

2 Ownership and Sharing of Data and Samples

This is 2nd in a set of 5 guidance notes aimed at supporting low capacity research organisations in negotiating the terms of a collaborative research contract with a better capacitated partner.

THERE IS A GROWING TREND within global health research, especially where research is publicly funded, to ultimately make available the data and samples collected for further research and application.

However, researchers engaged in partnerships where the sharing of data is planned should also carefully consider the ethical and legal implications of sharing data, and how they negotiate the use, ownership, control, access, storage, and management of the data in a way which means they and their organisation is not inadvertently disadvantaged, and that they fully and fairly benefit from their activities and that the capacity of their institutions is strengthened wherever possible.

▶ KEY QUESTIONS TO CONSIDER

What will be generated from the research? (dataset? tissue samples? Genetic material?)

- What are the associated risks and benefits related to the type of output generated?
- Will the generated outputs be dependent on previous research outputs of either partner?

What kind of access to the data/material will be required?

- Will this be open access, licensed access, restricted licensed access or managed closed access?
- Will an access or licensing agreement be required?
- What are the practical and technical implications for the partner controlling access?
- What are the ethical implications of access to the data/material?
- How will anonymisation and confidentiality of the data be achieved?

Who will own the data and control access to it?

- What are the risks and benefits related to owning and controlling the data/material?
- What additional resources are needed to facilitate ownership and control of the data/material entail and where will these come from?

What is the role of each partner in generating the data/material?

- Who will be responsible for collecting, analysing, cleaning, storing the data/material?
- What will this require in practical terms (financial, human resources & skills, infrastructure) ?

What are the potential benefits for your organisation of the data/materials?

(Publication, acknowledgements, intellectual property)

- What opportunities for benefits from the data/material (e.g. publications) will those involved have?
- Was there a data-sharing agreement in place that the subjects were aware of?
- What conditions will be placed on the data at original collection?

- How will acknowledgement of data/material producers be dealt with?
- What opportunities are there to analyse and publish? Has authorship been considered?
- What timeline is required for publication? What support could be provided to facilitate publication?
- What other incentives could be established to encourage researchers to share data/material?

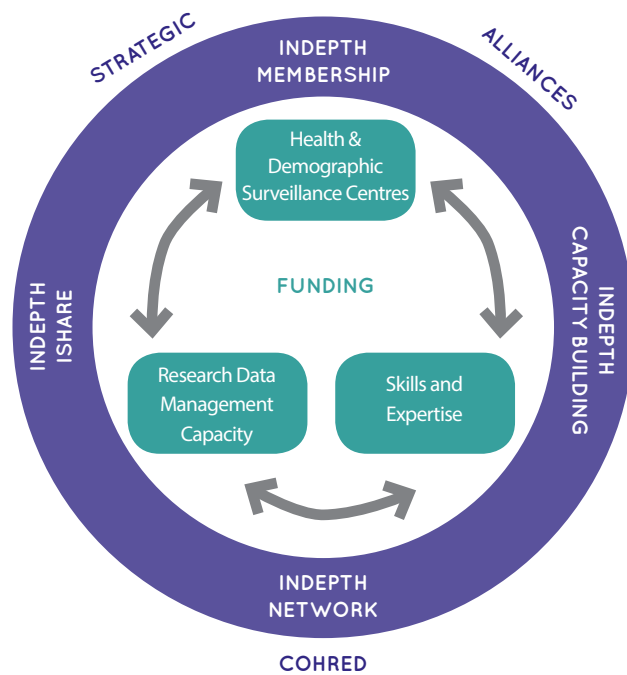
What will be required to ensure the data/material is available for secondary use?

- How and when will access be made possible, and who will be responsible for ensuring this?
- How will data/material quality be assured?
- What are the human, technical and financial

- resources required? Are these covered by the project funding?
- Will oversight mechanisms or data access committees be required to monitor and guide secondary users?

What institutional policies and relevant legislation should be referred to?

- Does your institution have a data sharing policy?
- What other kinds of agreements might be relevant? (e.g. material transfer, confidentiality)
- What national or other legislation might be relevant when negotiating data sharing and access conditions?



This document is intended as a tool to help think through the kinds of issues you may encounter in research contract negotiation.

The Malaria Genomic Epidemiology Network (MalariaGEN) is a partnership of malaria researchers in over 20 countries supported by the Grand Challenges in Global Health Initiative. In MalariaGEN, a number of attempts have been made to address the more exacting challenges (of data sharing), in addition to material transfer agreements and research contracts. First, the network developed a capacity building scheme in which young researchers from all partner sites were trained in the analysis of genomic data. Second, the network recognised the need to enable all contributing researchers to analyse their own data before it was made publicly available and incorporated this into the Malaria GEN Data Release Policy (<http://www.malariagen.net/home/downloads/16.pdf>). Third, the network sought to develop software that allows the remote analysis of genomic data – meaning that MalariaGEN researchers anywhere in the world could analyse data without the need to invest in expensive in-house infrastructure for data analysis and storage. (De Vries et al., 2011).

