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Revision of the Declaration of Helsinki

Cape Town

December 2012

Julian Kinderlerer

ege European Group on Ethics in Science and New Technologies

Who am I?

1. Professor of Intellectual Property Law at UCT
2. President of the European Group on Ethics

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1. **Professor of Intellectual Property Law at UCT**
2. **President of the European Group on Ethics**

My interests are in fostering innovation in Africa, and ensuring that the benefits of new technologies are available to those who need them. This includes the need to ensure the availability of appropriate therapies and information

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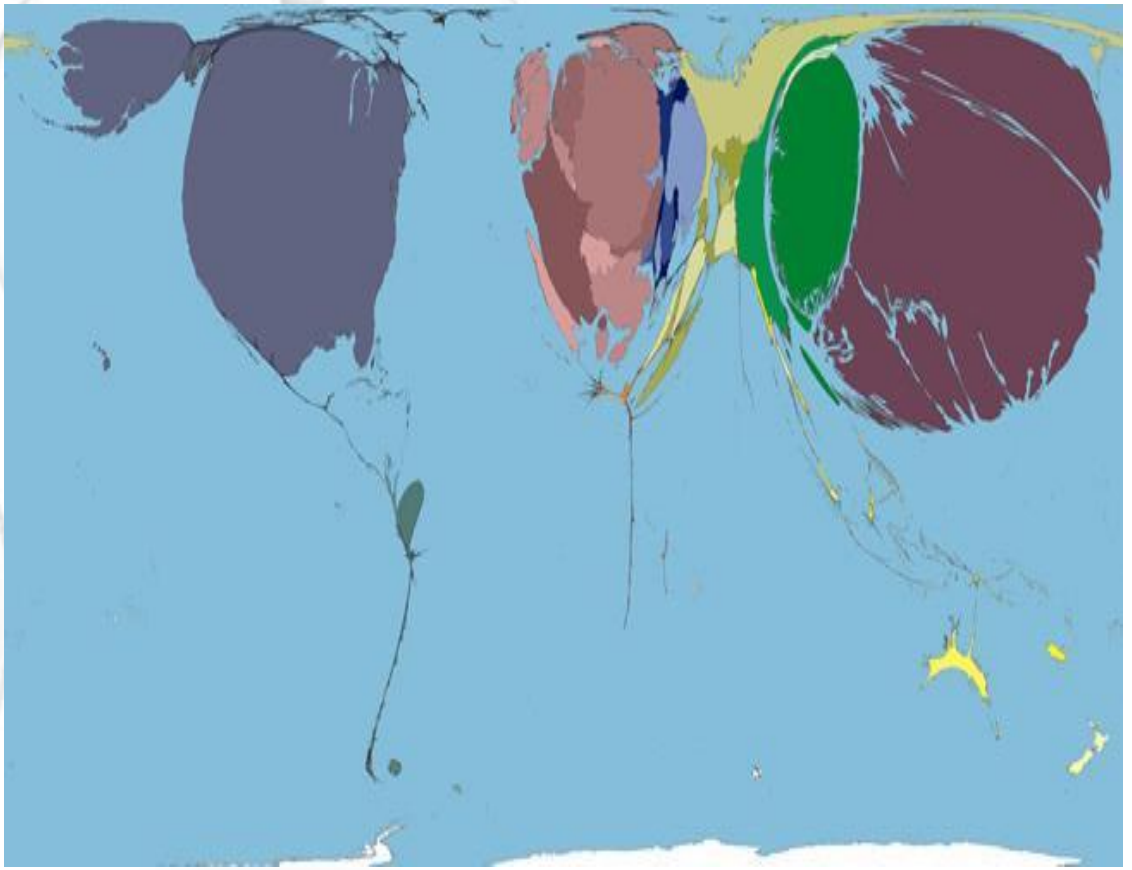

