ENPR-EMA WORK SHOP 28JUNE2015

WORKING GROUP 4:

DIALOGUE AND INTERACTION WITH ETHICS COMMITTEES

Allison Needham / Pirkko Lepola

EnprEMA WG 4 - Ethics

- **Enpr-EMA ad hoc Working Group since 06/2013 (Enpr-EMA Mandate)**

- **Task to develop pragmatic responses to be implemented within six months;**
  - **Examples of good practice when ECs consider trials relating to children and young people**
  - **Develop proposals to disseminate examples of good practice to ECs**

- **Final Report: Short term – and Long Term Recommendations (total of 12), published in December 2013 and discussed in CG meeting on January 2014**

- **Selection of 1 recommendation for the deliverable; *"A table that shows requirements/regulations regarding consent of children in Member States"***

- **Deliverable: Informed Consent and Assent Tool Kit for Paediatric Clinical Trials in Europe**

- **Will be published on Enpr-EMA web-site after publication in scientific paper (?/2015)**

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Final deliverable: Informed Consent and Assent Tool Kit for Paediatric Clinical Trials in Europe

- **Data including legislative surroundings of the informed consent requirements for pediatric clinical trials, listed by country – 27 EEA countries; 25 EU Member States and 2 EFTA counties; Norway and Iceland**

	Consent/assent from child		Consent from parent(s)/guardian(s)	General informed consent information	
Country	Legal age of consent	Mandatory /suggested age ranges defined for consent and assent	Number of required signatures	Official language requirements	IC template(s) / guidelines

EnprEMA WG 4 – Ethics

- **For Report: "Dialogue and Interaction with Ethics Committees - Plan for implementation"**

  Allison Needham, Pirkko Lepola, Jo Mendum, Peter Sallabank, David Neubauer, Ivana Silva (EMA), Dr. Richard Trompeter (GOSH/ IPTA, UK) and Dr. Alan Boddy (prev. Newcastle University / currently, the University of Sidney)

- **For Article: "Informed Consent and Assent Tool Kit for Paediatric Clinical Trials in Europe";** (not yet submitted)

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