



### F5 Ethical Considerations in the Use of Live Human Subjects in Bitemark Research

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After attending this presentation, attendees will be aware of the ethical considerations that should be taken into account when conducting bitemark research on live humans, including a brief history of human experimentation, the Institutional Review Board process, and the protection of vulnerable populations.

This presentation will impact the forensic science community by laying the ground work for the participants to consider the ethical ramifications in utilizing live human subjects in bitemark research and to move the discussion forward on prohibitions and/or guidelines if bitemark research is to be conducted on live human subjects.

Giving consideration to human research subjects goes back to the days following World War II when 26 Nazi scientists were held accountable for performing experiments on prisoners of war. Their trial at Nuremberg resulted in the first internationally recognized code of research ethics authored by the Nazi War Crimes Tribunal. The "Nuremberg Code" established the principles of voluntary consent which included: consideration of the capacity of subjects to consent, freedom of subjects from coercion, a comprehensive analysis of the risks and benefits of the research, minimization of risk and harm to the subjects, experimentation by qualified investigators, appropriate research designs, and the freedom of the subjects to withdraw at any time.

In 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established and the National Research Act was passed by Congress. The Act established the Institutional Review Board (IRB) and required all federally funded research projects involving human subjects be reviewed and approved by the IRB. In 1979, the Commission issued the Belmont Report which revised the principles to include all human research. The principles identified by the Commission fell into three basic categories: autonomy, beneficence, and justice. The Report provided guidelines to ensure research subjects' safety, total freedom of choice, and protection of vulnerable populations from coercion.

Much of the research on bitemarks has been done using live, anesthetized animals, and human cadavers. There has been significant insight gained from this research but there may be a limit to the extrapolation of the results from these models to live human victims. At some point consideration of using live human subjects will likely need to be considered. Currently, opinions by forensic experts on the ethics of this endeavor appear to be varied. The risks associated with bitemark research falls far short of the risks associated with many other human research projects. However, most would agree that producing a bitemark in a live human subject would require inflicting a brief but significant amount of discomfort. So the question becomes: is bitemark research on live human subjects ethical and if so, what ethical considerations are involved?

One ethical consideration is research design. Will the design provide useful, reproducible results? Have specific parameters been identified and can they be measured? Will it provide a favorable benefit- to-risk ratio? Have sufficient measures been taken to minimize potential harm to the participants? All of these need to be answered to the satisfaction of the IRB overseeing the research. The other, and for most researchers the most important consideration, is the recruitment and selection of volunteers. Great care must be given to this process to ensure absolute autonomy for the participants. This involves recruitment without pressure or coercion, disclosure and explanation of the research design including adverse effects (i.e., pain and bruising), a signed informed consent that includes complete disclosure of the risks, the ability to withdraw at any time without prejudice, and extreme care in the use of potentially vulnerable populations. Vulnerable populations are populations that can be more susceptible to pressure or coercion. These populations include children, the elderly, prisoners, the mentally or socially impaired, and, in the case of research by university faculty, students. IRB oversight is extremely important in any research involving live humans to prevent under-compliance of these critical ethical considerations.

The ethics of using live human subjects for bitemark research is a complex issue that will need to be decided by the forensic dental community. Discussion should be held in an attempt to arrive at a consensus on the ethics of this type of research.

**Research, Institutional Review Board, Ethics**