



Title:	Research Involving Potentially Addictive Substances		
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1 Research involving potentially addictive substances

With respect to cigarettes and alcoholic beverages, IRBs and researchers should be aware that under North Carolina state law these substances may not be distributed to or used by minors.

When research involving potentially addictive substances is proposed, the IRB must consider the subjects' capacity to provide ongoing informed consent if judgment is diminished by exposure to the substances. There may also be unusual potential for coercion in some circumstance, for example if such research involves subjects that are institutionalized.

The IRB must also be sensitive to the ethical context of the research, in that there may be other ethical dilemmas associated with these studies if they involve the use of deception or include randomization. It is critical that the IRB focus on the considerations of risk and benefit of such research.

In addition, research involving substances that may impair the judgment of subjects must include provisions for the safety of those subjects both within the research setting and if those subjects choose to withdraw from research while in an impaired state. For example, if a subject who is legally intoxicated should choose to withdraw from a study, he or she cannot be permitted to drive from the research setting.

Potential human subjects with a history of addiction or with direct access to the class of substances in their work environment should be excluded from studies using potentially addictive substance, unless the IRB makes a determination that there is a compelling reason for their inclusion and the study includes all appropriate safeguards to reduce the risk for these subjects.