Guidelines for Initiating a Research Agenda: Topic Selection and Evidence of Impact

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LEARNING OBJECTIVES

1. Describe factors portending significance and professional impact of potential research.
2. Identify knowledge and practice gaps leading to formulation of specific, meaningful hypotheses and research questions.
3. Apply rules related to informed consent and Institutional Review Board research approval.
4. Describe elements of the research budget and budgeting process.

ABSTRACT

The focus on scholarly productivity as an outcome measure for performance evaluations of personnel and/or units and benchmarking purposes is increasing in both the academic and clinical settings. This article presents avenues for identifying achievable research projects in both the academic and clinical settings. Factors for consideration when selecting a project include its significance or impact on the profession, feasibility for implementing the project, and ethical issues related to human subjects protection. A review of the literature is essential for identifying gaps in knowledge and for constructing the hypothesis or research question. Decisions concerning IRB submission, budget allocation, and collection of data must also be considered before implementation of the research design.

ABBREVIATIONS: DV- Dependent variable, IRB - Institutional Review Board, IV - Independent variable, NIH - National Institute of Health, ORI - Federal Office of Research Integrity

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INTRODUCTION

Conducting research has become increasingly important for medical laboratory practitioners and educators for professional development and personal growth. The academic and clinical preparation required for the medical laboratory profession equips the practitioner with important research skills. These skills include an understanding of the scientific method, a thorough background in statistics, and attention to planning and detail. Additionally, laboratory professionals possess the knowledge and expertise to blend didactic principles with clinical applications. Laboratory professionals are well suited for the development of relevant research projects that can contribute to the medical laboratory knowledgebase.

Strong rationales to pursue research and the subsequent dissemination of the findings are evident. Research is essential for the advancement of our profession through increasing the body of scientific knowledge of medical laboratory science. It enables one to assess quality, improve processes and to evaluate methods within the clinical laboratory. Further, it is imperative to educate health professionals through sharing research findings and its implications on diagnostic processes and management of therapy. In academe, there are personal and institutional benefits for pursuing a research

agenda. Though research and publications may be required for attaining tenure or promotion to the next academic rank, a productive history of research also affords status to the department and its institution. Certainly, research can also provide self-satisfaction as an element of one's goals through fostering creativity and innovation. The five basic types of research are summarized in Table 1.

Ideas for Research Topics

Research topics must be of significance to the profession, feasible to implement, and ethical in its treatment of human subjects.[1] To be significant, research must contribute to the state of knowledge such that its importance is readily identifiable with beneficial implications for the profession when one asks, "so what?" By conducting a literature review, the researcher can determine the extent to which information on the chosen topic has been studied and published or if it presents a new or novel research question. There must be sufficient and available resources, and an efficient process must be attainable to achieve feasibility. Further, the research interest must be ethical as required through human subjects protection. A research idea, which may initially seem exciting to the investigator, may actually prove to be undoable when considering ethics and feasibility.[1,2]

Table 1. Types of Research

Type of Research	Description
Basic Science	Seeks new knowledge or advances research in an area of knowledge.
Applied Research	Identifies relationships between concepts to solve a practical problem.
Clinical Investigations	Evaluate applications of research findings in the clinical setting. Usually a small study population
Clinical Trials	Determine effectiveness and safety of clinical treatments in larger patient populations.
Demonstration and Education Research	Examine the efficiency of treatments designed to promote health or prevent disease in a population

Adapted from Chatburn RL (2011) Handbook for Healthcare Research. 2nd Ed. Jones and Bartlett Publishers

Novices of research who spend most of their effort at the bench or teaching in an academic setting may find it difficult to initially identify a research topic. Where does one begin to select a significant, feasible, and ethical topic? Ideas often arise from clinical or teaching experiences. A clinical issue or challenge in teaching provides an avenue, as do new technologies or innovations. Conversations to include informal or formal inquires with mentors, colleagues, and those in other health-related disciplines often generate research ideas. Perhaps, a journal article, newsworthy item, or conference seminar may stimulate a research question that can be pursued.

Collaboration and networking open additional research venues. Networking with colleagues within departments or units, across departments, as well as in other institutions can produce further research ideas. A multi-disciplinary approach and team playing can create a diverse research project with input and critique from a variety of viewpoints. Additionally, collaborative efforts provide more possibilities for presentations and publications.

