

## **Work Package 7 – BIOETHICS**

### *Ethical and Legal Aspects of Biobanking*

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## Scientific goals and results

Goals from the final contract (2003/2004 and 2004/2005):

- a. explore issues in public and private law as well as ethical issues – in 12 specified articles
- b. maintain and develop the ongoing web-based biobank user service
- c. provide education on legal and ethical aspects of biobank storage and use

Ethical and legal arguments concerning biobank use have been further developed in 2004. New problems related to the application of the Biobanks Act and the Ethical Review Act have also been addressed.

## Publications from WP7

1. Hansson, Mats G. Building on relationships of trust in biobank research, *Journal of Medical Ethics*, in press.
2. Hansson, Mats G. *Integrity – from an evolutionary and ethical perspective*. Monograph. Carlsons Förlag, in press.
3. Helgesson, Gert. Children, longitudinal studies, and informed consent. *Medicine, Health Care and Philosophy*, in press.
4. Helgesson, Gert, Johnsson, Linus. The right to withdraw consent to research on biobank samples, *Medicine, Health Care and Philosophy*, in press.
5. Helgesson, Gert, Ludvigsson, Johnny, Gustafsson Stolt, Ulrica. How to handle informed consent in longitudinal studies when participants have a limited understanding of the study, *Journal of Medical Ethics*, prel. accepted.
6. Eriksson, Stefan, Helgesson, Gert. To give renewed information or letting people be – A suggested tool for identifying those research participants who rightly want only limited information, manuscript at reviewers, *Journal of Medical Ethics*, prel. accepted.
7. Gustafsson Stolt, U., Helgesson, G., Liss, P-E, Svensson, T, Ludvigsson, J. Information and informed consent in a longitudinal screening involving children: a questionnaire survey, *European Journal of Human Genetics*, in press (Epub ahead of print December 15, 2004).
8. von Essen, Ulrik. När, var och hur uppkommer en biobank?, *Förvaltningsrättslig tidskrift* 2004: 103–130.
9. Hansson, Mats G & Levin, Marianne (eds.). *Biobanks as resources for health*. Uppsala University, 2003. Among other papers, it includes:
  - von Essen, Ulrik. Focusing on personal integrity violation – legal guidelines for ethical practice. 129–148.
  - Helgesson, Gert. A Swedish standard for information and consent procedures in biobank research. 149–164.
  - Kaijser, Magnus. Examples from Swedish biobank research. 33–50.
  - Hellstadius, Åsa, Wolk, Sanna & Wessman, Richard. Intellectual property and biobanks. 207–225.
10. von Essen, Ulrik. Biobanksforskning – forskares möjligheter att få tillgång till vävnadsmaterial och personuppgifter. *Förvaltningsrättslig tidskrift* 2003 (2): 197–214.

11. von Essen, Ulrik. Biobanks- och registerforskning – etikprovning och materialtillgång. In Wolk, Sanna (ed.). *Biobanksrätt*, 2003: 177–234.
12. von Essen, Ulrik. Etikprovning av biobanks- och registerforskning. *Förvaltningsrättslig tidskrift* 2002 (5–6): 351–380.
13. Hansson, Mats G. Combining efficiency and concerns about integrity in the use of human biobanks. Submitted.
14. Wessman, Richard. Biobanken, marknaden och rätten. In Wolk, Sanna (ed.). *Biobanksrätt*, 2003: 303–321.
15. Website: [www.bioethics.uu.se/biobanker](http://www.bioethics.uu.se/biobanker) (Gert Helgesson responsible for the content)

Ulrik von Essen, Mats G. Hansson and Bo S. Lindberg have also contributed with Biobanker som hälsoresurs – educational material (landstinget).

### **Biobank user service**

Information and a number of papers and useful links are made available to holders and users of biobanks at [www.bioethics.uu.se/biobanker](http://www.bioethics.uu.se/biobanker). The site provides a biobank user service, where biobank users, and others, may send in questions and get the answers published on the site. Health care professionals, employees at pharmaceutical companies, and students were among the users 2004.

### **Educational and advisory efforts**

- 28/1 Lecture about biobanks and research ethics at the Swedish Chemical Products Agency
- 10/2 Meeting at the Federation of County Councils regarding uniform procedures for information and consent
- 17/2 Lecture at Rotary, Uppsala about biobank regulation
- 29/3 Meeting at the Federation of County Councils regarding uniform procedures for information and consent
- 31/3 Meeting at the Federation of County Councils regarding disposition of human tissue material
- 21/4 Course on legal and ethical aspects of biobanking for scientists and clinicians: “Biobanker i hälso- och sjukvården”, Uppsala
- 11/5 Lecture about ethical and legal regulation of human tissue sampling at Uppsala University Hospital
- 12/5 Meeting at the Federation of County Councils regarding disposition of human tissue material at Uppsala University Hospital
- 3/6 Lecture at WCN-meeting at Arlanda Conference Center about integrity
- 16/6 Meeting at the Federation of County Councils regarding disposition of human tissue material
- 27/8 Lecture about the ethics of biobank research and biobank regulation at Nordic Psychology Conference in Oslo
- 31/8 Lecture about ethical and legal regulation of human tissue sampling at Stockholm County Council, Häringe
- 1/9 Lecture about ethical and legal regulation of human tissue sampling for Biobank Ambassadors at Uppsala University Hospital
- 6/9 Lecture about ethical and legal regulation of human tissue sampling for research at Uppsala Clinical Research Centre.
- 13/9 Lecture about ethical and legal regulation of human tissue sampling for Biobank Ambassadors at Uppsala University Hospital
- 23/9 Lecture about the ethics of biobank research and biobank regulation at the European Conference for Epidemiological Studies in Bristol.
- 14/10 Lecture about the ethics of biobank and other kinds of regulation in biomedical research at the Nordic Conference for Social Pharmacy in Uppsala
- 29/10 Lecture about the ethics of biobank research and biobank regulation at the Graduate Seminar of Medical Epidemiology, Karolinska Institutet
- 26/11 Lecture about the ethics of biobank research and biobank regulation at the Graduate School of Epidemiology and Genetics at Karolinska Institutet

Consultations, by phone and via our website, have been given throughout the year.

