OWNERSHIP OF DATA AND SAMPLES

Within collaborative research, there is increasingly the expectation that the data and samples (tissue samples, biospecimens, genetic material and other biological samples) generated within the partnership will be shared, subject to legislative, contractual and ethics restrictions, both among partners and with other interested parties outside the partnership. When contracting around the sharing of research data, researchers need to consider the legislative, ethical and practical implications of how they negotiate ownership, control, access, storage, management (maintenance) and use. These issues need to be clarified upfront in the research contract.

As you think through each of these questions, consider whether and how they can be incorporated explicitly into the research contract.

What data, samples, materials will be generated from the research?

- Will the type of research partnership (e.g. private-public, industry-university) and purpose of the research project (e.g. epidemiological, clinical trial) determine what products (e.g. data set, tissue samples, genetic material) will be generated from the research?
- What are the associated risks and benefits related to the type of data generated for your organisation?
- Will the data generated by this research be linked to or dependent on previous research outputs of either partner?

What is the role of each partner in generating this data?

- Who will be responsible for collecting, analysing, cleaning, storing the data?
- What will this require in practical (financial, human resources & skills, infrastructure) terms?
- What rights to ownership and benefits from the data (e.g. publications) will those involved in each of these functions have?

Who will own the data and control access to it?

- What are the risks and benefits related to owning and controlling the data?
- Is ownership and control of the data linked to how the research is funded?
- What additional work or inputs will ownership and control of the data entail and where will the resources (e.g. costs) for this come from? (e.g. cleaning,

analysing, storing, maintenance)

- How will acknowledgement of data producers be dealt with?
- What opportunities will there be to analyse and publish?
- What incentives exist to encourage researchers to share data?

What level/s of access will be required?

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

What will be required to manage the data and make it available for secondary use?

- Are there pre-determined conditions of funding that require data to be released after a specified period?
- If not, how and when will access / future use be made possible, and who will be primarily responsible for ensuring this?
- What are the human resource and system/ technical inputs required?
- What projected costs will be involved and are these covered by the project funding?
- Does your institution have a data management policy or plan?
- How will you specify the responsibilities of secondary users? Will oversight mechanisms or data access committees be required?
- How will you ensure quality assurance?

What institutional policies and relevant legislation should be referred to?

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

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