

NIH / PHS Sharing Research Resources and Data Sharing Policy for PIs and Scientists



Life Sciences' Manfred
Auer and group

Learn about the different types of research resources and data sharing plans, what is required on all applications and what is only required on specific types of applications.

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What are you Sharing ?

- » Information
- » Data
- » Tools developed
- » Techniques
- » Protocols
- » Results

**Protect your Intellectual Property !
It's required by Contract 31**



What is the Starting Point?

- If you are starting with brand new research never explored before, you probably don't have any pre-existing data or materials to protect
- If you are building on previous science, collaborating with others, obtaining materials from others, remember to consider:
 - Background IP issues
 - Material Transfer Agreements
 - Existing (or pending) Patents
 - Background concepts not yet reduced to practice still need to be protected
- We cannot “freely” share what we don't have the rights to – don't make commitments in your proposal that we cannot act upon – ASK TECH TRANSFER !



LBL Technology Transfer

- SPO is not the expert office regarding Resource Sharing or Data Sharing Plans
- Contact LBNL Technology Transfer Office
 - Refer to website
<http://www.lbl.gov/Tech-Transfer/researchers/how-tt-works.html>
 - Contact Tech Transfer with questions



What might I inadvertently do that would jeopardize getting a patent?

- You can lose the chance to patent if you make a public disclosure before we file a patent application.
- A disclosure includes any publically available written, electronic, or oral description of the invention.
- Internal disclosures to Lab employees are fine.
- **Please contact Tech Transfer or the LBNL Patent group for advice before you publish or present.**



NIH – Resource Sharing

NIH considers the sharing of **unique research resources** developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

See Handout: excerpt from NIH website on the Availability of Research Results

See Handout: PHS SF424 section on *Sharing Research Resources*



Plan for Sharing Research Data (from R01 Parent Announcement)

The **precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data.** Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal Web site, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.



Sharing can have conditions

- **Sharing does not mean we give away patent, licensing, or material transfer opportunities**
- **Plan does not mean we have to “give” it, but that it has to be available and under what conditions**
- **Work with the Technology Transfer Office regarding any questions on disclosures, patents, MTAs, etc.**



Research Resources / Data Sharing

- **Don't Confuse Sharing Research Resources with Data Sharing Plans**
- **See examples of some language used by your colleagues**



Research Resources / Data Sharing

Unique research resources (research tools), such as:

- Synthetic compounds
- Organisms
- Cell lines
- Viruses
- Cell products
- Cloned DNA
- DNA sequences
- Mapping information
- Crystallographic coordinates
- Spectroscopic data

Data Sharing Plans

Final research data

NIH expects “timely release
and sharing”



Research Resources / Research Data

Unique research resources

Required on all Applications,
even if unique research
resources will not be
developed

Data Sharing Plans

**Required on some specific
Funding Announcements**

**Required on Applications that
exceed \$500,000 in Direct
Costs in any one year**



Data Sharing Resources

See Data Sharing Workbook published by
NIH in 2004

http://grants.nih.gov/grants/policy/data_sharing/data_sharing_workbook.pdf

Ask Tech Transfer **BEFORE** putting a plan in
an application



If we are not Prime

- Get a copy of the Resource Sharing and Data Sharing Plans of the Application for review by SPO
- If a private company is involved, Tech Transfer needs to review the Sharing Plans to confirm we are giving the private company rights the Lab does not normally give away



Special Data Sharing Requirements: Sharing Model Organisms

- Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible.



Special Data Sharing Requirements: Genome Wide Association Studies

- Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition.



Recommendations from UCOP

- **Keep it Simple**
- Ask Tech Transfer to review any Data Sharing Plan prior to submission to assure IP rights are properly retained
- Ask SPO to review a plan early in the proposal preparation process if there are any questions



Recommendations from UCOP

- **Keep it Simple**
- If sharing involves materials – are there Material Transfer Agreements to consider?
- How will the resources or information be shared if patents become available?



Recommendations from UCOP

- **Keep it Simple**
- Is there background IP involved?
- Are we alone in the proposal? If not, what are the expectations of our research partners, especially if we are not the prime agency or a private company is involved



Recommendations from UCOP

- **Keep it Simple**
- Use buzz words contained in request
 - “sharing”
 - “fewest encumbrances”
 - “access”
- Remember: IP Management will (usually) not be “graded” in evaluation



Recommendations from UCOP

- **Keep it Simple** (unless a detailed plan is required – then keep it as simple as possible)

If it's not asked.....don't offer



How to Submit the Plans

- Plans are submitted as a single document
- Updated, more detailed, plans might be required at JIT, especially for large program grants or complicated plans



Resources

- **LBNL Technology Transfer Office**
<http://www.lbl.gov/Tech-Transfer/researchers/how-tt-works.html>
- **Handout: *Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources***
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm
- **Sample language**
- **Handout: PHS SF424 section on *Sharing Research Resources***
- **Handout: Data Sharing Workbook published by NIH in 2004**
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_workbook.pdf



Questions

