

## Meeting report series

# Report of the 1<sup>st</sup> ISC WG Ethics and Governance teleconference

June 27, 2013

### Organization

Organized by: IRDiRC Scientific Secretariat  
Teleconference

### Participants

Prof Bartha Maria Knoppers, Montreal, Canada, co-chair  
Prof Jack Goldblatt, Perth, Australia, co-chair  
Prof Nils Hoppe, Hanover, Germany  
Dr Tsveta Schyns, Austria  
Dr David Townsend, Maastricht, the Netherlands  
Dr Christian Viertler, Graz, Austria  
Dr Simon Woods, Newcastle, UK  
Mrs Minh Thu Nguyen, Montreal, Canada  
Dr Peter Abuja, Graz, Austria

Dr Barbara Cagniard, Scientific Secretariat  
Ms Roseline Favresse, Scientific Secretariat  
Dr Sophie Höhn, Scientific Secretariat

### Apologies

Ms Megan Fookes, Sydney, Australia  
Prof Ingrid Holm, Boston, USA  
Prof Matthias Kretzler, Ann Arbor, USA  
Mrs Marie-Christine Ouillade, Paris, France  
Kurt Zatloukal, Graz, Austria

## REPORT

### Scientific Secretariat and mandate of the Working Groups

Following the welcome of the participants by the chair of the WG, the Scientific Secretariat was briefly introduced. The Scientific Secretariat is located in Paris and composed of four full time employees (project manager, communication manager, research scientist and assistant). Employees from Orphanet and the Fondation maladies rares (Rare disease foundation) also provide support in kind. The role of the Scientific Secretariat is to bring organizational support to IRDiRC Executive Committee, Scientific Committees and Working Groups by, among others, helping organizing meetings and teleconferences, writing the report of these meetings/teleconferences, and prepare any necessary documents upon request.

The mandate of the WG was briefly presented. WG will work through teleconference. The WG Ethics and Governance reports to the Interdisciplinary Scientific Committee, chaired by Hanns Lochmuller from Newcastle. There are three other WG reporting to this Scientific Committee (Biobanks; Data Sharing and Bioinformatics; Registries and Natural History).

### Issues and concerns for discussion

Each participant briefly introduced themselves and presented the topics they suggest the WG can work on.

#### Paediatric issues:

- ▶ Incidental findings: guidelines or policies would be necessary for clinical reporting on incidental findings.
- ▶ Whole Genome/Exome Sequencing (WG/ES) in children: WG/ES is certainly going to be increasingly used in children with developmental or other conditions at birth with no firm diagnosis.
- ▶ Participation of children in research.

#### Data sharing

- ▶ Attribution of scientific input (authorship) for data sharing and sample sharing: in order to promote data sharing and sample sharing, an authorship policy is needed. Indeed, authorship is a concern for researchers, particularly if there is the possibility that other researchers used their shared data or samples. Furthermore, equitable access is linked to results sharing.
- ▶ New EU regulations about data protection.
- ▶ Problem of patient confidentiality.
- ▶ Problem of access to databanks: standards for agreement are necessary.
- ▶ Development of new platform for data sharing will encounter issues under the WG scope (RD-Connect for example).

The creation of Global Alliance was mentioned. The purpose of this initiative, which gathered over 80 signatories in 43 countries, is to create a common system to share clinical data and genomic data. Global Alliance was officially launched in May and, for the moment, the signatories only provided a letter of intent.

### **Other issues**

- ▶ Patient registries without an oversight committee do not seem to work well. Several governance issues arise (ownership of data, best use of data, future use of tissues without consent, etc...).
- ▶ Next Generation Sequencing: there is a need for proper clinical reporting. Policy work on this topic is on-going. This may not be a specific issue for rare diseases and there may be commonality with other diseases such as cancer.
- ▶ Need of harmonization of international ethics.

### **Main deliverables**

- ▶ Collect short bio of all WG members
- ▶ Contact members unable to attend the teleconference to inquire about other issues they want the WG to discuss in September
- ▶ Diffuse the P3G statement on incidental findings in paediatrics
- ▶ Inquire other consortia/alliance to check how they deal with attribution of scientific input and equitable distribution for samples and data sharing
- ▶ Provide an update on Global Alliance and European data directive for September
- ▶ Find another teleconference provider
- ▶ Check existing IRDiRC policies and guidelines for authorship and IP
- ▶ Send a doodle to plan the next teleconference to be held the last week of August or first week of September