



Well I want help children! (But could they make the table + smaller)



Helping, Curing Children. Clinical Research

WHAT WE THINK!

I don't like the idea of getting pricked on the arm.



Me and MUM AND DAD
Me and the doctor.



Involving children and young people in health research – getting it right

NUFFIELD COUNCIL ON BIOETHICS



helping other people



It could hurt me and there might not be any cure.



People have check ups to see how they have progressed.

Doctors don't understand how children will get frustrated
By changing their ROUTINES!

What's this report about?



Health research with children and young people

This report is about how best to carry out **health research** – research that tries to find better ways of keeping children and young people healthy, as well as looking after them when they are ill or have a disability. There are many different kinds of research that children and young people might be asked to take part in. Some studies involve children who are healthy, and others involve children who have an illness or disability.

Why do research with children and young people?

Researchers can't just carry out this research with adults, because children are different from adults. Their bodies respond to treatments differently because they are still growing. They may also have different opinions about what matters to them.

Does research help children and young people who take part?

Researchers usually have some evidence that what they are doing may help children or young people with a particular condition. However, they need to collect information from lots of people, so they can be sure that they are providing care in the best way. This may or may not help children or young people who take part in the research. However, it

may help other children in the future. Sometimes research may show that the treatment does not work or is not necessary. This information is just as important.

What's the problem?

Adults often worry about the idea of asking children and young people to take part in research. This is because the main aim of research is to find out how to help people in the future, rather than to help the person taking part. Sometimes, research studies may involve burdens or risks.

BURDENS are things about research that people taking part might find unpleasant, or boring.

"Extra visits to a hospital or having to do diary notes because I think I've got a lot going on and I just wouldn't find the time for that as well. Things like blood tests and needles - I'm not scared of them or anything - they just make me uncomfortable. I just wouldn't want these."



Is research important?

If children and young people are not allowed to take part in research, researchers won't be able to find out how to improve their healthcare. It will also be difficult to find out the best ways of helping them to live healthy lives.

If children and young people are given the option of taking part, this will help doctors and other people providing healthcare to give them the most up-to-date care, just as they do for adults. Children and young people told us that they believe research is important, and that they should choose if they want to be involved. Many said they would take part if given the choice, because they wanted to help other children, or thought it might be interesting.

FOR EXAMPLE, RESEARCHERS MIGHT:

- ask children and young people about their daily lives, such as how much they exercise, what they eat, and whether they smoke
- find out how health conditions, such as asthma, affect children's lives
- find out whether a new treatment, such as a new medicine or vaccine, works better for children and young people than existing treatments
- invite children and young people to give their opinions about health services they have used, and how they could be improved

Ethical questions

Because research is important, we need to find ways of making sure children and young people are given the option of taking part in it. We also need to make sure that they are protected from harm. This report looks at ethical ways of involving children and young people in research.

ETHICS is about deciding what is the right thing to do. Often there isn't an easy answer because there are good things and bad things about all the options. Our report suggests **ways of thinking** about how to decide. But it can't give all the answers to every difficult question.



Image from our film of children and young people discussing taking part in research



WE THINK THAT:

- **Good research is well-designed research that asks important questions and is carried out ethically.**
- **Good research with children and young people is essential and must happen.** It should become part of routine care in hospitals and in other places where children are looked after. Researchers shouldn't feel they are doing anything wrong when they ask children and young people to take part in research.
- **Research must be carried out with children and young people, not on them.** If they choose to take part, they must be listened to, and feel that they are actively involved. From a young age, most children want to have a say in how they live their lives. This must apply to research too.

Inviting children and young people to take part in research



Communication and information

Children and young people need clear information about the research before they can decide if they want to take part. Good communication and good relationships with researchers are very important.

"... a researcher who gives you lots of information, gives you constant updates and asks you how you feel frequently, because you might ... not feel confident to bring a point up but if they ask you then you'll feel better talking about something."



Explaining research clearly to children and young people

Researchers need to make sure that they **explain** about the research in a way that is easy to understand – for example with information leaflets, games, videos, social networking sites or apps.

"If they had other ways of going through the research or the process – maybe if it wasn't just verbal, if they had, like, some visual aids maybe or clips. Things like that."



