

## Research bodies lobby EU governments over trials legislation

Rory Watson *Brussels*

Research organisations across Europe are joining forces to lobby their national authorities to ensure that EU legislation on clinical trials will be implemented as flexibly as possible when it comes into force next May. The move arises from fears that the terms of the directive, which is aimed at increasing protection for the participants of trials and harmonising regulations across Europe, could seriously reduce the scope for non-commercial trials.

With the help of the European Forum for Good Clinical Practice, representatives from the Institut National de la Santé et de la Recherche Médicale, Cancer Research UK, the European Organisation for Research and Treatment of Cancer, the European Science Foundation, and the UK's Medical Research Council met in Brussels for the first time last month to examine the implications of the legislation for sponsors of clinical trials.

Dr Richard Sullivan, head of clinical programmes at Cancer

Research UK, explained: "We realise that we need to share more information between ourselves. There are a lot of problems, and by sharing them we can potentially share the solutions."

The charity is already busy lobbying the Department of Health and working with the Medical Research Council to ensure that non-commercial trials are not threatened by the new terms and conditions. It is specifically concerned with the legislation's brief description of a sponsor as "an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial."

Critics also point out that the 26 tasks a sponsor has to undertake under the new legislation are so extensive that non-commercial organisations such as trusts and charities, unlike commercial drug companies, will be unable to satisfy them all on their own.

Although the legislation is designed to harmonise and simplify rules across Europe, it is already clear that countries intend to interpret the definition differently as they incorporate it into national law. Spain, for instance, is considering the concept of co-sponsorship, although some experts believe that this might be outside the parameters of the legislation. In the United Kingdom, thought is being given to partner-



### Wellcome Trust gallery opens at British Museum

Western medicine may focus on pills to cure patients' ills, but the inhabitants of the Nicobar islands, to the east of India in the Bay of Bengal, still build wooden figures, or hentakoi, to keep on good terms with the spirits and ensure the health and wellbeing of the community. The figures embody animal spirits that characterise an illness and help the *menluana*, the doctor-priest of the community, to capture the illness.

The figure shown above, which dates from the last quarter of the nineteenth century, is one of several items on permanent display from 3 November at the new Wellcome Trust gallery at the British Museum, London. The display, "Living and Dying," contains various ethnographic works, including an Easter Island statue and apocalypse figures from the Mexican Day of the Dead celebrations.

Lynn Eaton *London*

For more information see [www.thebritishmuseum.ac.uk](http://www.thebritishmuseum.ac.uk)

ships involving different bodies responsible for different stages of the process and oversight.

Dr Sullivan said, "This is all very new, and we will have to spell out who does what. It involves questions of law, the concept of liability, and the question of responsibility beyond your area. Can we define a sponsor so that it covers quality

partnerships? We need flexibility here. It is clear that you cannot have 'one size fits all,' as trials are very different."

He added that a new analysis of the 169 responses from commercial and non-commercial organisations to the legislation that will bring the directive into UK law shows widespread criticism of its terms. □

## Florida governor orders reinsertion of feeding tube

Fred Charatan *Florida*

A special session of the Florida Legislature has authorised the state's governor to order a feeding tube to be reinserted in Mrs Terri Schiavo, who has been in a persistent vegetative state since a cardiac arrest in 1990 (25 October, p 949).

The governor, Jeb Bush, last week overruled the appeals court judge, who in November 2002, at the husband's request, ordered the removal of the feeding tube.

After the governor's order reinstating the feeding tube, another judge agreed to appoint a special legal guardian for Mrs Schiavo.

Michael Schiavo, Mrs Schiavo's

husband and current guardian, and his lawyers, plan to challenge in court the constitutionality of the so called "Terri's law." He also appeared on television to discuss the case.

After the legislature intervened, and the new law was enacted, Mrs Schiavo's primary care physician, Dr Victor Gambone, resigned from the case. Other doctors expressed concern that the legislature's intervention may cause doctors to disregard the wishes of dying patients. Mrs Schiavo had not written a living will, but her husband has said that she once told him that she never wanted to be kept alive artificially.

"We are afraid of lawyers all the time," said Dr Lofty Basta, a retired Clearwater cardiologist and founder of Project Grace, a non-profit group devoted to educating people about planning for the end of life.

Randall Terry, founder of the antiabortion group Operation Rescue who has helped Mrs Schiavo's parents, Mr and Mrs Schindler, with prayer and protest in their fight to sustain their daughter, commented, "The Republican party wants to present itself as the pro-life, pro-family party. This pro-life, pro-family governor could not afford to not intervene in some way."

But Bruce Winick, a professor of constitutional law at the University of Miami's law school, said legislators in essence "made an end run around the judiciary, and that really threatens the

principle of the independence of the judiciary." Other legal scholars argue that the legislature's intervention politicises the case and violates the constitution's separation of powers of the three branches of government.

Stephanie Schneider, president of the elder law section of the Florida Bar Association and a former Broward County elder law attorney, said, "If a party doesn't like what a court does, they'll say, 'Let's just go to the governor's office.'" The case is likely to end up in the Florida Supreme Court and possibly the US Supreme Court.

An editorial in the widely read *South Florida Sun Sentinel* was strongly critical of the governor and legislature, saying, "They were wrong to involve themselves and their constituents in a tragic situation that is best left to the courts." □