

Concerns over consent in Indian drug trials

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[Photo: Estimates of the number of patients on drug trials in India range from 30,000 to 2 million \(Australia Network News\)](#)

[Map: India](#)

There's growing concern India's booming popularity as a destination for drug trials may be coming at the expense of participants who are unaware of the risks.

Pharmaceutical companies spend more than \$US50 billion a year on research and development, with India a growing region due to relatively low costs and a large and genetically diverse population.

Professor K.D. Bhargava, chairman of the ethics committee at M.Y. Public Hospital says many of the patients who take part in trials are poor and illiterate.

He's told Australia Network's [Newsline](#) program that makes gaining informed consent a difficult process.

"Most of the time, they do not like to get into details because they would not understand, and therefore leave it to us," he said.

"If I would talk to most literate of patients they also wouldn't understand."

[Video: Indian drug trials exploiting the poor \(Newsline\)](#)

Participating without informed consent is a breach of national and international guidelines for drug trials.

Evidence gathered by health campaigner Amulya Nidhi also reveals serious flaws in the way the hospital obtained consent.

"There is a thumb impression of one of the clinical trial subjects who participated," he said.

"It is written that a study has been going on and he's agreed with all these things.

"[But] there is no signature or thumb impression of any witness though it is compulsory to take the witness."

Industry spokesman Dr Arun Bhatt says audits are regularly conducted to ensure informed consent.

"For any hospital site we select...we do a check before any trial starts," he said.

"And if any hospital has such a finding, we may not take such a hospital in a trial at all."

Evidence has also emerged of serious conflicts of interest, with doctors being paid directly to recruit patients.

Many trials aren't registered, so estimates of the number of patients on drug trials range from 30,000 to 2 million.

Thousands have died during drug trials, but the cause of death is often unknown, as post-mortems are rarely carried out.

Across India, just 22 families who've lost loved ones have been compensated.

They've received around \$3,500 dollars - a figure recommended by the hospital ethics committees.

The government is now reviewing the level of compensation and is promising to strengthen laws and broaden the powers of investigators.

Source: <http://www.abc.net.au/news/2012-08-17/an-concerns-over-consent-in-indian-drug-trials/4204734>