"Just to be quite genuine, and just like, not sticking to a script... just chatting to you nice, not push you into anything, give you all the details. Like I said – don't overwhelm you just when they're coming to you and asking you at first, you don't need everything at that point – but when they start to show interest, just give you all the details, be honest with you, not try to like hide things from you."



Explaining research clearly to parents

Parents need clear information too. It is important that researchers work with parents of younger children to make sure that they are happy with what their child is being told and how it is being done.

"I would decide and explain to my child in a way that would encourage them to see the benefits and take part."



Being able to know what the researchers found out

Children, young people and parents must have the option of finding out about the outcome of the research – what the researchers found out as a result of doing the research and what difference this might make.

"Personally, I like seeing what my efforts have gone and produced, and how the information I give or the time I sort of give to do whatever it is ... it's nice to see that they're bearing fruit, and actually having an outcome."



Consent and assent

The law says that people can only take part in research if they have received enough information about the study, and if they have given their consent. In research with children and young people, it is usually parents or guardians who give consent.

Sometimes, children are also asked to give their assent to research – say that they agree to take part.

i CONSENT IS LEGAL PERMISSION

In England and Wales, the law allows a young person of 16 or 17 to consent to take part in research for themselves. However, parents can also consent for their children until they are aged 18. This means that researchers can ask for consent from either the young person or their parent.

In Scotland, 16 year olds are treated as adults, and their parents can no longer make decisions for them.

i ASSENT AND CONSENT ARE DIFFERENT

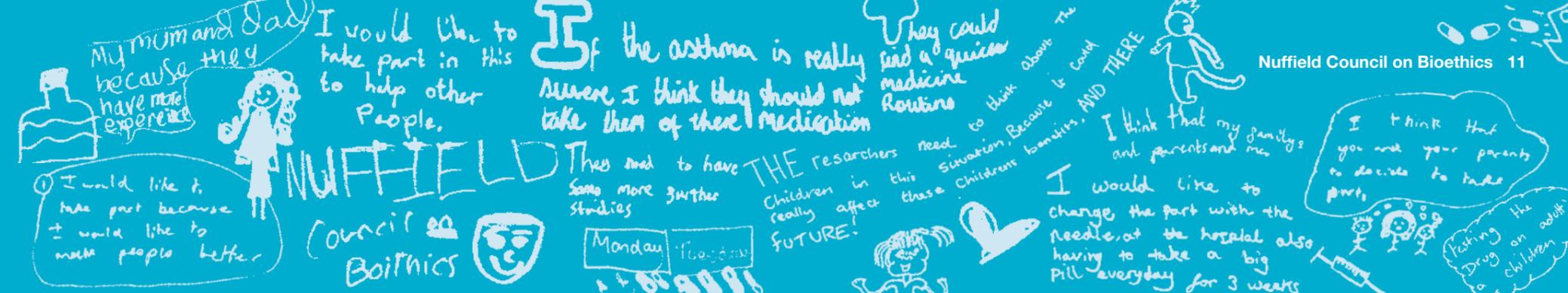
Consent gives researchers legal permission to go ahead. Assent is a way of showing that children and young people have been involved in the decision.

There is some confusion over how, in practice, children should be asked to give their assent:

- Some guidelines say that only children old enough to understand the research should be asked to give their assent.
- Some guidelines say that children should be asked for their assent from the age of three.
- Some guidelines say that children should be asked to sign an assent form to show that they agree.



Making shared decisions about research



WE THINK THAT:

- Wherever possible, a decision about taking part, or not taking part, in research should be a **shared decision** between a child or young person and their parents.

"I think ideally it's important to involve the whole family. A child is part of a family not really just themselves."



What if parents and children disagree about taking part in research?

Researchers should always try to help families come to a shared decision. However, this isn't always possible.

In most cases, if not everyone in the family agrees, then it's best if children or young people don't take part in the study. The law allows research to go ahead with just a parent's consent, even if their child disagrees. However, researchers may decide not to include children in a research study if they don't feel it's right – for example, if a child really doesn't want to take part, and the researcher believes that it would cause more harm than good to continue.

"if a child's, like, four or something – so is quite young – and then the parents want them to do research that maybe they don't want to do, obviously like don't take their first answer, but I don't think you should force them into it."

However, if the research is about the best way to give the treatment that a child is having, then researchers will be more likely to accept the parents' consent. For example, parents might decide that it is right for their young child to take part in research as part of their treatment for cancer, even if their child doesn't really want to.

