# China Strengthens Oversight of Human Subjects Research

On July 15, 2013, China National Health and Family Planning Commission (the "Commission") published the draft Administrative Measures on Medical Research Involving Human Subjects (the "Draft Measures") and is seeking public comments until July 19, 2013. After the Draft Measures become effective, the Commission will administer the implementation, including setting up a national database for registration and filing of all medical research involving human subjects (the "Human Medical Research").

The Draft Measures apply to all China-based independent legal entities ("Institution") engaging in the scientific research, technological development and scientific and technological application of medical sciences on human study subjects. The Institution can be a health care institution, a medical academic institution, a research institution, a food safety risk assessment institution, a family planning institution or other non-government entity. Under the Draft Measures, Human Medical Research includes: (i) physical, chemical or biological research on human physical and psychological phenomenon as well as diagnosis, treatment and prevention of diseases involving human subjects; and (ii) experimental application of medical technologies or products derived from biomedical research on human subjects, including medical research in the areas of new clinical techniques, preventive medicine, public health and food nutrition. The Draft Measures do not apply to clinical studies in connection with pharmaceutical products, biological products, medical devices and diagnostics, which are governed by the drug and device regulations.

The Institution shall establish a project review and approval mechanism to authorize the conduct of Human Medical Research. This mechanism must include (i) reviews by an academic committee comprised of experts in the areas of medical science, epidemiology, and statistics, (ii) reviews by an ethics committee, and (iii) informed consent. High-risk research may be re-examined by the provincial or national ethics committee. The Institution shall also establish an IP management system to effectively protect indigenous innovation and avoid infringement of any third-party IP. A dedicated account can be created and shall be managed by the Institution's financial department to fund the conduct of Human Medical Research, but no fees can be collected from human study subjects. The Institution shall perform a systematic, comprehensive and scientific evaluation of safety, effectiveness and compliance with ethical principles before rolling out the research results.

Failure to comply with the Draft Measures may subject the Institution and its legal representative to administrative penalties or criminal liabilities in severe cases. The underlying Research, if not registered in the national database, will not be qualified for any government incentives or subsidy and the research report would not be permitted for publication in any form.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.