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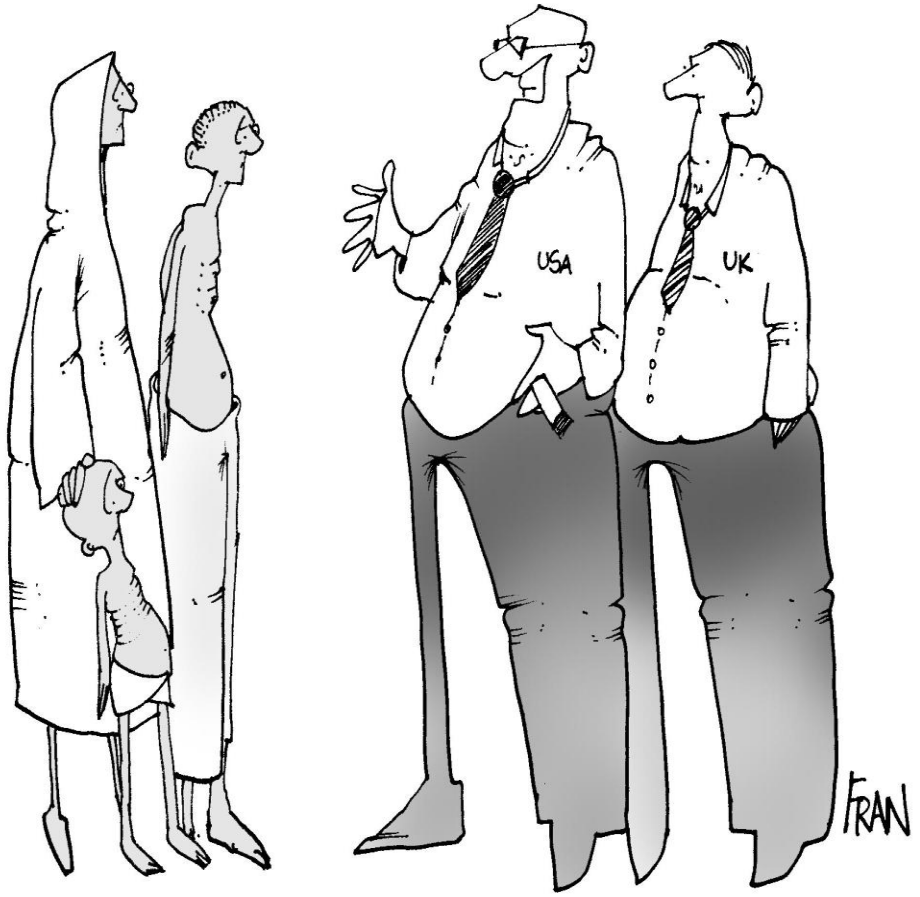

WE ALL HAVE TO MAKE SACRIFICES FOR THE ENVIRONMENT..AND YOU'RE OURS!

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The EGE is an independent, pluralist and multidisciplinary body advising the European Commission, Parliament and Council on ethics in science and new technologies in connection with Community legislation or policies.
The EGE members serve in a personal capacity and are asked to offer independent advice to the Commission

