neuro
Institut-Hôpital neurologique de Montréal
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November 18, 2019 | **#OpenScienceinAction** | www.theneuro.ca

Implementing Open Science

MTAs, Contracts, Collaboration, and Commercialization

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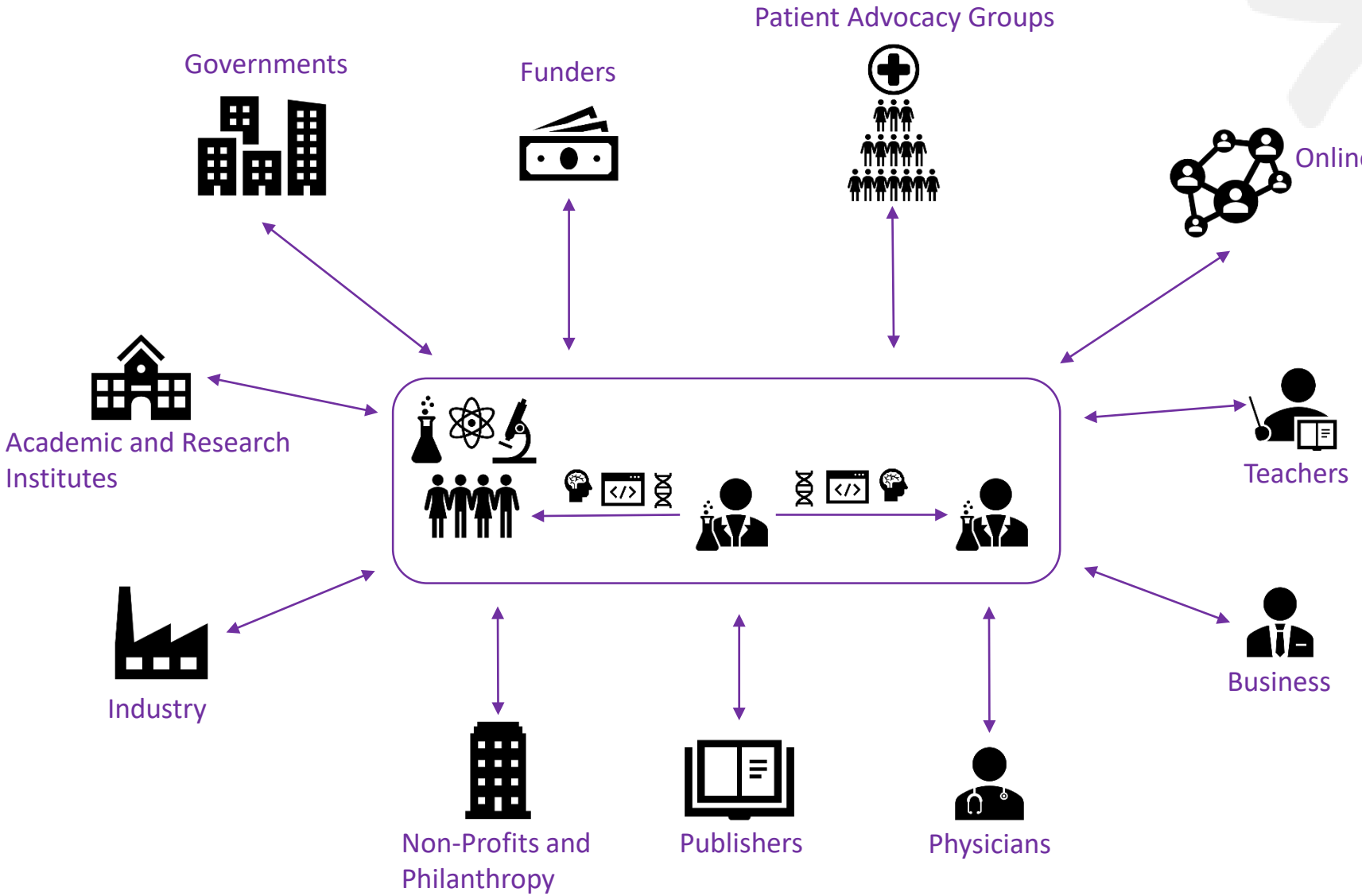
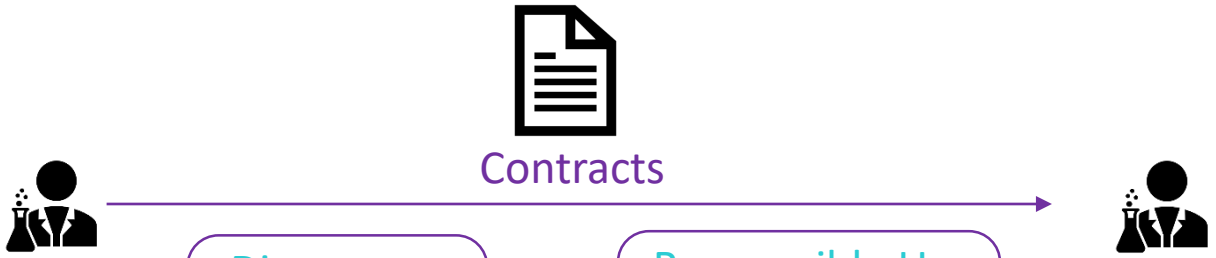


