

Final academic report for the 2016 project
“Global Genes – Local Concerns



1. Basic Information

<i>PI and Co-PI's</i>	<p>Professor Timo Minssen, LAW (PI since late 2015)</p> <p>Professor Klaus Lindgaard Høyer, HEALTH</p> <p>Professor Niels Tommerup, HEALTH</p> <p>Professor Søren Tvorup-Christensen, SCIENCE</p> <p>Professor Lars Allan Larsen, HEALTH</p> <p>Associate Professor Lotte Bang Pedersen, SCIENCE</p> <p>Professor Karsten Kristiansen, SCIENCE</p> <p>Professor Jun Wang, SCIENCE</p> <p>Professor Jens Hemmingsen Schovsbo, LAW (PI until late 2015=</p> <p>Associate Professor Janne Rothmar Herrmann, LAW</p> <p>Professor Klemens Kappel, HUM</p> <p>Professor Peter Sandøe, SCIENCE</p> <p>Associate Professor Lotte Bang Pedersen, SCIENCE</p>
<i>Project title</i>	Global Genes – Local Concerns
<i>Amount granted</i>	24.168.000 DKK

The interdisciplinary project design of Global Genes – Local Concerns features three biobanking and genomic screening models. Biological samples collected in e.g. Denmark and Pakistan have been (and are being) genetically screened with next generation sequencing methods, with a focus to identify mutated novel cilia- and centrosome-related genes that represent novel ciliopathy candidates, but have not yet been coupled to a disease. This biological/genetic focus was chosen since ciliopathies are pleiotropic causing dysfunction of a variety of organs. Genes encoding the ciliome constitute 1/20 of the human genome, but the number of known ciliopathies is still <100. The individual ciliopathy will likely be an orphan disorder, but will frequently have implications for phenotypically overlapping common complex disorders.

Moreover, since the cilium proteome is known, targeted approaches can be used to identify candidate disease genes and study their function.

Simultaneously, these models served as cases for studies of donor motivation, stakeholder attitudes/concerns and legal/commercialization issues to identify concrete barriers for cross-national biobank based research and utilization of research results.

The project furthermore analyzed how biobanks contribute to translational research in Denmark and abroad; opportunities and challenges for the regulation of translational use of biobanks; how inter-biobank coordination and collaboration occurs on various levels; and how academic and industrial exploitation, ownership and IPR issues are facilitated and addressed.

We have addressed the schism between the international character of the cooperation and the territorial nature of the legislation, by the inclusion of vulnerable donor populations in Pakistan. Pakistan is interesting also because a high degree of illiteracy contradicts the general rule of written informed consent put forward as essential in codes of conduct governing international collaboration.

Based on interdisciplinarity this project has worked to develop and embed new guidelines in a university setting. This will make UCPH a progressive contributor to the already existing unique Danish biobank infrastructure.

The research was carried out and organized within the following work packages:

Collection (Work package 1)

The goal of the work package on collection was to explore and trace donor and collaborator interests at multiple sites internationally during the process of collecting and setting up of a biobank in Denmark.

Biobanking – genetic screening (Work package 2)

The aims of WP2 was to provide candidate cilia and centrosome genes for WP3 for functional studies, and data and options for the other WPs. The WP2 groups have the necessary consents from the Danish and Pakistani research ethical committee's regarding exome and full genome screening, including the local setups for proper counselling of coincidental findings.

Functional analysis (Work package 3)

This work package addressed the biological function of identified candidate disease genes, plus hitherto uncharacterized genes known to be associated with cilia and centrosomes using mouse and human cell

cultures as well as zebrafish and mouse models with live cell and tissue imaging methods, transcriptomics and proteomic approaches.

Legal Framework (Work package 4)

The commercialization part of this WP analyzes which organisational and legislative choices biobanking may involve and whether publicly funded biobanks should engage in tech-transfer and the protection of research results through i.a. IPRs. Besides providing insights that will re-emerge in WP6, special emphasis will be laid on interconnecting WP4 with WP2 and WP3.

Ethical Framework (Work package 5)

The aim of WP5 was to address certain specific ethical challenges arising from biobanks operating across boundaries of diverse ethical norms and values. The focus was on the collection of samples planned in WP2 in Pakistan, and the specific ethical challenges this generated for various stakeholders.

Guidelines (Work package 6)

The aim of the guidelines is to optimize the efficiency and quality of cross-border biobanking by capturing the concrete results of WP1, WP4 and WP5 in order to provide an instrument that can provide concrete and ethically and legally sound guidance in biobanking projects generally.

Further information is also available on the project's webpage at: <http://globalgenes.ku.dk/>.

2. Research excellence and international impact of the project

2.1 Excellence in research based on interdisciplinary collaboration: Scientific discoveries and achievements

The project deals with legal, ethical and scientific challenges in cross-national biobanking and translational exploitation. Concentrating on biobanking in a university setting, the project aims to identify and ultimately overcome regulatory barriers to biobank research and the utilization of research results, while at the same time securing the ethical legitimacy of the research and the societal interests in access to information and innovation. To achieve this goal, the project has combined legal, bioethical, and social science perspectives with human genetic studies that involve patient material from multiple countries. More specifically the project has achieved the following results:

WP1: We have found that the expectations, hopes and concerns of the contributors to biobank research in contexts as diverse as Pakistan, Denmark and other European countries differ so much that harmonization of ethics rules seems to run counter to the participants' interests e.g. in establishing forms of contact that suit their specific situation. The concept of trust is associated with very different connotations and is established through very different practices. Furthermore, we have found examples of ethics rules that work against participants' interests and the work undertaken by researchers to care for them. The WP has also identified social dynamics affecting the willingness to share materials between research groups, e.g. what we have come to call 'data hugging' but also dynamics related to the work deemed necessary for the care of participants.

WP2: We have collected biological material via systematic identification of consanguineous families in Pakistan with microcephaly (MCPH), excluded the involvement of known MCPH-genes, and identified novel candidate MCPH genes by combined linkage mapping and exome sequencing. These candidate genes have been passed on to WP3 for functional analysis. Moreover, the analysis of the exome data in an number of unlinked families is underway. We have continued the world-wide expansion of The International Breakpoint Mapping Consortium to presently >160 participating centres from 51 countries, and have received DNA from >600 carriers of chromosomal inversions and translocations. We have mapped >240 of these by next generation sequencing, and thereby identified numerous candidate disease genes and regulatory domains. These will be analysed with respect to overlap with the ciliome/centrosome. Furthermore, we have identified ciliome/centrosome genes from other selected patient cohort (e.g. scoliosis, congenital heart disease), which have been passed on to WP3.

