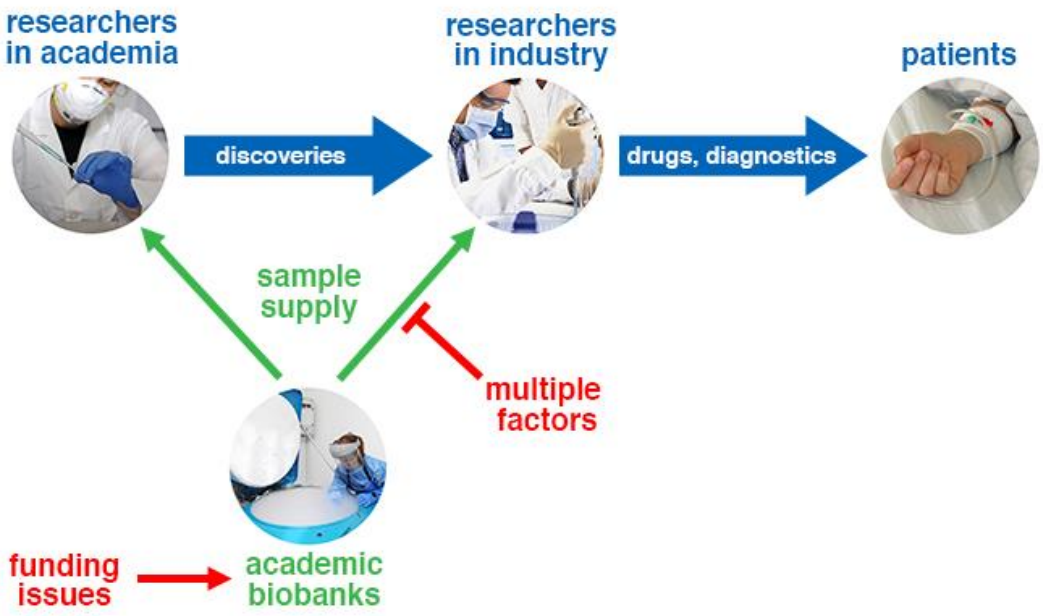

8. Why Biobank Access Policies Should Be Publicly Available

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The process of finding a suitable academic biobank is not easy for industry researchers. Not only must the biobank have the biosamples required, but also it must have policies that allow industry access. Biobank access policies may contain exclusion criteria that prevent industry access, or conditions of access that many companies would find unacceptable. Furthermore, a recent study has shown that most academic biobanks do not make their access policies publicly available, which makes it even more difficult for industry researchers to find suitable biosample providers.

These are some of the multiple factors that inhibit the supply of biosamples to researchers in industry (see diagram above).

Biobank Access Policy

A biobank's policies indicate the core values of its leadership and major stakeholders. As previously stated by Catchpoole (2015):

Motivation can be captured in policy which sets boundaries of practice of the biobank and reflects the core values of the different authorities, community groups,

and stakeholders who consider it a "biobank." ***Catchpoole, D.R.*** ***Biohoarding: treasures not seen, stories not told*** **.** J Health Serv Res Policy. *2015;21:140–142.*

In the case of an institutional biobank (like a hospital/university biobank), the policy makers will be senior representatives of the institution including senior academics, clinicians and clinical academics. Whoever handles the biosample requests (whether it is a biosample access committee, or the biobank manager), the rules set out in the biobank access policy must be followed.

Whoever is the acting gatekeeper, it is the biobank access policy that is key to deciding who has access to biosamples. If the access policy says 'No' then that is final.

Transparency About Biobank Access Policy

In the first study to investigate the public availability of biobank access policies, Langhof *et al* (2017) found that of 523 biobank websites screened, only 9% included a publicly available access policy. According to Langhof et al:

'... some authors have argued for a 'stewardship model', requiring biobanks to prioritize best use and avoid underutilization of samples. Thus, biobanks ought to make all necessary arrangements that facilitate the best possible utilization of the samples. A key task in this regard would be to facilitate the access to informative access policies. The lack of publicly available access policies would not only contradict this obligation of stewardship but could also diminish public trust, willingness to donate samples and public funding. Biobanks, therefore, should have meaningful access policies and make them publicly accessible. ***Langhof et al,*** ***Access policies in biobank research: what criteria do they include and how publicly available are they? A cross-sectional study****. European Journal of Human Genetics (2017) 25, 293–300*

The same 2017 study by Langhof et al, found that 16 out of 74 access policies contained an exclusion criterion that prohibited access by industry researchers. This was the most common exclusion criterion.

Conditions of Access

There may be conditions of access that are not included in access policies. For example, there may be the condition that a research collaboration must exist between the industry requester and the institution to which the academic biobank belongs. According to van Ommen *et al* (2015):

'... commercialization of human bodily materials is forbidden according to the Council of Europe's Oviedo Convention and by national legislation in most Member States, and financial compensation, even on a cost-recovery basis, is generally not accepted by the public. Therefore, only research collaboration can provide a sound basis for accessing human biological samples and associated medical data. This situation may be a source of conflict that makes access for industry difficult or even impossible in some cases'. ***Van Ommen et al,*** ***BBMRI-ERIC as a resource for***

pharmaceutical and life science industries: the development of biobank-based Expert Centres *.European Journal of Human Genetics (2015) 23, 893–900*

This statement shows that some people consider research collaboration to be an essential requirement for industry access to biosamples. Unfortunately, research collaboration (which implies co-publication) is an unacceptable condition for many industry requesters. This is because they may have concerns about intellectual property issues and may have patent applications underway. So in effect, this condition blocks access for many industry requesters.

Conclusions

Transparency about biobank access policy is important for ensuring public trust. Biobanks depend on public support in order to build up biosample collections, so the public can naturally expect to be informed on how biosample collections are shared and utilised.

Transparency is also important to facilitate biosample supply to external requesters like industry researchers: if it is clear from the beginning whether an industry requester will be eligible to receive samples, this will avoid wasted time on applications.

To encourage transparency, Langhof *et al* (cited above) recommend the following:

'... infrastructrures such as BBMRI-ERIC and P3G could require access policies as a prerequisite to listing in their registries. Similarly, public funders might require (and not only recommend) publicly available access policies with at least some opportunity for external access'.

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