China Human Genetic Resources Administration Office Asserts Authority to Approve Clinical Studies Sponsored by Foreign Companies in China Involving Human Sample Collection

The China Human Genetic Resources Administration Office (CHGRAO) recently indicated informally that clinical studies sponsored by foreign companies in China, either by themselves or through local CROs, should be approved by CHGRAO to the extent the studies involve collection of samples containing human genetic resources. Such approvals should be in place before the clinical study agreements are signed with the Chinese hospitals.

Since 1998, CHGRAO has been authorized to review and approve Sino-foreign collaborations involving human genetic resources (“Sino-foreign Collaboration”). Over the years it has not been particularly clear, due to lack of statutory definition and guidelines, what research projects constitute “Sino-foreign Collaboration” and under what circumstances research utilizing human biological samples triggers CHGRAO approval. In particular, there have been differing views on whether clinical studies sponsored by multinational pharmaceutical companies in China should be treated as Sino-foreign Collaboration since the studies are for verifying safety and efficacy instead of for the purpose of examining Chinese genetic information.

This recent indication by CHGRAO will add an extra layer of regulatory scrutiny of clinical trials by foreign companies to the China Food and Drug Administration (CFDA) approval process.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work or

Chen Yang  
Partner  
+86.10.5905 5600  
cyang@sidley.com

Lei Li  
Partner  
+86.10.5905.5505  
lei.li@sidley.com

Ling Su  
Strategic Advisor, Life Sciences  
+86.21.2322.9327  
ling.su@sidley.com

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