**To whom it may concern,**

**Regarding the document for public consultation : "**

**Draft list of fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database on medicinal products and made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004**

**"**

**COMMENTS FROM The EU FP6 integrated project "RISET" : Reprogramming the immune system for the establishment of tolerance, Contract N° 512090 IP, web site : www.risetfp6.org . Coordinator: Pr. Michel Goldman.**
**Person submitting the comments on behalf of the Riset consortium : Anne Cambon-Thomsen, cambon@cict.fr**
**Document prepared with the help of Aurélie Mahalatchimy (PhD in Law).**
**The document was highlighted by Kathryn Wood to the RISET consortium involved in clinical trials using cell therapy and in regulatory and ethical issues, upon suggestion by Anne Cambon-Thomsen. It was circulated in September 2008 to all the partners.**

**RISET is a research integrated project under FP6 dealing with biotherapies and especially cell therapy to the immune manipulation in the context of transplantation. Although several aspects of the project deal with diagnostic tests and assessment of markers for tolerance, one WP in RISET (WP3), under the leadership of Lucienne Chatenoud (Paris) is dedicated to clinical trials related to 1) tolerance induction. 2) Minimisation of immunosuppression. 3) Refining the use of tolerogenic drugs. More than 10 clinical pilot studies are being performed, in the context of transplantation.**

**People involved in this WP were especially asked to comment on the public consultation paper, but this possibility was also given to all partners.**

**No member of the consortium communicated substantial comments on this list of fields. However the members of the Riset Consortium continue paying attention to the evolution of the regulatory framework.**

**In case some late comments would be communicated we would send them to you for information.**

**On behalf of the Riset Consortium**

**Anne Cambon-Thomsen and Aurélie Mahalatchimy**

Dr Anne Cambon-Thomsen, Directrice de recherche au CNRS
UMR Inserm, Université Paul Sabatier - Toulouse III, U 558
Epidémiologie et analyses en santé publique : risques, maladies chroniques et handicaps
Département d'épidémiologie et de santé publique
Faculté de médecine. 37 allées Jules Guesde F-31073 Toulouse Cedex
Tel : +33 (0)5 61 14 59 59 (secrétariat U558 : 59 63). Portable : +33 6 79 41 13 48 Fax : +33 (0)5 61 14 56 23 E-mail : cambon@cict.fr

Equipe : "Génomique et santé publique : approche interdisciplinaire" **www.u558.toulouse.inserm.fr**
Plateforme Sociétale "Génétique et Société", GIS Genotoul, Génopole Toulouse Midi-Pyrénées **http://genopole-toulouse.prd.fr/**