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Regulating Contact Research Organizations

As you may be aware, the Health Ministry has recently amended the New Drug and Clinical Trials Rules, 2019 ("**NDCT Rules**") to include Chapter VA regarding Contact Research Organizations ("**CROs**"). As per the amendment to the NDCT Rules ("**CRO Amendment**"), CROs are defined as '*sponsors or bodies falling in academic, commercial or other categories or any other legal entity to whom the sponsor may delegate or transfer the tasks, duties or obligations regarding clinical trial* ("**CT**") *or bioavailability or bioequivalence study* ("**BA/BE Study**")'.

CROs are widely engaged by sponsors (particularly foreign sponsors) in India in the CT process, providing various services such as trial management, data collection, monitoring, and regulatory compliance. However, they have not been regulated so far except to the extent that their names were required to be disclosed in the CT protocols submitted to the regulator.

Registration of CROs:

CROs must obtain registration from the Central Licensing Authority ("**CLA**") to conduct CTs or BA/BE Studies on new drugs. Note that any already registered BA/BE Study center shall be deemed to be registered for the purposes of a BA/BE Study. The application for registration of a CRO will be made in Form CT-07B to the CLA, along with prescribed fee and necessary documentation including copies of agreements with relevant third parties and an undertaking of compliance. The registrations will be valid for five years, and may be renewed.

Conditions of registration and compliance obligations:

The registration will be subject to the fulfilment of condition similar to those imposed on sponsors, such as obtaining approval for the trial protocol from the Ethics Committee, permission from the CLA, registration with the Clinical Trial Registry of India before enrolling the first subject for the study, providing medical management and compensation in cases of injury to the study subjects, and maintenance of prescribed records. The CRO will also be required to fulfil compliance requirements such as having adequate facilities, qualified and trained staff, maintaining records and confidentiality, among other things.

Compliance window:

The CRO Amendment will come into force on April 1, 2025, providing a window of 6 months for CROs to obtain the registration. Non-compliance with the NDCT Rules is punishable under the residuary penalty of the DCA, which provides for imprisonment for a term ranging between one to two years, and a fine. Accordingly, from the date of effect of the CRO Amendment, operating as a CRO without a license will also be a punishable offence under the DCA.

Cancellation or Suspension of the Registration:

The registration of a CRO can be suspended or canceled by the CLA if the CRO fails to comply with the provisions of the Drugs and Cosmetics Act, 1940 ("**DCA**") or the NDCT Rules, after being provided with an opportunity to be heard. The CLA can take actions including issuing warning in writing, rejecting the results of the CT or BA/BE Study, suspending or canceling registration for certain period, or debarring the organization to conduct any CT or BA/BE Study as considered appropriate by the CLA. The CRO can appeal to the Central Government within 60 days from the date of receiving such orders.

Please get in touch with the attorney at the Firm you regularly work with or with Kirti Mahapatra at *kirti.mahapatra@AMSShardul.com* or Shahana Chatterji at *shahana.chatterji@amsshardul.com* in case you have further questions or would like to discuss any aspect of the CRO Amendment in greater detail.

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