



U.S. Department of
Health and Human
Services



National Institutes
of Health



National Heart, Lung,
and Blood Institute

CRADAs, Clinical Trials & NIH Gift Mechanism

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Development

National Heart Lung and Blood Institute

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National Institutes of Health




- **Mission:** The National Institutes of Health is the steward of medical and behavioral research for the Nation.
- 27 Institutes, Centers and Divisions
- 18,000 employees
- Total FY 2003 budget 27 billion dollars

National Heart, Lung, Blood Institute

- Research Focuses on diseases of the heart, blood vessels, lung, and blood; blood resources; and sleep disorders.
- Total FY 2004 Budget \$2.8 Billion
- Intramural Program (Internal R&D) consist of \$170 Million with a research staff of 420

NHLBI Office of Technology Transfer and Development

Provides TT Services to NHLBI as well as:

 National Institute on Deafness & Other Communication Disorders

 National Center of Research Resources

 National Institute of Nursing Research

 National Institute Arthritis & Musculoskeletal & Skin Diseases

 National Institute on Alcoholism & Alcohol Abuse

 National Institute of Environmental Health Sciences

NHLBI Office of Technology Transfer & Development

- Evaluates new inventions generated by NHLBI scientists and service center clients
- Assists in marketing Institute patents/inventions to industry
- Assists scientists in implementing transactional agreements, i.e. Material Transfer Agreements (MTAs), Confidential Disclosure Agreements (CDAs)

NHLBI Office of Technology Transfer & Development (Cont'd)

- Assists scientists in setting up collaborations with profit and not for profit entities through CRADAs and Clinical Trial Agreements (CTAs)
- Acts as a resource to our clients for a wide variety of technology transfer & intellectual property matters

CRADAs



NIH CRADAs

- Primarily used when collaborator wants to protect their IP
- Several Types of CRADAs:



Materials CRADAs – used to transfer in proprietary materials; no “collaboration” with outside party, \$ limit



Standard CRADAs – collaboration between parties; \$ and other resources involved



Clinical Trials CRADA (CT-CRADAs)

NIH CRADA Review Process

- Institute & Collaborator PIs develop Research Plan
- Institute performs actual negotiations with CRADA Collaborator
- NIH Office of Technology Transfer and Office General Counsel review the CRADA
- Internal CRADA Subcommittee reviews and makes the recommendation for approval

What is NOT an NIH CRADA

- A CRADA is NOT the same as a fee-for-service contract or Sponsored Research Agreement
- A CRADA is NOT to be used as means for NIH scientists to supplement their lab funding
- A CRADA is NOT an open-ended, ill defined, broad and/or informal collaboration
- Entering into a CRADA is NOT an endorsement of a particular company and/or its technology/products by NIH

Clinical Trial Agreements



NIH Clinical Trial Agreements

- Used to transfer in drugs and devices to be used in a human clinical trials setting
- NO option to negotiate licensing rights to inventions developed under the CTA
- Contains all standard terms found in typical MTA (confidentiality, publication)
- Used both extramural and intramural side

NIH CTAs (Continued)

Specialized language dealing with:

- protocol drafting
- continued supply of clinical agent in event of termination,
- confidentiality of patient data,
- reporting of adverse events & other regulatory-related issues such as IND filings & other interactions with the FDA

Types of Support under CTAs

- In-kind support of materials, e.g., drugs, devices, reagents
- In-kind support of services, e.g., laboratory services
- Financial support through a conditional gift to the NHLBI Gift Fund

NIH Gift Fund Mechanism



NIH Gift Fund Mechanism

Authority provided under: 5 U.S.C. 302;
Sections 231 and 465(f) of the Public Health

Service Act, as amended (42 U.S.C. 238, 286(f))

Unconditional Gifts

“a gift in which the donor doesn't impose some condition or restriction on the use of the gift or as a condition to be met in order to obtain the gift.”

Conditional Gifts

“a gift in which the donor imposes some condition or restriction on the use of the gift or as a condition to be met in order to obtain the gift.”

NHLBI Use of Conditional Gifts in Conjunction with CTAs

- Science drives the CTA not the gift.
- Maintain data safety and integrity at all times.
- Investigator has to provide a detailed budget of how to gift will be utilized.
- NHLBI tracks each individual gift regardless of \$ amount.

CTAs vs. CRADAs

Clinical Trial Agreements

- May involve funds
- No license options or IP rights
- Purpose is to conduct clinical research (and/or transfer materials)
- Does not have to be collaborative
- Easier & faster to negotiate & execute (IC review only)

CRADAs, M-CRADAs, CT-CRADAs

- Funds to NIH possible (but not required)
- License option to yet-to-be discovered CRADA inventions
- Purpose is to conduct research (of any kind)
- Must be a true collaborative effort
- Slower & more difficult to negotiate & execute (NIH central committee review)

Please feel free to contact:

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