WP3: We have successfully established the analytical platform to characterize the function of novel candidate disease genes as well as hitherto uncharacterized genes regulating the sensory output of primary cilia. The disease genes analyzed include three genes in MCPH, eight genes in congenital heart disease and one gene in scoliosis. We have further identified novel cilia-associated functions of several centrosome and ciliary proteins. Some of these have previously been associated with human disease, including ciliopathies and cancer, whereas others represent new candidate disease genes.

WP4: We have found that the regulatory framework leaves considerable doubt as to some of the fundamental issues regarding the collection and use of samples, and of data derived from these. In particular the international dimension and the new possibilities for uses of previously collected samples and data e.g. for personalized medicine or new diagnostic methods have raised complicated issues which the traditional and current legal framework find it difficult to handle. Because of these uncertainties the rights and duties of the involved stake holders need to be clarified thoroughly and by means of various legal instruments and mechanism, such as dynamic informed consent approaches, and clear and precise policies for the protection of IPR and the transfer of data and/or technology to partners. With regard to IPRs WP4 has found that the feasibility of IPR-policies depends on the specific types, set-ups and goals of biobanks and that some biobanks might have good reasons to refrain from being involved in IPRs. However, in many cases an appropriate balance of the IPR-user modalities will be crucial to enhance translational medicine.

WP5: We have completed empirical work (interviews) with donor families from rural Pakistan, elucidating the circumstances under which illiterate and uneducated donors consent to donate to research projects. In addition we have devised a conceptual analysis of how ethically valid consent may be based on trust (trust based consent), and we are working on an analysis of exploitation. We have held a stakeholder-workshop charting the major concerns and priorities among stakeholders in cross-national biobanking. Finally, we have co-organized a workshop with partners in Pakistan on the ethical challenges of consent to research involving vulnerable subjects from developing world countries.

WP6: Examples of guidelines have been collected from various universities by a research assistant embedded at the project. This assistant has also taken part in the ongoing work at HEALTH for the promulgation of guidelines there. A framework for assessing the sustainability of university run biobank is outlined in an article written by representatives from all WPs. The article is currently under review and mentioned in the publication list.

The impact of the interdisciplinary collaboration:

WP1: The social science component has learned more about the work ethos of clinical genetic counsellors and the medical researchers have learned to see ethical challenges as social phenomena. We have also been able to demonstrate that data-sharing entails social concerns for the uses of data itself.

WP2: The interdisciplinary collaboration between this WP and the other WPs can be divided into two: 1) The interaction with WP3 has provided methodological synergies between two natural sciences areas, which will rapidly be reflected in high-impact publications driven by these synergies; 2) The interaction with HUM and LAW may be more difficult to assess in terms of immediate bibliometry. However, these

interactions have been real eye-openers for all parties, which will facilitate a long-term truly interdisciplinary consolidation.

WP3: The interdisciplinary collaboration has led to new surprising discoveries related to the molecular mechanisms involved in birth defects and severe diseases in the adult. These discoveries have immediate impact for the affected families by providing a biological explanation for their disease. The potential of this translational counseling in terms of alleviation of sense of guilt, future family planning, and the establishment of diagnostic possibilities cannot be overestimated. In addition, our work has led to identification of new candidate disease genes, which may similarly benefit affected families in the future.

WP4: The interdisciplinary collaboration has enabled the participants in the legal work package to gain first-hand access to cases and to knowledge about related aspects. The collaboration has enabled this WP to make informed choices as to the identification of case studies. It has also enriched the discussions about the technical and the societal dimension of biobanking, including a better understanding of the various stake-holder perspectives such as scientists, patients, medical doctors, health care providers, policy-makers and industry. As described further below, the interdisciplinary approach has not only resulted in many WP specific papers, but it has stimulated a fruitful collaboration on several truly collaborative, cross-faculty papers on biobanking, IPRs and “big data” analysis, patient involvement and ownership.

WP5 By working together with physicians and geneticists in the project (WP2) and in Pakistan, we have gained access to donors and collecting practices in rural Pakistan. This has given us unique insight into practices and enabled us to conduct interviews with donors and other stakeholders.

WP 6: The interdisciplinary collaboration and results as described in WP 1-5 has provided WP 6 with significant data and interrelated insights that will enable us to identify the need for and to draft guidelines on how overcome regulatory barriers to biobank research and the utilization of research results, while at the same time securing the ethical legitimacy of the research and the societal interests in access to information and innovation.

An international conference with 16 speakers and more than 60 participants was held in February 2017 in Copenhagen to mark the conclusion of the project. The conference featured 4 tracks (Track 1: BIOBANKS & BIG DATA; Track 2: BIOBANKS & PATIENT INVOLVEMENT; Track 3: BIOBANKS, TRANSLATIONAL MEDICINE & TECHNOLOGY TRANSFER; Track 4: BIOBANKS, GUIDELINES & GOOD GOVERNANCE. Prominent European and leading US experts were invited. The conference resulted in a book published by international publisher Elgar with the title “Global Genes Local Concerns”. The book edited by Timo Minssen, Jens Schovsbo and Janne Rothmar Herrmann is as good as completed and the final manuscript will be to submitted to the publisher in April 2018.

2.2 Plans for future activities or embedment related to the project

Embedment

WP 1: A professorship was opened to ensure the long-term embedment. Klaus Hoeyer is now permanently employed in the Public Health Department.

WP 2: The International Breakpoint Mapping Consortium, with systematic mapping of chromosomal breakpoints obtained from collaborators world-wide, will continue and needs to be expanded by additional funding so we can meet our first vision of mapping 10,000 chromosomal breakpoints. As a result of this, we will identify numerous new disease genes, but more importantly, obtain data about the non-coding, regulatory part of the genome, which will be crucial for future efforts of large scale genome sequencing. The collaboration with Pakistan to identify and analyse consanguineous families with genetic disorders has also been very successful and will be continued.

WP2-WP3: The project has allowed us to establish and develop a research environment for combining disease gene discovery with functional analysis. This combination of technologies and expertise within a close physical distance has created a competitive edge, which will allow us to increase our publications in high-impact journals and attract larger grants. Indeed, several high-impact papers have already been published as a result of this project, and external funding for four postdocs has been secured to continue some of these projects; additional external funding for further postdocs/PhD students has been/will be applied for.

