An overview of Procardis ethics activities

Background
The Procardis team recognised at an early stage that the translation of genomic research into practice had the potential to present a number of ethical and social challenges not previously encountered in combination. It was clear that, in addition to their intrinsic importance, if not sensitively and appropriately addressed such issues would have the potential to become significant roadblocks to the successful completion of the research and its translation into practice. If these issues were to be addressed and high ethical standards attained, ethical issues needed to be identified and analysed, and the lessons learnt from these analyses must come to inform research and clinical practice. For these reasons, an ethics team, based at the Ethox Centre in Oxford, was established to help the Procardis team to identify and work through these practical ethical issues as they arose in the carrying out of the research and its translation.

Aims
Against this background, the aims of the Procardis ethics team were to:

- Provide on-going ethics advice and training to the Procardis project partners
- Carry out research on the ethical and social implications of genomics
- Disseminate the findings of the ethics research and other ethics activities within the Procardis network and to the wider scientific and policy community

Staffing
The Procardis ethics activities were carried out by Dr Paula Boddington (funded by the Procardis project from October 2007 – September 2010) and Professor Michael Parker (funded by the Ethox Centre, University of Oxford).

Ethics activities

(i) Ethics advice, support and training workshops
Throughout the Procardis project the ethics team has provided ethics support and advice to individual Procardis partners and to the Procardis team as a whole. This has taken the form of: input at Procardis network management meetings, ad hoc advice and support on request from individual researchers, and practical ethics workshops at partner institutions addressing ethical issues raised by the Procardis scientific and clinical team.

During the course of the Procardis project, the ethics team ran the following ethics workshops and open symposia:

- Oxford (April 2007) – ethics workshop
- Karolinska Institute, Stockholm (February 2008) – ethics workshop
- Karolinska Institute, Stockholm (February 2008) – open symposium
- Mario Negri Institute, Milan (March 2008) – open symposium
- Mario Negri Institute, Milan (March 2008) – ethics workshop
- Karolinska Institute, Stockholm (April 2008) – ethics presentation and discussion for Procardis partners
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Oxford (September 2010) – ethics workshop on ethical issues in data-sharing in genomics for Procardis partners

These workshops and open symposia were open to all members of Procardis as well as to local researchers. Reports of each of these workshops and of the key themes discussed at them were published on the Procardis website and also used to inform the subsequent ethics research activities (See below).

In addition to these workshop activities, Dr Paula Boddington provided individual training and mentorship to a number of Procardis scientists with an interest in developing their understanding of research ethics.

(ii) Research on the ethical and social implications of genomics

The ethics research activities in Procardis took the form of three ‘phases’. In the first phase of the project, through a series of workshops (listed above) and discussions at network meetings, the ethics team worked with Procardis network members to identify the key ethical issues they encounter or expect to encounter in their day-to-day practice as researchers and the challenges they expect to arise in the translation of their research into clinical practice. This work was complemented by a review of the relevant literature on the ethical and social implications of cardiovascular genetics and of the relevant national and international guidelines and legislation. In the second phase, on the basis of these ethics workshops and discussions, and informed by the literature review, a number of important ethical issues and key themes were identified. A discussion document on these themes was produced and circulated to the Procardis teams for critical review and comment. In the third phase, following agreement of these reports, a decision was made to focus the research activities of the ethics team on three key ethical issues identified as a priority by the partners. These issues were: informed consent in the context of genomics, the roles and responsibilities of researchers in translational genomics, and the translation of research into practice. The findings of this research are reported in the peer-reviewed publications listed below.

(iii) Dissemination

The dissemination activities of the Procardis ethics team took a number of different forms. These included: publication of regular ethics newsletters; publication of reports on ethics workshops and symposia; and international conference; and publications in peer-reviewed academic journals.

Newsletters reporting on the activities of the ethics team, and developments in guidelines and policy relevant to the Procardis activities were published regularly throughout the life of the Procardis project. The newsletters, which were edited by Dr Paula Boddington, were published on the Procardis website both for Procardis partners and for the wider public. Copies of the newsletters were also sent to a large number of relevant bodies and individuals across the member states of the European Union. In addition to the newsletters, reports on individual Procardis ethics workshops were also published on the Procardis website.

In September 2010 a major international conference on the ethics and governance issues arising in genomics research was held in Oxford. This conference was organised by the HeLEX Centre in Oxford, but with significant input from the Procardis ethics team both to the main conference itself and the organisation of a complementary Procardis satellite meeting. The conference was very successful, attracting 151 delegates from 20 countries.
In addition to their function as training and ethics support events, the open ethics symposia held at partner sites (listed above) were also valuable dissemination events drawing a significant audience on each occasion and raising the profile of the Procardis project with a wider constituency.

Finally, the research activities of the Procardis ethics team have led to a significant number of publications – in peer-reviewed academic journals, book chapters, and books. These publications, in date order, are as follows:


Boddington, P (2009). The ethics and regulation of direct-to-consumer testing Genome Medicine, 1(7):71

Hawkins, N, de Vries, J, Boddington, P, Kaye, J, and Heeney, C (2009). Planning for translational research in genomics Genome Medicine, 1(9): 87


Boddington, P (2010) Relative responsibilities: is there an obligation to discuss genomic research participation with family members? Public Health Genomics 13: 504-513


Boddington, P (2011) Ethical challenges in genomics research Springer in press