Radiology Research Handbook

Department of Radiology
THE UNIVERSITY OF VERMONT HEALTH NETWORK

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Introduction

One of the exciting aspects of working in radiology is that you are working in a rapidly evolving field. You have to adapt to survive, and part of that adaptation is to make best use of the tools available to you.

Times have changed, and technology has advanced in leaps and bounds. There is a new set of tools available to the radiologist. This amazing progress in a single generation has been achieved through both technical and clinical research. To be ready for the technological advances in your career, you had better keep an eye on today's literature. Are you using the best techniques currently available, or are you using older, inferior methods because that is what you (or your mentor) are more comfortable with? When a new technology arrives, can you evaluate the literature to determine whether it really is worthwhile, or just a way of selling new machines? How do you interpret some new MRI contrast technique? Do you trust the results? The consensus of the 1991 Radiology Summit Meetings (sponsored by the ACR) was that

"To improve understanding of the value and methods of research, all trainees and faculty should receive basic instruction in critically reading the medical literature, experimental design, and biostatistics. Those wishing to conduct research should receive more extensive training."

The goal of this handbook is to provide you with a useful resource, a guide to help you navigate and successfully complete a research study. This handbook contains basic research overview, list of resources and timeline recommendations.

Disclosure

The Radiology Research Handbook authors have no financial conflict of interest to disclose. The radiology Research Handbook authors have consulted and followed the manual outline from the University of New England Research Manual for Residents.

https://www.une.edu/sites/default/files/researchmanual.pdf

I. Conducting Clinical Research

Conducting clinical is an extensive learning process. This process can help you gain a greater appreciation for the effort involved in the research studies.

Conducting research contributes to the greater good of medicine and expands personal and professional knowledge. Clinical research is critical to the advancement of radiology.

This is a series of 23 articles published in AJR between 2001 and 2006. They address many common issues in radiology research, and can be taken as a consensus opinion on best practice.

1. Beam C, Blackmore C, Karlik S, Reinhold C. Editors' introduction to the series. *AJR Am J Roentgenol.* Feb 2001;176(2):323-325.
2. Blackmore CC. The challenge of clinical radiology research. *AJR Am J Roentgenol.* Feb 2001;176(2):327-331.
3. Crewson PE, Applegate KE. Data collection in radiology research. *AJR Am J Roentgenol.* Oct 2001;177(4):755-761.
4. Karlik SJ. How to develop and critique a research protocol. *AJR Am J Roentgenol.* Jun 2001;176(6):1375-1380.
5. Kazerooni EA. Population and sample. *AJR Am J Roentgenol.* Nov 2001;177(5):993-999.
6. Beam CA. Statistically engineering the study for success. *AJR Am J Roentgenol.* Jul 2002;179(1):47-52.
7. Herman CR, Gill HK, Eng J, Fajardo LL. Screening for preclinical disease: test and disease characteristics. *AJR Am J Roentgenol.* Oct 2002;179(4):825-831.
8. Joseph L, Reinhold C. Fundamentals of clinical research for radiologists. Introduction to probability theory and sampling distributions. *AJR Am J Roentgenol.* Apr 2003;180(4):917-923.
9. Karlik SJ. Visualizing radiologic data. *AJR Am J Roentgenol.* Mar 2003;180(3):607-619.
10. Karlik SJ. Exploring and summarizing radiologic data. *AJR Am J Roentgenol.* Jan 2003;180(1):47-54.
11. Blackmore CC, Cummings P. Observational studies in radiology. *AJR Am J Roentgenol.* Nov 2004;183(5):1203-1208.
12. Stolberg HO, Norman G, Trop I. Randomized controlled trials. *AJR Am J Roentgenol.* Dec 2004;183(6):1539-1544.
13. Crewson PE. Reader agreement studies. *AJR Am J Roentgenol.* May 2005;184(5):1391-1397.
14. Dendukuri N, Reinhold C. Correlation and regression. *AJR Am J Roentgenol.* Jul 2005;185(1):3-18.
15. Hollingworth W. Radiology cost and outcomes studies: standard practice and emerging methods. *AJR Am J Roentgenol.* Oct 2005;185(4):833-839.
16. Joseph L, Reinhold C. Statistical inference for proportions. *AJR Am J Roentgenol.* Apr 2005;184(4):1057-1064.
17. Joseph L, Reinhold C. Statistical inference for continuous variables. *AJR Am J Roentgenol.* Apr 2005;184(4):1047-1056.
18. Obuchowski NA. Multivariate statistical methods. *AJR Am J Roentgenol.* Aug 2005;185(2):299-309.
19. Obuchowski NA. ROC analysis. *AJR Am J Roentgenol.* Feb 2005;184(2):364-372.
20. Plevritis SK. Decision analysis and simulation modeling for evaluating diagnostic tests on the basis of patient outcomes. *AJR Am J Roentgenol.* Sep 2005;185(3):581-590.
21. Stolberg HO, Norman G, Trop I. Survival analysis. *AJR Am J Roentgenol.* Jul 2005;185(1):19-22.
22. Weinstein S, Obuchowski NA, Lieber ML. Clinical evaluation of diagnostic tests. *AJR Am J Roentgenol.* Jan 2005;184(1):14-19.
23. Gatsonis C, Paliwal P. Meta-analysis of diagnostic and screening test accuracy evaluations: methodologic primer. *AJR Am J Roentgenol.* Aug 2006;187(2):271-281.