It is helpful to keep a journal to record ideas for research topics along with positive and negative aspects of each idea while considering the significance, feasibility, and use of human subjects. The topics can be refined and clarified as you progress, seeking input from colleagues or literature sources. A topic generally begins as a very broad idea that will need to be narrowed down to a research question or hypothesis as the process evolves. Bailey offers a thorough exercise to assist in topic selection for research projects (see Table 2).[1,2]

Table 2. Exercise for Selecting a Research Topic

1. Write down questions derived from work experience.
2. Rank questions in order of interest and significance.
3. For each question, answer the following:
   a. Why does this question interest you?
   b. List all parts of the question.
   c. What significant problem is addressed?
   d. What is the rationale or theory base?
   e. What background information is needed to determine feasibility?
   f. What resources are needed to study this question?
   g. What are some of the obstacles that you foresee? Can they be overcome?
4. Identify the research question which provides the most significant and feasible study.

Adapted from Bailey DM (1997) Research for the Health Professional. 2nd Ed. FA Davis Publisher.

"Working smart" implies that the investigator uses time

wisely by utilizing available resources and opportunities. Current roles, responsibilities and functions can support the research initiative by applying skills to the project. For example, a medical laboratory science educator may apply her knowledge of education methodologies to a research project involving curriculum design. A clinical hematology instructor may readily use his laboratory skills to evaluate a new hematology analyzer. Researchers strive to build a track record; often this means by starting with small projects. One strategy for initiating a research agenda amidst a heavy work schedule is the concept of working on one short term project and one long term project at any time.

Aside from procuring adequate resources, time and timing are important items to consider when planning a research study. As the primary investigator, the researcher must be able to allot the necessary time to write the proposal, apply and receive approval from the institutional review board, recruit the subjects, and complete the project. Further, the research design may be influenced by the availability of the ascertained subjects.

Selecting a Research Plan

Literature Review

Once a topic is chosen, the next step is to conduct a thorough literature review to determine the research design, the framework of the project. The purpose of the literature review is to identify information published on the study topic and to recognize the strengths and weaknesses of existing research. The literature review also reveals gaps in knowledge and suggests means for the proposed study to add to the body of knowledge. The research topic or question may be adjusted based on the findings in the literature review. The literature review should be comprehensive and include peer-reviewed journal articles, books, book chapters as well as dissertations, meeting presentations, and government documents, if appropriate.

Reference librarians and other similar professionals can provide valuable assistance with the literature review. It is imperative to choose and to successfully navigate the most relevant databases to ensure thoroughness and completeness of the review. Research librarians can guide the researcher in the effective and efficient use of databases. They are knowledgeable on what is available on the institution's site or through inter-university loan agreements; research librarians can also inform the researcher on time requirements needed to obtain particular items. This assistance will save the researcher valuable time and reduce stress while developing the review. Some commonly used databases are summarized in Table 3.

Table 3. Useful Databases for Literature Review

MEDLINE®	Produced by National Library of Medicine and free though interface with PubMed (http://pubmed.gov). Proprietary interfaces include OvidSP and EBSCO. This database uses a controlled vocabulary MeSH (Medical Subject Headings) and contains biomedical information in professional journals.
CINAHL®	Provides a cumulative Index to Nursing and Allied Health Literature; it requires an interface with vendor EBSCO and contains journal articles (with full text), dissertations, conference proceedings, standards of practice, educational software, book chapters, health care books, clinical trials, research instruments, and clinical innovations.
Thomas Reuters WEB OF SCIENCE ®	Requires access to Web of Knowledge SM which is an academic searching and citation indexing service for sciences, social sciences, arts and humanities. This citation index has the ability to search by word, phrase, author and also by cited references. It provides bibliographic content and the ability to simultaneously search multiple databases.
EBSCO	Is a proprietary interface of MEDLINE® and offers full-text, research databases, e-journals, and e-books. This information service provides point-of-care decision support tools, organizational learning resources.

The literature review is an organized discussion of previous relevant research. It should be arranged either chronologically or by the research methods or trends. The review begins with a brief introduction of the research question and a summary of current research studies. Key points as well as weaknesses and controversies should be noted. It is important to incorporate only relevant studies, writing in a concise style. The literature review is concluded by discussing the value of the proposed study is pertinent and its contribution to the existing body of knowledge. It is important to create an accurate and thorough reference list when writing the literature review and to obtain and

file copies of articles used for future reference and documentation. Generating an accurate bibliography correctly formatted from the onset and revising the list as references are added are strongly recommended.

