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NEW PERSPECTIVE ARTICLE:

## Ethical Principles in Dental Research of Behavioral and Social Factors

### Principios éticos en la investigación odontológica sobre factores sociales y de comportamiento

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**ABSTRACT:** Given the importance of conducting research ethically when studying humans, this article involves considerations on basic ethical principles in dental research of behavioral and social factors. Research in these fields contribute to understand social interactions, attitudes, individual and group dynamics. As well, research in these areas not only delve into scientific knowledge of human nature, but also support evidence-based decision-making of health policies and interventions. The four main ethical principles apply to studies on behavioral and social factors. First, respect for persons dictates researchers must protect participants' autonomy, which is the basis for informed consent. Moreover, the principle of beneficence refers to act in such a way that participants benefit from taking part of a research study. Also, beneficence promotes participants' safety and well-being. Non-maleficence requires that researchers avoid or minimize harm to others. Justice implies fair treatment. Additional aspects of justice involve respecting participants' privacy and confidentiality. Ethical principles require interpretation. Therefore, some examples are provided, aiming that researchers overview and apply these norms. Ethical judgement and appropriate decision making are of great importance at any stage of research with human beings.

**KEYWORDS:** Autonomy; Beneficence; Dental research; Ethical principles; Human research; Justice; Non-maleficence.



**RESUMEN:** Dada la importancia de realizar investigaciones de manera ética cuando se estudian seres humanos, este artículo incluye consideraciones sobre principios éticos básicos en la investigación dental de factores sociales y de comportamiento. La investigación en estos campos contribuyen a comprender las interacciones sociales, las actitudes y las dinámicas individuales y grupales. Además, la investigación en estas áreas no solo profundiza en el conocimiento científico sobre la naturaleza humana, sino que también, respalda la toma de decisiones sobre políticas e intervenciones de salud, basada en evidencia. Los cuatro principios éticos principales aplican a estudios sobre factores sociales y de comportamiento. En primer lugar, el respeto a las personas exige que los investigadores protejan la autonomía de los participantes, que es la base del consentimiento informado. Además, el principio de beneficencia se refiere a actuar de tal manera que los participantes se beneficien al participar en un estudio de investigación. También, la beneficencia promueve la seguridad y el bienestar de los participantes. La no maleficencia requiere que los investigadores eviten o minimicen el daño a otros. La justicia implica un trato justo. Otros aspectos de la justicia implican respetar la privacidad y confidencialidad de los participantes. Los principios éticos requieren interpretación. Por lo tanto, se proporcionan algunos ejemplos, con el objetivo de que los investigadores revisen y apliquen estas normas. El juicio ético y la adecuada toma de decisiones son de gran importancia en cualquier etapa de la investigación con seres humanos.

**PALABRAS CLAVE:** Autonomía; Beneficencia; Investigación dental; Principios éticos; Investigación en humanos; Justicia; No maleficencia.

Dental research on the impact of behavioral and social factors on oral and craniofacial health and disease, is crucial to understand and address these conditions. Both behavioral and social sciences research involve basic and applied research. Many times, interaction with human participants to collect data about oral health perceptions or other aspects of overall health and well-being becomes necessary. For example, behavioral factors related to oral health can be studied by assessing knowledge, attitudes, beliefs, and emotions of participants. Specific examples include studying patient-reported outcomes such as, nutritional status, oral hygiene practices, pain management, treatment adherence, anxiety to dental treatment, and oral health-related quality of life. Whereas social factors, comprise studying economic, political, and cultural factors that may impact oral health promotion programs and healthcare delivery. Both, behavioral and social factors, may be examined by collecting

information through questionnaires or interviews. Depending on the aim and objectives of a proposal, the local Institutional Review Board (IRB) may classify a behavioral/social sciences research project as biomedical or non-biomedical. Many times, a very fine line divides this classification.