Reference:

https://www.une.edu/sites/default/files/researchmanual.pdf

II. Evidence-Based Medicine

During the residency, the residents will no doubt learn a great deal through their own experience. However, as an individual you will only directly see a limited number of cases. The faculty, with many years of experience between them, are also individuals with a (hopefully somewhat less) limited range of experience. Evidence-based medicine suggests that decisions should be based on the best available evidence from the medical literature rather than one's own limited experience. While the literature is itself far from perfect, it is the best that we have. Proper use of evidence-based medicine and continuing medical education are essential to clinical development throughout someone's career.

The whole idea behind evidence-based medicine is that knowledge is gained through systematic study rather than individual experience. Since radiology as a field has been rather slow to adopt this approach, there are opportunities to confirm (or deny) that what everyone assumed was the case really is (or is not).

III. ACGME Requirements for Radiology

Residents' Scholarly Activities
The curriculum must advance residents' knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care. Residents should participate in scholarly activity. Residents must have training in critical thinking skills and research design. All residents must engage in a scholarly project under faculty member supervision. The results of such projects must be published or presented at institutional, local, regional, national, or international meetings, and must be included in each resident's Learning Portfolio. The program should specify how each project will be evaluated.

There are similar requirements for faculty as well. More information on the ACGME requirements for diagnostic radiology can be found at https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/420_DiagnosticRadiology_2018-07-01.pdf

IV. Designing Your Research Study

Designing a research project can be an intimidating task. The mentors and people with research experience can guide you through this process. They will be able to help you answer the questions about your project such as how to choose the project, what is a sample size, how data will be analyzed, is it a prospective or retrospective study.
The answers to these questions will help you with the design of your study.

How to choose the topic for your research study?
It is important to find something that you are passionate or curious about. The objective of the study is encompassed by the hypothesis. The hypothesis is based on a theory you are trying to prove or disprove, and should be as specific as possible. What type of study will be necessary to test your hypothesis? Types of research studies are listed in Appendix III. One strategy for identifying research topics is to familiarize yourself with the wide range of research being conducted by your mentors and colleagues. There are frequently opportunities to develop ancillary studies related to ongoing work, for which mentors and data collection infrastructure are already in place.

First Step
A literature review is the first step in beginning your research study. The literature review will allow you to gain additional knowledge about the topic, and to determine if other studies have been performed with a similar hypothesis. If so, consider if your goal is to build upon the existing body of literature, or challenge the results. Also consider the strengths and weaknesses of the previously published data- this will help to improve the quality of your study and identify how you can make a valuable contribution to scientific knowledge.

Measure Methods
Once your study question has been crafted, it is important to determine how you will measure outcome variables. This will depend on the nature of your question: is the answer a dichotomous variable (only two possible outcomes; measured with a chi-squared test) or a continuous variable (multiple possible outcomes; measured with a t-test). Will your study have quantifiable variables or categorical variables? Refer to Appendix II for additional definitions for outcome variables as you outline your methods.

Research Subjects
One of the most important aspects of study design is sample size calculation. Before beginning data collection, it is important to perform a sample size calculation to ensure that your study has sufficient power. Contacting a biostatistician to assist with this calculation is essential to ensure accuracy.