ege European Group on Ethics in Science and New Technologies

EGE

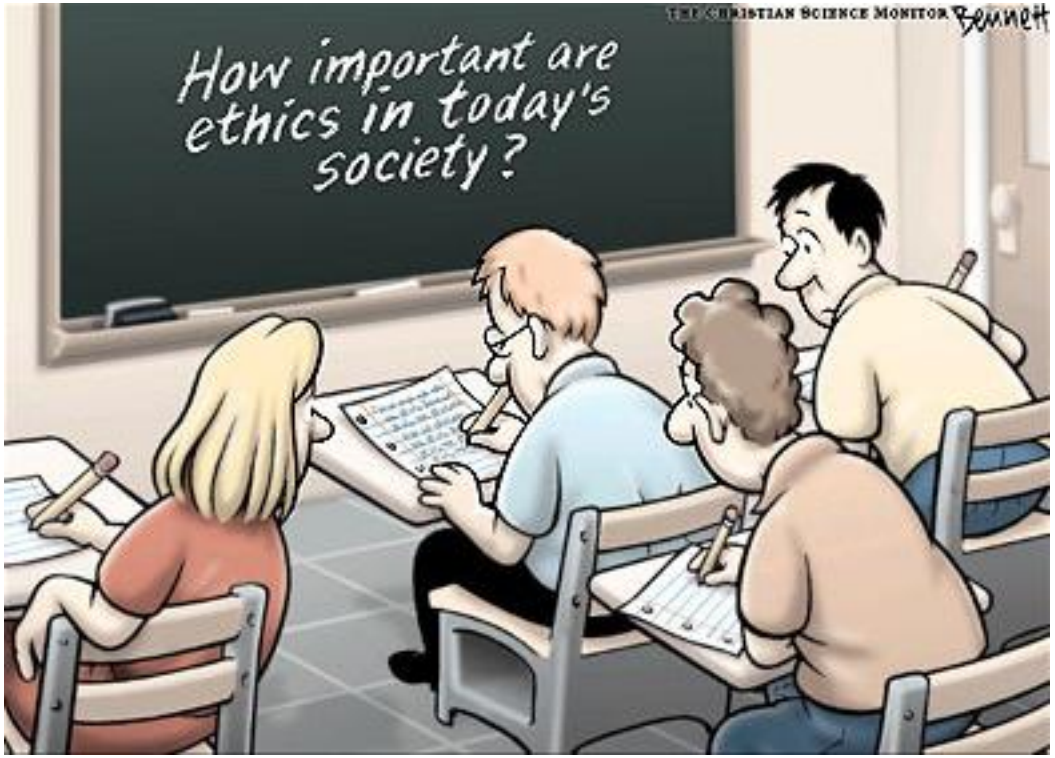
The Group has always consisted of scientists, lawyers, philosophers, ethicists and philosophers – a difficult balancing task with only 15 members. The range of expertise needed is vast, for we have to look at issues that relate to scientific disciplines that may not be reflected in our expertise, and therefore we have to spend time learning from those that have studied the discipline and from those that have studied the underlying ethical, legal and social issues before we are able to provide coherent advice.

EGE

- There are global issues, like those of climate change and the manner in which economic crises impact on individual rights or even the changes in the demography (ageing population, a change in the distribution of diseases and of the mechanisms of diagnosis and treatment).
- We have a responsibility to consider those living in Europe and those living elsewhere whose well-being may impact on ours.
- The impact of science and technology on our lives is constantly evolving, and the need to ensure that the ethical analysis are fully considered.

EGE

We are in awe of those who drafted the Helsinki Declaration, for it provided a standard, not to attempt to attain, but rather as an absolute baseline of behaviour for those conducting medical research.


How important are ethics in today's society?
THE CHRISTIAN SCIENCE MONITOR
Bennett

9 December, 1946, United States v. Karl Brandt *et al*

The defendants in this case are charged with murders, tortures, and other atrocities committed in the name of medical science. The victims of these crimes are numbered in the hundred of thousands. A handful only are still alive; a few of the survivors will appear in this courtroom. But most of these miserable victims were slaughtered outright or died in the course of the tortures to which they were subjected.

Who am I?


PASZPORT
RZECZPOSPOLITA
POLSKA


Ohne Aufenthalt
im Reichsgebiet!
Ein - Ausgereist:
Passkontrolle
Aachen-Hauptbhf.
20. Dez. 1936
20. Dez. 1936
20. OKT. 1936
Deutsche Botschaft
Paßstelle
1. OKT. 1936

Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. . . . The person . . . should have legal capacity to give consent . . . be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion . . . and . . . have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . .

….The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

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"ETHICALLY IMPOSSIBLE"
STD Research in Guatemala from 1946 to 1948

Presidential Commission
for the Study of Bioethical Issues

Washington, D.C.
September 2011

www.bioethics.gov

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South Africa: No excuses: Basson destroyed human life, says expert

Katharine Child - Sep 27 2011 Mail & Guardian

Dr Wouter Basson used his medical knowledge to destroy life while he was the head of the apartheid government's chemical and biological weapons programme, according to US bioethics expert Professor Steven Miles.

"The ethical core of medicine is to promote health. Dr Basson's work caused death and imminent death and brain damage," Miles on Tuesday told the Health Professions Council of South Africa (HPCSA) hearing into whether or not to revoke Basson's medical licence.

Basson was head of the government's chemical and biological warfare research programme, Project Coast, from 1981 to early 1993. In 2002, he was acquitted in the Pretoria High Court of a raft of criminal charges ranging from murder and fraud to drug trafficking. He now runs a cardiology practice in Cape Town.

ege European Group on Ethics in Science and New Technologies

EKSPERIMENTELE STAMSEL-OPERASIE

Etiese komitee 'is nie betrek'

Dokumente bevat nie MBR-goedkeuring

Elsabé Brits

KAAPSTAD. – Enige kliniese navorsing op mense en selfs diere in die land moet deur 'n etiese komitee van onafhanklike kenners hersien word.