Ethical Considerations and the IRB

Ethical considerations including respect for the subjects, beneficence, and justice are evaluated through the human subjects protection processes. The institutional review board (IRB), also known as the ethical review board or human subjects review board, is a committee that reviews, approves, and scrutinizes research involving human subjects at its institution. The IRB functions to protect the study participant's rights, welfare and privacy and also ensures that the elements of informed consent are met. Additionally, the design of research projects involving human subjects must ensure that the benefits gained from completing the project outweighs any risks, including both physical and emotional harm, to the participating subjects. Justice must also be considered in the design of the project to ensure that interested subjects will have equitable access to the benefits of the research. Another function of the IRB is to ensure that the institution is in compliance with state and federal regulations regarding the treatment of human subjects in research projects. The IRB process also serves to protect the institution and its researchers.[3]

There are different levels of review undertaken in the IRB process based on the risk to the subject. Exempt studies are at the lowest risk level, yet still require an informed consent document and the study to be conducted using ethical conduct. Examples of exempt studies include research conducted in commonly accepted educational settings; educational testing, such as aptitude or achievement tests; survey research; interview procedures; observation of public behavior; and collection or study of existing data, documents, pathological specimens that are publicly available. In all exempt reviews, the subjects' anonymity must be ensured; and their results cannot be linked to their identification.

Expedited reviews include those research studies that present no more than minimal risk to human subjects. Risk is minimal when the probability of harm or discomfort anticipated in the project is no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological testing. For example, collection of one tube of blood from a healthy participant for a research project presents no greater risk than having a specimen collected as a part of a routine physical examination. Examples of studies that might undergo expedited review include collection of blood samples or biological specimens using noninvasive techniques from healthy individuals; research on materials that has previously been collected for non-research purposes (data, specimens, results), and research on group characteristics that are not exempt (surveys, observations, quality assessment).

Full review research proposals are those that do not meet exempt or expedited review and, therefore, must undergo initial and ongoing review by the full IRB. This process involves additional assurances for human subjects protection, including the management of adverse events, additional documentation of the informed consent process, subject inclusion and exclusion criteria and justification, assurance of subject privacy, and the level of risk.

The investigator must consider this approval process and potential delays caused by revisions and additional documentation requested by the IRB committee when determining the timeline for completion of the study. In collaborative studies, for example, where a university and a health-care institution are involved in the project, it is necessary to complete the IRB process within both institutions. Information on training and documentation for those involved with human subjects can be found at the National Institute of Health (NIH) website at http://phrp.nihtraining.com/users/login.php. The Federal Office of Research Integrity (ORI) provides information about Ethics and the "Responsible Conduct of Research" at http://ori.dhhs.gov/education/products/.

Data Collection

The research process, especially data collection, must be achievable in order for the project to proceed. Data collection from human subjects requires the availability and willingness of subjects to participate in the study. Subjects must be recruited once the sampling method is determined and upon receipt of IRB approval. Recruitment may be accomplished through networking, advertisement fliers, newspapers, campus internet announcements, snow balling, or other mechanisms.

Once a subject is recruited, the informed consent process must be documented. Informed consent is a process where the research project is explained to the potential participant and documented with a written description of the process. Further, assurances that participation is voluntary must be clearly stated in the informed consent. Consenting to the project is evidenced by their signature. For minors and those who lack decision making abilities, a parent or legal guardian must consent to the research process.

Once the subjects are recruited and consented, data collection days and times must be established based on availability of the participants, investigator and facilities. This requires communication and cooperation between the investigators and participants. Equally essential to recruitment is retention of the participants; this is especially important for long range studies that may require the individual to return multiple times to participate in data collection. Sufficient number of subjects should be recruited at the onset to maintain adequate sample size in cases of attrition as the study progresses.

Facilities, such as a classroom, a meeting area, or a laboratory must be available and accessible and provide for a confidential environment when needed. Equipment and supplies must also be accessible and operating properly for accurate results.

Data, Scales, and Variables

Data are the pieces of information that are collected in the study. Quantitative data are in numeric form and are used in quantitative research; whereas, the data used in qualitative research are in the form of narrative descriptions.

