**American College of Neuropsychopharmacology**

**Statement on Clinical Trials and Safety Registry (ies) and Databases**

As part of its mission, the ACNP seeks to ensure the dissemination of relevant scientific advances on diseases of the nervous system, including psychiatric, neurological, behavioral and addictive disorders. Through its official activities and the efforts of its membership, the College will work to ensure that the highest quality of science and ethics are integral to the conduct of clinical trials in our field. To this end, ACNP endorses and commits to the of the inclusion of all clinical trials (including investigator-initiated trials) conducted to test the safety, efficacy or comparative effectiveness of any drug, biological product, or device intended to treat serious illnesses.

Members and Supporting Corporations of ACNP endorse and commit to abide to rules and practices for the reporting the description and the timely reporting of safety and efficacy data for *all* clinical trials to existing (e.g., clinicaltrials.gov and principles of Section 113 of the FDA Modernization Act) and future clinical trial registries and databases. All articles submitted to the ACNP sponsored journal, Neuropsychopharmacology, reporting on the results of clinical trials, must follow the recommendations of the International Committee of Medical Journal Editors (ICMJE) in their CONSORT Guidelines, and in their other recommendations concerning the reporting of clinical trials. Regardless of the venue, all results should be reported in an objective and complete manner, including a discussion of the limitations of the study.

ACNP encourages inclusion of information for Phase I clinical trials conducted solely for the safety of an unapproved drug, biological product, or device in those situations where some efficacy component is employed. Excluded, however, would be specific development of tools, such as biomarkers/surrogate markers, where the primary intent is methods development or general scientific knowledge such as is typical of translational research where specific support of a drug undergoing registration is not being pursued.

ACNP also supports and encourages the development of a mechanism (such as a secure website) for timely reporting of negative clinical trials data and adverse events of non-marketed drugs to be made available to investigators and sponsors of clinical trials.

ACNP will work with others to ensure that all current and regularly updated safety data are made available to clinicians, patients and family members. In conjunction with other stakeholders, the ACNP will encourage the development of standards for analyzing and reporting of post-marketing safety information from large databases, including the need for more case control studies.