Só het prof. Michael Pepper, stamselkenner en direkteur van die Instituut vir Sellulêre en Molekulêre Geneeskunde aan die Universiteit van Pretoria, gesê.

Dit is in reaksie op die terapeutiese kloning (of somatiese selkern-oordrag) wat in Oktober op Tommie Prins (32) in die Melomed-hospitaal in Bellville gedoen is.

Prins, oorspronklik van Villiersdorp, het aan *Die Burger* gesê hy woon tans op Robertson.

Die operasie is gedoen deur dr. Adriaan Liebenberg, 'n neurochirurg, en die stamselle is vervaardig deur dr. Gert Jordaan. Hy is nie 'n veearts nie, maar het 'n doktorsgraad in landbou, het *Die Burger* verneem.

"Al is die operasie suksesvol, en al het die navorsers toestemming van die minister van gesondheid gekry, moet daar steeds portuur-evaluasie gedoen word en daar moet 'n etiese komitee betrokke wees. Dit word wetlik bepaal," het Pepper gesê.

"Mediese praktisyns is bewus hiervan," het hy bygevoeg.

So 'n etiese komitee betrek gewoonlik kundiges aan universiteite, regskenners en bio-etici wat in die veld werk.

Nóg Jordaan nóg Liebenberg of Melomed het sodanige dokumente aan *Die Burger* verskaf, ondanks herhaaldelike versoeke. Jordaan het gister geweier om die goedkeuring van die Mediesynebeheerraad (MBR) aan *Die Burger* te gee "omdat ons alles (eer)gister gegee het".

Dié dokumente het geen goedkeuring van die MBR bevat of bewyse van 'n etiese komitee nie. "Los my uit. Ek wil nooit weer met jou praat nie, want jy fokus op die negatiewe. Ek weet nie waarmee is jy besig nie," het hy gesê.

"Ek maak embrionale stamselle. Ek kloon dit fisiek," het hy vroeër aan *Die Burger* gesê. Terapeutiese kloning moet eers deur kliniese toetsing en portuur-evaluasie gaan voordat dit gedoen mag word.

Die handleiding van die Nasionale Gesondheidsnavorsingsetiekraad lui: "Die primêre rol van 'n navorsingsetiekkomitee is om te waak oor die waardigheid, regte, veiligheid en welstand van mense wat aan die toetse deelneem.

"Die primêre verantwoordelikheid van elke lid is om onafhanklik te besluit sodat die uitvoering van die voorgestelde toets die deelnemers sal beskerm. Buitengewone aandag moet geskenk word aan toetse op kwesbare deelnemers."

Die standaarde waaraan etiese komitees en studies moet voldoen, bestaan uit 'n praktiese gids van 96 bladsye en kan gelees word by www.nhrec.org.za.

'Stamsel'-dokter reageer nie op raad se versoeke

KAAPSTAD. – Die Raad vir Mediese en Tandheelkundige Beroepe het amptelike vrae gehad oor die "stamsel-inplantings" wat drs. Gert Jordaan en Adriaan Liebenberg beoog het.

Die raad het in 2009 in 'n brief gesê hy het probleme met die toestemming wat oudminister Barbara Hogan aan Jordaan gegee het om met die stamselterapie voort te gaan.

"Ons voorlopige goedkeuring (2008) vir jou navorsing was op beperkte inligting gegrond. Daar is 'n paar kwessies wat die raad eers wil uitklaar," lui die brief.

Jordaan is gevra om die volgende aan die oorhoofse liggaam, die Raad vir Gesondheidsberoepe van Suid-Afrika (RGBSA), te verskaf:

- Die volle naam/name en mediesepraktisyn-nommers van die dokter(s) wat die prosedure sou uitvoer;
- 'n Verklaring van die betrokke dokter(s) met 'n uiteensetting van die kliniese saak en 'n voorlegging van die intervensie, asook die wetenskaplike bewyse om die prosedure te staaf; en
- Bewese materiaal wat die navorsingsuitkoms van die studie steun.

Die RGBSA het aan *Die Burger* gesê Jordaan het nooit op dié brief gereageer nie.

