

NCPHLL Leadership Forum Series: Applied Research

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The Association of Public Health Laboratories (APHL), through the National Center for Public Health Laboratory Leadership (NPHLL), convened a meeting focused on increasing the involvement of public health laboratories (PHLs) in applied research. The purpose of the meeting was to:

- Provide guidance for developing applied research projects;
- Discuss opportunities and potential barriers in performing applied research; and
- Identify components of successful applied research programs.

BACKGROUND

Within the scientific community, PHLs are generally not perceived as key players in the research process and basically a provider of services. Public health-related research is identified as a core function of PHLs. While some PHLs have been engaged in research for many years, others are just beginning to explore this option. According to an APHL survey, 69% of PHLs in the US have partnered with other public health disciplines to conduct applied or practice-based research and 37% have a formal research-supporting relationship with a university engaged in research. Advantages to participating in research include:

- Creates a rich scientific environment;
- Supports public health preparedness;
- Provides opportunities to grow in different areas of science;
- Presents career options and allows flexibility to staff beyond specified responsibilities;
- Raises the profile of the lab (e.g., publishing findings in journals); and
- Offers fiscal growth and flexibility (new investigator packages, seminar funds, interim funds).

Key Definitions

Basic research: Systematic study directed toward extensive knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind (NSF)

Applied research: Systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met (NSF)

Translational research: Transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical or population-based applications to improve health by reducing disease incidence, morbidity, and mortality (NCI Translational Research Working Group)

PHLs are well positioned to participate in research. They possess expertise, skills, and resources that are applicable to the research process. In particular, PHLs possess:

- Expertise in assay development and validation;
- Sample repositories;
- Experience in supporting clinical trials, food and environmental testing;
- Close ties to epidemiologists; and
- Experience in public policy research.

However, there are also many challenges to engaging in research. These issues include such topics as:

- A perception that labs provide services and do not perform research;
- A culture within the agency that does not encourage participation in research;
- An unpredictable fiscal climate;
- Priorities and ongoing work load;
- Administrative issues (e.g. grants management);
- Staffing (e.g., ability to rapidly hire specialized staff for the duration of a research project);
- Development of new skills;
- Access to collaborators;
- Maintenance of funds once they have been obtained (i.e., they do not disappear into the general fund); and
- Competition for external funds.

Identify your Lab's Strengths

Labs have unique resources that are critical to the research process.

- Technology platforms
- Subject matter expertise
- Level of interest in change
- Commitment of collaborators
- Grant experience
- Sample repositories
- Regulatory oversight

EXAMPLES OF PHL INVOLVEMENT IN RESEARCH

New York

The New York State Department of Health's Wadsworth Center has a long history of conducting research into the prevention and cure of communicable diseases with the support of the Commissioner of Health. The lab also has a legislative mandate for original investigations and research in matters affecting public health. The fiscal and administrative challenges related to managing research projects are addressed through Health Research, Incorporated (HRI), a nonprofit corporation affiliated with the New York State Department of Health and the Roswell Park Cancer Institute in Buffalo. The flexibility, speed, and technical expertise provided by HRI allow the Wadsworth Center to obtain external grant funding from Federal agencies, foundations, and commercial entities. Specifically, HRI supports the research process by:

- Accepting and administering external funds to support research projects within the Department of Health;
- Providing grant administration, technology transfer, accounting, purchasing, and human resources support; and
- Assuring funds are utilized in accordance with requirements of sponsor.

In its research-related work, the Wadsworth Center partners with academia, hospitals, private industry, and other PHLs.

Wisconsin

Another model for PHL participation in research is the Wisconsin State Laboratory of Hygiene's (WSLH) involvement in the National Institutes of Health (NIH) sponsored Clinical and Translational Science Awards (CTSA) Program. The mission of the CTSA Program is to create an environment that transforms research into a continuum from investigation through discovery to translation into real-life community practice, thereby linking even the most basic research to practical improvements in human health. There are currently 66 consortia funded through the program.

The UW Institute for Clinical and Translational Research (UW-ICTR) is a partnership between UW-Madison (with the William S. Middleton [Madison] VA Medical Center) and the Marshfield Clinic. The UW-ICTR is composed of five academic partners—the Schools of Medicine, Nursing, Pharmacy, and Veterinary Medicine and the College of Engineering. The consortium provides research services to members, including coordinating access to lab services. Other services include assistance with IRB development, grant writing, and study design; biostatistics and informatics consultation; and access to hospital-based research units. There are now more than 1,800 research members across Wisconsin.

