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Regulators don't have clear intent on few issues : ISCR

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In a latest statement by the ISCR, it has expressed displeasure at the way some of the regulatory initiatives are being introduced without a consultative process involving discussion with and feedback from various stakeholders of the clinical research process.

The association has in particular cited reference to office order no.DCGI/MISC/2013(107) dated August 30, 2013 regarding furnishing of information in respect of financial support, fees, honorarium, payments in kind etc. to be paid to the investigator as per contract entered into by the sponsor with the investigator/institution in clinical trials.

Explaining in detail of the concerns, the statement read out,"The intent of the regulatory authorities to request this information from sponsors/CROs while making a submission for a Clinical Trial Application is not clear. GCP Guidelines already prescribe that a sponsor/CRO must enter into a formal and legal agreement with the investigator/institution before the start of a trial. Details of agreements between sponsors/CROs and Investigators/sites, including the financial support, fees, honorarium, payments, research grants are maintained and available at the clinical research site. Should the regulatory authorities want to ascertain these details, they can always do so in the course of a site inspection."

"More importantly, we fail to understand the reason for requesting this information at the time of submission of a Clinical Trial Application since the final selection of sites for a trial study is contingent upon the approval granted by the DCGI and post a review by the NDAC. It would therefore be premature for sponsors/CROs to enter into final agreements with Investigators/sites prior to the grant of approval by the DCGI. Not only would the pre application process be time consuming and impractical, but if a site were not selected, there would be additional time and investment in making these contracts null and void which could cause misunderstanding with investigators/sites," mentioned the statement.

In ISCR's view, the two main concerns with the order are that a consultative process was not followed in introducing the Order and the logistical and practical challenges of conforming with such an order have not been taken into account. "If there is a need for regulatory authorities to seek this information, this could be provided for post approval and before a study is actually initiated at a particular site as is done for ethics committee approvals," it concluded.