Even though substantial improvements in the oversight of research with human participants has been implemented in Costa Rica during the last decade, due to enactment of Biomedical Law 9234 (1), there is still debate among several research actors whether ethical analysis of behavioral and social sciences projects, by an IRB or Ethics Review Committee, is required. For example, the University of Costa Rica is the only institution of higher education in Costa Rica, that promotes, and mostly requires, evaluation by the Scientific Ethics Committee or IRB, of non-biomedical research projects that study human participants,

executed by students and researchers of the institution. However, ethical responsibility of behavioral/social sciences projects still relies mainly on principal investigators, and scientific commissions of academic units. The latter are the first to review a proposal and decide whether it requires review by the IRB. Therefore, an overview of basic principles and state of the art of norms when studying humans is always necessary for ethics education. Awareness of the existence of these guidelines are essential for all who perform research on humans. Especially, for those students and researchers that execute non-health related research on human beings and are not required to complete a Good Clinical Practice Course, before initiating research on humans, as dictated by Law 9234 (1).

What behavioral and social science research ethics and biomedical research ethics share is the interest to protect participants. Thus, researchers are expected to respect the well-being and rights of the individuals and communities studied. Research on behavioral and social factors and derived data, poses ethical concerns especially when involving vulnerable groups. An extra special care should be taken to protect the rights and welfare of these persons. Vulnerable populations include children, individuals with disabilities, or marginalized communities. Researchers should keep in mind the principles of respect for persons, beneficence, non-maleficence, and justice (2) while designing and performing a study on vulnerable as well as with non-vulnerable populations.

Research with contemporary human subjects in behavioral and social sciences, involves studying humans and their cultures to gain insights into various aspects of their lives. Ethical considerations are paramount in such research, as it involves interacting with individuals and communities. It is recommended that researchers obtain informed consent, protect participant's privacy, and minimize harm. While research ethical principles were originally rooted in biomedical research, they

have become keystones in behavioral/social sciences research. Acquaintance with research ethics principles, good practices, and respect for people affects both researchers and the people studied.

It is recommended whether it is health-related/biomedical research or non-health related on humans and derived data, to obtain voluntary informed consent. Informed consent provides information to research participants and constitutes an important application of the principle of respect for persons. In addition, an important justification for informed consent is that it provides research participants autonomy, or the willingness to participate or not in the investigation. The voluntary nature of consent implies that the person understands that he/she will be participating in a research study, the purpose or objective of the study and the consequences it may have in one's life. Informed consent should not only address the identity of funders and sponsors, but also, who is responsible of protecting the individuals during and after the research process. Negotiating consent entails describing the anticipated use of derived data. Also, it implies explaining how data will be stored and efforts to keep this information safe. Researchers may decide to perform secondary analysis or share derived data with other colleagues. Hence, participants should be conveyed of this. In some research projects, devices such as audio or visual recorders and photographic records are used to gather information to store data, sometimes for long periods of time. In these scenarios, those studied, should be aware of the use of these technologies, its purpose, and be free to reject their use.

In certain situations, when studying behavioral factors, a written informed consent may be unsuitable. On this account, the researcher can make a justification to the IRB, proposing to collect an oral informed consent instead, or ask for exemption of the document. For example, an oral or written informed consent from everyone encou-

ntered in an observation site, may prevent the researcher from exploring social or cultural phenomena. As well, in cases where the study consists of observing people in public places or mass events, and there is no possibility of identifying the participants, dispense of informed consent may be granted by an ethics committee.

Currently, there are doubts in relation to the requirement of informed consent, when executing research based on data obtained from electronic health records. Some argue that there is a moral duty to participate in health record research, since the benefits obtained from research studies are greater than the harm associated. Others may argue that informed consent is not required for studies with anonymized data. However, patient information is personal data. Therefore, clinicians should inform patients if their records will be accessible for research purposes, since there may be chances patients could be identified. Thus, nowadays, it is more often in institutions that combine clinical practice and research, to include specific and broad consent models and opt-out solutions.

