Exploratory Workshop Scheme

Scientific Review Group for the Bio-Medical Sciences

ESF Exploratory Workshop on

Use of non-anonymized human genome sequence in research: Science and policy

Heidelberg (Germany), 10-11 December 2014

Convened by:
Michele S. Garfinkel

SCIENTIFIC REPORT

1. Executive summary

The workshop *Use of non-anonymized human genome sequence in research: Science and policy* took place in the main conference room of the EMBO building in Heidelberg, Germany, from 10-11 December 2014. With its long history of support of molecular biology, and co-located with the European Molecular Biology Laboratory, the site is of historical importance and is as well forward-looking with respect to the type of work supporting advances in understanding the human genome.

Fourteen external participants from twelve countries participated in the workshop; the ESF observer was Dr. Martin Röllinghoff. In addition to the convenor the group included a local organizer. The conference room was set up very comfortably with a steady supply of food and drink and easy access to facilities for printing, telephones, etc. Additional coffe breaks and lunches in the canteen facilitated informal interactions between the participants. The group was very dynamic and enthusiastic about the topic. Everyone participated actively in the discussions and at the same time all were respectful of dissenting views.

The aim of the workshop was to evaluate the current state of knowledge and to identify research and governance needs with respect to both the science and policy of the use of human genome sequences that have been by design made identifiable for research or other purposes. This is an important emerging issue and the intent was to produce information and material relevant for decisionmakers in government, academia, private industry, and elsewhere.

The first day focused on introducing both scientific concepts and concerns about governance, particularly with respect to individual patients or participants in clinical research protocols where the genome sequence of those individuals would be made available to others beside the investigator. This could be an issue of having the genomes available to other researchers, but it could as well be that such genomes are made generally public, as in several ongoing genome sequencing projects such as the Personal Genome Project.

The second day was devoted to issues of governance with respect to not only individual patients or research participants, but to communities as a whole. The discussions on this day generally focused on the sometimes fuzzy concepts of “the right to know” as opposed to a “right not to know”, and included formal talks looking at those concepts from the viewpoint of the scientists doing the work who, for example, might want to share information but may not be able to under the terms of the research consent; and from the view of stakeholders. The stakeholder views were presented both in terms of formal analysis, where diverse stakeholders were asked their views on sharing information, and as well from the view of patients: that is, from the vantage of individual patients but also their representative organizations.

Key findings:

Technologies for sequencing human genomes, for extracting and storing data, and for analysing those data are changing rapidly. This is both a cause and an effect of a move toward individualizing uses of human genomes, and toward greater (but not absolute) openness of knowledge and information derived from genome analyses. How to optimize all of those factors to advance science, health, and knowledge while respecting evolving views about privacy or anonymity remains to be more fully analysed.

The full scope of communities with interests in governance issues for the use of non-anonymized human genome sequence is just beginning to be understood, and identifying all stakeholders and having them fully involved in policy processes will require trust between all parties and involvement of everyone from individuals to governments.

A number of policy gaps and research needs were identified by the group. These fell into three overlapping categories: how best to promote and assure trust among stakeholders, determining the occasions in which keeping genomic data inaccessible would still be a priority, and how to make this field of work and its results as open as possible while still protecting participants from potential bad actors. These gaps are detailed in the Assessment below.

2. Scientific content of the event

The workshop *Use of non-anonymized human genome sequence in research: Science and policy* comprised five talks and two commentaries. These talks included views of basic science, clinical research, and policy and ethics concerns.

Concerns about protection of participants in research protocols that result in the production of identifiable data are among the major obstacles in moving from knowledge about human genome sequences to applications including medicines. One implication of these concerns is that as scientists develop technologies both for faster sequencing and better analysis, they should also develop better ways to keep the data from being widely distributed with identification. This is one approach to dealing with the complicated set of ethical, economic, and value judgments about the ready availability of identifiable human DNA sequences.

At the same time, however, the scientific values underlying this research demand completeness of the scientific record, reproducibility of research, and search for the truth. One pervasive argument is that the science will not be useful in progressing to applications such as personalized medicine if the full set of phenotypes (the set of metadata) does not accompany the sequence data.