- **Vast Network** of relationships within which scientific research is **embedded** and on which it relies

Pre IT-Revolution
"Transfer Gap"

IT-Revolution
"Transfer Gap"

"Trust Gap"



- **Protective Clauses** work well. They establish **Common Understanding** and are **Legally Enforceable**
- **IP Clauses,** especially for neuroscience, have been an **Utter Failure**

Why Has IP-Protectionism Failed?

- Property ownership isn't what most scientists and physicians care about
  - **The Neuro**: 84 current faculty -> 29 made ROIs -> only 5 made more than 3 ROIs (majority made 2 or less).

- We are still **working out the basics**
  - **Failure after failure** of clinical trials (e.g. Alzheimer's)
  - Very few truly **novel** and **effective** treatments for neurological disorders in 50 years

- **IP over knowledge** and **not products** = little worth + long delays
  - An **over-eager patent-first** model leads to long negotiations over real and potential IP that is of **extremely dubious worth**
  - **Negotiations** on reaching agreements and sending materials often take **months or years**
  - Often causes **delays in publishing results**, cutting off the **lifeblood of science**

Open Science is the Answer

- Open Science Depends On
  - Working Together
  - Sharing Resources and Credit
  - Tracking Use
  - Not Claiming Restrictive IP
- We Need Contracts and Agreements to Facilitate These Elements
  - Current Agreements Just Don’t Work

Open Science Agreements Toolkit (OSAT)

- A **toolkit** of standard agreements that can be used to structure relationships on an open science basis

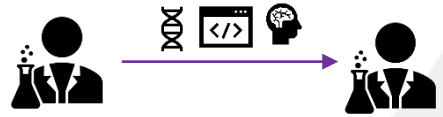
- Based on the **Lambert Toolkit** in the UK but with an open science orientation

- Standardized agreements have two main benefits
  - Increased certainty of terms leads to more partnerships
  - Reduction of negotiation time from 6-12 months to 2-3 weeks
    - C-BIG Repository MTA has **dropped transfer time from up to a year to ~one week**

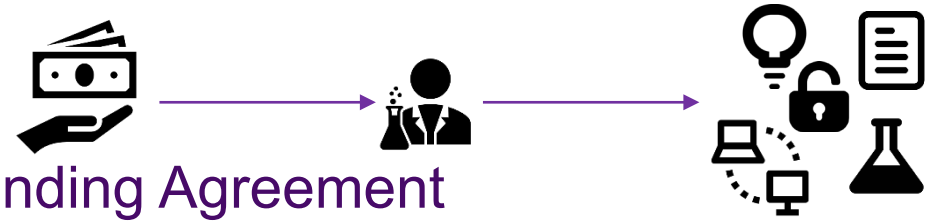
- The OSAT documents provide an alternative to current **IP-protectionist** and **patent-first** based agreements while **keeping protective clauses**

