



THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

Human Research Committee Standard Operating Procedure (SOP)

Mission: The function of the Human Research Committee is to identify issues relating to clinical research in the drug abuse field and recommend actions to the Board of Directors. Issues of concern to the Committee include topics relating to the ethics and safety of research with humans, methodological issues relating to design and measurement in studies with human subjects, and scientific issues of interest to clinical researchers and CPDD in general.

Committee Members: The Committee generally consists of members who have direct experience conducting research with human subjects and who reflect the diversity of research with humans (including, for example, treatment and laboratory-based basic research, epidemiological, imaging, behavioral, and neurophysiological studies). The Committee will also strive to have representation for researchers from different geographical areas across the US and when possible, it will include researchers who study a variety of different classes of drugs (e.g., licit and illicit, drugs of abuse and drugs used for pharmacotherapy, drugs used by varying routes of administration).

Committee Operations: One of the primary concerns of this Committee is to monitor ethical and safety issues relating to research with humans. The Committee will keep itself informed on current controversies and public concerns regarding human research. This includes issues such as appropriateness of certain subject populations for inclusion in research studies, screening and consent procedures, including determination of competence, and interactions with Institutional Review Boards and related scientific and regulatory organizations.

The Committee may consider and discuss methodological and scientific issues relating to human research. Methodological issues might include aspects of study design, measurement, data analysis, data storage and transfer. Scientific issues could include both theoretical and practical questions. The Committee is concerned with any issue that will advance or impede the conduct of high quality human research, and it will initiate efforts to disseminate information relating to, or resulting from, human research with drugs of abuse.

Specifically, the Committee is charged to:

- Monitor public discussion and activities of other professional organizations which have an impact on the conduct of human research
- Monitor federal legislation and regulatory actions which have an impact on the conduct of human research
- Provide a forum for informing and discussing all relevant issues
- Recommend actions to the CPDD Executive Committee and the Board of Directors