Informed Consent: Implications for Research Investigations

Informed consent is a topic applicable to many fields, and in recent decades has become considerably relevant to the provision of health care and to biomedical research. In the case of dentistry, for example, the way that clinicians interact with their patients has changed: dental regulators (eg, licensing bodies) and legal systems now require dental clinicians and specialists to be not only skilled in providing oral health care, but also in consulting appropriately with their patients and ensuring that they are empowered to make fully informed decisions about their health and treatment options. Such a patient-centric approach is closely associated with the increased attention in recent years to human rights, civil rights, and matters related to privacy vs freedom of access to information affecting an individual. These developments have also come to be applied to informed consent in research involving patients or healthy individuals and so are very relevant to all articles that are submitted for publication in the *Journal of Oral & Facial Pain and Headache*. Thus, a synthesis of the information presented in recent thoughtful and comprehensive publications[1,2] on the topic is warranted.

Like dental and health care practice in general, biomedical research is regulated and informed consent is a necessary prerequisite for various types of research investigations that involve human subjects. From a historical perspective, legal systems have had long-standing prohibitions against interference with the human body without consent and the concept of individual autonomy has been applied both ethically and legally. In the case of biomedical research, this application means that it is normally not justified to override the decisions of competent human subjects. These subjects should be enabled to come to their own reasoned decision to participate or not participate in a research study through the process of informed consent.

The assurance of informed consent is an ethical as well as a legal responsibility of the investigators conducting a research study involving human subjects. Nowadays, there are several requirements that must be met for valid consent, although legal regulations bearing on these requirements may vary somewhat from one jurisdiction to another. Thus, my following comments related to these requirements are only a general guideline. They include:

- All information relevant to the study has been provided to each subject.
- The information has been understood by each subject.
- Each subject is capable of consenting.
- Each subject is not coerced and has given consent voluntarily.
- Each subject who has consented can withdraw their consent at any time during the study.

Consent forms are important tools that allow the subject to reflect on the study's research procedures. The investigators need to inform each subject of the purpose and nature of the procedures as well as any risks and/or side effects of those procedures, and provide appropriate and truthful answers to any questions asked by the subjects. The language used verbally by the investigators and in the consent form should be such that the subject can readily understand it to reach an informed decision; use of medical and dental terms including those with Latin words may not guarantee full understanding on the part of the subject. There are processes that investigators can perform and indicators they can look for to ensure that the subject understands the research procedures. These include:

- Whether the subject can restate what has been communicated to them
- Whether the subject asks any questions about the procedures
- Whether diagrams or charts are useful additions to help ensure the subject's understanding
- Whether the time allowed for the subject to reach an appropriate level of understanding is realistic

However, not every subject may be capable, legally or otherwise, to provide informed consent; eg, children or persons who have learning difficulties or mental illness. Consent from patients or guardians for the former persons or legally designated decision-makers for the latter persons may be allowed in some jurisdictions. Concerns of the investigators regarding potential difficulties in obtaining informed consent from children and cognitively impaired subjects can be addressed by proactively having inclusion and exclusion criteria that exclude such subjects from the study (unless the study is specifically focused on these groups).

There are other elements of informed consent that investigators must consider. The investigators should

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keep up to date on the relevant literature bearing on the research procedures and, where applicable, their risks, side effects, and benefits. If a subject is not fully informed with current information about these procedures, there could be legal repercussions depending on the legal jurisdiction. The process of obtaining informed consent and the context, format, and content of informed consent also need approval by an appropriately constituted body for this purpose. Approval from an institutional review board has become the normal procedure by which ethical approval is provided for a research study, including informed consent.

It is sometimes difficult for investigators to obtain informed consent for a research study; eg, for the use of stored tissue samples or retrospective data from clinical records from which the patient or subject can no longer be traced to obtain informed consent. Some jurisdictions address this by allowing the study to proceed as long as it has approval from the investigators' local research ethics committee, institutional review board, or similar body.

The topic of informed consent is replete with numerous legal and ethical issues and constraints that may vary from one legal jurisdiction to another. The bottom line is that it is the legal and ethical responsibility of the investigators in a research study to ensure that the appropriate process has been followed and that the subjects are fully informed and their consent obtained before the research procedures are applied to the subjects. Subsequently, in manuscripts submitted for publication reporting a study's findings, the investigators also need to indicate that informed consent was obtained from each study participant. Scientific journals now routinely require that informed consent be obtained and indicated in articles that are submitted for publication and that involve research on human subjects.

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References

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