Identifying Key Relationships

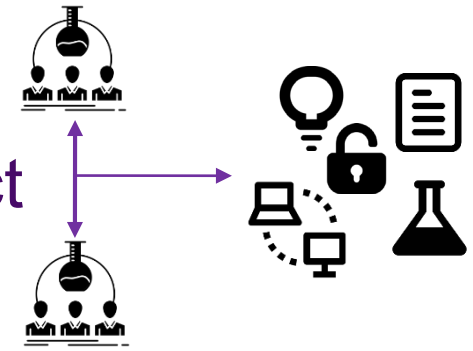
- Researcher-Researcher one time transfer
  - -> Open Science Material and Data Transfer Agreement



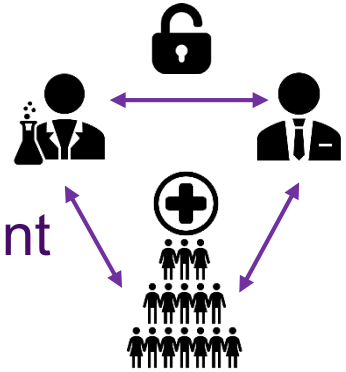
- Funder-Researcher
  - -> Open Science Funding Agreement



- Research Group-Research Group Collaborative Project
  - -> Open Science Project Agreement



- Ongoing Multi-Party Collaborations
  - -> Open Science Collaboration Agreement

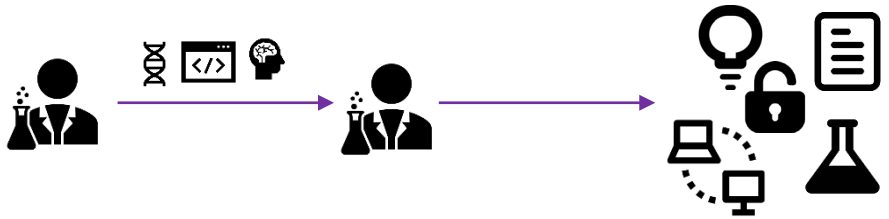


How to Use the OSAT

- **Access** the templates on the **OSAT Zenodo** (zenodo.org/communities/osat) or **OSF** (osf.io/4s8at/)
- **Download Agreement Template** in .doc format
- **Download Human Readable Summary** (*thank you* Creative Commons)
- Areas that need to be **filled in** are [highlighted in yellow]
- In-document **guidance** uses ****asterisks + green highlighting****
- Entire agreements are provided but **non-key provisions may be modified** to fit your context (see HRS and in-document guidance)

Open Science Material and Data Transfer Agreement (OSMDTA)

- **When**: Sending **physical materials**, **software**, and/or **data**
- **Who**: Researchers, Institutions, Repositories
- **Why**: Reduce IP related barriers, promote sharing, share credit



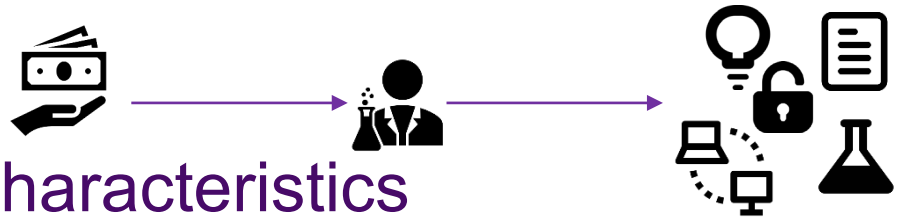
- Open Science Elements
  - **No restrictive IP** on transferred resources + modifications + results (A. 5)
  - **Deposit results** of research in an **online repository** (A. 6)
  - **Share credit** via co-authorship and acknowledgement (A. 6)
  - Use relevant **persistent digital identifiers** (A. 6)
  - **Send** resources, modifications, or results to others on the same terms (A. 3.2)

