Ethics and Research

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The American Cleft Palate-Craniofacial Association (ACPA) supports the conduct of research with the goal of improving the quality of care for individuals with oral clefts and craniofacial conditions worldwide. *The Cleft Palate-Craniofacial Journal* (CPCJ) is the official publication of the ACPA and publishes research and clinical activities related to cleft lip/palate, craniofacial anomalies, and related laboratory sciences. The annual meeting is an opportunity for researchers and clinicians to share their findings and provides the opportunity for discussion, debate, collaboration and developing next steps for investigation.

The ACPA is committed to ensuring that all human and animal* research that is presented at the annual meeting or published in the CPCJ adheres to accepted standards for the conduct and reporting of research findings. Therefore, authors of abstracts for presentation at the annual meeting and of manuscripts submitted to the journal are asked to verify that they have met the standards for review and approval of their research prior to submitting the abstract.

This document serves to counter several common misconceptions about the requirements for the conduct and reporting of research involving humans.

Misconception #1. The regulations for research oversight only apply in the United States.

Most countries have adopted legal and/or ethical standards for the conduct of research involving human subjects. In the absence of specific legal guidelines, researchers can turn to internationally agreed upon standards such as those described in the Nuremberg Code, World Medical Association Declaration of Helsinki, and the Council for International Organizations of Medical Sciences International Ethical Guidelines for Research.

All of these documents provide minimal standards that can be adopted by a research team. Each document emphasizes the need for voluntary and informed participation in research. Like the Belmont Report in the United States, these documents are responsive to the egregious treatment of human subjects scattered through human history and serve to aid researchers in avoiding such mistakes and abuses in contemporary research.

All of these standards extend beyond local or national laws and standards. The Declaration of Helsinki states “No national or international ethical, legal, or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.” Thus, core concepts such as the protection of patient confidentiality, the need for informed consent, and prohibitions against coercion, should be expected for any research in any setting.

Misconception #2. I don’t need research oversight or approval because

a. **the procedures are standard treatments and are not experimental,**
b. **the project is a report of my own data,**
c. **the project involves a survey, so it doesn’t pose a risk**

Research is defined by the Code of Federal Regulations (CFR) as any “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46-102). Pilot studies, preliminary investigations, surveys, reviews of existing data, are all considered research. The intent to present data at the annual meeting is an attempt to contribute to generalizable knowledge and thus meets the definition of research.

The standards for protection of human subjects (participants) in research include the use of “identifiable human material and data.” (WMA). Therefore, a study that involves a review of existing records is

considered research involving human subjects and deserves the same oversight and protection as any study involving human subjects.

Misconception #3. To conduct a review of my own case records, am I required to contact every potential participant to obtain their consent?

Authors who wish to present or publish identifiable photographs or specific data about an identifiable individual (e.g., a case report) must obtain informed consent from the subject or appropriate authorized representative (e.g., parent or legal guardian).

A review of existing data with human subjects does not necessarily mean that the researcher must contact every potential subject for permission to review the records. However, the researchers must develop a mechanism for de-identifying data in order to protect the confidentiality of those in the study. For example, a database that is developed in a review of records should not include patient name, date of birth, hospital identification number, street address, or any other specific information which can be used to identify a specific individual.

In the United States, studies that involve only a review of existing medical records usually qualify for expedited review and often will not require full Institutional Review Board (IRB) review, as long as confidentiality and other protections are well managed. An expedited review is completed by the chair of the local IRB because these studies most likely expose the prospective subjects to no more than "minimal risk." Nonetheless, the researcher still must submit the proposed protocol for review because it is the IRB, not the researcher, who makes the final determination about the risk exposure to subjects of the study based on the proposed protocol.

Misconception #4. I don't need to go through the review process until my abstract has been accepted.

If study is a "systematic investigation" with the intent to generate data that could be presented or published or otherwise contribute to "generalizable knowledge" (see Misconception 2) then the work should go through the review process. Investigators should not access any data without independent review of the protocol. Therefore, it should not be possible to submit a research abstract with data prior to review and approval for the study.

Misconception #5. These guidelines only apply if my research is funded with a grant or contract.

Internationally accepted guidelines for the ethical conduct of research apply to all research involving human subjects regardless of whether the research is funded by the investigator, the institution, or an outside agency. In the United States, the CFR applies to any investigation conducted in an institution that receives federal funding for research. It is important to note, however, that IRB oversight applies to all research conducted in the institution, not just the research that is funded. Remember, these guidelines have been established to protect all human subjects regardless of the type of research or funding source.

Misconception #6. The Institutional Review Board (IRB) process is meant to make doing research more difficult.

While some of these regulations are cumbersome, it is important to remember that the goal of research oversight is to protect potentially vulnerable individuals from abuse as subjects of research. As such, the oversight press helps the people who are studied, the institution, and the researchers.
Children, those unable to give voluntary consent, or those who are otherwise vulnerable, require additional protections, usually offered through oversight committees as well as the need to obtain permission from a parent, guardian, or another responsible party who is not conducting the research. Since much of the intervention related to cleft and craniofacial conditions occurs during infancy, childhood, and adolescence, many research protocols in this area are subject to special oversight to

protect these potentially vulnerable individuals. When the treating clinician is also conducting research, this introduces a potential conflict of interest or a different perspective of the degree of risk, thus increasing the need for oversight with a vulnerable patient population.

If you do not have an IRB you can use the guidelines to have another 3rd party review your protocol to ensure voluntary and informed consent, confidentiality, and the safety and welfare of those included in your study.

References and Resources:

The Belmont Report. Available from: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html. Accessed on August 22, 2009.

Emanuel EJ, Wendler D, Grady C. (2000). What makes clinical research ethical? JAMA. 283(20): 2701-2711.

Nuremberg Code: Directives for Human Experimentation. Available from: http://ohsr.od.nih.gov/guidelines/nuremberg.html. Accessed on August 22, 2009.

World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (Revised, 2000). Available from: http://www.wma.net/en/30publications/10policies/b3/index.html. Accessed on August 22, 2009.

*The conduct of animal research is also subject to oversight and national and international standards (Helsinki), however these standards will not be discussed further here.