What if young people don't want to involve their parents?

Sometimes it may be necessary to carry out research with young people without their parents being involved.

"At college we have to do a survey about our lifestyle ... children, well, teens would lie if their parents saw what was happening, if it was 'do you take drugs' or 'do you drink!'."

3 What about children and young people who CAN make their own decision?

WE THINK THAT:

- Children and young people who have the ability to understand information about the research and make a choice for themselves should be asked for their consent, not their assent.

Parents should usually be asked for their consent too, so that the decision is made together, as a family. One way of recording this shared decision could be for children and parents to sign a consent form together.

If the law says that a young person has the right to consent to research (16 in the UK) then, legally, only the young person's consent is needed. However, many young people still prefer to involve their parents, or another trusted person, when they make their decision. Researchers should encourage this.

2 What about children and young people who CAN'T make their own decision?

WE THINK THAT:

- As soon as children are able to express views or wishes about taking part in research (which may be as young as three), they should be **involved** in the decision.
- Some research guidelines say that children should be asked for their assent but there is little agreement on what this means in practice. We believe that assent should mean real involvement in the decision.

Being involved in an important decision is not the same as making the final decision. Some decisions need particular knowledge or experience. It is a parent's job to make the final decision if their child is not yet able to make their own decision without help.

The fact that children and young people have been involved should be recorded in some way but it isn't important how. For example, it could be in writing or drawing, in a voice or video recording, or using an app.

"... but suppose, say, the researcher thought the child maybe was being – not forced into it, but the parents were pushing more for it than the child, and if the researcher thought the child didn't actually want to do it, then at that point they should step in and say, 'if the child isn't completely at ease with doing it, then we'll choose another participant.'"

For research like this, researchers should ask the research ethics committee to agree that parents don't need to be involved. The committee might ask the researchers to discuss their idea first with people in the local area to explain why they believe the research is important. This may help parents to feel things aren't being done behind their backs, even if they don't know whether or not their own child is involved.



Deciding what research happens in the first place



Who gets to decide?

It is important to think about how research studies get the money to go ahead. Who gets to choose these studies, and why? There are lots of different sources of funding, including:

- governments;
- commercial companies, both big and small, that make money out of producing medicines;
- charities that fund many different types of research; and
- charities concerned with children living with a particular health condition.

Some research funders have very clear ideas about the kinds of research they want to fund, and what they think is most important. Others depend more on ideas that researchers come up with. Some research funders involve children, young people and parents by asking them what research they think is most important.

The **EUROPEAN MEDICINES AGENCY** (EMA) has started trying to involve young people in its work. The EMA is in charge of clinical trials of new medicines in Europe.



WE THINK THAT:

- People who choose what research studies to give money to must make sure that children, young people and parents are properly involved in these decisions.
- Government departments of health are in a good position to take the lead when looking at what areas of children's healthcare in their country particularly need research. They, too, must make sure they involve children, young people and parents in these decisions.

THE JAMES LIND ALLIANCE is a group that campaigns for a more systematic way of working out what research is most important. It sets up 'priority setting partnerships' (PSPs) which bring patients with a particular condition, researchers and health professionals together to agree what are the most important areas of research needed for that condition.

Encouraging research into new medicines

Governments can encourage commercial companies to do particular kinds of research by offering them extra rewards, or by making special rules. Many medicines given to children and young people have only been researched in adults. This is now changing. In Europe, the 2006 'Paediatric Regulation' says that when companies carry out clinical trials of new medicines with adults, they must include children and young people in the research, unless they get a waiver to say they don't have to.



WAIVERS IN THE PAEDIATRIC REGULATION 2006

A company may be given a waiver if they are developing a medicine for a condition that doesn't affect children, such as lung cancer. This means they don't have to involve children and young people in the trials. However, sometimes the way the medicine works might still be helpful for different conditions that do affect children and young people.

The Regulation also encourages companies to do research on old medicines – for example making a medicine available as a syrup, instead of a tablet, so it is easier for young children to take.

As a result of the Regulation, it is now much more usual for research into new medicines to include children and young people. This means that there is much better information for doctors on how these medicines will work if children and young people need to take them.

Although the Regulation has been very successful, some changes are still needed. Rewards to encourage research on old medicines haven't worked very well, and there are problems with the way waivers are given.