Other Provisions

- Context
- A. 1 Definitions
- A. 2 Request and Transfer Procedure
- A. 7 Warranties, Limitations of Liability, and Indemnification
- A. 8 Term and Termination (must remain in force)
- A. 9 Miscellaneous (e.g. Notices, Governing Jurisdiction, Governing Law, Severability, etc)
- Appendix A: Description of Material, Software, and/or Data

Open Science Funding Agreement (OSFA)

- **When**: Providing **funding** for research
- **Who**: Public or Private Funders
- **Why**: To ensure funded research is conducted on an open science basis



- Open Science Characteristics
  - **No restrictive IP** on results (A. 5)
  - **Openly share** data (online), software (online), and physical materials created over the course of research (+ persistent digital identifiers) (A. 5)
  - Publish **open access** (A. 5)
  - Can use funds to **offset OA publishing costs** + **costs of sharing resources** (A. 2.5 + 2.6)

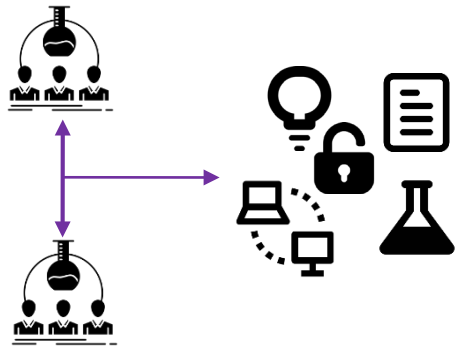
Other Provisions

- A. 1 Definitions
- A. 2 Use of Funds
- A. 3 Accounting and Records
- A. 4 Research Practices
- A. 6 Variation and Termination
- A. 7 Liability
- A. 8 Governing Law and Jurisdiction
- A. 9 Publicity
- Appendix A: Project Description
- Appendix B: Names of Grant Recipients and Collaborators
- Appendix C: Funder Specific Policies

Open Science Project Agreement (OSPA)

- **When**: Conducting a **collaborative project**
- **Who**: Two or more collaborators or collaborating research groups
- **Why**: Ensure that the all collaborators work on an open science basis

- Open Science Characteristics



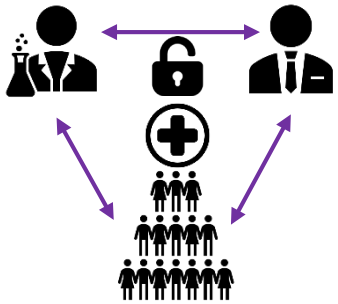
- **No restrictive IP** on results (A. 7)
- **Openly share** data (online), software (online), and physical materials created over the course of the project (+ use of persistent identifiers) (A. 7)
- Publish **open access** (A. 7)

Other Provisions

- A. 1 Parties to Agreement
- A. 2 Purpose of Agreement
- A.3 Definitions
- A. 4 Collaborative Project
- A. 5 Contributions of the Parties
- A. 6 Records
- A. 7 Transfer of Research Resources
- A. 8 Treatment of Research Resources
- A. 10 Publicity
- A. 11 Bringing in and Removing Parties
- A. 12 Term and Termination
- A. 13 Reporting on Progress
- A. 14 Miscellaneous
- Appendix A – Project Name, Collaborators, Contributions, Resource Management, Timeline, End Date

Open Science Collaboration Agreement (OSCA)

- **When**: Creating an **ongoing collaborative research effort**
- **Who**: Two or more partners (academic, non-profit, industry)
- **Why**: To ensure that the research conducted by the collaborative partnership is performed on an open science basis