WP4: At the general level the PhD course has been embedded institutionally at LAW and collaboration has been established between the project and LAW for the development of further courses aimed at PhD students generally. As explained above a number of positions have already been embedded at a number of the involved institutions. Generally, we regard the biobanking/big data interface as one of the areas that has the best prospects for attracting further funding and embedment. Research on various aspects of this interface will likely be part of future projects in CeBIL (Centre for Biomedical Innovation Law), which is led by PI Timo Minssen with the support of 35 million DKK grant from the Novo Nordisk Foundation, see: www.cebil.dk.

WP5: We intend to continue research on conceptual normative and empirical issues pertaining to medical research performed in developing world countries. This includes questions concerning informed consent, benefit sharing, various types of risks of exploitation and harm to vulnerable research subjects, outsourcing of research and other issues. We (A group headed by KK) have secured funding for a large project (10 mill. Dkr) which will continue some of the research outlined in WP5. We will attempt to secure funding for such projects from governmental and private funding bodies.

2.3 Publications

The publication strategy of the project has been to leave it to the individual participants to decide for their monodisciplinary research projects; but often to do so with co-authors from the other WPs and disciplines. This allows for the publication in the highest-ranking journals and thus maximizes the overall impact of the findings of the project. As of 2018 we have written and published a number of joint, interdisciplinary article projects to be written in the remainder of the project term. It has been (and remains) a challenge to find journals that allow for interdisciplinary projects and are commonly perceived as being attractive for the participants. However, a common framework for assessing sustainability of university run biobanks was the focus of yet another joint article which has recently been submitted to Higher Education (HIGH) .

The five most important completed publications (to date):

- Rajam, Neethu, Intellectual Property Rights and Publicly Funded Biobanks: Perspectives for Industrial and Research Partnerships within Biobanks in Europe, PhD thesis, defended in March 2018
- Schou KB, Mogensen JB, Nielsen BS, Morthorst SK, Aleliunaite A, Serra-Marque AMA, Saunier S, Bizet A, Veland IR, Akhmanova A, Christensen ST and Pedersen LB (2017) KIF13B establishes a CAV1-enriched microdomain at the ciliary transition zone to promote Sonic hedgehog signaling. *Nature Communications*, 8:14177, doi: 10.1038/ncomms14177
- Schmid, F, Schou, KB, Vilhelm, MJ, Holm, MS, Breslin, L, Farinelli, P, Larsen, LA, Andersen, JS, Pedersen, LB & Christensen, ST **(2018)** IFT20 promotes feedback inhibition of ciliary PDGFR α signaling by regulating the stability of Cbl E3 ubiquitin ligases. *Journal of Cell Biology*, 217:151-161. doi: 10.1083/jcb.201611050..
- Hoeyer, K, A Tupasela, MB Rasmussen (2017) Ethics Policies and Ethics Work in Cross-national Genetic Research and Data Sharing: Flows, Nonflows, and Overflows, *Science, Technology and Human Values*, 42(3): 381-404, DOI: 10.1177/0162243916674321
- Kongsholm, N. C. H. & Kappel, K. (2017). Is Consent Based on Trust Morally Inferior to Consent Based on Information? *Bioethics*, 31(6): 432-442.

Please see appendix A for the full list of publications, including several cross faculty publications that have been submitted, such as

(1) the book with Edward Elgar resulting from the conference

- Minssen T., Rothmar Herrmann J., Schovsbo J. (editors) , Global Genes, Local Concerns: Legal, Ethical & Scientific Challenges in International Biobanking (forthcoming in late 2018, Edward Elgar, ca. 500pp)_

, and (2) two collaborative cross -faculty papers:

- Nana Cecilie Halmsted Kongsholm, Ph.D.; Søren Tvorup Christensen; Janne Rothmar Hermann; Lars Allan Larsen; Timo Minssen; Lotte Bang Pedersen; Neethu Rajam; Niels Tommerup; Aaro Mikael Tupasela; Jens Schovsbo, Challenges for the sustainability of university-run biobanks, submitted to Higher Education in March 2018.
- Morten Ebbe Juul Nielsen, Nana Cecilie Halmsted Kongsholm, Jens Schovsbo, Property and Human Genetic Information, submitted to Journal of Community Genetics in March 2018._

See also the following pending high impact publications:

One of the most important papers sponsored by Global Genes is pending (about the largest international effort to use chromosomal breakpoints obtained via International Breakpoint Mapping Consortium to characterize the regulatory functions of a significant part of the genome::

- Mehrjouy M, Fonseca ACDS, Ehmke N, Novelli A, Benedicenti F, Mencarelli MA, Renieri A, Busa T, Missirian C, Hansen C, Abe KT, Speck-Martins CE, Vienna-Morgante A, Tommerup N. Regulatory variants of *FOXP1* in the context of its topological domain organisation. *Eur J Hum Genet.* 2018;26:186-96.

The final revision for the second most important paper has just been submitted:

- Halgren C, Nielsen NM, Nazaryan-Petersen L, Silahtaroglu A, Collins RL, Lowther C, Kjaergaard S, Frisch M, Kirchhoff M, Brøndum-Nielsen K, Lind-Thomsen A, Mang Y, El-Schich Z, Boring CA, Mehrjouy MM, Jensen PKA, Fagerberg C, Krogh LN, Hansen J, Bryndorf T, Hansen C, Talkowski M,

Bak M Tommerup N. Bache I. Risks and recommendations in Prenatally Detected *de novo* Balanced Chromosomal Rearrangements from Assessment of Long-Term Outcomes. *Am J Hum Genet* 2018:

2.4 Prizes, prestigious grants and awards [præpopuleret pba. midtvejsevaluering]

	<i>Name</i>	<i>Project title</i>	<i>Period</i>	<i>Amount</i>
<i>Novo Nordisk Foundation Research Grant (Grant number NNF17SA0027784)</i>	<i>Timo Minssen - JUR</i>	<i>Collaborative Research Programme in Biomedical Innovation Law</i>	2018-2023	35.000.000 (35 million)
<i>Swedish King Oscar, 2013-2014 N/A.</i>	Timo Minssen	<i>Prize for the best PhD thesis, Assessing the Inventiveness of Biopharmaceuticals under European and US Patent Law</i>	2014	N/A

