10/25/2017

WORKING GROUP 4:

DIALOGUE AND INTERACTION WITH ETHICS COMMITTEES

Pirkko Lepola

EnprEMA WG 4 - Ethics

WG4 re-organization since 01Nov2017:

Primary members -> drafting documents

- Pirkko Lepola, Chair (Finnish Investigators Network for Pediatric Medicines, Helsinki, Finland)
- Maxine Kindred, (Janssen Research & Development, Buckinghamshire, UK)
- Viviana Giannuzzi (Fondazione per la Ricerca Farmacologica Gianni Benzi, Valenzano, Italy)
- Heidi Glosli (Oslo University Hospital, NorPedMed, Oslo, Norway)
- Martine Dehlinger-Kremer (SynteractHCR Deutschland GmbH, Munich, Germany)
- Harris Dalrymple (PRA HealthSciences, Reading, UK
- Peter Sallabank (RegulinX, Surbiton, UK)
- David Neubauer (University Children's Hospital, Ljubljana, Slovenia)
- *Geraldine Boylan (Irish Centre for Fetal & Neonatal Translational Research, University College Cork, Ireland) ??*

Co-members -> reviewing documents

- Christina Manfredi (CVBF-Consorzio per Valutazioni Biologiche e Farmacologiche, Pavia, Italy)
- Jo Mendum (PRA HealthSciences, Reading, UK
- *Diane Hoffman (prev. Janssen Research & Development, US – Retired !) ??*

EnprEMA WG 4 - Ethics

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**

Enpr-EMA WG4 – Task 3

3rd Task: Partly harmonized core IC / Assent template with standard language (English) 2016-2017

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

3. Deliverable: "Partly harmonized of Informed Consent / Assent template -document"

- Based on identification of all similar elements across assents / consents of existing templates

Enpr-EMA WG4 – Task 3

3. Task: Executed by a ”Mini-Group of Consents”

- **Diane Hoffman :** Johnson & Johnson Pediatric Center of Excellence (Chair)
- **Maxine Kindred :** Johnson & Johnson Operations (Operational producer)
- **Heidi Glosi :** Oslo University Hospital (support)
- **Jo Mendum :** CRO, PRA (support)

3.Deliverable: Comparison of Assents from WHO, MCRN and Finland

- Identification of all similar elements across assents
- Prepared to include all elements
- Items included in the WHO template was added to the guidance as they were deemed important to the assent

- Guidance template provided January 2017
- Presented in Enpr-EMA Annual Workshop 16May2017
- Prepared the document for the Review process

Assent / Consent – Model template - includes instructions

Version 3.0 Enpr-EMa WG4 Ethics

Italics – instructional text.

Blue – example text

Study Title

Institution Name / Sponsor of the research

Include information about the institution, investigator that is conducting the research and also the name of the sponsor/organisation funding the research.

Document version and date

Specify the version and the date of the document

Template cont. (last page)

Thank-You

Thank them for taking the time to read the document and consider participation in the trial.

Certificate of Assent / Consent

NOTE: Especially for small children, the signature page of the assent / consent should be preferably integrated version; together with the patient information sheet, not exceeding the length of one page (all information included – both the patient information and signatures).

Inclusion of signatures for assent /consent will be based on country/site specific requirements according to local regulations and age range.

- Read & Agree / Disagree
- Signature of Child
- Signature of Researcher obtaining assent
- Other

Please note the new EU Ethics Guideline when it´s coming into force (2017) including new recommend age limits for consents and assents.

Enpr-EMA WG4 – Task 4

4. Task: Review process of the Template model

a) Review of the Template model by eYPAGnet -> Report (12Sep2017)

- Scottish Children´s Research Network
- Generation R –Liverpool´s Team
- KIDS Barcelona – Sant Joan de Déu Children´s Hospital

b) Review of the Template model by Ethics Expert; -> Commented (29June2017)

- Francis P. Crawley, Executive Director, Good Clinical Practice Alliance - Europe (GCPA), Belgium

4. Deliverable: The Consent / Assent template as guidance document for all Enpr-EMA stakeholders to be placed publicly available on Enpr-EMA web-site (-> by 06/ 2018)

NEXT STEPS:

- Comparison of the review responses with the EU Ethics Guideline (Revision 1); published in October 2017.
- Identification of any conflicting elements across template
- Correcting the template according to Ethics guideline (R1)and CTR
- Preparing to include all important elements from eYPAGnet Report
- Finalize the template and format

Enpr-EMA WG4 – Task 4

eYPAGnet
European Young Persons' Advisory Group Network

FEEDBACK REPORT ABOUT:

ASSENT DOCUMENT TEMPLATE FROM ENPREMA WP ON ETHICS

PARTICIPANTS:

- Scottish Children's Research Network
- Generation R – Liverpool's team
- KIDS Barcelona – Sant Joan de Déu Children's Hospital

METHODOLOGY:

Monographic session leaded by the facilitator of every YPAG planned in June of 2017. The content of the session was:

- Introduction of EnprEMA and the role that plays regarding the paediatric clinical research along Europe.
- Explain the objectives of the Ethics Working Group of EnprEMA and the benefits to offer a standardized template of the assent document.
- Introduction of the assent template proposed, deep reading and discussion about the main features.
- Collection of individual feedback of all the attendees through a questionnaire that includes open questions (n=12) about: need of additional information, format, summary, etc.

Enpr-EMA WG4 – News

New collaboration started with EUREC- European Network of Research Ethics Committees

- EUREC presentation in Enpr-EMA Annual WS, May 2016
- 1st Enpr-EMA WG4 presentation in EUREC meeting, 08Sep2016, Helsinki
- Enpr-EMA WG4 presentation in EUREC-ANCEI Congress in Barcelona,18May2017
- Discussion, "brainstorming" TC, 03Oct2017
- ***1st Meeting in London 13th November 2017, EMA***

THANK YOU!