GUIDELINES FOR THE USE OF DRUGS IN RESEARCH BY PSYCHOLOGISTS

The guidelines presented below are designed to insure adequate procedures for conducting research with drugs. It is assumed that all research that is covered by these guidelines has been reviewed to be scientifically valid, to insure that the potential benefits of the research outweigh the risks, and that adequate protection is afforded to the animal and human participants.

General Principle: Research with drugs is conducted by psychologists in a variety of settings including research and educational laboratories, and medical facilities. A psychologist or psychology student who performs research involving the use of drugs shall have adequate experience with and knowledge of each drug's action, or shall work in collaboration with or under the supervision of a qualified researcher.

Any psychologist or psychology student doing research with drugs should comply with the procedural guidelines below. Any supervisor or collaborator has the responsibility to assure that the individual who is being supervised complies with the procedural guidelines.

I. Definition of a Qualified Researcher:

1. A qualified researcher is an investigator who holds a Ph.D. based in part upon a dissertation which is experimental in nature, and in part upon training in psychology, pharmacology, neurosciences and related areas, and conferred by a graduate school of recognized standing (listed by the U.S. Office of Education as having been accredited by a recognized regional or national accrediting organization). A person may also be qualified by virtue of appropriate experience. This includes demonstrated competence defined by published research involving the use of drugs in a scientific journal, through education, or through equivalent experience, in order to demonstrate that the researcher has adequate knowledge of experimental design and the drugs and their actions.

2. In addition to the above requirements, the federal government requires scientific investigators whose research involves controlled substances to be authorized by the state in which they work to conduct research using controlled substances (21 U.S.C. Section 802 (21)). In addition, with controlled substances, investigators are required to register with the Drug Enforcement Agency of the Department of Justice and to file periodic reports describing, inter alia, the research protocol and any security provisions for storing the drugs (21 U.S.C. Sections 822, 823; 21 C.F.R. 1301.33; see generally 21 C.F.R. 1301). State and local governments may have additional registration requirements.

II. Definition of Drug:

In the Guidelines, the term "drug" includes: (1) all substances as defined by the term "drug" in Section 201(g) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sections 301, 321(g); and (2) all controlled substances, schedules I through V, as listed in Section 202 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. Sections 801, 812 (Pub. L. No. 91-513), as amended.

III. Procedures:

1. All drugs must be obtained legally and used under conditions specified by federal, state and local laws, as well as institutional policies. Information concerning these laws and regulations should be obtained from appropriate authorities and should be readily accessible to all who participate in the project.

2. Proper precautions must be taken so that drugs and drug administration apparatus (e.g., needles) are available only to authorized personnel. Access to the drugs must be regulated by standards appropriate to both laboratory and pharmacy settings. Additional security guidelines and recordkeeping requirements prescribed by law for scheduled drugs must be followed. There should be adequate safeguards to prevent diversion and insure that the drugs are used only for the intended purposes.

3. Individuals using or supervising the use of drugs in research covered by PL 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970, and its implementing regulations as well as all amendments to the Act should be familiar with their provisions as well as other drug laws relevant to their research.

4. Individuals using or supervising the use of drugs in research must familiarize themselves with available information concerning the mode of action, toxicity, and methods of administration of the drugs they are using.

5. The welfare of animals used in drug experiments must be adequately protected and the procedures specified by the local Animal Care and Use Committee followed. Both the APA's "Guidelines for Ethical Conduct in the Care and Use of Animals"[1] and the Public Health Service Policy on Humane Care and Use of Laboratory Animals[2] are recommended guidelines.

6. The welfare of humans participating in drug experiments must be adequately protected and the procedures specified by the local Institutional Review Board (IRB) followed. Research involving human participants is governed by APA's "Ethical Principles in the Conduct of Research with Human Participants"[3] and the Public Health Service Act (42 U.S.C. Sections 201 et seq.)[4].

7. Supervisory responsibility for the protection of research participants (e.g., animals, normal human volunteers, patients in treatment)

must be specified. Thus, psychologists may have responsibility for supervision of the research but they might not have responsibility for the medical protection of participants.

8. Psychologists noting the unscientific, unethical, or illegal use of drugs in research should take responsible action as mandated by the "Ethical Principles of Psychologists."[5]

9. The present guidelines should be brought to the attention of all individuals conducting research with drugs and conspicuously posted in every laboratory or clinical setting in which psychologists administer drugs.