

MINUTES

Ethics Working Group
European Academy of Paediatrics (EAP)
UEMS Section of Paediatrics
EAP Winter Meeting
Bruxelles

December 1, 2017 JOINT SESSION Rare Disease/Ethics WG
09.30 – 11.30

The ethics part

1. Attendance and apologies: 20 participants (see the list at the end);
apologies: Brierley, Crawley, Grosek.
2. Approval of the agenda

Approved
3. Approval of the Minutes, Hotel Tivoli Vilamura, Portugal <http://eapaediatrics.eu/wp-content/uploads/2017/05/Minutes-WG-Ethics-Vilamura-May-12-2017.pdf>
4. Manuscripts in 2017:
 - i) Reviewing and addressing the link between mass media and the increase in obesity among European children: The European Academy of Paediatrics (EAP) and The European Childhood Obesity Group (ECOG) consensus statement (Acta Paediatrica) – ahead of print (PDF attached)
 - ii) Health, Integrity, and Doping in Sports for Children and Young Adults (Resolution of European Academy of Paediatrics)

Ethics Working Group) (published in EJP see at:

<http://link.springer.com/article/10.1007/s00431-017-2894-z>

Still waiting for translations

We should attempt to achieve translations into major European and International Languages:

- German (Peter) – **WILL BE DONE SOON**
- French (Jean-Christophe)
- Spanish (Manuel) - **DONE**
- Portugese (Ines)
- Italian (? Francis will forward)
- Russian (? Francis will forward)
- Arabic (Ahmed)
- Chinese (Jean-Christophe will forward)

Decision: If there will not be further translations, David will send the Spanish and German version to Lenneke as Statement at the website and other Social Media

5. Manuscripts/statements in preparation:

- i) The performance enhancing drugs use in children in sport issue.
(Brierley Joe) Please read outline at:
<http://eapaediatrics.eu/wp-content/uploads/2016/11/Performance-enhancing-drugs-Brierly.pdf>
- ii) Sports in disabled children (Siderius Liesbeth) Please read manuscript outline at: <http://eapaediatrics.eu/wp-content/uploads/2016/11/Sports-and-art-in-disabled-children.pdf>
- iii) Statement of vulnerability in sports (Robert Ross-Russell, Martin White)
Decision: everybody will write the comments to the table and send them either to Rob or Martin or to complete it and then decide whether to write a statement or a manuscript out of the data.
- iv) **Guidelines for First-in-Children Clinical Trials of Investigational Medicinal Products** (Francis Crawley);
- v) **Paediatric Microdosing (A Working Paper on behalf of Francis P. Crawley & David Neubauer For Discussion by the Members of the EAP Ethics Working Group);**
- vi) The Role and Responsibility of the Paediatrician and Other Paediatric Healthcare Providers in Caring for Migrant Children
(A Declaration of the European Academy of Paediatrics)
- vii) **Guidelines for Informed Assent/Consent in Research Involving Paediatric Populations as Research Participants (Ethics Working Group of the European Academy of Paediatrics (EAP)*Draft Revision by Francis P. Crawley**

Decision: There are manuscripts in prep under i), ii), iv), v) and vii) see links and attachments – for further discussion at Spring Meeting, as well as Statement under iii) and statement/declaration under vi) – attached, however

the last one, should be adopted as soon as possible, after the approval of EC and then put on the website:

Statement on Child Trafficking and Slavery
Ethics Working Group
of the European Academy of Paediatrics (EAP)

5. AOB (Declaration of Geneva) Revised version (October 14, 2017)
<https://www.wma.net/policies-post/wma-declaration-of-geneva/>

Decision: david will contact the responsible persons and ask them why they did not accept our (EAP) corrections

6. Presentations:

- 1. Klaus Rose, Medical Science, Klaus Rose Consulting, Switzerland: Do we still need PIPs – 20 minutes and 10 minutes discussion**

Discussion followed regarding PROs and CONs about this topic (see attachemnt of the presentation for futher discussions)

David said that he is not any more the delegate of Slovenia, and so he has to give the chair to someone else – proposed dr Joe Brierley, who accepted it.

The meeting ended at 11.45
D. N.

List of attending members (please, check the e-mail addresses):

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Attachments:

- 1. Guidelines for First-in-Children Clinical Trials of Investigational Medicinal Products** (Francis Crawley) – manuscript in prep
- 2. Paediatric Microdosing** (A Working Paper on behalf of Francis P. Crawley & David Neubauer For Discussion by the Members of the EAP Ethics Working Group) - manuscript in prep
- 3. The Role and Responsibility of the Paediatrician and Other Paediatric Healthcare Providers in Caring for Migrant Children (A Declaration** of the European Academy of Paediatrics)
- 4. Guidelines for Informed Assent/Consent**
in Research Involving Paediatric Populations as Research Participants (Ethics Working Group of the European Academy of Paediatrics (EAP)*Draft Revision by Francis P. Crawley - manuscript in prep
- 5. Statement on Child Trafficking and Slavery**
Ethics Working Group
of the European Academy of Paediatrics (EAP)
- 6. Klaus Rose: presentation**