CLINICAL TRIALS of new medicines look at how well new medicines work, and whether they are better than existing treatments.



Making research easier for everyone



Research needs to become an ordinary part of the National Health Service (NHS) in Britain. It shouldn't be seen as something optional or unimportant. At the moment, it's often hard for people working in the NHS to find the time they need either to do research themselves, or get involved in research ethics committees.

WE THINK THAT:

- NHS managers should encourage worthwhile research in their hospitals and clinics.
- NHS managers, universities, and policy makers should make sure that members of research ethics committees have enough time in their working day to do this important job.



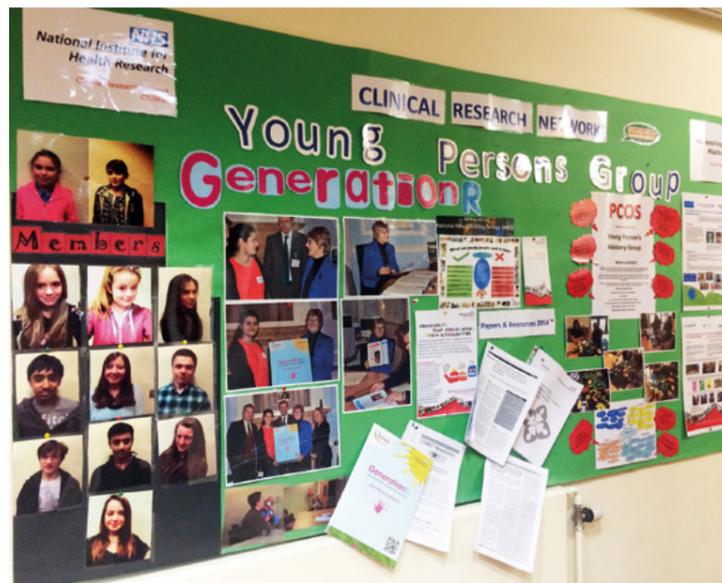
The general public, both adults and children, need to understand more about health research – both about how it's carried out and why it's important. Knowing more about research will make it easier for children, young people, and parents if they are ever invited to take part.

There are many ways in which this can be done – although no single easy way. For example:

- Researchers and research organisations could do more to tell people what they do, through open days, events for children and young people, and well-designed webpages.
- Schools, museums, youth clubs and other groups could offer opportunities to encourage people to learn more about research.

WE THINK THAT:

- The All-Party Parliamentary Group on Medical Research should take the lead in finding the best ways of increasing everyone's knowledge about research.



ALL-PARTY PARLIAMENTARY GROUPS

are groups of Members of Parliament (MPs) who are interested in a particular subject, and who meet regularly with experts in that subject. They look at ways in which laws or policies might change to make things better.

Resources and links

The films, animation, blogs, and articles we have produced are all available on the **Nuffield Council on Bioethics'** website (www.nuffieldbioethics.org/children). The websites and documents mentioned below can all be accessed via our website.

Young persons' groups

The **iCAN network** is a growing consortium of young persons' advisory groups, including groups in the UK, United States, Canada and France. The CRN: Children group in England has produced **GenerationR** magazine, showcasing how children, young people and parents can be involved in the design and delivery of research. They also provide a practical **Guidance document for researchers designing patient information leaflets** giving tips to researchers on presenting information clearly for children and young people.

The **Young Persons' Mental Health Advisory Group (YPMHAG)** gives advice to researchers working on mental health studies.

Resources for young people

Other resources that may be of interest to young people include interviews with young people who have experience of taking part in research, which are available on the website **YouthHealthTalk**. Information about how to get involved in research, and what studies are taking place at the moment is available on the **CRN: Children** website.

Other resources for researchers

The website **YoungHealthParticipation** brings together a range of useful resources on involving children and young people in research.

The National Children's Bureau has also published **Guidelines for Research with Children and Young People**.

Glossary

How words related to health research have been used in this magazine:

Assent

An agreement to do something, and a way of showing that children and young people have been involved in making decisions about taking part in research.

Burdens

Unpleasant or boring things about taking part in research.

Children and young people

Anyone who isn't treated as an adult in the country where they live.

Clinical trials

Research to see how well new medicines work, and whether they are better than medicines that are already used to treat children and young people.