## **Remaining deliverables within the present contract**

### ***1. Remaining topics to be treated in articles***

- how the Swedish statutes on biobanks and ethical review of research combine with relevant EU directives (Wessman)
- what results from combining legal intellectual property rights with recent legal regulations in the field of biobanks (Wessman)
- whether research on stem cells may result in patentable inventions (Wessman)
- trademarks as a means to securing the reputation of biobanks (Wessman)
- particular ethical problems tied to use of biobanks for research on stem cells (Helgesson)
- the ethics of research on anonymized samples (Helgesson)

Wessman is at present working on Europeisk biobanks- och immaterialrätt, for publication in *NIR*. Helgesson is at present working on a paper on the ethics of research on anonymized samples.

### ***2. Education***

We will participate in education on legal and ethical aspects of biobanking also in year 2005.

## **Plans for the future**

- The research group participates in the CCPRB Network of Excellence, which runs for 4 ½ more years. This means we will have a continued contact with medical researchers and will be updated on the ethical difficulties they encounter in international research studies using biobanks. Our work here aims at facilitating biobank research within international networks while protecting the interests of the individuals from whom the samples are taken. Continuous work on ethical and legal issues is of vital importance due to the increase in international collaboration using human biological samples.
- Additional biobank-related research is ongoing or planned at the Centre for Bioethics at Karolinska Institutet and Uppsala University, including both philosophical and empirical studies. There are many issues that still need to be addressed, for instance, in relation to longitudinal studies and to studies involving young children or other persons not competent to give informed consent. To give two examples: (1) A questionnaire will be sent out at the beginning of March where questions concerning research on children are asked, including questions concerning research on biobank samples (in cooperation with researchers at Linköping University). (2) An ethical analysis of the concept of "autonomy" will start this spring.
- We are interested in future cooperation with medical researchers concerning biobank issues. We can foresee difficult ethical and legal problems related to stem cell research and tissue engineering.

**Rekvirerat belopp 2004:**

2004-06-08	20 656
2004-06-08	48 385
2004-06-08	2 664
2004-07-28	720 382
2004-09-23	75 514
	<b>867 601</b>

**2004-06-08 ersättning för**

litteratur	1 874
Projektgruppsmöte/seminarium	15 845
Administrativ hjälp (påslag)	1 130
Overhead	154
Momskompensation (8,7%)	1 653
	<b>20 656</b>

**2004-06-08 ersättning för**

Resor	984
Litteratur	3 545
Språkgranskning	1 500
Dator & tillbehör	22 186
Programvaror	2 003
Kurser	8 000
Porto, telefon, kopiering	3 286
Administrativ hjälp (påslag)	2 648
Overhead	361
Momskompensation (8,7%)	3 873
	<b>48 385</b>

**2004-06-08 ersättning för**

Konferensavgift	2 285
Administrativ hjälp (påslag)	146
Overhead	20
Momskompensation (8,7%)	213
	<b>2 664</b>

**2004-07-28 ersättning för**

Lönemedel	548 203
Administrativ hjälp (påslag)	34 976
Overhead	79 546
Momskompensation (8,7%)	57 657
	<b>720 382</b>

**2004-09-23 ersättning för**

Korr lönemedel	57 466
Adm hjälp (påslag)	3 666
Overhead	8 338
Momskompensation (8,7%)	6 044
	<b>75 514</b>

**Utgifter specifikation**

Avgår högskolemoms	69 440
Omkostnadsuttag	130 985
	<b>200 425</b>

**Lönemedel 2004**

Ulrik von Essen (samarbetsavtal Sthlm univ inkl h-moms)	132 312
Richard Wessman (samarbetsavtal Ua univ)*	134 672
Gert Helgesson 7 månader	308 404
Webmaster	51 640
	<b>627 028</b>
Avgår högskolemoms 8% Sthlm univ	-10 585
<b>Totalt lönemedel</b>	<b>616 443</b>

**Övriga utgifter (rekvirerat med fakturaspecifikation)**

Resor	984
Litteratur	5 419
Möte/seminarium	15 845
Språkgranskning	1 500
Dator o tillbehör	22 186
Programvaror	2 003
Kurser/konferenser	10 285
Porto, tele, kopiering	3 286
	<b>61 508</b>

**Summa utgifter****878 375****Summa rekvirerade medel****867 601****Kostnader****878 375****Diff\*****-10 774**

\* Återstår att rekvirera 10 774 kr för Richard Wessman. Felaktigt avdrag för h-moms på rekv 0728 samt 0923. Då Wessman är anställd på Ua univ skall ytterligare avdrag för h-moms ej göras, se Mats rekv 17/9 04.