3 Ownership & Sharing of Data & Samples

COHRED
Council on Health Research for Development

This is the third in a set of five guidance notes aimed at supporting research institutions with limited access to research-contracting expertise in negotiating the terms of collaborative research contracts.

There is a growing trend within global health research, especially where research is publicly funded, to ultimately make publicly available the data and samples collected for further research and application. If there is assymetrical (public-private) funding between the parties in a research partnership, that may cause friction with respect to sharing of data and samples: be prepared.

In addition, researchers engaged in partnerships where the sharing of data is planned should also carefully consider the ethical, legal, and social implications (ELSI) 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 are not inadvertently disadvantaged. They should also ensure they fully and fairly benefit from their research activities, and that the capacity of their institutions is strengthened whenever possible.

KEY QUESTIONS TO CONSIDER

What will be generated from the research? (Dataset? Tissue samples? Genetic material? Living organisms? Transgenics?)

- ☐ Include a description of what will be produced by the project.
- ☐ What are the associated risks and benefits related to the type of output?
- ☐ Will the output(s) 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 this require an access or licensing agreement?
- ☐ 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 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 and distributing (if applicable) the data/material?
- ☐ What will this require in practical terms (financial, human resources & skills, infrastructure)?

What are the potential benefits of the data/materials (publication, acknowledgements, intellectual property, financial benefits) for your organisation?

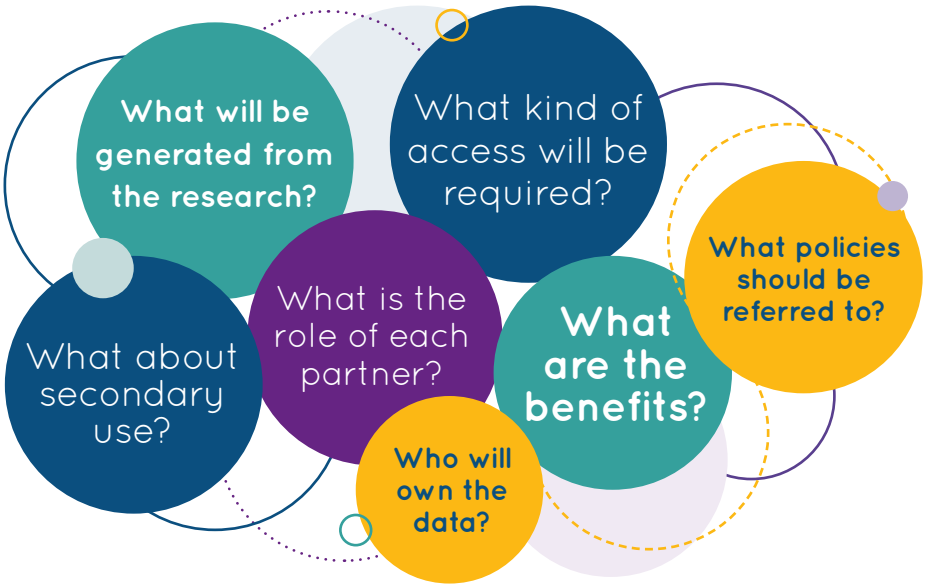
- ☐ What opportunities for benefits from the data/material (e.g. publications) will there be for those directly involved in the research?
- ☐ Was there a data-sharing agreement already in place that the subjects were unaware of?
- ☐ What conditions will be placed on the data at the time of collection?
- ☐ How will data/material producers be acknowledged?
- ☐ 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 are there that can be utilised to entice researchers into sharing 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?
- ☐ Is there need for Institutional Review Board (IRB) oversight?
- ☐ 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 referenced?

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



CASE STUDY

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 MalariaGEN Data Release Policy (http://www.malariagen.net/home/downloads/16.pdf). Third, the network sought to develop software that allows for the remote analysis of genomic data – meaning that MalariaGEN researchers around 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

access are terms that refer to different categories of access (e.g. 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 to data and samples should be done in a controlled manner.

A DATA MANAGEMENT PLAN

is a formal document that outlines how you will handle your data both during your research, and after the project is completed.

A MATERIAL TRANSFER AGREEMENT

is a specific contract which governs the transfer of research materials between parties involved in a research project.

A NON-DISCLOSURE AGREEMENT

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., & Kwiatkwoski, D. (2006). Data sharing and intellectual property in a genomic epidemiology network: policies for large-scale research collaboration. *Bull World Health Organ, 84*(5), 382-387. http://www.who.int/bulletin/volumes/84/5/382.pdf
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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.

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TIPS

- **Issues around ownership and access to data/material** need to be clarified upfront in the research contract, to ensure that data and samples will be well-managed during the contract performance, and prepared for preservation in the future.
- **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. It is important to consider how you think your organisation will best benefit from the data and reach an agreement which enables you to do this.
- Consider developing an **institutional data/material sharing and access policy**, if you do not already have one, as this will be vital when negotiating sharing issues with any major research institution or company.
- It is always useful to have practical procedures for data management and storage (i.e. a data management plan) in the policy.
- Not all data/material generated in research will be suitable for re-use due to ethical or legal restrictions. A research contract can describe the kinds of data/material that will remain the exclusive ownership of an institution.
- It is useful to have a Research Ethics Committee or IRB review the ethical implications relating to proposals for the release and use of 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. Reach agreements 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 WITSWATERSRAND

FEEDBACK

This is the first version of this guidance note, and we constantly strive for improvement. In the next phase, we will be transforming these generic guides into a web-based decision support system. We would be pleased to receive your feedback, comments or suggestions for further improvement to these guides, or for the future of this project, to cohred@cohred.org

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