NUFFIELD COUNCIL ON BIOETHICS

Response to Draft Canadian Institutes of Health Research Ethics Guidance for Developing Research Partnerships with Patients

January 2019

Introduction

1 The Nuffield Council on Bioethics is a UK-based, independent organisation that examines and reports on ethical issues arising from developments in biological and medical research that concern the public interest. We provide independent advice to policymakers.

2 In our response to the draft guidance, we would like to highlight some key conclusions and recommendations of two Nuffield Council reports that are relevant to the issues discussed in the guidance: *Children and clinical research: ethical issues*[1] and *The collection, linking and use of data in biomedical research and health care: ethical issues*[2] *(both published in 2015)*.

3 We welcome the approach taken in this guidance of developing research partnerships, and seeing the value of collaboration in research. Indeed, a central concept in our *Children and clinical research: ethical issues* report is the idea that children who take part in research should be seen as *active participants* in research and should be involved as far as possible through all stages of research including prioritisation, design, planning and review. The importance of involving children and young people in the decisions and policies that affect their lives was a central theme and an integral part of the ethics framework in this report.

Key points

4 When we published our report in 2015, we were aware that its recommendations represented a significant shift in the current research practice, so we set out additional guidance for researchers and those responsible for the scrutiny of research. The following prompts[3] are designed to assist in the development of any research involving children and young people, but the principles could also apply more widely to all participants in medical research, so will be important to consider in the CIHR guidance:

[1] Nuffield Council on Bioethics (2015) '*Children and clinical research: ethical issues'* available at www.nuffieldbioethics.org/project/children-research

[2] Nuffield Council on Bioethics (2015) '*The collection, linking and use of biomedical research and heath care: ethical issues'* available at www.nuffieldbioethics.org/biodata

[3] Summary of report Children and clinical research: ethical issues available at www.nuffieldbioethics.org/wp-content/uploads/Children-and-clinical-research-key-recommendations.pdf

- Have you involved children, young people and parents in the development of your study?
    - in the design of the study itself? (e.g. the number of appointments or interventions required)
    - in the development of easy-to-understand information about the study?
- Does your study represent a fair offer to prospective participants?
    - Are you confident that the value of the study, and its likely risks, burdens and benefits, have been carefully weighed up from the perspective of potential participants?
- Have children, young people and parents been involved in identifying possible benefits, risks and burdens?
- Are you able to demonstrate how you will communicate, and discuss, information about the study appropriately and sensitively with potential participants and their parents, so that they are able to make free and informed choices about whether to take part?
- Does everyone in your team who will be interacting with participants have the necessary communication skills?
- Are the particular methods you have chosen for involving children and young people in decisions about taking part the most appropriate ones?
- Decisions about research participation should, wherever possible, represent a shared decision between parents and children/young people. How will you encourage shared decision-making?
- Will clinicians be responsible for recruiting children and young people, for whom they are providing care, to take part in research? If so, is this the most appropriate approach? Have you considered alternative approaches?
- Does the information provided for children, young people and parents explain how and when they can find out about the outcomes of the research? Will those outcomes also be explained in accessible language?

Data collection, analysis and interpretation

5 The responsible use of research data to improve well-being through improved health advice, treatment and care is to be welcomed. However, it must be clear to all participants in research that their data is protected by measures which manage threats to welfare and prevent possible harms to individuals, groups or the wider public caused by failure to use data appropriately or by misuse of data.

6 In our report *The collection, linking and use of data in biomedical research and health care: ethical issues* we recommend that the use of data in biomedical research and health care should be in accordance with a publicly statable (capable of being articulated in a way that is meaningful, and understandable to those with interests at stake) set of morally reasonable expectations and subject to appropriate governance. We set out four principles for data initiatives (i.e. data-driven research using biological or health data):

- **Respect for persons:** the terms of any data initiative must take into account both private and public interests. Enabling those with relevant interests to have

a say in how their data are used and telling them how they are, in fact, used is a way in which data initiatives can demonstrate respect for persons.

- **Respect for human rights:** the terms of any data initiative should respect people's basic rights, such as the right to protection of private or family life. This includes limitations on the power of states and others to interfere with the privacy of individual citizens in the public interest.

- **Participation:** decision makers should not merely imagine how people ought to expect their data to be used, but should take steps to discover how people do, in fact, expect their data to be used, and engage with those expectations.

- **Accounting for decisions:** data initiatives should include formal accountability, through regulatory, judicial and political procedures, as well as social accountability through periodic engagement with a broader public, as a way of re-calibrating expectations. Data initiatives must tell affected people what will be done with their data, and must report what actually has been done, including clear reports of any security breaches or other departures from the established policy.

10 Further explanation of these principles, and examples of good practice relevant to data initiatives, can be found in Chapters 5 and 6 of our report[4].

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[4] Chapters 5 and 6. Nuffield Council on Bioethics (2015) '*The collection, linking and use of biomedical research and heath care: ethical issues'* available at www.nuffieldbioethics.org/biodata