	<i>Name</i>	<i>Project title</i>	<i>Period</i>	<i>Amount</i>
<i>Jorcks Fonds Forsknings Pris (Jorck's Foundation Research Prize):</i>	Timo Minssen	Achievements in Biomedical Innovation Law	2017	200.000 DKK
<i>ERC Grants related to the project: Consolidator Grant</i>	Klaus Hoeyer	Policy, practice and experience in the age of intensified data sourcing in European healthcare	2016-2020	DKK 14.986.000
<i>EliteForsk-prisen (Elite-Research Award) granted by the Ministry of Education and Research</i>	Klaus Hoeyer	EliteForsk	2017-2020	DKK 1,200,000
<i>Distinguished Research Fellow, Monash University</i>	Klaus Hoeyer		2018	Australian Dollar 7,000
<i>DNRF Center of Excellence related to the project</i>				

	<i>Name</i>	<i>Project title</i>	<i>Period</i>	<i>Amount</i>
<i>EliteForsk:</i> <ul style="list-style-type: none"> - <i>EliteForsk Awards</i> - <i>EliteForsk Travel Scholarships</i> 				
<i>DFF</i>	Niels Tommerup	International Breakpoint Mapping Consortium		DKK 4.648.219

<i>Other</i>				
<i>FKK</i>	Klemens Kappel	The Social Epistemology and Social Psychology of Complex Disagreement		DKK 6.300.000
<i>Novo Nordisk Foundation</i>	Klemens Kappel	Convergent Ethics and Ethics of Controversy		DKK 10.000.000
<i>FSS</i>	Jens Andersen (SDU), Søren Tvorup Christensen, Lars Allan Larsen, Lotte Bang Pedersen	Ciliopathies and congenital heart disease: the Role of novel ciliary proteins in signaling and cardiogenesis		DKK 4.363.200
				DKK

	<i>Name</i>	<i>Project title</i>	<i>Period</i>	<i>Amount</i>
<i>FNU</i>	Søren Tvorup Christensen, Lotte Bang Pedersen	Coordination of PDGFR α and TGF β signaling at the primary cilium		2.390.158

2.5 International research collaboration

On the common level the project has facilitated collaboration, student exchange and joint publications with prominent experts within its broad field through the various activities, workshops, the kick off conference, the final conference, and the PhD-course in collaboration with BBMRI.

Concrete examples include:

WP1: The project has facilitated collaboration with Brígida Riso (Portugal), Michaela Meyrhofer (BBMRI) University of Lausanne, Lund University and a Sino-Nordic Biobanking network, but also a range of high-ranking academics who have come to Denmark and hosted members of the project abroad. The WP has also participated in COST Action IS1303: Citizen's Health through public-private Initiatives: Public health, Market and Ethical perspectives (CHIP ME).

WP2: The project has facilitated collaboration with the groups of Shahid Baig (Human Molecular Genetics Laboratory, NIBGE, Pakistan); Angela Vienna Morgante (Universidade de São Paulo, Brazil); Caroline Cismani (The Cyprus Institute of Neurology and Genetics, Cyprus); Prof. Orsetta Zuffardi (University of Pavia, Italy); Dr. Antonio Novelli (Istituto CSS Mendel, Italy); Prof. Joris Vermeesch (UZ Leuven, Belgium); Prof. Albert Schinzel (University of Zürich, Switzerland); Dr. Frenny Sheth (FRIGE's Institute of Human Genetics, India); Dr. Fatma Silan (Canakkale Onsekiz March University, Turkey), among others). Many more collaborations are in the pipeline. WP members participated in international/national genetic conferences and meetings in Europe, North- and South America, and Asia, as part of the organization of IBMC. Visiting researchers include Peter Jacky, Oregon US; Constantia Aristidou, Cyprus; Ana Carolina Fonseca, Brazil; Caroline Schluth-Bolard, France. Many more are pending.

Niels Tommerup's Group is collaborating with the International Breakpoint Mapping Consortium (IBMC); Pakistani-Danish genetic collaboration & the European Epilepsy Network. The group had also a considerable number of visiting researchers (15), and joint publications (IBMC: 6, Pakistan: 4, Epilepsy: 4), and visits in foreign universities (3)..

WP3: The project has facilitated collaboration, student exchange and joint publications with prominent experts in the field of disease gene discovery and functional analysis, including Prof. D. Norris (MRC Harwell, Oxford, UK), Prof. S. Saunier (Imagine Inst, Paris), Prof. A. Akhmanova (Utrecht Univ., NL), Prof. W. Pu (Children's Hospital, Boston, USA), Prof. V. Christoffels (AMC, Amsterdam, NL), Prof. R. Anderson (Univ. Newcastle, London, UK). WP members have been invited to participate in or organize 13 international networks or conferences in the fields. Visiting researchers include Doctors R. Giles (Utrecht Med Center, NL), J. Gopalakrishnan (Univ. of Cologne), E. Lorentzen (MPI, Martinsried, D), P. Satir (AECOM, NY, USA). Organization of the EMBO Workshop Cilia 2018 in Copenhagen this fall (ca. 400 delegates, <http://meetings.embo.org/event/18-cilia>).

WP4: The project has facilitated collaboration, visiting research fellows, student exchange and joint publications with prominent experts in the field of disease gene discovery and functional analysis, including Dr. Karine Sargsyan, Medical University of Graz, Martin Buijsen, Erasmus University of Rotterdam, Jane Kaye, University of Oxford, Michiel Verlinden and Isabelle Huys, University of Leuven, Kathy Liddell and Jeff Skopek (University of Cambridge), Aaron Kesselheim (Harvard Medical School), Ellen Law (Broad Institute) and Nicholson Price (Harvard Law School/UNH).

The new Center for Advanced Studies in Biomedical Innovation Law (CeBIL) (www.cebil.dk) is anchored in Copenhagen but involves and employs leading international experts at Harvard Law School, Harvard Medical School, University of Cambridge, Michigan University and IFRO, Copenhagen.

WP5: The project has facilitated collaboration with the groups of Shahid Baig, Pakistan, and Genome Denmark.

3. Research based educational activities and research training

7 PhD students have been supported by, and graduated as a result of, the grant.

To achieve this success, the researchers have offered a high number of courses aimed at BA, MA and PhD students at Faculties and within their respective fields of expertise.

For research training the main contribution of the project – which is in fact a very substantial one – has been the successful establishment and offering of a true interdisciplinary course aimed at PhD students:

The core teaching curriculum has been developed based on the research that has been going on in the project. In 2014 a PhD course was offered for students based on the research that was being conducted in the project. The course was attended by most of the PhD students involved in the project, as well as other PhD students who were interested in the topic.