Depending on your specific study design, it will also be important to determine how to select or recruit your study population. This should be done in a fashion to limit bias. You must also consider what inclusion and exclusion criteria are important in evaluating your hypothesis.

Make sure that you know where your project is going to take place, hospital, outpatient clinic, etc. You will also need to keep in mind the timeline goal of competing your research study.

Consider not only the time required to collect the needed data, but also time for getting human subjects review or other regulatory approvals, time for drafting a manuscript describing the study results, and time for incorporating feedback from your mentors and collaborators.

This is where all your hard work pays off. Unless you have experience in this arena, finding someone to assist you will be so very helpful. You will need this information when applying for funding or IRB approval.

Biostatistics and Data Analysis

There are "Lie, Damned Lies and Statistics" (a quote popularized by Mark Twain, who attributed it to the British Prime Minister Benjamin Disraeli). Biostatistics allows you to generalize your findings from your limited sample of subjects to the wider population. It is important to be able to understand at least the language of statistics, as well as to be able to critically evaluate published findings. For example, extremely large studies can determine subtle effects with a very high level of statistical confidence that have almost no clinical relevance. It could be argued that there is an unhealthy obsession with p-values in research, and especially the magical (but completely arbitrary) $p<0.05$.

Connecting with a biostatistician early in your study design will save time and ensure the accuracy of your statistical evaluation. The biostatistician will assist in determining the optimum method for data analysis.

Radiology residents have access to biostatisticians through the Larner College of Medicine at UVM. If medical students will be involved in a research project, they will need to be credentialed. Research coordinator can assist with this process.

Literature Search

There are various databases to search the literature, including PubMed, MedLine, Google Scholar and Web of Science. Some of these are free (Google Scholar, PubMed), while others can be accessed through a UVM library subscription. It's worthwhile getting familiar with how to build a search. Typically you can search by author, year, keywords, words in the title, and words in the abstract.

The staff at the UVM Dana Medical Library can help you with database searches, as well as providing classes which are open to all UVM and FAHC faculty, staff and students. Further information can be found at
http://library.uvm.edu/dana/about/FAQ/database.php

EndNote Reference Manager

If you're going to be writing proposals, IRB applications, abstracts and papers with more than a handful of references then using a reference manager can save you a lot of time and effort.

EndNote is available through UVM (https://www.uvm.edu/it/software/), and allows you to search online databases, create your own local library of papers (including the full text PDF if it available) and easily insert references into a Microsoft Word document while automatically updating the bibliography.

Further information can be found at:
https://researchguides.uvm.edu/endnote

References:

https://www.une.edu/sites/default/files/researchmanual.pdf
https://www.uvm.edu/biostatistics
https://dana.uvm.edu/services/statistics

V. Institutional Review Board

The research projects must be submitted to the Institutional Review Board for approval. The Research Protection Office/IRB is there to ensure compliance with federal regulations in the protection of human research participants.
Our IRB has a very detailed website, accessible at https://www.uvm.edu/rpo/human-subjects-research. All required forms and templates are available as electronic, as well as a link to the research protection/compliance course/GCP/additional consent CITI training. All personnel involved in research will need to complete the required CITI training and the certificates of completion need to be sent to radiology research coordinator. The IRB training speaks about the human subjects's protection in research and covers the research study design along with the consent form elements.

The research project proposals will be submitted through the CLICK system. Your submitted project will be reviewed by the IRB and will be considered as approved, approved with modification and revisions, exempt or denied. The role of the IRB is to ensure that the research projects that they review are safe and ethically sound for the subjects to participate.
The UVM IRB Board consists of members with varying backgrounds and they review all research projects and activities involving human subjects.