WSLH was not an original member of the UW-ICTR. The lab approached the consortia and asked to participate. The benefits of participation include the potential for greater involvement in research, a higher profile on campus, increased grant funding/revenue, and access to more partner organizations. WSLH now receives approximately one request per month from researchers. In addition, multiple lab staff have received research grants. To support research, WSLH has developed the Research Support Center. The Research Support Center facilitates the process of applying for and managing a grant and provides such tools as a standard contract, standard pricing, workload estimates, proposal coordination, and budget development. The Research Support Center also provides input for developing a marketing plan, which promotes WSLH's research-support services.

WSLH participation in the CTSA Program is relatively unique. Other PHLs reported that they have been unsuccessful in building relationships with their local CTSA consortium.

POSITIONING THE PHL TO ENGAGE IN RESEARCH

To successfully engage in research, PHLs must undertake specific activities related to the research process. Below are two examples of activities that support involvement in research.

Knowledge Management

While some PHL assets are readily apparent, other assets are less tangible, such as the skills and expertise of staff. To take advantage of all available assets, PHLs need to adopt knowledge management practices.

Knowledge management comprises a range of practices used by organizations to identify, create, represent, and distribute knowledge for reuse, awareness, and learning across the organization. This type of management is a way for organizations through a conscious and comprehensive process to generate value from their intellectual and knowledge-based assets. Key steps of the knowledge management process include the creation, validation, presentation, distribution, retention and application of knowledge. To implement knowledge management practices, PHLs should:

- Develop a working definition of knowledge;
- Recognize that knowledge is possessed by individuals (i.e., staff);
- Encourage thinking and reasoning;
- Base decisions on knowledge;
- Encourage experimentation; and
- Avoid over reliance on information technology at the expense of human interface.

Institutional Review Boards

Creation of an Institutional Review Board (IRB) proposal can seem like a daunting process for those wishing to engage in research involving human subjects. An IRB is charged with protecting the rights and welfare of subjects in research studies by reviewing research plans and activities. Any institution that accepts research funding from the Federal government must have the IRB review all research involving human subjects, even research projects that are not supported by Federal funds. All organizations conducting federally supported research must register with the Federalwide Assurance (FWA).

Many large research institutions have their own IRB. Centralized IRBs can be used by organizations that do not have an IRB in place. Centralized IRBs charge a fee for their services.

IRBs review submitted research studies and either approve, require changes, or disapprove the study. For approved studies, the IRB conducts ongoing reviews. Expedited reviews can be conducted for studies that involve minimal risk or when minor changes need to be made to an approved protocol. Some studies, such as surveys or interviews without personal information, are exempt. For PHLs, research may be exempt from IRB review if the research involves the collection or study of existing data, documents, records, and pathological or diagnostic specimens. These sources must be publicly available or the information must be recorded in such a manner that subjects cannot be identified, directly or indirectly.

Once a study is approved, researchers must report any changes to the protocol and any adverse effects. In addition, they must ensure IRB training for all staff involved in the research. An annual review report must be submitted to the IRB.

Requirements for IRB Approval

- Risks are reasonable in relation to anticipated benefits
- Risks to subjects are minimized
- Selection of subjects is equitable
- Informed consent is administered
- Informed consent is documented

Where appropriate...

- Research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- Safeguards have been included to protect vulnerable subjects

Use of Excess Specimens in Research

PHLs need to be aware of the legal issues and Federal regulations related to the use of excess specimens in research. Proposed changes, recently announced in the *Federal Register* (Vol. 76, No 143), are being considered that will require written consent for research use of biospecimens, even those that have been stripped of identifiers. These regulations would apply to all studies, regardless of funding source, that are conducted by a US institution that receives Federal funding for human subject research. Studies that are currently considered exempt from the regulations would no longer be fully exempt.

Legal Issues

- Courts have held that “once a physician or researcher excises tissues or collects other specimens, they are no longer the property of the donor but instead become the property of the research institution.”
- Some states have enacted legislation to supplement Federal law. Most deal with DNA samples and genetic information.

Federal Regulations

Three documents regulate specimen usage in research: 1) HHS 45 CFR Part 46 (Common Rule); 2) FDA 21 CFR Parts 50, 56, 312, and 812; and 3) Health Insurance Portability and Accountability Act (Privacy Rule).

POTENTIAL RESEARCH PARTNERS

Participants identified entities that could serve as research partners for PHLs.

