of the sample (intellectual property).
- Distribution of genetic material to secondary users (even the parties are not yet defined).
- Criteria for the distribution of genetic material to secondary users.
- Location of secondary users (national vs international).
- Type of primary or secondary users (academic, not-for-profit, for profit/commercial).
- Compensation to subjects, if any.
- Personal vs society benefits.
- Options for contacting subjects in the future (possible only for non-anonymized/anonymous samples).
- Post-testing options for communication and sharing of genetic results with subjects.
- Sharing of unintended genetic results, particularly if directly relevant to medical care, with subjects, family members, or health care providers.

Modified from Anderson *et al*¹.

should facilitate the creation of the necessary sample sets that will be the foundation for advances in our field.

An item of particular relevance is the future use of the sample. While our immediate needs are usually the driving force for action, in the case of IC, it is necessary for investigators to take time, step back from their own work and possibly in consultation with others think of all and any possible future uses for the samples and discuss those in the IC.

How does one handle clinical consent in the context of ethnically identified population-based studies? The National Institute of General Medical Sciences has issued a "Points to Consider" document for those planning genetic studies that involve identified communities (www.nih.gov/sigs/bioethics/named-populations.html). Our own group has conducted studies using those parameters and we have found that among other things, sharing IC documents ahead of time in meetings with community members leads to the identification of valid and important issues that can result in an improved IC document and a better IC process.

There may never be a perfect IC. However, careful consideration of the topics discussed here and in the article by Anderson et al (1) may help investigator, refine their IC procedures in a way that will make it possible for samples to be used in studies that will advance the field of pharmacogenomics.

We encourage submission of papers to our EELS section addressing topical issues in the area of IC.

REFERENCES

- 1 Anderson DC *et al.* *Pharmacogenomics J* 2002; **2**: 285–292.

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