Die *South African Medical Journal* beskryf die vereistes vir 'n nuwe intervensie só in sy September-uitgawe: "Om te toets of 'n nuwe intervensie werk en veilig is, word studies eers *in vitro* (proefbuis) gedoen. Voor die kliniese fase hersien kenners dit en dit word gepubliseer. Daarna word aansoek gedoen vir kliniese toetse in klein getalle mense."

Voorts is die enigste betroubare bronne dat 'n behandeling werk onafhanklike, goedgekeurde kliniese toetsing, bewyse van etiese komitees, publikasie in akademiese vaktydskrifte en herhaling met dieselfde resultate deur ander laboratoriums.

Liebenberg het eergister gesê hulle werk nie met 'n universiteit saam nie, "want daar is jaloesie op professionele vlak en dit is 'n lelike ding . . . dit neem te lank en daar is burokrasie".

Die rede hoekom hulle die prosedure so lank stil gehou het en nie die portuur-evaluasieproses gevolg het nie, is "omdat ons nie die duisende mense wat ons hulp wil hê, sal kan help nie." – **Elsabé Brits**

PROF. KAY DE VILLIERS GEE SY MENING

Nóg vrae oor operasie

‘Geweldig baie navorsing moet nog gedoen word’

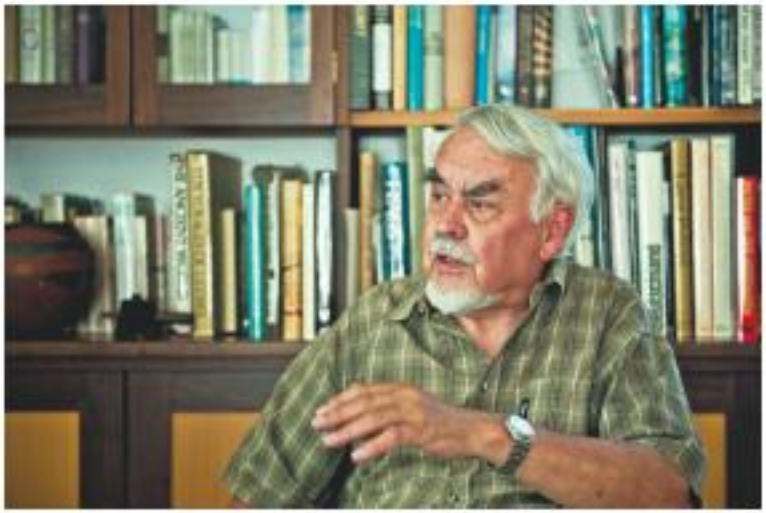
Elsabé Brits

KAAPSTAD. – Dit is gebruiklik om ˙n ¨pioniersoperasie¨ vooraf in ˙n internasionale akademiese vaktydskrif soos *Nature* of *Science* te publiseer sodat dit krities geëvalueer kan word.

Só het prof. J.C. (Kay) de Villiers by navraag gesê aangaande die ¨stamsel-operasie¨ wat onlangs op die verlamde Tommie Prins uitgevoer is, maar wat nie op dié manier aangekondig is nie.

De Villiers was die eerste houer van die Helen en Morris Mauerberger-leerstoel in neurochirurgie aan die Universiteit van Kaapstad en drie verwante akademiese hospitale. Hy het afgetree, maar geniet internasionale erkenning in die neurochirurgie.

¨Daar is geweldig baie navorsing wat nog gedoen moet word voordat so ˙n operasie aangepak kan word. Dit is ˙n groot probleem wat met kennis, geduld en deernis aangepak moet word,¨ het hy gesê.



Prof J.C. (Kay) de Villiers vroeër tydens ˙n onderhoud met Die Burger. Foto: JACO MARAIS

Hy vind dit ook vreemd dat die dokters wat die operasie gedoen het daarna as ˙n ¨Chris Barnard-oomblik¨ verwys.

¨Ek het Chris self goed geken en het as neurochirurg met hom saamgewerk. Chris het jare lank dierenavorsing gedoen, sodat daar redelike hoop op sukses was toe hy sy eerste operasies op mense uitgevoer het. Hy het nie blindelings geopereer nie.