Private Sector

PHLs are encouraged to engage in mutually beneficial research relationships with the private sector. The advantages PHLs bring to such relationships include the availability of valuable specimen repositories, their role as the end-users of products, and an ability to validate new technologies. Opportunities for partnering with the private sector include clinical trials and federally supported research projects (e.g., Biomedical Advanced Research and Development Authority [BARDA]). Many companies also have private corporate foundations to fund projects. When working with the private sector PHLs need to remember that companies are focused on the bottom line and promoting their products. For example, they are interested in working with researchers who will publish their findings.

Other PHLs

PHLs can partner with each other on studies. For example, laboratories with more experience in research could partner with those that have less experience and help to build skills.

State Health Department

PHLs need to work within their state Department of Health to better define their role as participants in research and to better market their services. Also, many PHLs do participate in research activities but receive little credit for their efforts. They should be equal partners in research, not just sources of data for epidemiologists and others conducting public health research.

Academia

Universities have existing infrastructures to support research and many experienced researchers who have well established reputations. Students are often required to conduct research projects and are looking for opportunities. For example, PHLs can offer rotations for pre-med and medical students. Schools of Public Health also conduct a significant amount of research.

National Organizations

National organizations such as the Association of State and Territorial Health Officers (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE) can help to promote the involvement of PHLs in applied research.

Clinical and Translational Science Awards (CTSAs)

The NIH will be funding more CTSAs and the consortia are required to collaborate. Few PHLs are currently participating in consortia. PHLs should be more aggressive in joining consortia when they become available.

How to Position your PHL to Engage in Applied Research

(Needs Assessment/Strategic Planning)

- Identify areas of expertise (What makes your lab unique?)
- Identify champions (i.e., who will sell applied research to management, staff, policymakers?)
- Assess staff skills (e.g., research experience, grant writing, published articles, etc.)
- Form a workgroup to guide research activities
- Identify research priorities
- Identify existing/potential partners
- Set short- and long-term priorities
- Develop a marketing strategy (i.e., brochures, tours)
- Identify funding sources

ADVANCING PHL PARTICIPATION IN APPLIED RESEARCH: NEXT STEPS

Participants suggested activities that can support greater involvement by PHLs in applied research.

Making the Case for PHLs in Research

- Publish research findings in journals and/or present them during scientific meetings under oral or poster format.
- Compile a listing of all articles published by APHL members (to demonstrate the role PHLs can play in research).
- Reach out to academic, community, and corporate partners.

Supporting PHL Staff

- APHL should develop strategies for reaching beyond lab directors so that information on applied research can be disseminated to key lab staff.

Creating Research Opportunities

- APHL should provide seed money for applied research projects.

To Facilitate Collaboration

APHL should:

- Create a listserv devoted to applied research;
- Compile a list of potential projects that PHLs could participate; and
- Sponsor a forum of stakeholders (e.g., academia, private sector, federal agencies) to explore strategies for encouraging collaboration.

Opportunities for Applied Research

Participants were asked to identify applied research opportunities for their labs. Suggested studies fell into six categories.

- Select Agent-Approved Research
- Rapid Testing/Screening
- Diagnostic/Clinical
- Food/Environmental
- Specialized or reference testing
- Best Practices
- Development of new procedures

ACTION STEPS

- Explore formation of an APHL Taskforce focused on applied research. Work under the Infectious Disease Committee, Environmental Health or Food Safety Committees to forward the agenda of applied research (workgroup member volunteers: Martin Evans, Sara Vetter, Sanjib Bhattacharrya, Lucy Desjardins, Maria Ishida, Pete Iwen, Amy Dean, Jill Taylor).
- Explore development of an APHL White Paper presenting the case for PHL involvement in applied research.
- Report on forum proceedings at session on applied research at APHL Annual Meeting.
- Explore corporate sponsored meeting to partner and support research with PHLs and corporate members.
- Consider developing webinars and/or continuing education opportunities focused on applied research.

APPENDIX 1: GRANT WRITING BASICS

Funding Sources

Potential funding sources include the Federal government, foundations, and corporations. Funders have different priorities. For example, the Federal government is focused on activities that meet the needs of the American people. Foundations have their own funding priorities based on their mission. Carefully explore potential applied research funders to ensure that your proposed project matches their funding priorities.

Learn More about the Funding Opportunity

Depending on the funding source, applicants have various options for learning more about a funding opportunity. For Federal solicitations, there are often pre-submission and/or technical assistance conferences (e.g., conference calls, webinars). Applicants are also able to submit questions regarding the solicitation in many instances. Foundations and corporations often encourage potential applicants to approach them informally to determine if their project fits with the organization's funding priorities.

