



The TEDDY Working Group on Ethical Issues in paediatric research

Annagrazia ALTAVILLA



European Network of Excellence for Paediatric Clinical Research

Why this Working Group?

- **Paediatric research peculiarities:**
 - Ethical challenges
 - Limits ⇒ *e.g. the lack of harmonisation of ethical /legal frameworks among countries*
- **New provisions:**
 - Updated ICH Topic E11 guideline
 - Updated EC Ethical Recommendations
 - New CT Regulation ⇒ *new rules, definitions and procedures soon applicable*

What has been done so far?

➤ Publications/surveys

- EU survey on ethical and legal framework of clinical trials in paediatrics (*Altavilla et al. J. Int Bioethique, 2008*)
- Impact of the new european paediatric regulatory framework on ethics committees: overview and perspectives (*Altavilla et al. Acta Paediatrica, 2012*)
- Clinical Trial Application in Europe: What will change with the new regulation, (*Giannuzzi, Altavilla et al. Sci Eng Ethics, 2015*)
- Paediatric research under the new EU regulation on clinical trials: old issues new challenges (*Gennet E., Altavilla, EJHL 2016*)
- *The ethical framework for performing research with rare inherited neurometabolic disease patients (Giannuzzi et al. EJP, 2017)*

➤ Contribution to EnprEMA WG4 Ethics

- Comments on the revision of EC Ethical Recommendations 2008 (2017)
- Harmonised consent / assent template
- Risk / benefit assessment in paediatrics

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WHAT

- To contribute to the EnprEMA WG4 Ethics task on harmonised consent / assent templates (to continue)
- Ethical review of TEDDY projects, applications and activities
- To advice on ethical aspects on data handling and sharing
- Participation in public consultations

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WHAT

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Please note that, by submitting your comments, you will accept and approve the possible publication of such comments.

DATA PROTECTION

News

Events

Public consultations

Grants

Calls for tender

Calls for expressions of interest

Contract archive




Newsroom archive

Should these comments also contain personal data, and you do not object to the publication of such data, please include the following sentence, either at the end of your comments, or in the covering message: ***I/we hereby consent to the publication of personal data contained in this/the attached document.***

Should these comments also contain personal data/business secrets and/or any other data you do not wish to be made public please also provide us with a non-confidential version of your comments.

The Article 29 Working Party welcomes comments on the Working document on Adequacy Referential (wp254) and on the Working Documents on Binding Corporate Rules for Controllers (wp256) and for Processors (wp257). Such comments should be sent to the following addresses by 17 January 2018 at the latest.

JUST-ARTICLE29WP-SEC@ec.europa.eu and **presidencceg29@cnil.fr.**

- Working document on Adequacy Referential (update of Chapter One of WP12), wp254 
- Working Document setting up a table with the elements and principles to be found in Binding Corporate Rules, wp256 
- Working Document setting up a table with the elements and principles to be found in Processor Binding Corporate Rules, wp257 

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- **Operational roles** ⇒ to coordinate activities, to draft documents...

HOW

- **Advisory role** ⇒ to review documents, to provide inputs and suggestions

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Interested members

- Annagrazia Altavilla (Espace de Réflexion Ethique PACA-Corse)
- Federico Martín Torres (H. C. U. de Santiago de Compostela | Fundación Ramón Domínguez)
- Cristina Serén Trasorras (H. C. U. de Santiago de Compostela | Fundación Ramón Domínguez)
- Viviana Giannuzzi (Fondazione per la Ricerca Farmacologica Gianni Benzi onlus)

....others?

New members are welcomed!

Comments and proposals for discussion

*Name of the WP :
Ethical and legal issues in paediatric
research ?*