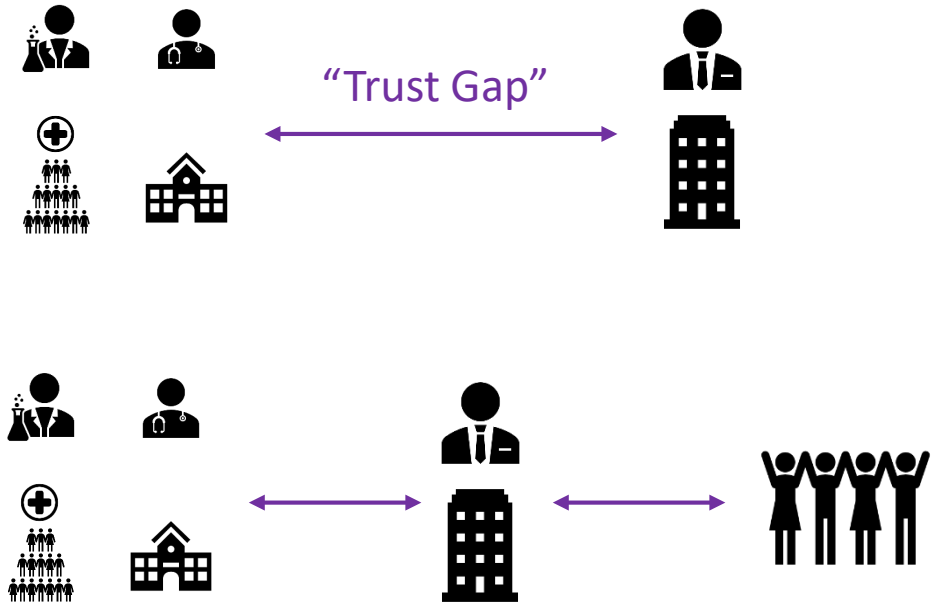
- Open Science Characteristics

- **No restrictive IP** on results (A. 7)
- **Openly share** data (online), software (online), and physical materials created over the course of the collaborative effort (+use of persistent identifiers) (A. 7)
- Publish **open access** (A. 7)

Other Provisions

- A. 1 Parties to Agreement
- A. 2 Purpose of Agreement
- A. 3 Definitions
- A. 4 Collaborative Project
- A. 5 Contributions of the Parties
- A. 6 Records
- A. 7 Transfer of Research Resources
- A. 8 Treatment of Research Resources
- A. 10 Publicity
- A. 11 Bringing in and Removing Parties
- A. 12 Term and Termination
- A. 13 Governance (Strategy Board + Executive Committee [w/ Chief Executive])
- A. 14 Miscellaneous
- Appendix A – Collaborative Research Effort Name, Party Representatives, Party Collaborators, Contributions, Resource Management

But What About Commercialization?



- Working with industry and other institutions to deliver the products that improve lives
- M4K Model
  - Relies on **Regulatory Exclusivity** as main form of IP
- WDR5 Inhibitor
  - Collaborative effort + results released to public domain
  - Used know-how and other publicly available information to get patent + $1B investment + Cdn clinical trial

The Essence Open Science Commercialization

- **Release** as much **information as possible openly**
- Providing **sufficient funding** or **exclusivity** to ensure adequate market position
  - Regulatory Exclusivity (100% data release)
  - Know-How Based Advantage + Later IP (100% data release on initial effort + helps build common tools)
  - Government or Non-Profit Led/Funded Efforts
- Other Options?
  - Embargo Periods?
  - Conditional IP Options or Limited Blinding to Results?

Future Directions

- **For you: Hack It!**
  - Beta versions online
  - Open source contract development
- **Collect comments** on uploaded versions
  - e.g. Jurisdictional Relevance, Ease of Use, Languages, & Other Kinds of Agreements Needed
- **Upload** updated versions by the **end of November 2019**
- **Facilitate** the use, modification, and re-sharing of OSAT docs by stakeholders (e.g. other institutions, funders, industry, non-profit)
- Make the agreements **implementable online**
- **Track** uptake
- **Develop** templates for **current** and **future** commercialization strategies

Feedback

- Happy to receive all feedback and questions on the OSAT and Commercialization Models
- OSAT documents available at the OSAT OSF account (link) and the OSAT Zenodo (link)
- Can give feedback now or send it to Prof. Gold (richard.gold2@mcgill.ca) or Dylan Roskams-Edris (dylan.roskams-edris@mcgill.ca)
- After receiving feedback we will create updated versions and upload them
- Thanks to
  - The Neuro
  - HBHL
  - The Structural Genomics Consortium