



NCURATV 2008 Satellite Broadcast Workshop Series
Complex Agreements
Glossary of Useful Terminology
June 10, 2008
11:30 am – 3:30 pm EDT

<i>Conflict of Interest (COI)</i>	
NIH regulations and National Science Foundation policy promote objectivity in research and minimize financial conflict of interest by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under agency grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. These agency policies set important standards between the primary recipient and subrecipients of funds in collaborative relationships.	
NIH regulations	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-026.html
NSF policy	http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510
<i>Data Use Agreement or Health Insurance Portability and Accountability Act (HIPAA)</i>	
In a research context, this is an agreement between parties that specifies permitted uses and disclosures of a limited set of information about an individual(s) when that information is protected by the Health Insurance Portability and Accountability Act. The data use agreement limits who can use or receive the data; and specifies that the recipient may not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law.	
DHHS Summary of the HIPAA Privacy Rule	http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf
<i>Export Controls (general)</i>	
The term <i>Export Controls</i> now has both a specific (see below) and a generic meaning like Kleenex in that it has become shorthand for the set of policies that govern the shipment of or provision of technology, know how, and financial assistance overseas to certain countries where such assistance is controlled for economic purposes or national security. The most sensitive of the technologies that are controlled are defense related technology, or items that may have a potential military application (dual use). The governing regulations are the Export Administration Regulations (EAR), the International Traffic in Arms Regulation (ITAR), and the Office of Foreign Assets Control (OFAC). (see below)	
<i>Export Administration Regulations (EAR)</i>	
The Bureau of Industry and Security (“BIS”) of the U.S. Department of Commerce implements and enforces U.S. export control regulations relating to the export of “dual-use” goods and technologies (having both civil and military applications) as well as exclusively civil items. Items subject to the jurisdiction of BIS are listed on the Commerce Control List (“CCL”) found in the Export Administration Regulations. Whether a license is required to export or reexport an item on the CCL is determined by examining the precise classification of the item, the destination of the item, and the end-user. BIS also maintains the Denied Persons List and the Entities List, which identify specific persons and entities to which exports are not permitted without the prior approval of BIS. The CCL covers such things as materials, chemicals, microorganisms, and toxins; materials processing; electronics; computers; telecommunications and information security; lasers and sensors; navigation and avionics materials; marine-related materials; and propulsion systems, certain space vehicles, and related equipment.	
Index to the CCL	http://www.access.gpo.gov/bis/ear/ear_data.html .

Genome Wide Association Studies (GWAS)	
<p>The National Institutes of Health (NIH) is interested in advancing the use of data obtained through genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. The goal of the GWAS policy is to facilitate broad and consistent access to NIH-supported GWAS data in order to speed the translation of basic genetic research into therapies, products, and procedures that benefit the public health. Collaborating institutions need to address if they are proposing to conduct GWAS research, or plan to access GWAS data in the NIH repository as part of the proposed research. NIH announced the final policy for the sharing of data obtained through NIH-supported or conducted GWAS</p>	
NIH.gov	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-026.html
International Traffic in Arms Regulations (ITAR)	
<p>The Directorate of Defense Trade Controls (“DDTC”) of the U.S. Department of State regulates the export of defense goods, technical data, and defense services. DDTC administers the International Traffic in Arms Regulations (“ITAR”). The ITAR cover such things as guns and armaments, ammunition, launch vehicles and missiles, explosives and other incendiary agents, vessels of war, tanks and military vehicles, aircraft, military training equipment, protective personnel equipment, fire control equipment, auxiliary military equipment (including cameras and cryptographic devices, software, and components), toxicological agents, spacecraft systems, nuclear weapons, and classified articles as well as technical data and services that relate to the enumerated categories.</p> <p>Generally, a defense article is an item developed for a military application that does not have a predominant civilian application. Unless an exemption applies, a license must be obtained before any defense article is exported to a foreign country or foreign national. Authorization by DDTC is also required for any agreement under which a U.S. person will furnish assistance to foreign persons in the development, design, production or use of a defense article or under which a U.S. person will license to a foreign party the right to manufacture U.S.-origin defense articles abroad. DDTC maintains a list of “debarred” persons and entities whose exporting privileges have been revoked as a consequence of violations of the ITAR.</p>	
Munitions List	http://www.fas.org/spp/starwars/offdocs/itar/p121.htm
Material Transfer Agreement (MTA)	
<p>A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even some types of software. Three types of MTAs are most common at academic institutions: transfer between academic or research institutions, transfer from academia to industry, and transfer from industry to academia. Each call for different terms and conditions.</p>	
A Quick Guide to Material Transfer Agreements at UC Berkeley	http://www.spo.berkeley.edu/guide/mtaquick.html

National Council of University Research Administrators (NCURA)	
A professional association of people involved in the administration of sponsored programs at colleges, universities and teaching hospitals in the USA. Already well known for its outstanding regional and national meetings and its fine educational programs, including its TV series, it has just begun a program of Peer Review. "The completely confidential peer review is conducted by a team of nationally recognized research administrators who thoroughly review the sponsored programs area. The review utilizes National Standards that represent the core and vital functions of sponsored programs-regardless of size and type of institution."	
NCURA	http://www.ncura.edu/content/
Non-Disclosure Agreement (NDA), or Confidentiality Agreement	
A contract between two institutions outlines proprietary or confidential materials or knowledge that investigators wish to share with one another for research purposes, but wish to restrict from other use. Generally, the recipient institution is restricted from disclosing the information to any other party. An NDA creates a confidential relationship between the parties to protect trade secrets, research data, materials, etc. NDAs can be "mutual", meaning both parties are restricted in their use of the materials provided, or they can only restrict the recipient institution.	
From Wikipedia	http://en.wikipedia.org/wiki/Non-disclosure_agreement
Office of Foreign Assets Control (OFAC)	
The Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury administers and enforces certain country-specific controls that take the form of economic embargoes against countries, including countries subject to comprehensive embargoes such as Cuba, Iran, Syria, and Sudan, and countries subject to limited sanctions or embargoes such as the Balkans, Cote D'Ivoire (formerly Ivory Coast), Iraq, Liberia, Myanmar (formerly Burma), , North Korea, Zimbabwe, and the Palestinian Territories (Palestinian Authority). The scope of these economic and trade embargoes varies from country to country. OFAC has adopted regulations that detail the scope of the embargo against each country. OFAC also maintains lists of Specially Designated Terrorists and Specially Designated Nationals and Blocked Persons, with whom U.S. persons are prohibited from engaging in any transactions due to U.S. foreign policy and national security concerns. Transfers of Items and Information to individuals or entities on these lists are prohibited without the prior approval of OFAC.	
Current list of embargoed countries	http://www.treas.gov/offices/enforcement/ofac/faq/answer.shtml#9
Teaming Agreements	
Teaming agreements are used to establish Contractor Teams whereby a potential prime contractor agrees with one or more other companies to have them act as subcontractors under a specified acquisition program. This allows the companies to complement each other's capabilities and it offers the sponsor the best combination of expertise. Teaming arrangements are normally formed before the submission of the proposal and should be fully explained in the proposal. Contractor team arrangements are particularly appropriate in complex research and development programs. Quoted verbatim from the Office of Sponsored Programs, Georgia Tech.	
Office of Sponsored Programs, Georgia Tech	http://www.osp.gatech.edu/policies/teaming.shtml