In this workshop, we took on the question of what it would mean for individual human DNA sequences in research protocols to be fully open and accessible, with attached phenotypic data. There are already some examples of this openness but we will consider what will happen in the event that researchers would eventually want access to hundreds of thousands or even millions of genomes, and what others outside of the research and patient communities might want to do with those data.

The workshop was framed by focusing on the following questions:

1) As research communities, are we at the end of useful data that can be extracted from anonymized genomes?
2) What does the consent process look like for making genome sequence publicly available? Can exceptions be made in protocols that call for unfettered public access to data if the participant does not want specific sequences made public?
3) How much interpretation of data do researchers owe to research participants?
4) How do these changes affect the way that research is done? What becomes easier and what becomes more difficult?

An important feature of the workshop was the mix of disciplines represented by the participants. A large part of the workshop time was devoted to discussions between the participants that encouraged the elicitation of new ideas. Structured questioning was used in some portions of the discussions to draw out specific knowledge, and to prompt exchanges between participants from different disciplines.

One theme that we took on directly as a question at the workshop but as well emerged in many of the discussions was about the rate of change of the technologies, and of people's feelings about privacy and anonymization of their data. Thus, this report captures views of a particular expert group at a specific time, and we would hope to keep the information updated as a service to all of the communities concerned with and/or excited by the changes that human genome sequencing may precipitate.

Jan Korbel, EMBL

Dr. Korbel started the workshop with an overview of using genetics to understand disease and disease mechanisms, with some detail about his own experiences in clinically-relevant research. Along with colleagues at the DKFZ (German Cancer Research Center), he studies childhood brain tumours, the most common cause of death in children worldwide after car accidents. He and his colleagues had identified rearrangement events confined to individual chromosomes, now known as *chromothripsis*, to indicate the explosive or shattering nature of molecular reordering. Chromothripsis in brain tumour medulloblastoma is linked with hereditary mutations in the *TP53* gene (known from its role in Li-Fraumeni syndrome). Thus, by identifying a patient, others in the family may be identified as *TP53* mutation carriers, or potential cancer patients, as well, and may benefit from this information since tumour surveillance in individuals with Li-Fraumeni syndrome is associated with a survival benefit. How the Korbel group should deal with this has never been made fully clear: in Germany, it could be considered a crime to not pass on information to a person who may benefit from it, in particular in cases where individuals are at an appreciable risk of death, or of developing a deadly condition if not receiving the medically relevant information. But sometimes patients (or their parents) indicate during patient consent that they do not wish to receive such information based on genetic findings. Korbel and colleagues did discuss these findings with the medical doctors in charge, and eventually decided to return this genetic information to the doctor, rather than to the research subject, or that child's parents. Korbel worked with the German ethics group EURAT to describe better for the future how consenting processes and return of information may be pursued. Human beings may become the best genotyped/phenotyped organism in biology. As both cause and effect, there will soon be much more identifiable data about human genome sequences than for any other biological organism. This will also require changes in thinking about "protection" of subjects and scientists; and in the way data are stored.

Discussion:

The direct point of the discussion was about how a researcher might or might not benefit from the availability of large numbers of identifiable human genome sequences, irrespective of whether those sequences were available to individuals outside of the study. For the moment, there does not seem to be any special benefit in having those sequences available outside of the laboratory or clinical setting, but the value of having phenotypic data along

with genotypic data, in such a way that the subject may be identifiable, is becoming clearer. Several participants emphasized that while we are discussing identifiability in this workshop, we should not necessarily assume that loss of anonymity for research subjects is a given. Others emphasized that what we are discussing (and that Dr. Korbel was essentially discussing in his talk) is about protecting research subjects, but that there are many ways to possibly do that, not just by making the individuals anonymous to researchers (or to the public).

Misha Angrist, Duke University

Dr. Angrist discussed the issue from the perspective of a sharing economy, or more to the point currently, the un-sharing economy. He emphasized first that “privacy” is a presumption of being anonymous or otherwise unidentifiable. But is that something that is useful or desirable in absolute terms? He compared the situation to another area where we have lost presumptions of privacy, specifically in the consumer sector as structured by online information providers or vendors. In those cases, we give up some privacy in return for something else: generally information, but sometimes actual goods. In the health research sector, we may give up privacy (at least within a research protocol) and get nothing in return. He gave a specific example of the Million Veteran Program in the United States: when surveyed by the Veterans Health Administration, most veterans said they would want health information returned to them (including genomic data), but they have been denied these results anyway. Angrist pointed out that in some cases, even the relationship between the patient and their own doctors may be fettered by consent processes.