In 2015 the course was expanded to collaboration with Lund University and BBMRI.se. The course attracted more international students, as well as expanded the scope of the teaching and lectures, which were presented. In both courses a key element of the teaching experience was field trips to local biobanks (Danish National Biobank and Beijing Genomics Institute). During this PhD course we also piloted the use of Massively Open Online Course (MOOC) technologies so as to make the lectures open to anybody around the world. Although only two students completed the course online, we had over 20 students following the lectures from different parts of the world. This format was further developed in the course. We presented the platform in spring 2016 at the annual meeting of the International Society for Biological and Environmental Repositories (ISBER).

In addition to the formal training that has been offered during the past three years, the PhD students have developed an informal seminar series where they visit each other's departments and present and discuss their work. The students have found this very useful in facilitating informal discussions and knowledge dissemination. The PhD students' network in the Global Genes Local Concerns project is an interdisciplinary network, offering all the PhD students in the Global Genes Local Concerns project possibilities for informal contacts and networking. Interdisciplinary meetings have been held at LAW, HEALTH and SCIENCE.

Whereas the below tables concentrate on post-graduate research projects, it should finally be recalled that all involved researchers have supervised numerous students in several completed master thesis projects within areas that directly relate to the "Global Genes, Local Concerns" project. This also includes research based student teaching, such as in the courses "European Pharmaceutical Law, IPRs and the Life Sciences - from research and development to market approval and commercialization", "Health Law" and "European Intellectual Property Law in an International Context".

<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP2</p> <p>Name: Malene Bøgehus Rasmussen</p> <p>Faculty: HEALTH</p> <p>Title/Area of PhD project: Systematic reexamination of chromosomal inversions in Denmark.</p>
<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP2</p> <p>Name: Manaossadat Mahdizadeh Mehrjouy</p> <p>Faculty: HEALTH</p> <p>Title/Area of PhD project: Phenotypic consequences of chromosomal breakpoints.</p>
<i>PhD students with other sources of financing</i>	<p>Title of work package, if relevant: WP3</p> <p>Name: Karen Koefoed</p> <p>Faculty: HEALTH</p> <p>Title/Area of PhD project: Functional analysis of candidate genes in congenital heart disease.</p>
<i>PhD students with other sources of financing</i>	<p>Title of work package, if relevant: WP3</p> <p>Name: Srinivasan Sakthivel</p> <p>Faculty: HEALTH</p> <p>Title/Area of PhD project: Functional analysis of candidate genes in congenital heart disease</p>

<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP2</p> <p>Name: Malene Bøgehus Rasmussen</p> <p>Faculty: HEALTH</p> <p>Title/Area of PhD project: Systematic reexamination of chromosomal inversions in Denmark.</p>
<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP3</p> <p>Name: Louise Lindbæk</p> <p>Faculty: SCIENCE</p> <p>Title/Area of PhD project: Functional analysis of candidate genes in primary microcephaly</p>
<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP3</p> <p>Name: Stine Kjær Morthorst</p> <p>Faculty: SCIENCE</p> <p>Title/Area of PhD project: Regulation of vesicle trafficking at the primary cilium</p>
<i>PhD students with other sources of financing</i>	<p>Title of work package, if relevant: WP3</p> <p>Name: Johanne Bay Mogensen</p> <p>Faculty: SCIENCE</p> <p>Title/Area of PhD project: Characterization of membrane protein trafficking and cellular signaling at the primary cilium: implications for cardiomyogenesis</p>

<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP2</p> <p>Name: Malene Bøgehus Rasmussen</p> <p>Faculty: HEALTH</p> <p>Title/Area of PhD project: Systematic reexamination of chromosomal inversions in Denmark.</p>
<i>PhD students with other sources of financing</i>	<p>Title of work package, if relevant: WP3</p> <p>Name: Raj Rajeshwar Malinda</p> <p>Faculty: SCIENCE</p> <p>Title/Area of PhD project: Cellular Mechanisms Regulating Ciliary Disassembly and EMT: Roles of Ion Transport and Implications for Cancer</p>
<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP4</p> <p>Name: Berit Faber</p> <p>Faculty: LAW</p> <p>Title/Area of PhD project: Legal pathways for donor's rights in international biobanks –Tools for balancing the rights and wishes of donors in biobanking with the need for new research, to be defended in 2018.</p>
<i>PhD students financed via the grant</i>	<p>Title of work package, if relevant: WP4</p> <p>Name: Neethu Rajam</p> <p>Faculty: LAW</p> <p>Title/Area of PhD project: Industrial and research partnerships in publicly funded Biobanks: The potential role of Intellectual Property Rights, defended in March 2018</p>

<i>PhD students financed via the grant</i>	Title of work package, if relevant: WP2 Name: Malene Bøgehus Rasmussen Faculty: HEALTH Title/Area of PhD project: Systematic reexamination of chromosomal inversions in Denmark.
<i>PhD students financed via the grant</i>	Title of work package, if relevant: WP5 Name: Nana Cecilie Halmstad Kongsholm Faculty: HUM Title/Area of PhD project:

4. External funding [præpopuleret pba. midtvejsevaluering]

Please list the amount of external funding obtained to date with relation to the project using the outline below. If the same grant has two or more grant holders the total amount granted as well as the sub amounts should be listed.

<i>Source</i>	<i>Grant holder</i>	<i>Project title</i>	<i>Period</i>	<i>Total amount granted</i>	<i>Sub amount (if more than one grant holder)</i>
<i>Kræftens Bekæmpelse</i>	<i>Klaus Lindgaard Høyer</i>	<i>Forandrede patientroller</i>	<i>2015-2016</i>	<i>DKK 250.000</i>	
<i>Svend Andersen Fonden</i>	<i>Lars Allan Larsen, Søren Peter Olesen, Elke Ober</i>	<i>State-of-the-art biomedicinsk forskningsfacilitet til zebrafisk</i>	<i>2015</i>	<i>DKK 1.500.000</i>	<i>Total amount was used to establish facility</i>

