

ENPR-EMA WORKSHOP 02JUNE2016

WORKING GROUP 4:

DIALOGUE AND INTERACTION WITH ETHICS COMMITTEES

Pirkko Lepola

EnprEMA WG 4 - Ethics

Current WG4 members in 2016:

- Pirkko Lepola, Chair (Finnish Investigators Network for Pediatric Medicines, Finland)
- Diane Hoffman, co-Chair (Janssen Research & Development, Philadelphia, U.S.A.)
- Martine Dehlinger-Kremer (SynteractHCR Deutschland GmbH, Germany)
- Jo Mendum (PRA HealthSciences, Reading, UK)
- Peter Sallabank (RegulinX, Surbiton, UK)
- David Neubauer (University Children's Hospital, Ljubljana, Slovenia)
- Adriana Ceci (CVBF-Consortio per Valutazioni Biologiche e Farmacologiche, Italy)
- Viviana Giannuzzi (Fondazione per la Ricerca Farmacologica Gianni Benzi, Italy)
- Heidi Glosli (Oslo University Hospital, NorPedMed, Norway)

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Role:

Develop pragmatic responses to be implemented within six months (approx.);

- Examples of good practice when ECs consider trials relating to children and young people
- Develop proposals to disseminate examples of good practice to ECs

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- **First Report**: Plan Report - Recommendations (12), published in December 2013 for Enpr-EMA (only)
- **1 Task: Deliverable**: “Tool Kit” - Informed Consent and Assent for Paediatric Clinical Trials in Europe
 - Published on Enpr-EMA web-site on 18 December 2015
 - Will be updated by the Enpr-EMA from now on
- **1. Article**: *“Informed Consent and Assent Tool Kit for Paediatric Clinical Trials in Europe”*; Published 25May2016, Archives of Disease in Childhood
 - Authors: Pirkko Lepola, Allison Needham, Jo Mendum, Peter Sallabank, David Neubauer, Saskia de Wildt

- EMA Home ->Partners & Networks ->Networks ->Enpr-EMA ->Enpr-EMA activities
- http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199234.pdf



European Network of Paediatric Research at the European Medicines Agency

NOTE: Corrected data in new article !

Informed Consent for Paediatric Clinical Trials in Europe 2015

Pirkko Lepola, Allison Needham, Jo Mendum, Peter Sallabank, David Neubauer, Saskia de Wildt

Country	Consent / assent from child		Consent from parent(s) / guardian(s)	General informed consent information	
	Legal age of consent	Mandatory / suggested age ranges defined for assent (or consent if assent not used)	Number of required signatories	Official language requirements	IC template(s) / guidelines / information sources
Austria	Not specified Practice 14 years	8-13 years EC may require younger assents	Both parents	German	http://www.medunigraz.at/ethikkommission/Forum/index.htm http://www.ethikkommissionen.at/ http://www.ulbk.ac.at/strafrecht/schell/schell-einfuehrung-in-die-arzneimittelpruefung-bei-kindern-und-jugendlichen---kks--klds-ip.pdf
Belgium	18 years	4-11 years (some sites do not use under 12 years) 12-14 years 14-17 years	One parent at recruitment, but both parents at some point for signatures	Dutch, French German at site request	http://www.fagg-afmps.be/en/human_use/medicines/medicines/research_development/ethic_committee/templates_informed_consent/ Do not have paediatric templates

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
 Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
 Send a question via our website www.ema.europa.eu/contact

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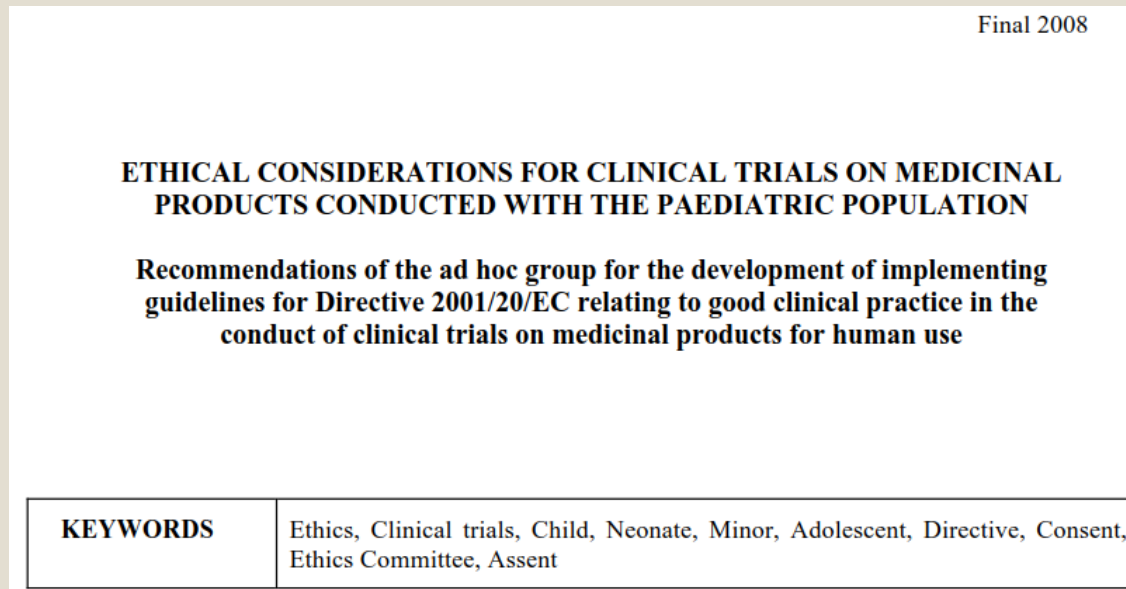
Additional WG activities in 2016:

- Contribution to *PROPOSED CHANGES TO THE U.S. COMMON RULE Implications for Pediatric Research (Federal Policy for the Protection of Human Subjects)*
- Included comments on two points relating to paediatric research:
 - 1. the value of taking an international perspective when revising the Common Rule
 - 2. Informed Consent
- Comments submitted on January 2016 by Mark Turner, the behalf of the Enpr-EMA

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NEW Tasks 2016:

- 2. Task: Take part to Public Consultation of the *“Ethical considerations for clinical trials on medicinal products conducted with the paediatric population” (2008)*, open June-September 2016



- The consultation will be done in collaboration with the EFGCP CMWP (European Forum for Good Clinical Practice, Children’s Medicines Working Party; WP 1: Review of the European Ethics Guideline
- With the consideration of risk benefit issues and risk assessment
- **Contributes the started revision work by collaborating with a small group of PDCO members, lead by the Ralf Herold, EMA**

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3. Task: Background facts:

1. New EU CT Reg. (impl.approx.10/2018) will harmonise the clinical trial application (CTA) process, but IC/Assent issues remain with each Member State.
2. There are noticeable differences between national IC and assent requirements in Europe due to national laws and regulations (See: Tool Kit data)
3. These discrepancies can present challenges for multicentre paediatric CTs

Planned deliverable: “Partly harmonized of IC / Assent templates”

Way to work:

- Isolate and collect the issues repeatedly comes to be solved with ICs and Assents
- Compile standard sections, reflecting the revised “EU Guideline” age categories
- Review all existing templates and verify those also with the “Tool Kit” data
- Draft partly harmonized (as much as possible) core templates (3 ?) with standard language (English)
- Make recommendations, what type of visual aid could be used, and what is publicly available.