In addition to Dr. Angrist’s talks, we were able to have **Christoph Bock** from the CeMM in Austria and **Effy Vayena** from the University of Zurich provide commentaries. Dr. Bock added a medical genomics view, and he introduced the "genetics clinics of the future" project, a new Coordination and Support Action funded by the European Commission. Furthermore, he briefly presented the "Genom Austria" project, which is the Austrian member of the International Network of Personal Genome Projects. Genom Austria aims to stimulate discussion about the future of genomics in a broad societal context, and it provides a handful of volunteers with the opportunity to get their genome sequenced, interpreted, and donated to the public domain (i.e., freely shared on the Internet).

Dr. Vayena added that we should think about the many possible models for the collecting and sharing of information: we frequently think in terms of the clinic, but the growing trend is outside the clinic (for example commercial sequencing and diagnostic companies). She noted that especially from legal perspectives, we may assume that by saying that no one will have a guarantee of anonymity or privacy that the problem is solved. Being transparent about privacy limitations is laudable, but it does not address the problem of limited privacy. What other values should the policy community be thinking about?

Discussion:

This session uncovered a number of concerns that would benefit from additional analyses and from larger conferences including more stakeholders. As well, there were some points where it would seem that at least in some places, policy decisions could be at least initially discussed by decisionmakers.

First, identifying the full set of stakeholders is a task in itself. Even for those that might agree that the “owner” of the genome is the major stakeholder, identifying ownership in this case may not be so straightforward, and does not exlude the importance of other stakeholders’ views.

Next, there was an interesting discussion about what “misuse” of a publicly-available resource means. This is an area that needs more analysis, but in brief, the concerns were, first, how would misuse be identified in the first instance, how would this be punished, and are there misuses that we simply would not have the means to punish?

Another interesting discussion noted that the information from the genome sequence of an individual contains both health-related and non-health related information. Further, with the type of clinical research that people would like to carry out that includes significant amounts of phenotypic and other metadata, there will be health information easily derived from non-sequence information. The implications of these combinations have not been played out, and there was some circling back to older arguments about “being anonymous” as opposed to “being protected from misuse”. For example, people seem to enjoy sharing some wellness information publicly (for example, exercise sites where “today I biked 50 km” will be posted next to your name, and other health information). When such information is brought into a research or clinical setting, does the nature of it change?

Finally, there was a useful discussion about fairness, sharing, maximizing outcome, and being careful about treating genome data as being unique. The group wanted to push on issues about community and what we gain from knowledge about each other, and how far that goes before it starts damaging individuals. But this may be true of many types of data, not just genome data, and as a research or policy community we would want to be careful about knowing where that line is.

Anne Cambon-Thomsen, University Toulouse III

Dr. Cambon-Thomsen started by noting that the underlying problem that precipitates concerns about uses of human genome sequence and whether people are identifiable within or outside clinical work is that there has been a blurring of the limits between clinical work and basic explorations of the genome; medicine and research; health and non-health related information, clinical utility and personal utility (e.g., curiosity), and the nature of database driven research. She presented ideas derived from her own work, including the analysis done in her team of stakeholder views. In brief, she pointed to a need to construct a continuum of types of “privacy” or “knowing”, those rights may vary depending on what type of information is being looked at. Older concerns about privacy (documented uncertainties, best interests of the patient or research subject, own interests v. family interests) are all relevant here as well. The detailed stakeholder results may be found in the studies GEUVADIS (looking at views of members of research teams of putting one’s own sequence information in public databases) and TECHGENE (looking at communication between research participants). The critical points of those studies were that “meaningful” results should always be disclosed (but with some disagreement over what “meaningful” means); for now there should be no WGS (whole genome sequence) for children; and, in general it is thought that ethicists have come to these questions late and somewhat negatively.

