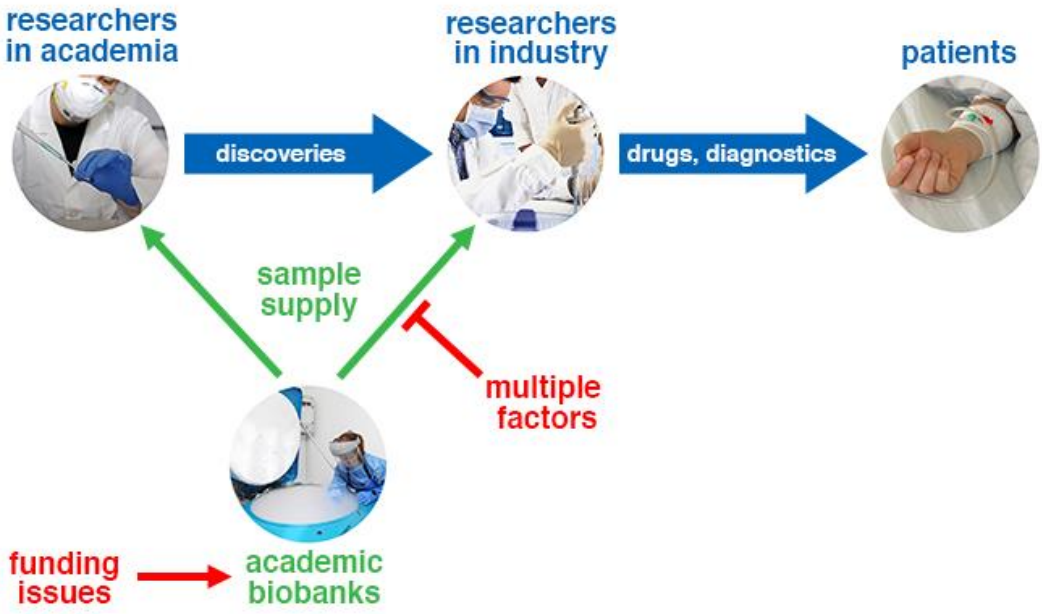

7. Acceptable Transactions in Biobanking

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This is one of a series of articles on the topic of 'Biobanks and Industry'. In this article we consider what financial transactions in biobanking are legally acceptable, focussing particularly on the Council of Europe's Oviedo Convention.

Background

One of the multiple factors that inhibits the supply of samples from academic biobanks to researchers in industry, is concern about legal issues. There is uncertainty about what is and is not legitimate in terms of financial transactions. As noted by **Evers et al (2012)**, '*European law is based on principles that categorically prohibit selling parts of the human body*'. At first sight, this authoritative statement might seem to prohibit financial transactions in biobanking. However, there is an important distinction to be made between (1) selling parts of the human body and (2) charging a fee for processing and supplying biosamples for research purposes.

The Oviedo Convention

The Council of Europe's **Oviedo Convention** (1997) was the first international legally binding instrument on the protection of human rights across the whole biomedical field. Article 21 of this important high-level convention states that:

'The human body and its parts shall not, as such, give rise to financial gain'.

Petrini and Ricciardi (2018) have commented that this article in the Oviedo Convention is '*One of the articles most susceptible to diverging interpretations*'. They suggest this is not due to any lack of clarity in the text of article 21, but rather to the multiplicity of different situations to which the convention applies.

It is true that the wording of article 21 might seem to prohibit biobank commercialisation. However, as Lenk and Beier pointed out in their 2011 article '**Is the commercialisation of human tissue and body material forbidden in the countries of the European Union?**', on closer inspection of European documents like the Oviedo Convention, it becomes apparent that:

'... the ban on commercialisation of body material is not as strict as it may appear at first sight, leaving room for the commercial practice of tissue procurement and transfer'.

From the perspective of researchers in industry (pharmaceutical, diagnostic and small/medium size biotech companies), this is good news, because it is doubtful they would obtain all the biosamples they need via non-commercial routes alone. From the perspective of general public it is also good news, because we all stand to benefit when industry gets new drugs and diagnostics validated and approved. Industry needs access to biosamples in order to do this.

Reasonable Remuneration is Legally Acceptable

An **explanatory report** supplementing the Oviedo convention, states that:

'... technical acts (sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport, etc.) which are performed on the basis of these items may legitimately give rise to reasonable remuneration.'

Based on this paragraph, it is legitimate to charge a fee for sample processing. It is also legitimate for this fee to provide reasonable remuneration. However, the question of what would constitute reasonable remuneration has been left unanswered.

Reasonable remuneration must be at least cost recovery - any less and the supplier would be making a financial loss which would be unreasonable! Some would argue that reasonable remuneration should be more than cost recovery, perhaps even standard commercial rates.

Components of Cost Recovery

The cost of biobanking activities were assessed by **Clement et al, (2014)** in a study involving 16 different biobanks in Europe. The findings were very revealing, and so some detail is provided here. First, the authors of the study produced a list of 46 tasks in biobanking and to each task they assigned an indicator of the expertise required, and the duration or complexity of the task. They used this information to produce a calculation grid which was completed by each of the 16 biobanks and resulted in a cost analysis for the supply of different biosample types. They reported that:

'One remarkable finding of this assessment was that the highest fraction of the cost (from 60 to 80%) was attributed to the management and biobanking expertise required to ensure compliance with quality standards, ethical standards, and legal requirements, regardless of the nature of the biological resource.'

So in other words, the majority of the cost was for the large number of biobanking tasks necessary to process the biosample.

It can be argued that the biosample as such is worthless. For example, **Eliason (2012)** stated that:

'... without the services provided by the acquisition and biobank teams, the tissue in reality would have no value for research because it would be discarded as medical waste.'

So it seems quite reasonable for biobanks to claim that 100% of the fees charged in biosample transactions are for sample processing services. It is also reasonable for them to claim that tissue as such is not being sold.

Conclusion

One thing is clear: under European law it is legitimate for biobanking transactions to include a reasonable fee for the processing of biosamples. At the very least this can be a cost-recovery fee.

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Disclaimer: the author of this article works independently and any views expressed are his own.

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