



Ethical issues in large-cohort research

Social relevance and distributed responsibilities

Garrath Williams
Lancaster University, UK

Overview



1. Some concrete ethical issues in IDEFICS and I.Family
2. A wider ethical issue: the search for policy relevance and 'impact'

Some concrete issues



- Many difficulties of ‘informed consent’
 - Complex study – very hard to explain
 - Family involvement
 - Consent has to be broad
- Storing children’s data/samples in long term
- Feedback, requests for genetic information
- Use of incentives for participation
- Sensitive questions – puberty, alcohol, binge-eating...
- Innovative sub-study – fMRI with children

What we are asking you to do

As part of the study, we are asking you to agree to take part in the following:

- A basic medical examination including simple bodily measurements and saliva and urine sampling;
- To take part in a short interview about the medical history of your family and who belongs to your family;
- Fill in a form to tell us what foods and drinks you like;
- Report what you ate and drank on the previous day using a computer program. We will ask you to do this three separate times;
- Questionnaires concerning your diet and family life;
- Do some computer games, such as a card game, to help us understand how you make choices;
- Wear a small device called an accelerometer for several days – this measures how much you move about.
- If you agree, we will take a small amount of blood. If you wish, we will give you back results on your blood lipids, markers of inflammation etc.



What we are asking your children to do

We are also asking you to agree that your child(ren) take part in the following measures:

- A basic medical examination including simple bodily measurements and blood, saliva and urine sampling;
- Wear a small device called an accelerometer for several days – this measures how much your child moves about;
- Fill in a form to tell us what foods and drinks your child likes;
- If your child is 8 or older, we will ask him or her to do some computer games, such as a card game, to help us understand how he/she makes choices;
- If your child is 8 or older, we will ask him or her to report what he or she ate and drank on the previous day using a web-based computer program. We will ask your child to do this three separate times.
- If your child is 12 or older, we will ask him or her to fill in questionnaires concerning his or her diet and lifestyle. These include questions about attitudes to food, body image, puberty, smoking and alcohol, and his or her friendships.

Resolving these issues



- In general, “ethics” does not speak with one voice
 - Need to balance different considerations
 - Appropriate solutions may vary across countries
- Sometimes the law imposes an answer...
 - Though that answer may differ quite starkly!
- Sometimes ethics committees impose an answer...

Neural correlates of healthy food viewing and food choice in tweens and their parents

I hereby confirm that I have read the information letter for participants <version-date>. I have had the opportunity to ask additional questions. These questions have been answered adequately. I have had enough time to think about participation.

I know that my participation is fully voluntary, and that I can withdraw my consent at any time, without having to give a reason.

I consent to be informed of chance findings that require medical intervention and I consent that in this case my general practitioner is notified.

I consent that my research data will be processed in the way described in the information letter.

I consent that my research data will be kept 15 years after the research.

I consent that my research data will be linked to my research data from the IDEFICS and I.Family studies.

I consent that my research data can be used for further analysis.

I would like to be informed of the results of this study on a group level [yes/no]

I consent to participation in the above mentioned study

.....

A wider ethical question

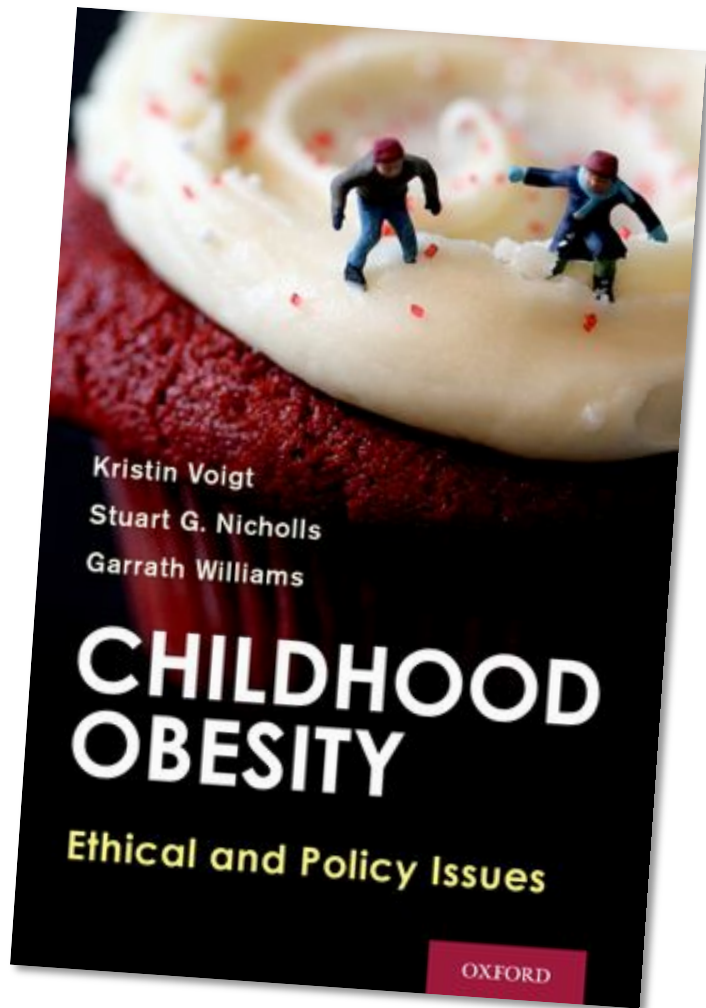


- Research ethics tends to emphasise consent and REC procedure
 - But many recent critiques of this narrow focus – e.g. problems of waste and distortion in research, questions about research priorities
 - We are asking *a lot* of our participants – but to what end?
- The imperative to generate positive impact
 - “What do your study results tell us to do?”
 - A fair question – but naïve!

Problems for policy impact



- Two sorts of complexity that block the challenge, “Tell us what to do!”
 1. Scientific complexity
 - We can only contribute to an emerging picture, not deliver unambiguous/incontestable results!
 - Unclear what social/economic changes would lead to changes in diet, activity, behaviour etc
 2. Complexity of policy making
 - Who will listen?
 - Who has the power to make changes?



Our approach



- Even for clearest evidence, need complex coordination to create social change
- Why?
 - Many actors with many existing priorities, roles and responsibilities
 - Our priority – health – is never the whole story for them
 - Rarely obvious who should do what – or what costs/side-effects would be

So what can/should we contribute?



- We can explore different options for action – for individuals, parents, policy-makers
 - Highlight possible benefits, costs and risks
 - Look for ‘synergies’ with existing responsibilities & other priorities → minimise costs & risks
- Look for better ways to communicate with different stakeholders
- But stay modest – room for different opinions & need for debate
 - Social/policy responses are a shared responsibility – and so is deciding what these should be



In sum



- Many detailed ethical issues for a study like ours
 - Not always clear or indisputable answers
- Important questions about benefits and impact
 - However good our data and solid our findings, no clear or indisputable implications either!

Thank you



- To my collaborators within the I.Family and IDEFICS projects
- Especially to Stuart Nicholls and Kristin Voigt
 - In IDEFICS, we gratefully acknowledge the financial support of the European Community within the Sixth RTD Framework Programme, Contract No. 016181 (FOOD) - <http://www.idefics.eu>
 - In I.Family, we gratefully acknowledge the financial support of the European Community within the Seventh RTD Framework Programme Contract No. 266044 - <http://www.ifamilystudy.eu>