Noam Shomron, Tel-Aviv University

Dr. Shomron started by describing that, although he is a molecular biologist focused on understanding the basic mechanisms of rare genetic diseases, patients would come by his laboratory asking him to diagnose them. Clearly there is a desire and need for more direct return of results to patients, and an implication that these are people less worried about privacy and more worried about a health issue. Dr. Shomron went on to describe several studies where there clearly could be sensitivities about sharing data, or data being made public (specifically, schizophrenia, post-traumatic stress disorder, and Alzheimer disease). Dr. Shomron indicated that DNA is not the only sensitive genetic information collected. RNA, for example is another molecule that harbors valuable information about the individuals. Finally, he could foresee a time when patients (initially) and eventually everyone would at least be able to carry their information with them (e.g., through a phone app), implying also an eventual possibility of sharing that information more widely.

Discussion:

The talks of Dr. Cambon-Thomsen and Dr. Shomron were discussed together, allowing the participants to integrate a view of the basic research/research participant relationship with the views of other stakeholders.

A key point was that the idea that knowledge constantly changes is difficult both to communicate, and to deal with practically. How do we assure that participants in research or clinical trials, or even through their individual doctors, receive updated information. In all cases, should they receive such updated information? This was a particular concern in terms of basic clinical research protocols.

Although as a group we made a point not to talk about consent processes in detail, as this has been covered in many meetings and papers, the group did discuss how we might think about new types of consent. The possibility of individuals withdrawing from protocols was discussed in some detail, and this is an issue that does have unique problems with respect to human genome research. Certainly, once a genome has been made public, that sequence will never go away. But in principle at least some classes for factual or interpreted data can be removed (though others may know how to recreate it from the sequence).

As at other points in the workshop, the group did not have a consensus on the value of privacy/anonymization and some participants did think that it is not worth giving up these ideas quite yet and perhaps we can find a way to make them work while not slowing down science.

Alastair Kent, Genetic Alliance UK

Mr. Kent discussed his views through a lens of considering what patients and their families want from the biomedical community as more data are collected and potentially shared and made public. He pointed out that in the societal and professional discussions, it is only the patients (and their families) that are essentially involuntary to the process. By thinking about whether more sharing and openness could change that, we could bring a different model to

how research is done. We of course want to think about protection of people involved in research or treatment, and there are always the unknowns. But trust has essentially always gone one way in research (as a subject, I trust you as a researcher) and now the inverse needs to become true as well, with researchers trusting their subjects/patients to know what information they want, what they want to share with the world, etc. One important point is that it is not the genome itself that patients (or anyone) is concerned about keeping "secret", it is the information implied by it. Patients understand that as a matter of proportionality: sharing genome data really does help research. Sharing other personal data may or may not. Mr. Kent suggested a model for this where classes of information may be freely shared, but that there would be penalties for sharing anything beyond that.

Discussion:

Workshop participants were interested in some of the practicalities of dealing with large numbers of disease-specific organizations (Mr Kent's alliance, for example, has 160 member organizations). A clear concern was about how resources are then allocated. Mr Kent spoke to a critical role for public funding bodies and large philanthropies to try to exercise some kind of balancing function. Some workshop participants also expressed concern about rare v. common diseases in funding decisions.

There was also some discussion about the inclusion of patients on reviewing panels for papers and, more commonly, for grant proposals. There was a sense that scientists might be uncomfortable with this (particularly for reviewing papers) but it is something that is happening, particularly in medical journals, and so may be worth discussing exactly what the parameters of the involvement for patients (and scientists) should be.

Finally, several of the workshop participants emphasized that although the trend is clearly toward more openness of the phenotypic information attached to sequence data, that as a research community we can still consider safeguards for the use of such data. It was suggested, for example, that individuals who want access to the data would need to register that intent, and perhaps event that individuals whose information was being accessed could be notified. These issues were not discussed in any technical detail and would require further technical and policy discussions to evaluate.

3. Assessment of the results, contribution to the future direction of the field, outcome

The participants of the workshop took very seriously their charge not only to identify problems associated with the use of non-anonymized human genome sequence in research, but to think about options for decision-makers as to how to try to mitigate any potential problems, and how to encourage responsible use. The group identified a number of policy gaps:

1) *How best to promote and assure trust among stakeholders?*

The idea that all of the participants in and beneficiaries of non-anonymized research protocols need to trust each other is apparent on its face; the group detailed the issues here in a policy-relevant manner.