<i>Source</i>	<i>Grant holder</i>	<i>Project title</i>	<i>Period</i>	<i>Total amount granted</i>	<i>Sub amount (if more than one grant holder)</i>
<i>Vera og Carl Johan Michaelsen's Legat</i>	<i>Lars Allan Larsen, Søren Peter Olesen, Elke Ober</i>	<i>State-of-the-art biomedicinsk forskningsfacilitet til zebrafisk</i>	<i>2015</i>	<i>DKK 1.000.000</i>	<i>Total amount was used to establish facility</i>
<i>Gerda og Aage Haensch's Fond</i>	<i>Lars Allan Larsen, Søren Peter Olesen, Elke Ober</i>	<i>State-of-the-art biomedicinsk forskningsfacilitet til zebrafisk</i>	<i>2015</i>	<i>DKK 400.000</i>	<i>Total amount was used to establish facility</i>
<i>Carlsberg Foundation</i>	<i>Stine Falsig Pedersen, Søren Tvorup Christensen, Lotte Bang Pedersen</i>	<i>Regulation of polarized trafficking of ion transport proteins and signaling receptors in epithelial cells</i>	<i>2015</i>	<i>DKK 300.000</i>	<i>Total amount was used to purchase microscope for live cell imaging</i>
<i>NOVO Nordisk Fonden</i>	<i>Lotte B. Pedersen, Søren Tvorup Christensen</i>	<i>Regulation of Hippo signalling by primary cilia and kinesin-3 motor proteins</i>	<i>2015</i>	<i>DKK 700.000</i>	<i>Total amount was used to purchase microscope for live cell imaging</i>

<i>Source</i>	<i>Grant holder</i>	<i>Project title</i>	<i>Period</i>	<i>Total amount granted</i>	<i>Sub amount (if more than one grant holder)</i>
<i>NOVO Nordisk Fonden</i>	<i>Lotte B. Pedersen, Søren Tvorup Christensen</i>	<i>Regulation of Hippo signalling by primary cilia and kinesin-3 motor proteins</i>	<i>2016-2017</i>	<i>DKK 1.200.000</i>	
<i>Fondet for Lægevidenskaberne Fremme</i>	<i>Lars Allan Larsen</i>	<i>Karakterisering af sygdomsgener ved medfødt hjertefejl</i>	<i>Jan. 1, 2014 – Dec 31, 2015</i>	<i>DKK 130.000</i>	
<i>Aase og Ejner Danielsens Fond</i>	<i>Lars Allan Larsen</i>	<i>Identifikation af sygdomsgener ved recessiv familiær</i>	<i>Nov 26, 2013 – Dec. 31,</i>	<i>DKK 100.000</i>	
<i>Hjerteforeningen</i>	<i>Lars Allan Larsen, Karen Koefoed</i>	<i>The role of SMAD Specific E3 Ubiquitin Protein Ligases (SMURFs) in cardiac development and defects</i>	<i>July 1, 2015 – June 30, 2017</i>	<i>DKK 185.000</i>	

<i>Source</i>	<i>Grant holder</i>	<i>Project title</i>	<i>Period</i>	<i>Total amount granted</i>	<i>Sub amount (if more than one grant holder)</i>
<i>IRFD (FNU)</i>	<i>Søren Tvorup Christensen, Lotte Bang Pedersen</i>	<i>Coordination of PDGFRA and TGFb signaling at the primary cilium</i>	<i>June 1, 2016-May 31, 2018</i>	<i>DKK 2.390.158</i>	
<i>Kræftens Bekæmpelse</i>	<i>Lotte Bang Pedersen</i>	<i>Regulation of Wnt signaling at the primary cilium by kinesin-3 motors and caveolin-1</i>	<i>Jan. 1, 2017-Dec. 31, 2018</i>	<i>DKK 1.400.000</i>	
<i>EMBO Courses & Workshops Programme</i>	<i>Lotte Bang Pedersen</i>	<i>EMBO Workshop: Cilia 2018</i>	<i>2017-2018</i>	<i>Ca. 250.000 DKK (€33.500)</i>	<i>Total amount to be used for the scientific conference Cilia 2018 (http://meetings.embo.org/event/18-cilia)</i>

<i>Source</i>	<i>Grant holder</i>	<i>Project title</i>	<i>Period</i>	<i>Total amount granted</i>	<i>Sub amount (if more than one grant holder)</i>
The Danish Heart Association	Lars Allan Larsen	Studying the rare to understand the common in congenital heart disease	2017-2020	DKK 1.000.000	

<i>Novo Nordisk Foundation Research Grant (Grant number NNF17SA0027784)</i>	<i>Timo Minssen – JUR</i>	<i>Collaborative Research Programme in Biomedical Innovation Law</i>	<i>2018-2023</i>	<i>35.000.000 (35 million) DKK</i>	<i>35.000.000 (35 million) DKK</i>
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<i>IFPMA</i>	<i>Timo Minssen-JUR</i>	<i>Scientifically independent webinar series on TRIPS & The Life Sciences, co-sponsored by Faculty of Law</i>	<i>2017</i>	<i>58.326 CHF = 370.000 DKK</i>	<i>370.000 DKK</i>
<i>No specific input provided</i>	<i>Niels Tommerup</i>	<i>No specific input provided</i>	<i>2016-2017</i>	<i>4,9 milll. DKK</i>	<i>4,9 milll. DKK</i>

5. Private and public sector collaboration, innovation and impact

5.1 Private and public sector collaboration

The project has been presented at a number of occasions both nationally and internationally. Furthermore, individual members of the project have engaged in collaboration with both the private and the public sector in matters either directly or indirectly related to the project. These collaborations include a number

of public talks and presentations both in Denmark and abroad and both aimed a public institutions and decision makers and at companies etc.

Examples include:

WP1.

Klaus Hoeyer

2018 Studying Big Data Ethnographically. Invited talk for Explorative workshop on Big Data: Challenges and opportunities for epistemology and ethics, University of Copenhagen, Faculty of Science, January 24.

2017 Det informerede samtykke: Intentioner, politik og praksis. Invited presentation for Etisk Udvalg under Strategien for Personlig Medicin, Ministry of Health, Copenhagen, November 24.

2017 The Politics of the Archive. Invited presentation at The Politics of Biobanking Symposium, Medical Village, Lund, Sweden, November 16.

2017 Data-intensive healthcare and the public-private distinction. Invited paper at The Expansion of the Health Data Ecosystem Workshop, Maastricht, November 8.

2017 Epilogue: the agency of frozen body parts. Invited presentation at the Minerva-Gentner Symposium Frozen: Social and Bioethical Aspects of Cryo-Fertility, Tel Aviv, Israel, October 1-3.

2017 The Datafication of Biobanks. Invited presentation at the CHIP-Me final conference, Galway, Ireland, September 4.

2017 Data as promise. Reflections on contemporary Danish visions of health data. Invited talk at the Digital Healthcare Workshop, Nottingham University, Nottingham, UK, June 20.

