GRiP – Tools for Interoperability

Questions and Considerations for Ethics Committees Evaluating Paediatric Drug Trials

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LEADING ARTICLE

Ethics Review of Pediatric Multi-Center Drug Trials

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Abstract The assessment of safety and efficacy of therapeutics for children and adolescents requires the use of multi-centered designs. However, the need to obtain ethical approval from multiple independent research ethics boards (REBs) presents as a challenge to investigators and sponsors who must consider local requirements while ensuring that the protection of human subjects is consistent across sites. In pediatrics, this requirement is complicated by pediatric-specific ethical concerns such as the acquisition of assent and consent and the need for pediatric expertise to assess the scholarly merit of the proposed research. Efforts to tackle these challenges have focused on the process of ethics review, which will improve efficiency. In addition to improving process, we suggest further research to fill gaps in the evidence base for recommendations and decisions made by REBs, specifically their effectiveness to protect human subjects. Evidence gathered will contribute to the successful development, adoption and implementation of harmonized guidance to apply ethics principles in order to protect children through research rather than from research.

Key Points

Assessment of the safety and efficacy of therapeutics for children requires multi-centered designs.

Ethics review of multi-center trial protocols presents challenges to research ethics boards, investigators, and sponsors who must consider both general and local institutional regulations and requirements for human subjects' protection.

Although streamlining ethics review processes may improve efficiency, there is an urgent need for the development, adoption and implementation of ethics guidance to protect children through research rather than from research.

1 Introduction

Pediatric clinical research is essential in order to assess the safety and efficacy of new treatments for children. His-

Aims

1) To collect and evaluate available guidance on key issues identified by EC's during the ethical evaluation of pediatric research.

2) Synthesize the appraised guidance to prepare a document outlining the specific questions that need answering and the considerations that should be made in the ethics review of paediatric clinical trial research

GRiP project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 261060

Process

1) Invite experts – ethicists with ped expertise
2) Select 5 main ethics questions for pediatric drug trial ethics review
3) Collect guidance
4) Conduct content and quality appraisal of guidance
5) Synthesize guidance to prepare ‘layered’ document
6) **Pilot tool and obtain feedback**
7) *Finalize tool and explanatory document*

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Task Working Group

- **Francis Crawley** – Executive Director, GCP Alliance
- **Robert "Skip" Nelson** – Deputy Director and Senior Pediatric Ethicist, FDA
- **Hugh Davies** – Paediatrician and National Ethics Advisor, NRES UK
- **Bobby Farsides** – Professor of Clinical and Biomedical ethics and Chair, Nuffield Bioethics
- **Pau Ferrer** - Professor of Bioethics, member of International GCP working group
- **Allison Needham**, MSc supported by **Martin Offringa**, Professor of Pediatrics and Head, Child Health Evaluation Sciences Unit, Sick Kids Research Institute, Canada

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What are the key pediatric specific questions that should be asked during the ethics review of a drug trial protocol?

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GRiP – YPAG

International consensus guidelines for the formation of young person advisory groups

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Anne Junker

The Hospital for Sick Children in Collaboration with GRiP Partners

Disclaimer

- I am not a member of GRiP
- I am not a member of this Task Working Group
- I have not first-hand contributed content to the developing guidance

- ❖ I do oversee a YPAG and the program guidance
- ❖ I am involved in review and advice about the international consensus guideline and website