First, it would be critical to have a comprehensive list of stakeholders. As an exercise in the workshop, the participants did an initial listing of possible stakeholders:

- Governments
- Academia
- International organizations
- Health departments within governments
- Legislators
- Funders
- Editors
- Researchers in genomic projects
- Research participants
- Patient organisations
- Ethics committees
- Medical associations
- Scientific associations
- Biobanks
- DTC companies
- Pharma
- Biotechnology companies
- Pharma
- Diagnostics manufacturers
- IT companies
- Media
- Privacy interest groups
- Insurance companies
- Doctors
- Clinics

This is likely not a comprehensive list and as well there was a discussion as to which of these count truly as “stakeholders”, as oopposed to those who may have powerful voices and their own agendas, and that may be involved in the discussions, but ultimately are not stakeholders in the issue of having access to non-anonymized sequence. That sorting would need to be done more rigorously.

Second, there was much discussion about how trust fits in with governance systems and mechanisms. Much of the concern in the research policy community is about trust with respect to informed consent for participation in research protocols. It is researchers whose reputations generally suffer if something goes wrong, and this would likely include any perceived damages to a research participant caused by their genomic data being publicly available. There was some discussion as to how to fix this at the consent level (particularly with respect to being able to show how a consent process is trustworthy), but also the general concept that there is a special responsibility for researchers to be involved in discussions about governance.

Finally, it was noted that there are other important parts of the foundation to successful research governance. Trust is necessary, but not sufficient, and those other principles (such as responsibilities, duties, legal obligations, valuing scientific advance, etc.) need to be considered in more detail as well, and to the degree there are conflicts in, how those conflicts would be resolved.

2) *How to determine the occasions in which keeping genomic data inaccessible would still be a priority?*

As a matter of framing the workshop discussions, participants were asked to assume that in the near future, genome data would be readily accessible and identifiable by design. As part of exploring the implications of this, there was some concern expressed in the room that society did not need to necessarily accept this premise right away, and that we should think about if we have missed an opportunity to assure some privacy/anonymity for research participants while not slowing down the advance of science.

Without solving the implied problem (or whether there even is a problem) of the tradeoff between anonymity and speed of scientific advances, the group did note that on the technical side, we had not discussed the possibility of encrypting data, and what the implications of that are. This certainly needs further analysis. As well, there was a more general concern that in the framing we may be underestimating the number of people who not only would not want their information shared with others, but actually may not want to know their own information themselves. Do researchers have some kind of responsibility to protect people from their own information? This is a fairly long-standing problem but the need to fully understand it and come up with solutions if necessary will quickly become acute.

3) *How to make this field of work and its results as open as possible while still protecting participants from potential bad actors?*

Related to both of the first two issues, the group noted that as well we do have to preprare for the possibility of malicious individuals wanting to exploit the data irrespective of whether the data are made available by design. Because even scientists in the field of data cannot entirely anticipate what new analytic tools will become available, it was suggested that both data protection and legislation (i.e., “people protection”) need to be looked at in more detail. In the first instance, it may be the case that more effort needs to be put into data encryption, design-for-privacy, etc., so that in cases where the data should be shared only on an extremely limited basis, or when the research participant wishes to invoke a “right not to know”, the research community will have a mechanism to deal with that.

With respect to legislation, it was pointed out that in general laws and regulations are meant to tell what an individual cannot do. This may be too limiting for the field, and at the same time, may cut off future advances. Approaching this problem with a view toward what should be allowed would at minimum be a useful exercise in understanding the scope of people’s concerns. Whether such legislation needs to be written, would be written in such a manner, and how it would actually be implemented of course all remain to be seen.

In addition to the identification of policy gaps, there were as well several concepts that came up a number of times as observations or concerns:

Technologies for sequencing human genomes, for extracting and storing data, and for analysing those data are changing rapidly. This is both a cause and an effect of a more open

sharing of information derived from genome analyses, and a move toward individualizing uses of human genomes. The openness is not absolute, but privacy and anonymity are not absolute either. How to optimize all of those factors to advance science, health, and knowledge while respecting evolving views about privacy or anonymity remains to be more fully analysed.