2017 The data politics of digitalized healthcare, Invited presentation, Brocher Foundation, Geneva, Switzerland, June 22.

2017 Hvem har adgang til vores sundhedsdata? Invited participation in panel debate, Folkemødet, Bornholm, Denmark, June 16.

2017 Personalized medicine: Data intensification and evidence-making in Danish healthcare.
Invited talk at KU Leuven, Belgium. March 23.

2017 Datapolitik i Sundhedsvæsenet. Invited talk at the symposium Mød Eliteforskerne, the Royal
Danish Academy of Sciences and Letters, Copenhagen, March 13.

2017 Post-Truth? Personalized medicine, data intensification and evidence in Danish healthcare.
Invited talk at Sheffield University (Medical Humanities Programme), Sheffield, England, January 30.

2017 “When an entire country is a cohort”: research conscription in Denmark. Invited presentation
at the Liminal Spaces workshop, Wellcome Trust, London, England, January 26.

2016 Salvage accumulation and global tissue flows. Invited presentation at the East Asian Tissue
Economies Workshop, Tsinghua University, Beijing, September 7.

2016 Genetic Non-knowledge: Remaking Kinship Relations Through Biobank Research. Invited talk
at École des Hautes Études en Sciences Sociales for the seminar, Biobanques: Quelles reconfigurations
pour le vivant? Paris, May 12.

2015 Intensified data sourcing in Europe. Invited presentation at the Biobanking and Big Data
Symposium, organized by Lund University and BBMRI-ERIC, Lund, November 3rd.

2015 It's all about the money – or is it? Invited presentation at the symposium Donors, Money and
Body Parts: What are the Issues? Newcastle University, Newcastle upon Tyne, September 22.

2015 Lost and Found. Relocating the Individual in the Age of Intensified Data Sourcing. Invited
presentation at the Me Medicine vs. Me Medicine Symposium, Amsterdam, September 9.

2015 Biobanking: The ethical Challenges. Invited paper, 'Biobanking for Research Purposes'
Symposium, Masaryk University, Brno, May 25-26.

2015 The Challenges of Intensified Data Sourcing in a Research Radical Country: The Case of
Denmark. Invited paper, 'The Ethics of Biomedical Big Data', Oxford University, Oxford, April 25.

2015 Udgør biobanker og registerforskning et problem – og i givet fald for hvem? Invited presentation at local hearing organized by the Danish branch of World Medical Association, Copenhagen March 23.

2014 A platform for what? Exploring the social life of moral hopes and concerns in cross-national genetic research. Invited paper, 'Global Life Sciences and Bionetworking' Conference, Sussex University, Brighton, November 10-12.

2014 Tillid, Donorholdninger og Fortrolighed. Invited presentation at the symposium Forskning i Sundhedsoplysninger, Danish Council on Ethics, Ministry of Health, Copenhagen, June 19.

Aaro Tupasela

The biobanking course and symposiums offered in collaboration with Lund University were also developed in conjunction with a number of companies and organizations including LIF, Medicon Village, SweLife, EpiHealth, and Multihelix. In addition, the events have been in part sponsored by large pharmaceutical companies, which illustrates the interest that private industry has had towards our activities.

WP2: Medical genetic research always involve collaboration with numerous stake-holders, from patients and families, to patient organizations and hospitals. In WP2 this is a global and rapidly changing effort driven by the detection of new diseases and disease genes.

WP3: Ongoing collaborations include Rigshospitalet (DK), Aarhus University Hospital (DK), Center for Spine Surgery (DK), The Kennedy Center (DK), The Danish Heart Association (DK), The American PCD Foundation (USA), European Society of Cardiology.

WP4: UCPH Summer course for Pharma professionals in Pharmaceutical Law and Policy involving teachers and professional “students” from many European and US Pharma companies, such as Novo Nordisk, Lundbeck, GSK etc.- Collaboration of open innovation platforms with industry Membership of PI of Scientific Advisory Board member at the Copenhagen Centre for Regulatory Sciences (CORS) with many industry representatives.

The Global Genes colleagues at the faculty of Law have during the project period given far more than 100 combined talks at international high profile conference, e.g. at Harvard Law School, Oxford, Cambridge,

Stanford, Max Planck, international industry conferences etc., see for example at:
[http://jura.ku.dk/cebil/staff/profile/?pure=en%2Fpersons%2Ftimo-minssen\(7ded1eca-75f2-4e95-ab13-4f66cb51ec0b\)%2Factivities.html](http://jura.ku.dk/cebil/staff/profile/?pure=en%2Fpersons%2Ftimo-minssen(7ded1eca-75f2-4e95-ab13-4f66cb51ec0b)%2Factivities.html)

WEBINARS

Timo Minssen and Jakob Wested organized scientifically independent webinar series on TRIPS & The Life Sciences, co-sponsored by Faculty of Law and IFPMA (International Federation of Pharmaceutical Manufacturers and Associations), see: <http://jura.ku.dk/cebil/research/trips/> .

- 27 April 2017: Perspectives on limitations to patentability
- 28 June 2017: Procedural aspects of compulsory licensing under TRIPS
- 29 November 2017: Bolar provisions – Recent developments and possible scenarios
- 18 January 2018: Data Exclusivities and TRIPS Art. 39.3

5.2 Application and commercialisation [if relevant]

	<i>Title(s)</i>
<i>Invention disclosures</i>	
<i>Patent applications</i>	
<i>Patents issued</i>	
<i>License agreements</i>	
<i>Spin-out companies</i>	

WP2, WP3 have initiated a collaboration with the private diagnostic sector (AROS A/S) to develop a new platform for targeted analysis of the regulatory part of the human genome.

WP 4:

PI is Legal expert member in ERA Syn Bio and Applied Sys Bio networks including industry and academia. Several spin-outs and consultancy opportunities could arise here. Also an application to the Novo Nordisk Foundation was successful (Timo Minssen) which further strengthens ties with the private sector.

With Faculty approval, Timo Minssen is involved in strictly limited consulting activities specializing on large research infrastructures: <https://www.xofficio.eu/about> (with former ESS-ERIC Head of Legal).

5.3 Societal impact

The project has no formal strategy for influencing decision makers, but engaged decision-makers at different levels through dialogue as appropriate for each WP. Talks have been given to organisations and professionals throughout the project, for example. As has already been explained above in 6.1. the project members have been involved in a number of activities which no doubt have an impact on society e.g. by informing decisions makers or institutions.