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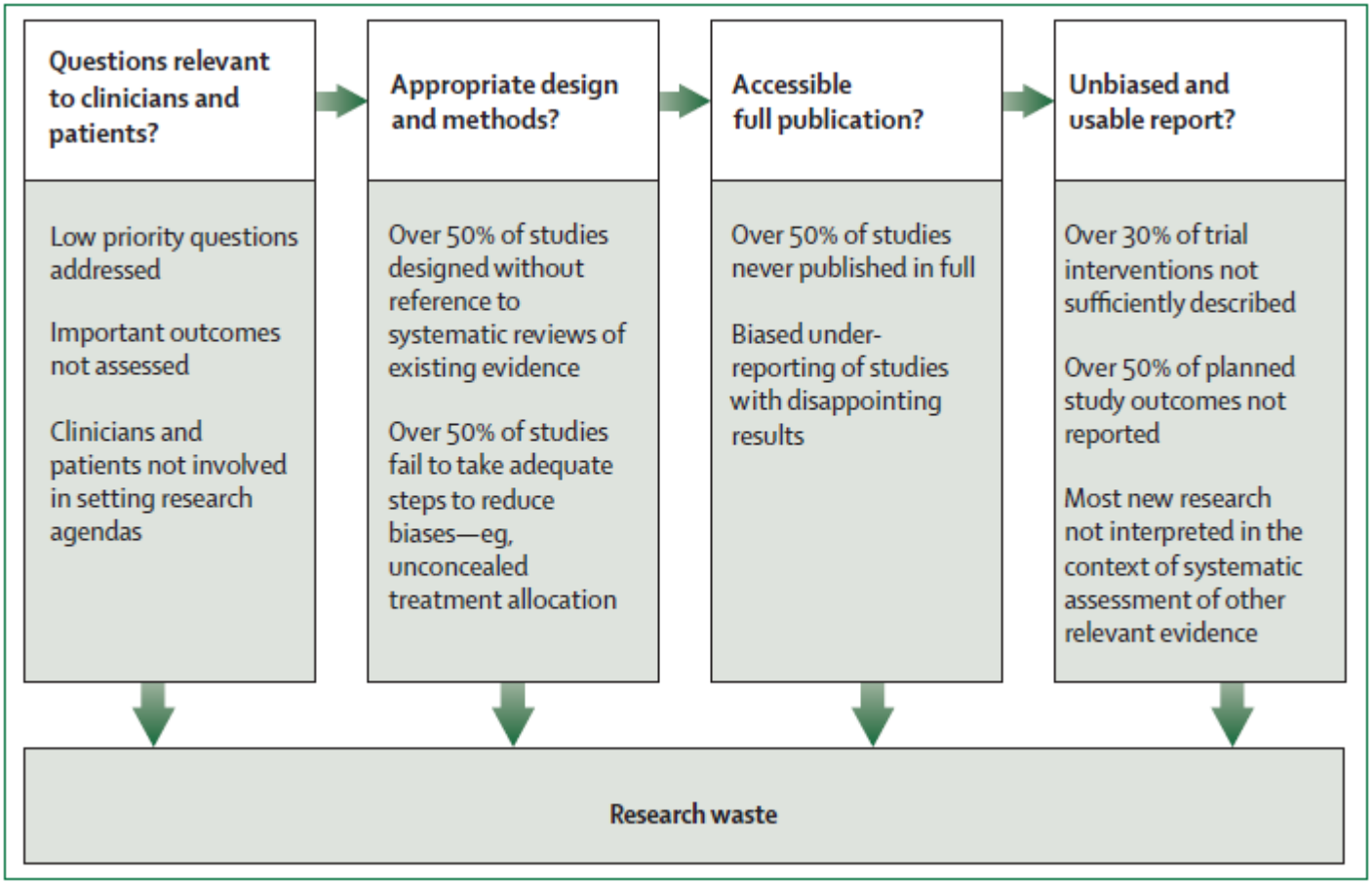
Rationale for YPAG:

Avoidance of Waste in the Production and Reporting of Research Evidence

Iain Chalmers, Paul Glasziou Lancet 2009;374:86-89.



