

Intellectual Property, Data Ownership and Data Sharing

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Dueling imperatives: Protecting the confidentiality of data

- Academic competition and priority
- Inventions – effect of publication and sharing on patentability
- Obligations to industry (could be sponsorship agreement, some materials transfer agreements)
- Utility in negotiations with industry for research collaboration and sponsored research
- For clinical data, including basic data from human tissues, respecting rights of confidentiality of human subjects – consistency with informed consent forms, IRB restrictions, potential for identifiability

Dueling imperatives: Sharing data

- Replication
- Journal requirements
- Expectations of public benefit underlying IRB approval (IRB weighing of risks and benefits; commitments to participant or donor)
- Funder's requirements – federal (for NIH, see: http://grants.nih.gov/grants/policy/data_sharing/data_sharing_chart.doc)
 - general statements of obligation
 - data sharing plans, submitted with the application, for direct costs >\$500K
 - Certain RFPs and awards (e.g. re transfers to funder repositories)
 - Genome Wide Association Studies
- Funder requirements – industry
 - Ownership
 - Limitations on uses: purposes, alternate funders, longitudinal

CHB Data Policies – document retention

- Documents relevant to inventorship and patents: 20 years.
- Other lab data: no less than
 - mandated duration under funder's terms (may be different for government vs. industry/contract-specific);
 - basic science: 6 years from publication, or completion of an unpublished study
 - FDA: 2 years after later of (a) date on which clinical investigation is terminated; or (b) data is no longer required to support an FDA pre-market approval application, notice of completion of product development protocol (devices only), or FDA is notified of discontinuance of application
 - other clinical: 6 years after final report, except that records of clinical care and adverse incidents, if not placed in medical record, should be maintained for period required for medical records

CHB Policy on Inventions and Intellectual Property

- On the intranet at:
http://www.childrensinnovations.org/Docs/Childrens_Policy.doc
- **Follows federal law in assigning all copyrightable materials to CHB, and all inventions to CHB in the context of an administrative structure that funds development by the hospital, and distributes revenue back to the research endowment with a share to the inventor.**
- “The Hospital owns all research results and intellectual property, whether tangible or intangible, developed by any person on the premises of the Hospital, or through substantial use of the Hospital's resources or facilities, or that relates to the research conducted by such person for the Hospital, or by a person within the scope of his or her employment by the Hospital.”
- Applies to medical and research staff, employees, students, fellows, visiting scientists and volunteers and “any other persons who may utilize the Hospital's resources and facilities, regardless of such person's obligations to other institutions.”

CHB Policy on Inventions and Intellectual Property

- Intellectual property is defined broadly, and “includes, but is not limited to, research notebooks, data, databases, photographs, original drawings and diagrams, computer programs, as well as chemical and biological materials such as proteins, genes, gene products, DNA probes, cell lines and transgenic animals.”
- Requires materials transfer agreements (MTAs) and Tech and Innovation Development Office (TIDO) approval for all transfers – contact the Clinical Trials Office within TIDO

CHB Policy on Data Management, Retention and Availability

- Lab Notebook Standards in every notebook; Policy is on CHB Research Ops web-page:
(<http://web2.tch.harvard.edu/researchoperations/>)
- From Executive Summary (see full policy for details):
 - **“B. Who should hold data?** The lab that generated it, or a collaborator or contractor as long as it is kept accessibly.” (Copies may also be in other locations.)
 - **“C. Who owns data?** CHB for data developed under CHB grants or within your CHB role. By contract, CHB may assign ownership to others, like industry sponsors.””
 - **“D. You need to make sure that data is readily available, in an organized fashion, for investigations and oversight.** You have a serious obligation to make sure that data remains available under government regulations. If you do not have it readily accessible, then the government can sanction you, or infer research misconduct.”

CHB Policy on Data Management, Retention and Availability – Executive Summary

- **“E. Data sharing with collaborators and others.**
Certain sponsors, and of course journals, require you to share data with others. The scope of the sponsor obligation varies by funding, and to some degree by the reasonableness of the request. Other sponsors and contracts restrict data sharing, such as industry sponsored agreements. Clinical research information is also specially protected, and sharing it with others without IRB approval may be prohibited.”
- See full text for more information

CHB Policy on Data Management, Retention and Availability

- **“Departing faculty, fellows and research staff – what should you do?** Departing faculty, fellows and research staff need to coordinate what happens with data when they leave the institution, with their chiefs, collaborators, and the office of research administration (to make sure there are no sponsor restrictions). They also need to check with the IRB if they are taking clinical research data, or data from an IRB-approved protocol involving identifiable tissues or data. Copies of data are generally freely available. If original data are taken by you, it is with the implied agreement by you that you will promptly share it with collaborators, your department and others at CHB who request it.”

THANKS

CALL OR E-MAIL IF YOU NEED HELP:

- **Research Operations (lab procedures, notebook standards)**
- **Office of Sponsored Programs (grant-related questions, e.g., developing a data sharing plan)**
- **Tech Innovation and Development Office (inventions)**
- **PI or Academic mentor**
- **Office of General Counsel (legal issues)**