HOW-TO GUIDE:

GOVERNANCE IN BIOBANKING

INTRODUCTION

Biobanks are no longer seen as mere repositories. Rather they are increasingly taking and expected to take a more proactive role within the biomedical research landscape, thereby requiring greater expertise that span different professional fields. Trust in particular is and will continue to be a core pillar of biobanking. In that respect, trust should be fostered in order to promote longevity. Bearing this mind, there is a need for appropriate governance structures that provide the necessary oversight with regards to the daily operations of biobanking, and that ensure that daily processes run effectively and smoothly.

Whilst regulatory frameworks vary between different Member States, this how-to guide focuses on addressing general issues relating to governance that are commonly seen as challenge areas, notwithstanding varying regulatory requirements. Indeed, we suggest how biobanks can adequately prepare themselves with regards to develop their own governance structure and networks, including how to facilitate trust that ultimately assist daily operations and sustaining longevity of biobanks.

Five key challenge areas have been identified through research conducted by BBMRI-ERIC ELSI, experts from National Nodes and survey collaborators:

- public-private partnerships
- adapting to the GDPR
- everyday practices relating to data usage
- public and participant engagement
- the need for professional support and networks

These areas are increasingly encountered by biobanks, that require foresight and planning that should be taken into account. This guide makes practical suggestions relating to each scenario in order to encourage biobanks to prepare themselves and integrate solutions into their own governance structures.

PUBLIC-PRIVATE PARTNERSHIPS

We are increasingly seeing a greater number of public-private partnerships. Indeed, public institutions can no longer rely on a finite amount of funding from projects to sustain biobanking and associated biomedical studies. The involvement of industry is therefore needed for sustainable biobanking, enabling the pooling of expertise and resources that ultimately seek to benefit the greater public.

The challenge however comes as a result of much distrust and scepticism on the part of research participants and the general public with regards to the involvement of industry in research projects, and the latter's intentions when it comes to having access to biosamples and data. This in turn can impede kickstarting and conducting research studies.

PRACTICAL SUGGESTIONS:

Potential solutions to overcoming such mistrust require biobanks and coordinators of research studies **to be proactive, and to take responsibility.** Indeed, it can be seen that participants and the public expect a proactive approach from biobanks and see biobanks as being responsible for protecting and safeguarding the interests of participants. Biobanks should therefore be seeking to fulfil this role, such as below:

I. Viewing Industry as an Equal Partner

Viewing the involvement of private organisations as equal partners in the context of the collaboration should be highlighted and communicated to research participants. This therefore includes communicating the conditions of this partnership, as well as what the particular partner from industry is contributing to the collaboration and how they are ultimately giving back to the community.

As a result, we would encourage that biobanks and/or coordinators of biomedical research projects are transparent and as specific as possible with both participants and the public, outlining the following aspects of the partnership:

- That the collaboration does involve partners from industry and what the nature of the collaboration / research is;
- Which private partner(s) are involved;
- Why the private partner(s) is needed; and
- What the private partner(s) will be doing.

The above points should be easily accessible and made available in any PR material, as well as be made clear in the informed consent documentation.

II. Developing a Risk Mitigation Plan

The reality is that sometimes things can and do go wrong in the context of collaborations. In order to minimise damage, it is important that there is a plan and procedure in place with respect to PR and governance in order to ensure that biobanks can respond swiftly and effectively. It is consequently important:

- To have a due diligence / screening process in place to assess whether the involvement of a particular private partner is suitable;
- To ask whether the private partner has their own risk mitigation plan in place, and if so, to request this; and
- To develop identify risk areas, as well as safeguards to minimise such risks in a risk mitigation plan.

Once again, the above should be communicated with participants, and be made publicly accessible.

ADAPTING TO THE GDPR

Since the GDPR came into force, it has brought changes to practice within the biobanking and BMS (biomedical science) field, varying in extent depending on the Member State. It has also brought with it much confusion for researchers, including a feeling of general reluctance of accepting and integrating the GDPR in the context of daily operations.

Once again it is necessary that biobanks take a lead role in shifting the mindset of researchers into viewing the GDPR as supportive tool, rather than as a limiting tool, and also clarifying any confusion. If not and because of the relative novelty and associated uncertainty that has come with the GDPR, there is the pitfall that researchers are under the false impression that they are not able to process health and biomedical data, or alternatively that they make matters unnecessarily complicated and inefficient. This consequently results in research being impeded.

PRACTICAL SUGGESTIONS:

In order to uncloud ambiguities and address the concerns of researchers, biobanks have a role in providing tailored support to their researchers that sets to translate GDPR jargon into practical guidance, which ultimately results in less ambiguity and therefore smoother operations and processes.

There are various approaches to consider when doing so. However, it would be advisable to look at existing internal structures and expertise that could take the role of offering such support in the first instance:

- Is there anyone there anyone who is already providing clarifications and support to fellow colleagues concerning the GDPR? This may be a particular individual or indeed existing units within the infrastructures. Furthermore, Ethical Committees may also respond to such questions.
- If not, is there anyone who could take on the task of providing GDPR support? This could include existing personnel with the necessary expertise, or the legal department.
- What kind of forums could be used to allow researchers to ask questions relating to the GDPR? This could include existing weekly/monthly unit meetings to enable researchers to ask GDPR specific questions.