► KEYWORDS

OPEN ACCESS; MANAGED ACCESS; LICENSED ACCESS; RESTRICTED ACCESS

THESE TERMS REFER TO DIFFERENT CATEGORIES OF ACCESS: FOR EXAMPLE: FREELY AVAILABLE, AVAILABLE, BUT THROUGH A GATEKEEPER, AVAILABLE ON PROVISION OF A LICENSE, OR RESTRICTED TO PERSONS WITH CERTAIN CLEARANCE. IT IS HELPFUL TO UNDERSTAND THAT PROVIDING ACCESS CAN BE DONE IN A CONTROLLED MANNER.

MATERIAL TRANSFER AGREEMENT

THIS IS A SPECIFIC CONTRACT WHICH GOVERNS THE TRANSFER OF RESEARCH MATERIALS BETWEEN PARTIES INVOLVED IN A RESEARCH PROJECT

DATA MANAGEMENT PLAN**NON-DISCLOSURE AGREEMENT**

THIS IS A SPECIFIC CONTRACT WHICH PROVIDES FOR THE TRANSFER OF CONFIDENTIAL INFORMATION BETWEEN PARTIES FOR CERTAIN PURPOSES, WHILE RESTRICTING THE DISCLOSURE OF SUCH INFORMATION TO THIRD PARTIES.

WHERE TO GO FOR ADDITIONAL HELP

CHOKSHI, D; Parker, M and Kwiatkowski, D. (2006) Data sharing and intellectual property in a genomic epidemiology network: policies for large-scale research collaboration. *Bull World Health Organ* vol.84, n.5, pp. 382-387.

Doshi P, Jefferson T, Del Mar C (2012) The imperative to share clinical study reports: recommendations from the Tamiflu experience. *PLoS Med* 9(4):e1001201. doi:10.1371/journal.pmed.1001201

Fitzgerald, Anne M., Pappalardo, Kylie M., Fitzgerald, Brian F., Austin, Anthony C., Abbot, John W., Cosman, Brendan L., O'Brien, Damien S., & Singleton, Bill (2007) Building the Infrastructure for Data Access and Reuse in Collaborative Research : An Analysis of the Legal Context. The OAK Law Project, Canberra, Australia.

Sankoh O, Ijsselmuiden C, 25 others . Sharing research data to improve public health: a perspective from the global south. *The Lancet* - 30 July 2011 (Vol. 378, Issue 9789, Pages 401-402) DOI: 10.1016/S0140-6736(11)61211-7

Schroeder, D., Cook-Lucas, JM, Arnason, G, Andanda, P, Kimani, J and Fournier, V (2013). 'Donating Human Samples: Who benefits? Cases from Iceland, Kenya and Indonesia'. In D Schroeder and J Cook Lucas (eds.), *Benefit Sharing: From Biodiversity to Human Genetics*. Springer, Netherlands, pp. 95-127.

The INDEPTH Network Data Access and Sharing Policy

The MalariaGEN Policy on Building Capacity for Data sharing

OECD Principles and Guidelines for Access to Research Data from Public Funding

See also <http://www.cohred.org/FRC> where you will find a useful guidance tool on developing and implementing guidance on research contracting, entitled: Where there is no lawyer: Guidance for fairer contract negotiation in collaborative research partnerships.

See also the UK Government's Lambert Toolkit: <http://www.ipo.gov.uk/lambert>

ACKNOWLEDGEMENTS

This work was supported by the African Health Initiative of the Doris Duke Charitable Foundation. Thanks also go to the Fair Research Contracting Consortium members, Renata Curi of Fiocruz, and specifically to Pamela Andanda and Cathy Garner who provided advice on the development of this particular guidance note. We would also like to thank XXXX who provided an external review of the final product.

Issues around ownership and access to data/material need to be clarified upfront in the research contract

Ownership and access are not the same thing. You can provide access to the data or material without relinquishing your ownership.

Data/material sharing requirements can differ substantially between funding partners – for example the time provided before data/material release is expected can be quite different. It's important to consider how you think your organisation will best benefit from the data, and come to an agreement which enables you to do this. This could be a specific length of time, or it could mean additional support in producing the first publication.

Consider developing a policy if you do not already have an institutional data/material sharing and access policy as this will be vital if dealing with any major research institution or company when negotiating on sharing issues.

It is always useful to have in the policy the practical procedures for data management and storage (i.e. a data management plan).

Not all data/material generated in research will be suitable for re-use due to ethical or legal restrictions and thus a research contract can also describe the kinds of data/material that will remain the exclusive ownership of an institution.

It may be useful to have a Research Ethics Committee or Institutional Review Board review the ethical implications relating to proposals for the release and use of the data/material or to act as oversight in the negotiation process around data ownership and access.

Ownership of samples may have a direct impact on the sharing of data/material, consequently, you should agree on the ownership of samples beforehand.

QUOTE FROM A CONSORTIUM MEMBER



"Researchers from low capacity research organisations should realise that their countries' burden of disease is a valuable resource for purposes of research. Without the burden of disease all the financial or other contributions from the better capacitated partner will not yield the desired results. The burden of disease must therefore be used as a valuable resource for negotiating the terms of the research agreement including ownership and sharing of data and samples." "Research and data need significant cases on which to base results. This is a key lever in negotiating access to cases for research."
PROFESSOR PAMELA ANDANDA, ASSOCIATE PROFESSOR OF LAW, UNIVERSITY OF THE WITWATERSRAND

FEEDBACK

We would value your feedback, comments or suggestions on whether this guidance note has been useful to you. Contact: cohred@cohred.org