Indian Society for Clinical Research
C/o. Pfizer Limited, Pfizer Center, 5, Patel Estate,
Jogeshwari (West), Mumbai – 400 102.
Tel: 022- 6570 6167 / 6693 2028
Email : info@iscr.org, Website : www.iscr.org

To,
The Secretary
Ministry of Health and Family Welfare
Nirman Bhawan, C-Wing
New Delhi 110 001

July 24, 2014

Dear Sir,

ISCR is a professional not-for-profit organization representing clinical research professionals in the country. ISCR members include pharma companies, CROs, Clinical research professionals, Ethics Committee members, academicians and Investigators. ISCR works very closely with different stakeholders, including the government and regulatory bodies and operates through six councils - Regulatory, Ethics, Training, Media, Clinical Data Management, Biostatistics & Medical Writing (CDM, BS & MW) and Investigator Councils; and three Regional Chapters.

We are writing to you with respect to the office orders dated July 3, 2014 issued by the DCGI Directorate towards implementation of the recommendations of the committee set up in February 2013 under the Chairmanship of Prof Ranjit Roy Chaudhury. -We appreciate the intent behind these orders, however there is a need to consider the potential impact that some of these orders are likely to have as well as operational aspects of the implementation of these. We are therefore submitting the following points for your kind consideration :

Subject Covered by Office Order	**Impact**	**Recommendations**
Procedure for review of application of Clinical Trials and New drugs	While the New Drug Advisory Committees (NDAC) have been renamed as Subject Expert Committees (SEC), there is no clarity on how their functioning will be improved. There is no clarity as regards the frequency of SEC meeting and timelines of approval from the time of SEC Meeting	• Functioning of NDACs / SECs should be standardized by way of adoption of SOPs **(Contd.)**

Indian Society for Clinical Research
C/o. Pfizer Limited, Pfizer Center, 5, Patel Estate,
Jogeshwari (West), Mumbai – 400 102.
Tel: 022- 6570 6167 / 6693 2028
Email : info@iscr.org, Website : www.iscr.org

Subject Covered by Office Order	Impact	Recommendations
		• The nature of the studies that need evaluation by SEC should be agreed upon. Following proposals do not merit a complete SEC review : ○ Subsequent protocol with same study drug in same indication ○ Study protocols with an already approved drug in an approved indication/dose ○ Protocol amendments ○ Extension Studies ○ Surveillance Studies ○ Disease registries • The number of experts identified to be part of each of the SECs should be adequate in numbers so that appropriate back ups are available and meetings need not be rescheduled due to non-availability of experts. • Meeting schedules should be made available well in advance and be adhered to • Minutes of the meeting should be posted on the CDSCO website within 7 days of the meeting
Limiting number of Clinical Trials an Investigator can undertake at a time		In line with the recommendations of the committee under the Chairmanship of Prof Roy Chaudhury this decision should be left with the Investigator and the EC.

Indian Society for Clinical Research
C/o. Pfizer Limited, Pfizer Center, 5, Patel Estate,
Jogeshwari (West), Mumbai – 400 102.
Tel: 022- 6570 6167 / 6693 2028
Email : info@iscr.org, Website : www.iscr.org

Subject Covered by Office Order	Impact	Recommendations
	Limiting the number of studies without consideration of the above mentioned factors which allow an investigator to undertake a certain number of studies will lead to the following challenges: • Sponsors may be forced to select less experienced investigators, may compromise study conduct and may end up selecting very few sites/ not conducting the study. Taking less experienced investigators will compromise patient safety and data integrity of the study. • It would be a challenge to select the sites for specialized, complex indications • Both sponsors/ investigators would not know where they stand with the numbers at the beginning of feasibility, as the study initiations are happening more than a year later • Many studies are end point driven (e.g. survival, specific medical event), where patients are followed up for end points/survival post treatment, thus stay open for long time with minimum work and efforts – on the basis of number, the investigators conducting such studies cannot participate in other studies • Downsizing of already developed research infrastructure at good, experienced sites and loss of skilled research staff would not help create a conducive environment to research • Experienced and skilled investigators will not be able to participate in a significant path breaking study that they may be interested in so as to make a difference to the patients • ***Indian patients would be the main losers as they would not have the opportunity to participate in the studies where they get access to newer, better investigational products – especially in areas of unmet medical needs, where they have exhausted all the current treatment options!***	

Indian Society for Clinical Research
C/o. Pfizer Limited, Pfizer Center, 5, Patel Estate,
Jogeshwari (West), Mumbai – 400 102.
Tel: 022- 6570 6167 / 6693 2028
Email : info@iscr.org, Website : www.iscr.org

Subject Covered by Office Order	Impact	Recommendations
Providing Ancillary Care to the Clinical Trial subjects	There is no clarity as to how the ancillary care will be defined and who will take a decision in this regard	Operational clarity is required around this aspect, clarifying the roles and responsibilities of various stakeholders It is also important to note that the patient may prefer to go to his primary care physician for other illnesses during the study and he/she should have that choice.
Number of subjects in Phase III Global CT	It is not clear what is meant by "adequate" subjects and who will take a call on this and how.	Provide clarity on the criteria for assessing the adequacy of subject numbers and data requirements

May we also point out that the committee also had very pertinent and significant recommendations pertaining to functioning of the CDSCO, empowerment and skill up-gradation of the regulatory infrastructure. We do hope that concrete steps are being taken towards implementation of the same. We trust the above will be considered in a favourable manner by you and we look forward to an opportunity to discuss these in person with you.

Thanks and kind regards,

Yours sincerely,

Dr. Suresh Menon
Chair – Regulatory Council &
Executive Committee Member of ISCR

cc: Addl. Secretary – Mr.R.K.Jain
cc: Jt. Secretary – Dr.Arun Panda
cc: DCGI – Dr. G.N. Singh