Radiology research coordinator can help you with many aspects of the forms. In some cases, there is standard wording that can be used (for example, in describing the safety aspects of MRI). While the IRB forms can look daunting, the main aspects that you will probably spend time on are the purpose, objectives, study design and procedures
The Data Management Office (DMO), formerly known as Jeffords Institute for Quality (JIQ), can be utilized for the research projects. The DMO has its own research forms that need to be completed and sent to the DMO separately from the IRB form. The forms need to be submitted to the DMO for their review. You will need to receive the DMO approval prior to submitting the forms to the IRB.
https://www.uvmhealth.org/medcenter/Pages/Departments-and-Programs/Jeffords-Institute-for-Quality-Operational-Effectiveness.aspx
If your project involves the study of cancer, you will need to submit research forms to the Protocol Review and Monitoring Committee. You will need to receive this committee's approval prior to the IRB approval.
https://www.med.uvm.edu/uvmcancercenter/members/protocol-review
The following IRB self-determination tool guides whether the project is quality improvement versus research requiring IRB review.
https://www.uvm.edu/rpo/forms/not-research-self-determination-tool

This link within the "Will the activity involve HUMAN SUBJECTS?" section provides more information on assessing if there are human subjects in the research project.
https://www.uvm.edu/rpo/determine-if-project-requires-irb-review

References:
https://www.une.edu/sites/default/files/researchmanual.pdf
https://www.uvm.edu/rpo/irb-policies-and-procedures

VI. Funding Your Project

One of the most challenging aspects of research is obtaining funding, which is essential for certain types of research projects. This can help offset the cost of protected time and research resources, such as statistical support, scanner time, and materials. Refer to Appendix I. Funding Application Resources for additional information.

Funding Resources

PIVOT is a web-based tool that brings together a funding database representing tens of billions of dollars in available funding from federal, non-federal and international sponsors in all disciplines and a scholar expertise database populated with over 3 million scholar profiles including UVM faculty and scholars worldwide. Pivot matches profiles with suggested funding opportunities and with potential collaborators at UVM and at other institutions. Investigators can use the funding database to set up customized searches and receive e-mail alerts about new opportunities that match their research interests.

Trainees and faculty are encouraged to create a Pivot profile (it's free) and explore funding opportunities:
https://www.uvm.edu/spa/pivot-funding-collaboration-tool-searchable-databases

Radiology professional societies, such as RSNA and ARRS, are one of the main sources of funding for trainees and junior faculty. In addition, the RSNA offer courses in grant writing and research methodology. See appendix for funding application resources.

It is also helpful to speak with your mentors and colleagues who are familiar with research funding in your area of research – they may be able to suggest funding opportunities that match well with your proposal. These may include external funding opportunities, as well as internal grants programs within the College of Medicine or UVM Medical Center.

UVM Medical Center Radiology Research Awards

The purpose of the internal grant is to provide scholarly project seed funding for a resident, fellow or faculty investigator in the Department of Radiology.
The grant amount of $10,000 will be awarded annually. The grant funding may be distributed over multiple awardees at the discretion of the Radiology Awards Committee

Grant Writing

There are many educational resources available on the grant writing process. Refer to Appendix I. Funding Application Resources for a list of popular grant writing courses.

External grant applications require institutional approvals, in part to certify that the budget has been prepared appropriately. Julie Macy, Team Lead - Proposal Submission and Award Administration at the UVM Sponsored Project Administration can be very helpful with this part of the process.
https://www.uvm.edu/spa

Grant Proposal Manager Services at the University of Vermont are available to grant seekers. The Grant Proposal Manager, Jeralyn Haraldsen, Ph.D, provides additional resources necessary to shepherd complex proposals through the writing and submission process, and supports new faculty grant writing efforts.

https://www.uvm.edu/ovpr/grant-proposal-manager-services

Often times a biosketch is required for submission of a grant. A biosketch is similar to a CV, though more succinct. Information on the NIH biosketch, the most widely used format, is available at:
https://grants.nih.gov/grants/forms/biosketch.htm

References:
https://www.une.edu/sites/default/files/researchmanual.pdf

VII. Manuscript Writing and Publication

The first step in manuscript preparation is to determine authorship. This should be transparent and formally discussed upfront. The authorship expectations should be clear to everyone participating in the manuscript preparation.

Next, you must determine where you would like to submit your work. Every journal has different submission and formatting requirements, and by identifying where you plan to submit your work early on in the process you can limit the amount of time spent later on these types of edits.

Do not be discouraged by the "Revise and Resubmit" invitation. Often the revisions necessary are minimal and with a small amount of additional work, your manuscript will be accepted for publication.

If your manuscript is not accepted for publication at the target journal do not despair. Many valuable articles are published in journals with lower impact-factors; the value of these journals should not be underestimated. This is especially true for case reports or case series. Consider the comments of the reviewers in deciding whether to revise your study analyses or manuscript text. Re-evaluate what the ideal target journal would be for your work and modify the formatting of your manuscript before submitting to that journal.

