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THE Consumers Association of Penang (CAP) refers to the recent call by the Health Ministry urging all clinical research centres in Malaysia, including those in private hospitals and universities, to register their studies. ♦

Although there seems to be some obligation for those who obtain research grants from the ministry, there is no mandatory requirement for local or overseas researchers who are not on government grants to register their trials and the results

CAP has been calling for guidelines linked to clinical trials to be made law. Among other things, clinical trial legislation could ensure that rigorous safety precautions are in place to protect trial subjects from potential dangers or fatal outcomes of a trial. ♦

A clinical trial law would also make it compulsory for all necessary information to be given to trial subjects before they agree to take part in a trial. Compensation for mishaps could also be included in legislation. ♦

Last but not least, legislation would make it mandatory for all clinical trials to be registered. The results obtained from trials, even if they put the test drugs in an unfavourable light, should also be captured. ♦

This legal requirement would be along similar lines to an amendment of the US Food and Drug Administration Act, recently passed in Congress, which requires clinical trials to be registered and their results placed in a public database. ♦

In view of the serious mishaps in clinical trials, Malaysia should in fact avoid granting permission for trials as far as possible ♦ unless their usefulness has been very clearly demonstrated. ♦

In the interest of human safety, CAP calls on the Health Ministry not to entertain any further requests to conduct trials in the country, at least until clinical trial laws are in place and can be fully enforced; and only if a clear potential benefit has been established. ♦

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President, Consumers Association of Penang. ♦