Clinical Proteomic Technology Assessment for Cancer (CPTAC)

Management of Data, Research Resources and Intellectual Property,

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Topics

- Data Sharing
- Research Resource Sharing
- Intellectual Property (IP) Management

From the RFA-CA-07-012

Objective 1: Evaluate performance of proteomic technology platforms and standardize approaches to developing applications using these platforms;

Objective 2: Evaluate proteomic platforms for their ability to analyze cancer-relevant proteomic changes in human clinical specimens;

Objective 3: Establish systematic ways to standardize proteomic protocols and data analysis among multiple laboratories;

Objective 4: Develop and implement uniform algorithms for sharing bioinformatics and proteomic data and analytical/data mining tools across the scientific community;

Objective 5: Develop well defined and comprehensively characterized sets of standard/reference materials and reagents to serve as resources for the research community.

Expected Focus of IP and Data/Research Resource Management Plans

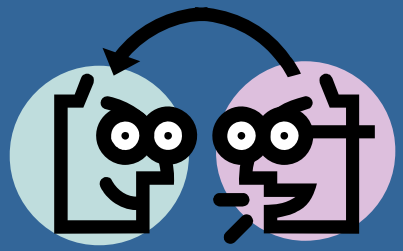
- ✓ Expect a concerted and coordinated effort within and between consortia and with the broader research community to share research materials and data.
- ✓ Expect assistance with the broader integration of proteomics technologies for cancer applications.
- ✓ Expect a demonstration of your efforts to reduce commercialization barriers so that the new technology developed under this cooperative agreement will have a significant impact on cancer diagnosis and treatment.

Expectations for Data and Research Resources Sharing

- **NCI expects data and resources to be shared within a relatively short time-frame.**
  - **Communications and sharing should take place on a nearly daily basis and almost immediately after collection of the data or production of materials.**
  - **Strongly suggest one agreement for consortium members with terms that promise intra-consortium sharing of data and research resources.**

- **It is expected that results will be confirmed and next steps in the developmental process will be discussed collaboratively both within the consortium and <u>across consortia</u>.**
  - **To succeed, you need to suggest a plan for working together with other consortia; NCI strongly suggests an umbrella agreement (s) to minimize admin burden.**

Data Sharing Plan



- Describe schedule for sharing data.
  - **expected to occur within a relatively short time-frame. Zero - minimal delays.**
- Describe type of format for datasets.
- Describe method of sharing the data analytical tools. (e.g., websites, databases, personal communications).
- Describe criteria and terms of data release (preferably unrestricted, but if an agreement is needed make sure you describe how you will provide for minimal constraints and no reach through!).

Research Resources

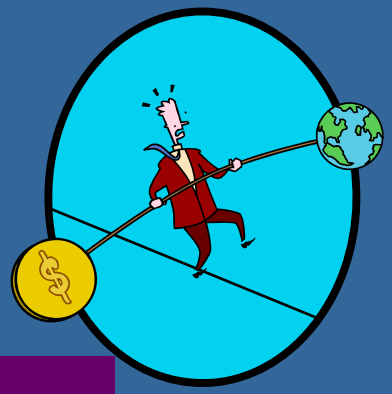
What research resources does NCI expect you to share within and between consortia and the broader research community?

- **standard/reference materials and reagents**
- **datasets and bioinformatics tools.**
- **optimized protocols for biological and clinical specimens:**
  - **Collection**
  - **Annotation**
  - **Storage**

Research Resource Sharing Plan

- Include how research resources will be shared with the research community. Examples:
  - supplied by the lab,
  - supplied through an in-house repository
  - supplied by commercial supplier(s)
- Include terms under which the research resources will be shared. Examples:
  - UBMTA
  - NIH Simple Letter Agreement
  - License (non-exclusive preferred; limited exclusive)
- Aim to keep it simple and efficient!

IP Management



A Balancing Act:

- Sharing resources with the research community under reasonable terms.
- Patenting and licensing practices that encourage further commercial development of biomedical inventions.
- Recognize that inventions may have both commercial AND research tool aspects and describe how you will manage this balance.

Intellectual Property Considerations

- Provide assurance that outside relationships (i.e. sponsored research agreements and licenses)
  - permit the right to distribute research tools
  - does not hinder academic freedom
  - assures the right to publish
  - Provide strategies for commercial development of inventions that take into consideration:
    - Non-exclusive preference
    - If exclusive then keep the boundaries as small as possible thereby allowing maximum freedom for future research and development

Intellectual Property Considerations

- Applicants should address in their plan opportunities to coordinate patent prosecution and licensing activities. Examples:
  - Consider designating one organization to take the lead on patenting and licensing of related inventions
  - Consider assigning intellectual property rights to related inventions to an invention management firm
  - Consider agreeing in advance that if multiple parties are to independently license related inventions, the total of stacked royalties will not exceed a predetermined percentage rate
- In all cases, Institutions should reserve a research use license under any commercialization license.

Submission requirements of IP and Sharing Plans

- Data Sharing and Research Resources Sharing plans are expected to be in the application.
- The Data Sharing Plan will be considered by the review panel.
- Program staff will consider the adequacy of the resource sharing plans prior to award.
- The IP Plan is a “just in time” requirement.
- All final plans must be in place before award.
- The plans become part of the Terms and Conditions of the award.

RFA-CA-07-005

Advanced Proteomic Platforms and Computational Sciences for the NCI Clinical Proteomic Technologies Initiative

- Research project grants (R01, R21, R21/R33) to support highly innovative research in the quantitative analysis of proteins and peptides of interest in clinical cancer studies.
  - the development of innovative technology for protein and peptide detection, recognition, measurement, and characterization in biological fluids that will overcome current barriers in protein/peptide feature detection, identification, quantification, and validation.
  - computational, statistical, and mathematical approaches for the analysis, processing, and facile exchange of large proteomic data sets.
- Data and research resource sharing are expected to be the same as for CPTAC (RFA-CA-07-012)

NIH Sharing Policies and Guidelines

- Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts (1994) http://ott.od.nih.gov/spons_research.html
- Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts (1999) http://ott.od.nih.gov/pdfs/64FR72090.pdf
- NIH Data Sharing Policy (2003)

  http://grants.nih.gov/grants/policy/data_sharing/
- Examples of plans can be found at: http://ttb.nci.nih.gov/IPPlans.html /

Commercial concerns

- What about my existing patent rights?
  - They are yours to keep!
  - Because they already exist then NCI would expect that they be addressed as part of any plan to let us know how they will be effectively used to achieve the goals of this initiative
- Can we commercialize technologies that we play are a part of creating under this initiative?
  - Yes. Commercial development is encouraged, but with the caveat that the you recognize the goal of this initiative to share the resources efficiently with the research community. It is essential that your plan describe how data resource sharing will be balanced with any commercialization effort.

Key Closing Factors

- Work closely with your technology transfer/development or IP management staff before submitting your application!!
- If the technology is properly managed from the start, this can be win-win situation for your Institution and for the NCI

Contact Information

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