A strategic approach when identifying common challenge areas and how to address them could comprise of:

- Having a GDPR session with researchers that focuses on primarily collating experiences with regards to the GDPR in the context of their daily operations;
- Identifying common scenarios and challenge areas encountered by researchers;
- Requesting the appropriate individual/team or legal department to develop and deliver solution-oriented presentations that addresses such scenarios and provides practical information that are tailored to the researchers – one example would be what researchers need to do when collaborating with US partners; and
- Ensuring such information is visible and accessible, whether it be by way of a presenting the information on posters, or making it available on the website.

More often than not, it has been observed that there is no continuous institutional support, one individual or team responsible for offering practical guidance concerning the GDPR implementation, and as a result such tasks are seen as complementary and are not adequately recognised or credited. It would therefore be important for biobanks to formally recognise such activities. In either instance, the individual or team identified to provide GDPR support, as well as the particular forum used to encourage researchers to ask questions should be made visible and promoted within the organisation.

In the long term, it is advisable to offer a formal and distinct service concerning GDPR issues, as well as other ethical and legal issues, beyond the legal department and creating a dedicated position which is responsible for supporting researchers with ELSI issues in the context of their daily operations.

EVERYDAY PRACTICES RELATING TO DATA USAGE

Researchers often have enquiries concerning everyday practices relating to data usage, such as what to do when a data request needs to be made at another institution for secondary processing of data. Whilst questions often relate to informed consent, they can also extend beyond this and the original informed consent template. **Rather they concern the governance of data usage**. Without the proper support systems in place for researchers, it has been seen that procedural inefficiencies and delays in operations result.

PRACTICAL SUGGESTIONS:

To avoid this, it is advisable that biobanks consider how they can best provide such support and once again turn to existing options if possible, such as:

- Identifying an individual / team who is already providing such support;
- Extending the role of the legal department to be on hand on answer such questions;
- Using Ethical Committees; or
- Creating a dedicated role to provide ELSI support

In addition to having a point of contact for ELSI support, a further aspect to consider includes the format to be selected when providing and making information available, as well as identifying the appropriate communication structure. This could take the form of:

- FAQs;
- Online-based support with a central email address; and/or
- A central hotline.

PUBLIC AND PARTICIPANT ENGAGEMENT

It has been observed that biobanks which actively engage with participants and the public see the benefits of integrating such an approach into their existing biobanking practices. Given that biobanks tend to be publicly funded, participant and public support is needed in order to ensure sustainability and longevity of biobanks. This can only be done through engagement.

Merely providing information sheets to participants is no longer enough and once again, biobanks are expected to take more proactive roles.

PRACTICAL SUGGESTIONS:

In addition to the use of social medial, face-to-face and other offline modes of and spaces for engagement should also be considered. Whether engagement or PR activities are conducted within the biobank or whether such tasks are outsourced, it is important to ensure that personalised strategies are used, such as sharing stories that participants and the public can relate to. Ultimately this will assist in effective engagement. Potential suggestions include:

- Reach out to the local press to share biobanking developments with the local community;
- Engage with science communication activities and outreach activities in order to integrate and share biobanking activities within the community. This could include getting involved with existing science fairs/weeks, engaging with science and arts programs, arranging visits and excursions to the biobanks, organising 'hand-on' experiences, or visiting schools;
- Enabling participants to have direct contact with researchers and other biobank staff, such as the DPO.

THE NEED FOR PROFESSIONAL SUPPORT AND NETWORKS

As it stands, there is an increasing number of researchers and biobanking staff within the community who are isolated and do not currently benefit from existing networks due to the substantial workload. It has long been established that there is a significant benefit when creating and using spaces in order to exchange, share and ultimately learn from each other. Creating and making use of such spaces can assist with both short- and long-term issues, thereby improving operations and strengthening networks. Peer to peer support results in improved governance structures.

PRACTICAL SUGGESTIONS:

The objective of such deliberative spaces is to encourage discussion in terms of what works, what doesn't work and potential solutions. Such discussion should centre around individual experiences, with the aim of having a transparent and open dialogue between peers. Different approaches could be used in order to organise such discussions:

- To arrange or request dedicated spaces for such 'Governance Cafes' during conferences. This would allow researchers and biobankers within existing networks to come together in order to have discussions concerning experiences and operations;
- Identify an external coordinator, for example someone within the extended university network or at the National Node, who could organise such discussions at regional and national levels.

Such meetings do not have to take place often. Indeed, an annual discussion using existing platforms for exchange, such as EBW, would suffice.

CONCLUDING STATEMENT:

It is becoming increasingly clear that biobanks should adopt a forward thinking and strategic approach with regards to governance, by developing mechanisms to identify both successful and challenge areas, as well as solutions. This serves to improve governance structures, thereby making daily biobanking operations more efficient.

Furthermore, it is also apparent that there is the need for a dedicated ELSI role within biobanks, which would aim to support researchers with their daily operations concerning ethical and legal practices. Whilst such a role is often not formally recognised or valued, it does present a significant benefit for biobanks to bring such expertise in house in order to respond to the specific needs of researchers and the biobank.

RESOURCES

In addition to the provision of in-house support, it is also advisable to identify external support services offered. This includes services offered by:

- Relevant national Regulatory Authorities;
- Your National Node;
- BBMRI-ERIC; and
- Any other relevant research infrastructures.

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