A variable is an attribute or characteristic of a person or thing that takes on different values; it is an item that varies and can be measured. Variables may be either continuous or discrete. Continuous variables can be expressed on a continuum with quantified intervals on an infinite scale of values. These values are limited only by the sensitivity of the measuring instrument. By contrast, discrete variables take on a finite number of values between two points.

There are different types of measurement scales; it is key to identify the measurement scale for each variable in a study as well as its sensitivity. Nominal or categorical measurement scales permits the researcher to classify characteristics of people, objects or events within a limited number of categories; examples of categorical variables include race, group membership, educational degree, marital status. An ordinal scale can be used if categorical variables can be placed into a meaningful order; however, the distance between the categories is not known. Examples of ordinal data include faculty rank or class placement. When the distance between ordered categorical variables is equal, it is deemed an interval scale. Examples of interval scales include temperature scales and many laboratory values, such as glucose, total protein and other chemical constituents of plasma as well as blood cell counts.

Interval scale variables can be continuous or discrete. Continuous variables can theoretically have an infinite number of values between any two points, such as blood pressure values. Discrete interval variables consist of indivisible units, such as the number of students in a class or the number of patients treated in a clinic. Dichotomous discrete variables can take on only two categories; examples include living or deceased or if a condition is present or absent. The most precise measurement scale is the ratio scale, because it consists of interval data that also includes a true zero point. Thus, the precision of measurement scales can be summarized as follows: Ratio > Interval> Ordinal > Nominal.

It is best to collect data using the most precise measurement scale possible, though these data can always be converted to a less precise scale. However, the opposite is not true. For example, a researcher may collect laboratory data, such as glucose levels in mg/dL. She may later convert these to interval data, such as those values that are less than 100 mg/dL, those that are between 101 and 200 mg/dL, and those that are over 200 mg/dL. She could not, however, record ordinal data and then convert to interval or ratio data.

Independent variables (IV) are also known as the predictor variables, treatment or manipulated variables. The IV is the presumed cause of variable that influences the dependent variable (DV). The DV is also known as the outcome or criterion variable and is the presumed effect. The DV is hypothesized to depend on or to be caused by the IV. There may be single or multiple

dependent and independent variables in a study. Also depending on the research question or study design, a variable that is the dependent variable in one study may be identified as the independent variable in another study.

Confounding variables are factors that may interfere with the study. They can be controlled for by using random sampling selection grouping or by matching subjects within groups. Another method is to form homogenous samples by grouping subjects based on the confounding variable. Statistically, the researcher can use analysis of covariance (ANCOVA), a statistical tool, to remove the effects of the confounding variable.

Costs and Budget

There are several research costs to consider, especially when working on a limited budget. Personnel costs may include those associated with data collection, laboratory testing or for consultants, such as a statistician. Costs related to subject recruitment may include supplies, printing, postage and shipping as well as incentives if these are being used.

Academic institutions utilize an Office of Sponsored Projects to oversee post-award administration of sponsored program awards and provide financial reports to sponsors. This office also interprets rules and regulations of financial operation for the research community and acts as the depositor of federal and nonfederal funds.

Costs may be categorized as direct or indirect costs.[4] Direct costs are those expenses that are specific and deemed allocable to the sponsored project. In other words, these costs must directly benefit and be attributable to the project. Allowable direct costs are determined in accordance with institution policy and sponsor policies and must be reasonable, necessary and consistently treated. Personnel costs are evaluated based on their role and their percent involvement in the project. Their institutional base salary and amount requested for the research study including salary and fringe benefits are also considered. The use of consultants and other experts is also included in direct costs in the budget.

Indirect costs are those institutional costs that are included in a research budget over and above the direct costs. These may include administrative costs, facility costs, and other "overhead." Depending on the funding source, these may or may not be included in the budget. Other indirect costs are not allowable and include memberships and subscriptions, general office supplies, computer supplies, general purpose software, ordinary postage, and local telephone charges.

Summary

There are various avenues to pursue topics for research studies, found in both clinical and academic experiences. Evaluating the feasibility and ethical considerations are important in determining if a research idea can become an attainable research project. Data collection may begin upon receipt of approval from appropriate IRB committees. Defining the variables, identifying the measurement scales, and determining the budget guide the construction of the research design.

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