Planning your Proposal

Finalize your project, read the request for proposals (RFP), select your writing/review team, develop an outline, identify materials that will be required (e.g., resumes, letters of support), develop a timeline for completing the proposal, and initiate contact with the finance department to aid in the development of the budget.

Developing the First Draft

Tips

- First draft should be too long – plan to cut information
- Do not stop to correct
- Use the writing rules learned in school
 - One idea per paragraph
 - Topic sentences that are not negative
 - Lead in sentences from section to section
 - Active rather than passive voice
 - Rewrite sentences to reduce words
- Mimic the format of the RFP
 - Same headings
 - Use bullets when they use bullets
- Be positive, focus on your strengths

Secrets to a Strong Proposal

- Write a strong abstract—this is a reviewer's first impression
- Break up the text—use SmartArt, text boxes, etc.
- Make sure your budget reflects the proposed activities in your proposal

When to Seek a Grant....

- Expertise established by publication
- Partnerships in place
- Testable hypothesis formed
- Preliminary data collected

Resources

Federal Government

<http://funding.niaid.nih.gov/researchfunding/grant/pages/default.aspx>

http://grants.nih.gov/grants/grant_tips.htm

<http://www.epa.gov/ogd/recipient/tips.htm>

<http://www.arc.gov/funding/HowtoWriteaGrantProposal.asp>

http://www.samhsa.gov/samhsaNewsletter/Volume_17_Number_5/WinningGrantProposal.aspx

Foundations

<http://www.foundationcenter.org/>

Corporations

<http://grantspace.org/Multimedia-Archive/Webinars/Introduction-to-Corporate-Giving>

APPENDIX 2: ELEMENTS OF A PROPOSAL WRITING CHECKLIST

Getting Started

- Read request for proposal (RFP)
- Determine if your project fits the goals of the solicitation
- Get approval to submit a proposal
- Meet with any potential partners
- Inform those in your organization that you will need to work with (e.g., finance department)
- Identify writing/review teams, assign responsibilities
- Develop timeline for writing proposal
- Determine submission process (electronic, hard copy, etc.)
- Submit letter of intent (if required)
- Explore IRB requirement
- Develop and submit questions about the solicitation (if appropriate)

Developing the Proposal

- Develop outline based on RFP
 - To create the outline, cut and paste text from the RFP.
 - Follow the format provided in the RFP, section by section, heading by heading.
 - Integrate review criteria in the appropriate section. This way, your proposal will respond to all the requirements specified in the RFP and be presented in a format that makes it easy for the reviewer to determine if you have addressed each requirement.
- Determine formatting based on submission requirements (e.g., double spaced, margin size, etc.)
- Collect necessary data for proposal and determine best way to present it (e.g., tables, graphs, narrative text)
- Conduct literature review (if appropriate)

- Write first draft
 - Goals and objectives
 - Methodology
 - Project timeline
 - Expected deliverables
 - Evaluation plan
 - Contingency plan
 - Boilerplate text (organizational description, resources, etc.)
- Write abstract
- Initial round of revisions
 - Meeting page limitations?
 - Includes all essential information?
 - Coherence
 - Tone
 - Does it accurately present your strengths?
- Review of first draft
- Incorporate reviewer comments
- Develop second draft
- Review of second draft
- Incorporate reviewers comments
- Copy editing

Additional Activities

- Complete any required forms (for Federal grants)
- Develop budget/budget narrative
 - Includes indirect costs
 - Include in-kind support
- Complete appendices (resumes, etc.)
- Collect letters of agreement/letters of support/material transfer agreements

Submission

- Develop cover letter
- Get required signatures

APPENDIX 3: TECHNICAL WRITING

Peer-reviewed journals offer a variety of opportunities and challenges to publish quality research findings. These include: scientific papers; review articles; commentaries; notes; case reports; and editorials. Another venue for communicating research findings are professional conferences through either oral presentations or poster presentations. In all cases, the author should present significant information that has not been previously published.

Why Publish?

- It is the necessary endpoint of research
- Contributes to the scientific body of knowledge
- Supports the collective mission of the PHL community
- Self fulfillment

There are ethical considerations related to publishing in peer-reviewed journals. Violations can result in sanctions by the professional organization associated with the journal. They can also have serious career implications. In submitting an article, all authors—not just the lead authors—are attesting to the validity of the research, that it is original work, and that it has not been published previously.

