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INTERNATIONAL RARE DISEASES RESEARCH CONSORTIUM

**Meeting report series**

# Report of the 1st ISC Working Group on Biobanks teleconference

July 16, 2013

## Organization

Organized by: IRDiRC Scientific Secretariat
Teleconference

## Participants

Dr Alastair Kent, London, UK, chair
Dr Veronika Karcagi, Budapest, Hungaria
Dr Marina Mora, Milano, Italy
Dr Emmanuelle Rial-Sebbag, Toulouse, France
Dr Susan Wallace, Leicester, UK
Dr Nikolajs Zeps, Crawley, Australia

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

## Apologies

Pr Mats Hansson, Uppsala, Sweden
Pr Jan-Eric Litton, Karolinska, Sweden
Dr Yaffa Rubinstein, Bethesda, USA

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# REPORT

## Introduction of the Scientific Secretariat

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 French Foundation for Rare Diseases 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.

## Introduction of the Working Group

The Working Group on Biobanks was then introduced emphasizing that it would be helpful to agree on the principles of the preparatory document, and that it would be important to try to create a framework for harmonization, interoperability and open access to biobanks. This working group should aim to be practical in its approach by identifying achievable goals, especially by taking the various national laws into consideration.

## Practical academic scientific issues and concerns for discussion

The working group started by discussing the action plan document.

**Promote a single set of standards for collecting, storing, annotating and communicating data:**

- Is it a good idea?
- Is it feasible given the diversity of samples that might be collected by biobanks and the data that might need to be reliably associated with them?
- How might the WG set up a framework that would determine what those standards might be and how they might be put into place?

Other existing groups, for example the International Society for Biological and Environmental Repositories, or the OECD (Organisation for Economic Co-operation and Development), that belong or do not belong to BBMRI (Biobanking and Biomolecular Resources Research Infrastructure), have produced standards.

Following that discussion, the WG established a list of 8 issues they should work on.

**1. Identify the unique challenges in rare disease research**

- Identify what is unique about rare diseases that deviate significantly from the existing standards that would need to be addressed
- Identify what is particular about collecting samples and data for rare diseases
- Encourage some areas more than others to share data because of the small amount of data in some cases

**2. Think about the analysis that might be undertaken, making sure that the samples are fit-per-purpose**

**3. Issues of quality-checking, certification/accreditation and voluntary inherence**

- Propose rules for self-assessment (first step)
- Propose certification in order to check quality standards based on existing tools of development of international modules online web access (second step):
    - The concept of risk (Luxembourg)
    - International standard toward certification (Switzerland)
    - Canadian tissue research network (Canada)
- Propose accreditation (third step)

Not all participating countries might be ready yet to belong to an accreditation system. It is an important aspiration, but it requires to first layout a pathway.
BBMRi could help establishing which criteria the WG could use to create a certification for all biobanks of all nations.

**4. Issues of transport of loads, samples and data between collections and countries**

- To what extent harmonization between countries allows transport of loads?
    - Make a policy on material transfer agreements
    - Emphasize sharing of data and samples

The transport of loads of specimens or data is different. In Europe, transport of loads is supposed to have a harmonized legal framework for exchanging data, but this is not really the case. This legislation is currently under revision, which will be very important for future international collaboration.
The question of sharing is a key point in the rare disease area.

**5. Special issues around children and pediatric research**

- Ethical and legal issues
    - Different attitudes exist in different countries
- Problem of the transition to adult re-consent

Many of rare diseases are diseases of children. An appropriate framework is required for allowing ethical research on children and finding a cure to diseases. Samples from children pose particular issues, especially when it comes to lethal diseases or when children become adults.

*Note post-teleconference: The ISC has a WG on Ethics and Governance that is going to work on pediatrics issues and with which biobanks-related pediatrics issues can be discussed.*

**6. Issues of historical collections of samples**

- Potential value
- Issues around consent
- Issues on what was collected, under what condition it has been stored and how useful it might be
- Biobanks WG should create a framework to see the value of historical collections
- Biobanks WG could suggest to pass public historical collections to biobanks

**7. Issues on return of information**

- Clear rules in term of individual results
- Problem of therapeutic misconception

**8. Issues of the ownership of the samples**

- Define the boundaries in term of the relationship between ownership and gift
- Jurisdiction terms

## 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
- Supply provisions as an example of collection of resources
- Provide examples of international standards and tools accessible online and compare them to see to what extent they are compatible
- Collect examples of how BBMRI could help establishing which are the criteria used for certification
- Provide templates for material transfer agreements between nations
- Send references on material transfer agreements between nations
- Send information on P3G, a pediatric platform that is looking a lot of the ethical issues in children and pediatric research
- Send a doodle to plan the next teleconference to be held in three or four months