

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:204  
ANSWERED ON:01.12.2004  
CONTRACT RESEARCH ORGANISATIONS  
Paraste Shri Dalpat Singh

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

- (a) the action being taken to control the Mushrooming Contract Research Organisation;
- (b) the steps being taken by the DCGI for accreditation of this CROs ;and
- (c) the preventive measures being taken so that the Indian patients are not made Guinea Pigs?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE ( SMT. PANBAKA LAKSHMI)

(a) to (c): Good Clinical Practices (GCP) guidelines for clinical trials on pharmaceutical products in India issued by Ministry of Health describes Contract Research Organisations (CRO) as follows:-

`An organization to which the sponsor may transfer or delegate some or all of the tasks, duties and/or obligations regarding a Clinical Study. All such contractual transfers of obligations should be defined in writing. A CRO is a scientific body-commercial, academic or other`.

Presently, there is no provision under Drugs & Cosmetics Act & Rules, for accreditation of CRO, however, the Schedule `Y` under the Drugs and Cosmetics Rules, 1945, and the `Good Clinical Practices` guidelines issued by this Ministry, have provisions prescribing norms to be followed whenever clinical trials with Indian patients are carried out.