Consent

A legal term for when a person agrees to do something, such as take part in research.

Ethics

Ways of thinking about the right thing to do.

Fair offer

An invitation to take part in health research that children and their parents can trust.

Parents

Anyone who does a parent's job. This might be a guardian or a grandparent who looks after their grandchild full time, as well as children's mums and dads.

Policy-makers

People who decide on the rules, for example about research.

Regulation

The rules on how something should be done (for example, how research should be carried out with children).

Research ethics committee

A group of people who are interested in research, and make decisions about whether inviting children and young people to take part in research is a 'fair offer'.

Vulnerable

Describes a person who is particularly likely to be harmed.

Welfare

Things that are good for a person, such as their wellbeing or happiness. This includes having a chance to learn new things.

Waiver

When a person or organisation is freed from a responsibility to do something.

People we talked to as part of this project



- Young people and parents in our **stakeholder group** who advised on our project
- Children, young people, parents and professionals who replied to our **online consultation**, and commented on drafts
- Children and young people from schools in Brighton (see our **Youth REC film**) and in Wimbledon (see our **blog**)
- Young people, and community representatives in Kilifi, Kenya
- **Members of Young Persons' Advisory Groups (YPAGs) in Liverpool, London, Aberdeen and Connecticut**
- Children and young people who took part in our animation workshop



The quotes in this magazine are all from children, young people and parents who have taken part in this project.

Summary

In this report, we present the following conclusions and recommendations:

Good research is important for children and young people

- Well-designed health research that asks important questions is essential in order to improve children's health and healthcare.
- Research should always be carried out **with** children, not **on** children. If children and young people choose to take part in research, they should be listened to, and feel that they are actively involved.

Different situations for children and parents

- We describe three situations where the questions about how to treat children and young people fairly in research will be quite different:

1. **Children and young people who are unable to say what they think about taking part in research** (for example, very young children, or older children and young people who are too unwell or upset at the time). Parents will usually make decisions based on what they think is best for them.
2. **Children and young people who can say what they think about taking part in research, but can't make a decision without some help.** Parents will think about their child's wishes, as well as what they, as parents, think is best. As children get older, parents will see their job as helping them start to make their own decisions.
3. **Children and young people who can make their own decisions, but aren't yet treated as adults in the country they live in.** Children's and young people's wishes will usually be the most important thing to take into account. Parents are there mainly to support and advise. However, it's still their job to think about their child's welfare.

Making sure children and young people aren't vulnerable

- People often worry that children and young people may be vulnerable in research. The best way of making sure this doesn't happen is for researchers to involve children, young people and parents when they design their studies, and to take their opinions on board.

The job of research ethics committees

- Before researchers are allowed to go ahead with research involving people, they have to get approval from a research ethics committee. This committee should make sure that any invitation to children and young people to take part in research is a **fair offer**: an invitation that children and their parents can trust.

Making decisions about taking part in research

- Children, young people and parents all need clear information about a research study before they are asked to take part. Good communication and good relationships with researchers are very important.
- Wherever possible, a decision about taking part in research should be a **shared decision** between a child or young person and their parents. Young people who are able to make their own decisions should be asked for their own consent.
- Children who can't yet make their own decisions about research should be as **involved** as they want to be. This is what we mean by 'assent'. It's their parents' job to make the final decision.

Deciding what research happens in the first place

- People who choose what research studies to fund must make sure that children, young people and parents are involved in these choices.

Making research easier for everyone

- Good research needs to become an ordinary part of the National Health Service. People running health services should encourage worthwhile research in their hospitals and clinics. Children, young people and adults all need to know more about research. That way, it's much easier for them to decide what to do if they are ever invited to take part in research.





Well I want help children! (But could they make the table + smaller)



Help the children



Helping, Curing Children. Clinical Research

WHAT WE THINK!

I don't like the idea of getting pricked on the arm.



NUFFIELD Council on Bioethics



Me and MUM AND DAD Me and the doctor.

I would like to take part in this to help other people.

THE researchers really affect these children in this future!

need to think about the situation, because it could children's benefits, AND THERE



Testing the drug on adult's children

helping other people

It could hurt me and there might not be any cure.



will get FRUSTRATED

Having a lolly pop makes me feel better!



People have check ups to see how they have progressed.

Doctors don't understand how children will get FRUSTRATED By changing their ROUTINES!