

Introduction

The Council's terms of reference charge it, among other things, 'to identify and define ethical questions raised by recent advances in biological and medical research.' The developments with which this report is concerned are not peculiar to biomedicine although their impact on biomedicine raises significant and distinctive issues. The relevant 'recent advances' that the Working Party is responding to are principally two, and they are closely linked:

- first, the unprecedented quantity and variety of data collected through technologies of biological measurement (e.g. genomic and imaging data) and the accumulation of these stored data (e.g. medical records, biobanks), increasingly in machine readable formats;
- second, the development of more powerful ways of transferring, linking and manipulating data afforded by information technologies, and of analysing these data afforded by data science.

The report contains 17 propositions relating to these developments, four principles for ethical governance of data initiatives, and 17 specific recommendations for action. It has a broadly tripartite structure. The first part is largely descriptive: it describes some of the relevant advances in data collection and use, and the conditions and influences that are pushing it in particular directions. It describes the limitations of existing security, legal and governance measures that have been applied to the new uses of data and the challenges that therefore arise. The middle part explores the nature of the morally relevant values and interests at stake in data initiatives and develops a way of understanding data initiatives as social practices. Through a consideration of how the values are incorporated through the social processes involved in their formation and governance, it proposes a way of securing morally desirable outcomes. In the light of this, the third part of the report draws examples of good practice and identifies areas for improvement in selected data initiatives taking shape in health care and institutional research contexts. The intention is that, in addition to making specific recommendations, the report will provide an enduring resource and a support for constructive engagement with questions about the ethical use of data in health care and biomedical research.