GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:140
ANSWERED ON:05.03.2010
CLINICAL RESEARCH
Thamaraiselvan Shri R.

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

(a) the mechanism set up and guidelines prepared by the Government to monitor and conduct clinical research in the country;

(b) whether some hospital chains in the country are collaborating with the academic institutions both in the public and private sectors for the clinical research;

(c) if so,whether permission has been granted by the Government for the said purpose; and

(d) if so,the details thereof and if not, the reasons therefor?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a)to(d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 140 FOR 5TH MARCH, 2010

(a) There is no statutory guideline for conduct of clinical research in the country, however, research on human subjects is governed through different guidelines/acts, like the Drugs & Cosmetics Act for clinical trials, the ethical guidelines for bio medical research on human subjects of ICMR; the Pre-conception and Pre-natal Diagnostic Techniques (PC&PNDT) (Regulation and Prevention of Misuse) Act which covers some aspects of Human Genetic Research. The evaluation mechanism of clinical research proposals is done through two committees in institutes conducting research that is the research committee which evaluates study protocols in view of good Clinical Practices for Clinical Research in India 2001 and the Institutional Ethics Committee which evaluates research ethics.

(b) No data base for collaboration is maintained on clinical research being conducted by various agencies.

(c)&(d): Do not arise.