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Aims

1) To develop guidance for ‘best practices’ to create Young Person Advisory Groups

2) To make this information broadly available

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Process

1) Invite the experts
2) Collect existing guidance from current YPAGs
3) Conduct content and quality appraisal of guidance
4) Synthesize guidance to prepare document and website
5) **Pilot and obtain feedback**
6) *Launch!*

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Task Working Group

- existing YPAGs
  - UK Clinical Research Network: Children Specialty
  - Scottish Children's Research Network
  - Young Persons Advisory Group (YPAG), Vancouver, Canada
  - Kids and Families Impacting Disease Through Science (KIDS) of the American Academy of Pediatric (AAP) in the USA
- Dr. Cor Oosterwijk, vice-president of the European Genetic Alliances' Network patient and public involvement expert,
- many fellow GRiP members
- **Winnie Chan**, MPH supported by **Martin Offringa**, Professor of Pediatrics and Head, Child Health Evaluation Sciences Unit, Sick Kids Research Institute, Canada

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KidsCan

A little about you

- You're a doer! You also have a boundless curiosity
- You want to help change things for the better in your community
- You want to learn how research is done in your community

Things you could be doing

- Trying out new ideas and technology to help improve healthcare
- Advising researchers on how to better find solutions to real problems
- Collaborating with people like you around the world

KidsCan

Could you be a fit?

Step 1: Application letter

A

Write us a letter (at minimum 1 page and at most 2 pages long, Times New Roman font, size 12). Include, in your letter, answers to the following:

- **What is important to you?**
- **Who are you as a person?**
- **Why do you want to join KidsCan?**

Tip: Mention what you read, volunteer work, any blogs you write, sports you play, links to your work, art you made etc.
Important: Tell us *why* you do the things you do!

B

Email your letter to kidscan@cfri.ca with the **subject** "Application letter". Then fill out the form on the right! Your application must include steps 1 and 2.

Step 2: Form

Age group *

Select an Age Group

Want to add any comments? (140 characters or less)

Send form

All done! Don't forget to email your letter!

Resources

Press to view the Advisor Guide.

Advisor Guide

Achievement Charts

Research Education for Advisors

coming soon

Learning: Ethics

TCPS 2: CORE TUTORIAL on centre button

Tips

Home

What is this online platform

This platform was developed to harmonize information and guidance for researchers who are looking to involve youths in the design of clinical trials. This online platform hopes to help research networks and/or institutions to develop their own Young Persons Advisory Groups (YPAGs) in a systematic manner based on research findings and experiences from existing YPAGs.

What is a YPAG

A Young Persons Advisory Group, or YPAG, is an organization composed of youths actively participating, as partners, to provide counsel to and support various research projects and initiatives. As shown in the United Kingdom, the United States, and Canada, their ability to provide fresh perspectives on a research study have resulted in much valued knowledge and changed attitudes about the involvement of young people. While working to learn more about clinical research, well-prepared youths can help researchers develop research questions, design trials, transfer of knowledge for improved communication with the target population, and brain storm methods for dissemination of findings. Many YPAGs also work on research projects of their own and participate in science conferences where they present their findings and speak to the importance of their YPAG involvement in research!

Menu

Establish a Steering Committee

The establishment of a Steering Committee is the first step towards establishing a supporting network for the YPAG. The Steering Committee can include leading stakeholders of groups most involved in the operations of the YPAG, such as hospitals, heads of PPI teams or leading PPI researchers, leaders of research committees or ethics boards, education department leads, chairs of grants offices, etc. Members of the Steering Committee may be individuals with vested interest outside the project that may help guide the development of the program and help to see it incorporated as a permanent part of the institute.

A Steering Committee will be key in making strategic decisions regarding current operations and future opportunities. All changes and/or issues in the operation of the YPAG will first pass through the Steering Committee. Within the Steering Committee, a leader must still stand to take responsibility as the head or chair of the Steering Committee and the group. He/She will lead the committee in the establishment of the YPAG, systematic decision making processes, and management of staff and stakeholders.

As Steering Committees consist of multi-faceted leaders from a number of different groups, members will represent the views of many different aspects of research and will also be key points of contact to a larger network of stakeholders. This will be of great importance when recruiting projects to be reviewed by the YPAG and in the incorporation of the YPAG as a permanent fixture among researchers.

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