

New DCGI Requirement for BE NOC For Export Purpose

Title – DCGI has issued New Pre –Screening Checklist for BA/BE Applications on their website

Effective From – This new Checklist will be effective from 1st February 2014

Major Changes / Highlights of the New Pre Screening Checklist

1. Sponsor has to provide an undertaking mentioning, he will provide complete medical care as well as compensation for injury or death.
 - a. Above statement should be added to Informed Consent Form.
 - b. In Case of injuries or death details of compensation should be intimated.
2. Studies involving Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substance in healthy volunteers & patients needs Risk Management Strategy submission
3. Address of IEC Location & Study Site location
4. Reports of any study related deaths in last 3 years
5. IEC registration Copy to be attached.
6. Audio Video recording System to be submitted along with ICF
7. Details of Number of beds at the center including ICU beds for effective handlings of SAEs in emergency situation.

An Application for BA/BE NOC for export purpose is now required to be filled ever for Drugs approved for more than 4 Years.

Reference-

[DCGI Revised Checklist for Pre –Screening of Application](#) - Date of last visit 22-01-2014

[List of Approved BA/BE Center](#) - Date of last visit 22-01-2014

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Glossary for some of the above terms

BA/BE	Bioequivalence Studies
Sponsor	Company/Person who is getting the Study Conducted
IEC	Independent Ethics Committee
ICF	Informed Consent Form
SAEs	Serious Adverse Events.

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