Funders (philanthropic, governmental, and others) do have some power to change the nature of these debates, either by what they decide to fund (should more money be put into researching better encryption systems?) and how they dictate results of research are displayed (e.g., could a funder dictate that genome sequence results be anonymized? How would that be enforced?).

Also needing further attention is an understanding of the nature of the interactions of researchers with patients or research participants with respect to genomic information. Currently, many of those interactions are mitigated by conditions of consent, especially for the return of secondary results, or new information that emerges after the primary research has ceased, but where scientists or others are still looking at data. It could be the case that such interactions are not desired by all of the parties, but in the cases where they are, current rules make this very difficult. How the community might incentivize these interactions (or decide it does not want them) needs further attention.

The aim of sharing is likely to vary significantly between different stakeholder communities. Are there are enough commonalities between stakeholder communities that specific types of sharing might be set as a policy matter? Or, would the only policy in that case be to reward the act of sharing, irrespective of how broad the sharing is? As well, general concerns were aired about how data might or might not be shared under any version of the European Data Directive; this is an area clearly needing much more discussion.

There were a number of areas where, although the observations have been well documented in the past, the issues came up frequently enough in the workshop that it is worth noting them. A key issue was a concern about the diversity of participants in human genome studies, both in demographics and in age. As in discussions about the inclusion of children as research participants generally, different views of the value and potential harms of including children in genomics studies were expressed.

Another concern, going back even to the beginnings of human genome projects, is that it is unclear how it will be possible to assure there are enough people to expertly analyse human genome data, and to communicate it to research participants and to patients. There have long been discussions as to whether the communicators would be doctors, genetic counsellors, or perhaps even for-profit companies. And are these the same people who do the analyses, or are these different expert roles? Although an old question, it is one that is now critically important.

Finally, and not unique to human genomics studies, are ongoing problems with the accuracy, harmonization and compatibility of databases. Although the technical details were not discussed at length, the general sense from people who have had to rely on these databases recently is that there are problem that go beyond problems of convenience for researchers, and rather are causing research to slow down. Again, this is not a new problem but is rapidly becoming a critical one.

Follow-up plans

Virtually all of the participants indicated an interest in doing some kind of follow-up work, whether that would be one-on-one collaborations with people they had met at the workshop, group-authored contributions to peer-reviewed journals or other media, or working together on follow-on conferences.

Several workshop participants have associations with relevant journals or may be guest editors for upcoming issues. They will keep the group informed as to possibilities for submitting work on our topic, either individually or as a group. As well, there are several scientific journals or magazines aimed at scientists and including editorial or op-ed space for policy or governance essays, at least some people in the group would definitely want to consider submissions to at least a few of those.

Workshop participants identified a number of regular conferences to which we should consider submitting a session. This includes areas such a bioethics, scientific research, and social science; and as well would include large multidisciplinary international meetings. Sessions would likely involve a few members of the group organizing and giving session talks, and as well finding others from outside this workshop to participate.

EMBO staff, as part of our usual work, would like to expand on this report to be able to offer more background information to scientists, and other interested parties. We would as well consider repackaging this report and any expansion into usable materials for decision-makers. All other members of the workshop group would of course be included as they would like.

4. Final programme

Tuesday, 9 December 2014

Afternoon	*Arrival*
Evening	*Dinner on your own; available at hotel. Contact organizers for suggestions in Heidelberg city if you prefer*

