Paediatric Clinical Research Infrastructure Network

PedCRIN Parent Consultation Tool

Format PedCRIN meeting guide for Adults

Description	This tool is a basic guide about the way parents can be 'consulted' about a paediatric clinical study. 'Consultation' is asking parents for input about the study. The tool describes a specific way of consultations: a 'focus group', a face-to-face meeting. There are other ways to ask patients for input. For example, interviews or questionnaires. These are not described in this tool.
Key words	Patient involvement, patient engagement, focus group, clinical research, paediatric research, parental involvement

Disclaimer: The meeting guides are formats and need to be adapted for the local circumstances. If a researcher wants to organize a parent (adults) consultation focus group for about their trials, please consult the patient consultation experts.

V1, 06 APRIL 2021

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PedCRIN has received funding from the European Union's Horizon 2020 programme under grant agreement number 731046

Abbreviations

PedCRIN	Paediatric Clinical Research Infrastructure Network
YPAG	Young person advisory group
FSJD	Fundacio Sant Joan de Deu
VSOP	Patient Alliance for Rare and Genetic Diseases

Keynotes

Why we need to use it in neonatal/paediatric studies?

Consultations of parents about clinical trials concerning their children are important because parents can advise investigators about their needs and priorities. That way the researchers can adapt information about the study or study design/procedures that can enhance inclusion and retention as well as use relevant outcome measures.

What kind of information it provides?

It gives a basic guidance for the organization of face-to-face meetings with parents. The different phases of the meeting are described and topics for discussion are listed.

How this document is useful and at which stage of the trial it should be used?

This document describes the consultation in basic terms. If the researcher follows this procedure, she will obtain useful information of parents about a prospective clinical trial. It should be used because it is important to consult the trial target group in order to enhance the chances to organise a successful and relevant clinical trial.

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1.1. Introduction

The objective of this tool is to support consultations, with parents (adults), about the three clinical trials that are supported by PedCRIN. This tool specifically focusses on consultations with parents of children that have the specific disease the trial is focussing on or have experience with the conditions/circumstances of the clinical trial.
The goal of the consultations is to explore and assess how parents can be involved in the design, execution and finalization of clinical trials in paediatrics.
Involvement of parents in clinical research is needed to increase trial success, for example on account of recruitment rates or outcome measures.
PedCRIN develops tools for these consultations. The experiences with and evaluation of this tools will be used to evaluate existing tools and to create a tool that can be widely used in future research.
This tool offers specific examples of meeting guides:

Format meeting guide parents (face to face groups with parents (adults)

The meeting guides are formats and need to be adapted for the local circumstances. If a partner wants to organise a parent (adults) consultation focus group about their trials please contact Eric Vermeulen VSOP (e.vermeulen@vsop.nl) further detailed information on how to use these materials, experiences with and evaluations of the tools

2. Format PedCRIN meeting guide parents

This meeting guide consist of activities that should be performed before, during and after the consultation with parents (adults). Due to the type of clinical trials selected for PedCRIN this meeting guide for adults focusses on parents of (very young) children. So the participants are not patients themselves.

3. Preparation

- Contact patient organisation or interest group;
- Explain the purpose of the consultation to the contact person of the patient organisation / interest group and ask them if they want to cooperate and what role they can play (for example: contact and invite their members for the consultation, share information about other research projects they are involved in etc.);
- If parents are willing to participate contact them and set a date and time for the consultation (aim for 6-8 participants for a consultation);
- Organise a venue/location/meeting room;
- If not available, write a summary of the clinical trial;
- Share relevant information with the participant about the clinical trial, for example: Trial protocol, summary of the clinical trial, informed consent material / procedure, (information about) questionnaires / tools used in the trial, etc.;
- If not available, make a reimbursement form for travel expenses of participants.
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4. Consultation

The consultation preferably last no longer than 2 hours. It can last longer of course, but participants are most involved and energetic during the first 2 hours.

4.1. Welcome and introduction (15 min)

- Getting to know each other;
- Explaining the plan for the consultation (for example: recording of the consultation and their permission, topics being discussed, etc.);
- Etc.

4.2. Discussion session I (45 min)

During this session the first topic(s) will be discussed with the parents.

Depending on the number and type of topic(s) the organisers and / or the clinical researchers want to receive feedback on this part of the consultation can contain one or more topics. For example:

- Informed consent material
- Informed consent procedure
- Trial protocol (randomisation, type of design, etc.)
- Logistics of the clinical trial
- Outcome measures of the clinical trial
- Communication about the trial results.

Break (10 min)

4.3. Discussion session II (40 min)

During this session, topics about the clinical trial that were not discussed during the first session can be discussed. Another option for this session is to discuss with the parents how they would like to be involved in research and research design. Topics that can be discussed:

- At what point in research design would they want to be involved? (for example: setting the research agenda; when the research design is being discussed, or the logistics, or the type of outcome measures; when developing the informed consent material or procedure; or when they develop the communication plan, etc.)
- How would they want to be involved? (for example: via questionnaires, email, interviews, meetings with researchers, etc.)

4.4. Closure (5 min)

- Thank everybody
- Hand out reimbursement form for travel expenses (if not done already)
- Explain the procedure after this consultation (notes are sent to participants for confirmation)

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5. After the consultation

The organisers of the consultation will make a report of the consultation that will be shared with the participants. The participants can correct or add to their contribution as rendered in the report. The researchers write a (summary of the) report in English and discuss this with the investigators.

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