Steps to Writing an Article

Identify the Journal

Determine what type of articles they accept and what is the best format for your information (e.g., article, editorial, notes etc.). Contact the journal if you have questions.

Identify Additional Assets that are Required

Will you need statistical or informatics support?

Develop a Title

An effective title should be short and include key, searchable words. Do not use abbreviations or acronyms in the title.

Write the Article

Journals have a specific format for submissions. Many require articles to comply with the following format: abstract; introduction; methods; results; and discussion.

- *Introduction*

The introduction provides the background and context for the paper—it should take up less than 20 % of the text. Summarize the relevant findings in the literature, introduce the research question, and discuss the purpose of the paper and its importance.

- *Materials and Methods*

Describe methods, analytical procedures, and statistical applications. Only include information that was available at the beginning of your study—no new information.

- *Results*

Present your results using text, tables, graphs, and charts—use the most effective format.

- *Discussion and Conclusion*

Analyze the findings, compare results, and draw conclusions. Highlight the major aspects of the study and leave the reader with a meaningful statement.

- *Acknowledgements*

Acknowledge the funding source and those who assisted in the research or the writing of the article but do not qualify for authorship.

- *References*

Follow the format for references required by the journal.

Internal Review

Ask colleagues to review the article before you submit it. As appropriate, include statisticians, informaticians, and other colleagues. Reviewers do not necessarily need to have expertise in the area of the study. They should review it for general readability and clarity.

Revisions

Reviewers often ask for revisions.

TIPS & TOOLS FOR APPLYING FOR A GRANT

To **INITIATE**, ask:

1. Do we have a testable hypothesis?
2. Do we have the resources, personnel, and facilities to test the hypothesis?
3. Are there partnerships or collaborators with similar interests who could contribute scientifically and make the proposal more likely to be successful?
4. Do we have any preliminary data that supports our hypothesis?
5. Do we have expertise in all the areas that will be required to test the hypothesis?
6. Do we have a track record of publications in the area to demonstrate credibility?
7. Have a “Chalk Talk”. Invite colleagues to an informal seminar where you present your specific aims – what you plan to do and what you want to achieve - and ask them to critique and look for holes in your argument.
8. Assess whether you are ready to apply for funding. Remember that many funding agencies limit the number of times you can re-submit an application, so you don't want to submit if you are not ready.

The next step is to look for potential funding sources!

KNOW YOUR FUNDER

1. Get as much information as possible from the funding source prior to submitting a proposal.
2. Ask yourself why they should trust you with their money?

You've found yourself a grant that fits...

PROPOSAL PREPARATION ENTAILS:

1. A plan with timeline
2. A tasklist
3. Drafting and writing
4. Editing
5. Reviewing
6. Submitting proposal

PLAN

- Read (no, really READ) the application
- Build a working document with Narrative Description, Evaluation Criteria, and required attachments
- This is your skeleton (working draft that you will feed into)
- Coordinate a team – consider different levels, time availability, outside partners
- Share the “skeleton” and the original unmarked application before first meeting

TASKLIST

- Meet with team
- Assignment of tasks, get people to “own” their piece(s)
- Work backward from deadline to determine deadlines for tasks, timeframe for follow up meetings, drop dead date for final application

DRAFT AND WRITE

- Draft your writing, gather your “pieces” – long and lengthy, no editing.
 - Important information goes first
 - Keep it concise
 - Follow or mimic words and format of application
 - Be active, not passive
 - List strengths; stay positive; give examples of success. This is your chance to really highlight your capabilities.
 - Consider graphics to illustrate points; break up the text and rest the eye.
 - Estimate budget. Work with administration to make sure all institutional costs (fringe, indirect, core charges, etc.) are included.
- Write your abstract and make sure it syncs with budget.
- Include an evaluation plan - how will you evaluate whether or not you met the objective(s) of your research?

EDIT

- Reduce words
- Ask yourself if you have clearly described what you propose to do AND what benefit to science and health will result from your work?
- Format – bullets, bold, white space okay
- Proofread. Ask others to proofread in case you missed something.

REVIEW

- Make sure it looks professional.
- Ask colleagues who are experienced in grant writing to read and constructively critique. It is useful to have reviewers who know the field well as well as some in related fields but who have some distance.
- Give the reviewer(s) adequate time to review & provide feedback.

SUBMIT PROPOSAL

- Be sure you submit the proposal in the format requested (electronic, 3 hard copies, etc.).
- If possible, contact agency and indicate that you have submitted a proposal and ask for next steps.

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