22/02/2017

WORKING GROUP 4:

DIALOGUE AND INTERACTION WITH ETHICS COMMITTEES

Pirkko Lepola

EnprEMA WG 4 - Ethics

Current WG4 members since 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-Consorzio 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**
  - **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**
- **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)**
    - **Comments submitted on January 2016 by Mark Turner, the behalf of the Enpr-EMA**
- **Second 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
  - **Contributed by EFGCP CMWP (European Forum for Good Clinical Practice, Children's Medicines Working Party; WP 1**
  - **In collaborating with a small group of PDCO members**

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3. Task; 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

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.**

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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

- Guidance template provided January 2017* (*page 7)

BY;

- 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

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1. Identification of all similar elements across assents

TYPES OF ASSENTS	INSTITUTIONAL NAME	INFORMATION SHEET:	PURPOSE:	CHOICE OF PARTICIPANTS:	PARTICPATION IS VOLUNTARY:	INFORMATION ON THE TRAIL DRUG DRUG NAME:	PROCEDURES:	RISKS:
		Introduction	Why are you doing this research	Why are you asking me?	Do I have to do this?	What is this drug & what do you know about it?	What is going to happen to me?	Is this bad or dangerous for me?
Finland Template								
MCRN Template								

COMPARISON OF ASSENT DOCUMENTS

DISCOMFORTS:	BENEFITS:	REIMBURSEMENTS:	CONFIDENTIALITY:	COMPENSATION:	SHARING THE FINDING:	RIGHT TO REFUSE OR WITHDRAW:	WHO TO CONTACT:	PROVIDE A COPY?
Will it hurt?	Is there anything good that happens to me?	Do I get anything for being in the research?	Is everyone going to know about this?	What happens if I get hurt?	Will you tell me the results?	Can I choose not to be in the research? Can I change my mind?	Who can I talk to or ask questions to?	

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1. Identification of all similar elements across assents, cont.

CERTIFICATE OF ASSENT			IF ILLITERATE:	NAME AND SIGNATURE OF WITNESS:	NAME AND SIGNATURE OF RESEARCHER:
Read it and agree.	Does not agree.	Signature of child:	Thumbprint of participant:		

2. Prepared to include all elements & Items included in the WHO template was added to the guidance as they were deemed important to the assent

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3. Items included in the WHO template

Pediatric Assent Template Sub-Group of EnprEMA
Jan-2017

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.

Introduction

A brief introduction to ensure the child knows that this is a research study. The person obtaining consent should give their name, explain who they are and clearly state they are doing the research.

We would like to invite you to participate in our research study. Please read this information carefully and talk to your mum, dad, carer or anyone else you feel comfortable talking to about the study. There may be some words you don't understand or things you would like explaining in more detail because you are interested or concerned. Please ask us if there is anything that is not clear or if you want to know more. Take all the time you need to decide if you want to take part.

The Purpose of this Research

Explain the purpose of the research in clear simple terms.

- *Include information about what research is*
  - Research is a careful experiment to find out the answer to an important question.
- *Include information about the purpose of the trial.*
  - We want to try and find out if/why……
- *Include information to confirm that an ethics committee has reviewed the planned research and has given their approval for it to take place in [region/country]*
  - Before any research can take place it has to be checked by a Research Ethics Committee. This is a group of people who look at the planned research and decide if it is OK to do or not. This study has been looked at by XXXXXXX and they have given their approval for the research to take place in [region/country].

The Investigational Product

Include information about the trial drug, the reason for its development, how much is known about it and whether it has been studied in children before. Provide as much information as is appropriate and understandable.

Choice of Participants

Include information explaining:

- *why they are being invited to participate / why they are suitable for the trial*
- *number of participants globally / in their country*
- *that they do not have to participate and they can change their mind at any time*
  - You do not have to be in this research. It is your choice. You can think about it and tell us later if you want. You can say yes now and change your mind later and it will still be OK.
- *that no-one will be cross or angry if they decide they do not want to participate at any time. They can say No at any time.*
  - No-one will be mad or disappointed with you if you say no.
- *regardless of their decision the doctors and nurses will still take care of them in the best possible way.*
  - Whatever you decide, the doctors and nurses will still take care of you in the best possible way.
- *that the researchers will also talk to their parents/guardians to get their permission for the child to participate*
  - We will also talk to your parents/guardians who will also have to give their permission for you take part.
- *If new information becomes available the doctors / nurses will discuss this new information with them and they will be asked if they would still like to continue to participate in the study.*
- *The doctors may decide at some point that the child is no longer suitable for participation and they will be informed if this is the case. The doctors and nurses will still take care of them in the best possible way.*

Procedures

Include information about what is going to happen to the child during the trial. Including:

- *How many times they will be seen, for how long*
- *The procedures that will take place*
- *What is considered "extra" to what would normally happen*
- *Length of Trial*
- *Anything specific the child will have to do (or not do)*

Risks/Discomforts/Benefits

Include information about possible side effects, discomforts, risks of the procedures and any potential benefits (to the participants or maybe other children in the future with the same disease). Tell the participant that if they feel different in any way they should tell their parents/guardians and the doctor. Address any worries you think a child may have (eg, missing school or holidays).

Compensation

Include information about what happens if something goes wrong or they get injured during the trial.

If something goes wrong, you become ill or get injured during the research we will look after you. We have given your parents information about who to contact.

Reimbursements

Include information about whether the patients will get anything for their participation or if they (or their parents) will be reimbursed for expenses. Some children may worry that their parents will have additional financial burden by them participating in the study (eg, if the trial site is much further away from their home)

Confidentiality

Include information about who will know the child is taking part in the trial and arrangements for making sure they cannot be identified by anyone else (eg, their name and address will not be used).

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and that information will be locked away so no-one else can see it.

When The Trial Is Over

Tell the child:

- *what will happen to them when the trial is over*
- *what will happen with the results*
- *whether you will make arrangements for them to be informed about the results*
- *what will happen to all the information collected during the trial*

Contact Information

Include details for people who the participant can contact to talk to, find out more information, ask questions to or complain about something.

You can ask questions now or later. Below are some names and numbers of people you can contact for more information, to ask questions to, to complain to or even just to chat to. If you want to talk to someone else that you know that's OK too.

Thank-You

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

Certificate of Assent

Inclusion of signatures for assent will likely 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