Another ethical standard a researcher should endeavor is participants' right of privacy. Privacy refers to an individual's right to control access over personal or private information provided for research purposes. The researcher must also protect confidentiality and any information relating to the private sphere of informants. Furthermore, researchers must bear in mind that in countries such as Costa Rica, the legal system protects people against the processing of personal data. This implies that individuals are not obliged to reveal their racial or ethnic background, political views, religious/spiritual or philosophical convictions or beliefs, political opinions, or anything related to their health, life, or sexual orientation (3). Thus, research with humans in Costa Rica, should be conducted in accordance with the country's applicable legislation.

The ethical principles of beneficence and non-maleficence can be traced back to the time of Hippocrates, "to help and not harm". Essentially, promoting human welfare is the focus of these principles. The ethical principle of beneficence entails to conduct research only if some individual benefit or social value could be derived from the investigation. Social and individual benefits include improvements in health, psychological or social support for personal problems, educational services, childcare services, social and cultural welfare, or any other valuable (or good) outcome received. In dental research an example of a benefit a participant can receive is to be updated on his/her oral health status. Another benefit a participant may get from participating in a dental research study is teaching individuals about good oral hygiene practices.

Researchers must make a sound judgement of potential risks imposed on research participants, not only long-term or permanent damages, but also temporary reactions, such as stress or discomfort. Minimal risks are acceptable if they are outweighed by an individual benefit. In the case of investigations without apparent individual benefits for the participants, the risks must be minimized (4). When estimating potential risks, the different types should be considered: physical risks, psychological risks, social risks, economical risks, legal risks, among others. Moreover, the magnitudes of these risks need to be assessed as minimum, moderate, significant, or severe. It is recommended that when sensitive issues are investigated, appropriate support services by social workers, psychologists, or healthcare professionals are provided.

Non-maleficence is the obligation not to intentionally harm people and communities participating in investigations. This principle requires researchers to minimize harm to participants while fulfilling the study's objectives. Potential negative

consequences of research range from physical damage to minor aches or pain. Physical abuse occurs when research participants are exposed to harm that may affect their physical integrity or health during the research process. Other less evident potential damages include exploitation, stigmatization, or emotional distress. The latter, refers to the short or long-term reactions of individuals due to their participation in a study. These feelings may be acute anxiety, stress or guilt, deterioration of self-respect or self-confidence.

Another type of risks are legal risks, that may exist when behavioral/social research obtains information related to behaviors that are considered illegal or socially unacceptable. In these cases, if the information comes to public light or reaches the hands of third parties, either because it is a legal obligation to report it to the authorities or due to a leak of information, the participants of the study are exposed to be prosecuted. For example, legal risks must be taken in consideration when proposing a project that works with undocumented immigrants in Costa Rica. The current Migration and Immigration Law (5), presents a series of provisions, which if combined with the regulations of the law and the Penal Code, imply that public workers are obligated to report individuals that are in a situation of migratory irregularity, but above all if these persons commit or have committed criminal offenses.

At last, the ethical principle of justice implies addressing issues of equity in the selection of the participants. Researchers must justify scientifically, the reason of including a specific social group in a study, guaranteeing these individuals are not being chosen because of the ease of access to them. Power imbalances can be avoided by obtaining an informed consent in an appropriate manner. Additionally, justice encompasses

a fair allocation of burdens, risks, and benefits of research among all groups and classes in society, regardless of age, gender, socioeconomic status, culture, and ethnicity. This principle requires the inclusion of diverse population groups so that all can benefit of research findings. Inclusivity should be promoted in research.

To conclude, it is important to constantly overview the principles of research ethics, since these are mandatory components of all research involving humans. Ethical considerations should be implemented since the conception of the study, the protocol development, data collection methods, analysis, and dissemination of results. It is the responsibility of any dental scientist that performs research in behavioral/social sciences to have sound knowledge of basic research principles and incorporate these norms throughout the investigation of human participants. Research ethics fosters respect of the rights and well-being of participants, while promoting the advancement of knowledge in the field studied.

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