Concrete examples include:

WP1: We have been in dialogue with and contributed papers to (see above) the WMA on their work with new guidelines, the Ethics Council, The WMA, and locally the Faculty of Health and Medical Sciences.

WP2: Our results will improve diagnosis and counselling in prenatally detected de novo balanced chromosomal rearrangements. Similarly, our data will highlight the importance of chromosomal breakpoints in regulatory domains and provide an invaluable aid for the future interpretation of genetic variants and mutations that will be detected by future full genome sequencing projects.

WP3: The disease-related genes and molecular mechanisms uncovered will aid in future diagnosis and patient care.

WP4: As mentioned above, we have presented ideas derived from the project at several conferences and meetings where decision makers have also been present and have taken part in discussions e.g. with the Ethical Council, the Danish National Biobank and private companies where the insights derived from the project have been presented or have informed our own opinions on the topics discussed.

Timo Minssen was Expert Board Member of EU Commission study on the economic impact of pharma incentives: 590/PP/GRO/SME/16/F/121. Title: Study on the economic impact of supplementary protection certificates (SPCs), pharmaceutical incentives and rewards in Europe. Timo Minssen was also legal experts member in two ERA projects on Synthetic Biology and Systems Biology .

5.4 Public outreach

The project has no formal strategy for influencing decision makers. As has already been explained above in 6.1. the project members have been involved in a number of activities which no doubt have an impact on society e.g. by informing decisions makers or institutions.

Concrete examples include:

WP1: We have been in dialogue with and contributed papers to (see above) the WMA on their work with new guidelines, the Ethics Council, the WMA, the Danish Society for Genetic Epidemiology, and locally the Faculty of Health and Medical Sciences.

WP2: Our results will improve diagnosis and counselling in prenatally detected de novo balanced chromosomal rearrangements. Similarly, our data will highlight the importance of chromosomal breakpoints in regulatory domains and provide an invaluable aid for the future interpretation of genetic variants and mutations that will be detected by future full genome sequencing projects.

WP3: The disease-related genes and molecular mechanisms uncovered will aid in future diagnosis and patient care.

WP4: We have presented ideas derived from the project at several conferences and meetings where decision makers have also been present and have taken part in discussions e.g. with the Ethical council, the Danish National Biobank and private companies where the insights derived from the project have been presented or have informed our own opinions on the topics discussed.

Selected Media interviews from 2016 – 2017: see

For example: Mixed views on Broad's fate after EPO revokes CRISPR patent
Press/Media: Press / Media, 18/01/2018

Commentators have offered differing opinions on the impact of yesterday's decision by the European Patent Office (EPO) to revoke a CRISPR/Cas9 patent owned by the Broad Institute of Harvard and MIT.

In that context Timo Minssen was interviewed by the Life Science Intellectual Property Review

And:

- Medicinalindustri vil fortsat skjule oplysninger om forsøg, Interview of Timo Minssen by Anne Ringgaard, 3 pp, www.Videnskab.dk (01.02 2018)

BLOGS

PI Timo Minssen contributes regularly to Harvard Law School's Bill of Health blog:

<http://blogs.harvard.edu/billofhealth/category/contributors/timo-minssen/>

PODCASTS

Podcast-interview: Unlocking the full potential of Open Innovation in the Life Sciences through a classification system, Press/Media: Press / Media, 14/12/2017

Podcast recording commissioned by the European Biopharmaceutical Industries Organization (EBE). The interview was carried out, recorded and featured by the media company Vital Transformation.

<https://www.ebe-biopharma.eu/podcast/ebe-podcast-on-open-innovation-timo-minssen-niclas-nilsson/>

WEBINARS

Academically independent webinar series and debates on Trips and the Life Sciences in collaboration with the support of industry organization IFPMA , see: <http://jura.ku.dk/cebil/research/trips/>

The series included the following webinars (usually involving two experts discussants with diverging views on life science developments) :

- 27 April 2017: Perspectives on limitations to patentability
- 28 June 2017: Procedural aspects of compulsory licensing under TRIPS
- 29 November 2017: Bolar provisions – Recent developments and possible scenarios
- 18 January 2018: Data Exclusivities and TRIPS Art. 39.3

6. Concluding remarks

Our concluding recommendations and ambitions for the future of the project can be summarized in this way:

- Large scale, international biobanking and more efficient and sophisticated uses of a growing amount of biological data is becoming increasingly important in the developments of new (precision-) therapies. But scientific opportunities are as great as the risks associated with new applications and internationalization. Thus, there is a growing need for further interdisciplinary studies in this area. Our Global Genes project has already achieved good results with many significant papers published already and several other publications in review. It has thus created an excellent platform to take UCPH's research to the next level in this important area.
- The use of biobanks as large research facilities (ex. BBMRI- ERIC) also involves issues that overlap with some questions tackled by the 2016 CoNeXT projects (ex. ESS- ERIC).
- Expectations, hopes and concerns of the contributors to biobank research in contexts as diverse as Pakistan, Denmark and other European countries differ so much that harmonization of ethics rules seems to run counter to the participants' interests e.g. in establishing forms of contact that suited their specific situation. The concept of trust is associated with very different connotations and established through very different practices.
- A more transparent legal framework and flexible regulations are necessary to create an optimal environment for translational pathways in personalized medicine.

- Yet, predictable regulations remain important for fostering data reliability, public trust” and product safety. Moreover, legal certainty and the availability of well-defined IPRs remain necessary for product development and the economic sustainability of biobanks.
- An effective utilization of biobank collections and sound policies to govern their use will require a thorough understanding of the large diversity found in organizational characteristics and goals of biobanks.
- The legal framework should not just concern “rights”. It must also deal with the obligations to act as stewards for the agency commons to provide a supportive infrastructure for transactions and interactions between stakeholders, and to respect the participants’ freedom to exercise their moral choices and responsibilities.
- This requires a clear and adequate system for obtaining consent which provides flexibility but at the same time puts up road blocks.
- Equally important are discussions of strategies and policy choices for publicly funded biobanks with regard to IPRs directed to HBMs, the associated data stored in the biobank and the results of the research using the HBM and associated data.
- Operators of publicly funded biobanks will have to take the necessary decisions pro-actively and rather sooner than later in order to enhance translational medicine and to fully exploit the great possibilities of personalized medicine.
- The most recent and forthcoming cross-faculty publications that are the direct result of the Global Genes project have been highlighted in yellow in the attached publication lists.