> **Enige mediese ingreep moet ˙n redelike verwagting op sukses inhou voordat dit aangebied kan word.**
>
> —PROF. J.C. (KAY) DE VILLIERS

¨Wat my bekommer oor hierdie operasie met die stamselle, is die afwesigheid van die beklemtoning – of selfs die noem van – probleme wat verwag kan word indien daar werklik hergroei van senuselle in die rugmurg sou wees.

¨Om enige optrede te regverdig bloot weens die omvang van die ongesteldheid, sou ˙n gevaarlike standpunt wees. Enige ingreep moet ˙n redelike verwagting op sukses inhou voordat dit aan die pasiënt aangebied kan word.

¨Wanneer toestemming vir enige operasie van ˙n pasiënt verkry word, moet die voordele en die redelike risiko˙s verduidelik word. Indien hy aan ˙n eksperimentele prosedure blootgestel word, moet hy hiervan in kennis gestel word.

¨Daar sal ook voldoen moet word aan die vereistes van die etiese komitee van die inrigting waar die operasie gedoen word.¨

■ Tot op hede het dr. Adriaan Liebenberg, wat die operasie op Prins gedoen het, Gert Jordaan, wat die stamselle geproduseer het, en die Melomed-hospitaal in Bellville, waar die operasie uitgevoer is, nog nie op versoeke van *Die Burger* gereageer vir inligting dat só ˙n etiese komitee betrokke was en kliniese navorsing gedoen is nie.

EUROPEAN COMMISSION

Brussels, 17.7.2012
COM(2012) 369 final

2012/0192 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(Text with EEA relevance)

{SWD(2012) 200 final}
{SWD(2012) 201 final}

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The purpose of the proposal aims "at achieving an internal market as regards clinical trials and medicinal products for human use" while at the same time setting "high standards of quality and safety for medicinal products".

The EGE has concerns regarding the draft regulation:

1. the marginalisation of research ethics committees
2. the nomination process for the reporting member state
3. the narrow grounds upon which another member state can disagree with the reporting member state
4. the timelines for review and authorisation which in our view are simply unrealistic.

The EGE has concerns regarding the draft regulation:

The draft provides for an investigator to consider a refusal to participate or a withdrawal by an individual.

The EGE believes that any “explicit” wish in relation to either participation or withdrawal by an incapacitated adult or a minor must be respected

The EGE has concerns regarding the draft regulation:

The proposed Regulation does not refer to ethics committees but rather leaves it to the Member State concerned to determine the appropriate body or bodies to be involved in the assessment of a clinical trial, indicating that it would be a matter of internal organisation within each Member State.

The EGE is deeply concerned that any reference to the notion of 'ethics committee' will disappear out of the European legal framework for clinical trials and question the validity of omitting a globally accepted mechanism for safeguarding the rights of research participants and investigators alike ….

The EGE has concerns regarding the draft regulation:

Multi-disciplinary evaluation of clinical research was established in the second version of the Helsinki Declaration in 1975 and has subsequently been incorporated into legally binding documents such as the Council of Europe Convention on Biomedicine and its Additional Protocol on Biomedical Research.

Changing the structure of ethical evaluation of Clinical Trials is likely to hamper the marketing authorisation process of new medicines, and, instead of increasing competitiveness of Europe, it may adversely affect it.

The EGE has concerns regarding the draft regulation:

The EGE has emphasised the importance of ethical research in its Opinions:

25 Ethics of Synthetic Biology,
22 human Embryonic Stem Cells in FP7 Research Projects,
21 Nanomedicine
19 Umbilical Cord Blood Banking,
17 Clinical Research in Developing Countries,
15 Human Stem Cell Research and Use,
13 Healthcare in the Information Society
11 Human Tissue Banking,
10 Ethical Aspects of FP5
4 Gene Therapy.

The EGE recommends that EU Institutions

- Explicitly provide for research ethics committee evaluation of proposals in the interests of protecting the rights of research participants
- Give consideration to how best to avoid any type of ethics shopping, which may weaken the legitimacy of the evaluation e.g. by rotating the reporting member state function
- Consider expanding the grounds upon which a Member State can disagree with the Reporting Member State in the interests of building consensus and respecting ethical subsidiarity
- Set realistic timelines which should serve to expedite the process while allowing a robust consideration of the issues.