Wednesday, 10 December 2014

8.45	**Shuttle from Hotel ISG to meeting site: EMBO Conference Room, top floor, EMBO building, Meyerhofstrasse 1, 69117 Heidelberg**
09.00-09.05	**Welcome by Convenor** **Michele Garfinkel** (EMBO, Heidelberg, Germany)
09.05-09.25	**Presentation of the European Science Foundation (ESF)** **Martin Röllinghoff** (Scientific Review Group for the Bio-Medical Sciences)
09.25-09.35	**Roadmap for the workshop, ground rules** **Michele Garfinkel** (EMBO, Heidelberg, Germany)
09.35-12.40	**First thoughts about identifiable data**
09.35-10.10	**Initial interventions from participants**
10.10-10.50	**Implications of Big Data Analytics in Cancer Research** **Jan Korbel** (European Molecular Biology Laboratory, Heidelberg, Germany)
10.50-11.20	*Coffee / tea break*
11.20-12.40	**Structured discussion**
12.40-13.45	*Lunch*
13.45-17.30	**Elaborating policies for research**
13.45-14.15	**Put Your Money Where Your Thumb Drive Is: Reimagining the Researcher-Participant Relationship** **Misha Angrist** (Duke University, Durham, NC, United States)
14.15-14.45	**Commentaries** **Christoph Bock** (CeMM, Vienna, Austria), **Effy Vayena** (University of Zürich, Switzerland)
14.45-15.15	**General discussion**

15.15-15.45	*Coffee / tea break*
15.45-17.15	**Structured discussion**
17.15-17.30	**Summary of day, plan for tomorrow**
17.30-19.00	Free time (participants may be interested in a short walk in the old town area prior to dinner, with organizers)
19.00	*Dinner at Restaurant Zur Herrenmühle, Hauptstraße 239, 69117 Heidelberg*

Thursday, 11 December 2014

8.45	**Shuttle from Hotel ISG to meeting site: EMBO Conference Room, top floor, EMBO building, Meyerhofstrasse 1, 69117 Heidelberg**
09.00-12.30	**Governance**
09.00-09.30	**The Fiction of Anonymisation of Genetic Data: Stakeholders Views and Consequences for Governance** **Anne Cambon-Thomsen** (University Toulouse, France)
9.30-10.00	**Sequencing Non-anonymized DNA Samples: What Constitutes a Valid Informed Consent?** **Noam Shomron** (Faculty of Medicine, Tel-Aviv University, Israel)
10.00-10.30	**General discussion**
10.30-11.00	*Coffee / tea break*
11.00-12.15	**Structured discussion**
12.15-13.30	*Lunch*
13.30-16.15	**Research participants as policy stakeholders**
13.30-14.10	**Patient and Family Perspectives on Participation** **Alastair Kent** (Genetic Alliance UK, London, United Kingdom)
14.10-15.00	**Structured discussion**
15.00-15.15	*Coffee / tea break*
15.15-15.45	Open discussion, all sessions
15.45-16.15	PLANNING FOR FURTHER WORK
16.15	*End of workshop and departure*

5. Final list of participants

1. Misha ANGRIST, Duke University, United States
2. Christoph BOCK, CeMM Resarch Center for Molecular Medicine of the Austrian Academy of Science, Austria
3. Anne CAMBON-THOMSEN, University Toulouse III-Paul Sabatier, France
4. Gert HELGESSON, Karolinska Instituet, Sweden
5. Heidi Carmen HOWARD, Uppsala University, Sweden
6. Alastair KENT, Genetic Alliance UK, United Kingdom
7. Jan KORBEL, European Molecular Biology Laboratory, Germany
8. Paula MARTINHO da SILVA, PLMJ, Portugal
9. Colin MITCHELL, University of Oxford, United Kingdom
10. Salvör NORDAL, University of Iceland, Iceland
11. Mauro PETRILLO, European Commission Joint Research Centre, Italy
12. Noam SHOMRON, Tel-Aviv University, Israel
13. Sirpa SOINI, National Institute for Health and Welfare THL Biobank, Finland
14. Effy VAYENA, University of Zurich, Switzerland

15. Michele GARFINKEL (convenor), EMBO, Germany

Martin RÖLLINGHOFF (ESF representative), Erlangen-Nuremberg Universität, Germany
Sandra BENDISCIOLI (local organiser), EMBO, Germany

6. Statistical information on participants

For a total of 15 participants (including the convenor but excluding the ESF representative and the local organiser):

Gender distribution:

7 women, 8 men

Country distribution: (1=6.6%, 2=13.2%)

Austria: 1 person
Finland: 1
France: 1
Germany: 2
Iceland: 1
Israel: 1
Italy: 1
Portugal: 1
Sweden: 2
Switzerland: 1
United Kingdom: 2
United States: 1

Age distribution:

30-40: 3 people (20%)
41-50: 6 (40%)
51-60: 4 (45%)
60-70: 2 (15%)