Great resources to use as a guide when preparing the manuscript structure:

Kliewer MA. Writing it up: a step-by-step guide to publication for beginning investigators. AJR Am J Roentgenol. 2005 Sep;185(3):591-6.

Other suggested readings:

1: Budovec JJ, Kahn CE Jr. Evidence-based radiology: a primer in reading scientific articles. AJR Am J Roentgenol. 2010 Jul;195(1):W1-4.
2: Provenzale JM. Revising a manuscript: ten principles to guide success for publication. AJR Am J Roentgenol. 2010 Dec;195(6):W382-7.
3: Provenzale JM, Stanley RJ. A systematic guide to reviewing a manuscript. AJR Am J Roentgenol. 2005 Oct;185(4):848-54.
4: Provenzale JM. Ten principles to improve the likelihood of publication of a scientific manuscript. AJR Am J Roentgenol. 2007 May;188(5):1179-82.

Reference:

https://www.une.edu/sites/default/files/researchmanual.pdf

VIII. Radiology Residency Mentorship Program

The department of radiology at the University of Vermont Medical Center has established a residency mentorship program. The aim of the Mentorship Program is to provide residents and junior faculty with one-on-one professional and scholarly development specifically focused on the areas of research, teaching, and/or advocacy.

IX. Radiology Research Committee Meetings

Radiology Research Committee Meeting meets quarterly.
Please let the director of research and radiology research coordinator know if you are interested in joining the meeting.

X. Current Research in Radiology

Please see radiology research coordinator for more information on the current research projects in Radiology.

XI. People and Resources

Bruno Soares, MD Director of Radiology Research
Aida Arapovic, Radiology Research Coordinator
Jay Gonyea, UVM MRI Research Facility Manager
Radiology Research Committee Members

APPENDIX I: Funding Application Resources

Academic Development Resources for Faculty and Trainees

GRANT WRITING

RSNA Advanced Course in Grant Writing

https://www.rsna.org/education/workshops/advanced-course-in-grant-writing

In this intensive, four-part course, you'll get hands-on experience in preparing a grant application for the National Institutes of Health (NIH), National Science Foundation (NSF) or other funding institution. Led by a faculty member with expertise in preparing and submitting grants, this course provides insight into the entire grant preparation process and includes a personalized review of your proposal. Participants are selected through a competitive application process. You'll leave equipped with a polished grant proposal as a principal investigator.

RSNA Writing a Competitive Grant Proposal

https://www.rsna.org/en/education/workshops/writing-a-competitive-grant-proposal

Led by a faculty of leading researchers with extensive experience in grant applications and funding, this 1½-day, in-person workshop will give you valuable tools to pursue funding from the federal government, foundations or societies. Using a combination of instruction and interactive small group sessions, the NIH-funded researchers will provide guidance on writing grant applications with an emphasis on reviewing your specific aims.

FACULTY DEVELOPMENT

AUR Faculty Development Program

https://www.aur.org/AnnualMeeting/Faculty_Development_Program/

The goal of the AUR Academic Faculty Development Program is to bring together promising junior radiology physician faculty members early in their academic careers for a one-day program of education and networking.

ARRS Clinician Educator Development Program

https://www.arrs.org/ARRSLIVE/CEDP

Each year 30 junior faculty members are selected to receive a $1,000 grant to attend a one-day workshop held at the ARRS Annual Meeting to gain proficiency in teaching skills and designing educational activities.

RSNA Eyler Editorial Fellowship

https://www.rsna.org/journals/editorial-fellowships/eyler-fellowship

The William R. Eyler Editorial Fellowship provides an opportunity for mid-career radiologists to further their experience in radiologic journalism by working with RSNA journal editors and publications staff.

RSNA Olmsted Editorial Fellowship
https://www.rsna.org/journals/editorial-fellowships/olmsted-fellowship
The William W. Olmsted Editorial Fellowship for Trainees is for residents and fellows in training interested in scholarly publication and editorial processes at medical journal offices.

RESEARCH
RSNA/ASNR Comparative Effectiveness Research Training
https://www.rsna.org/en/education/workshops/comparative-effectiveness-research-training
Co-sponsored by RSNA and the American Society of Neuroradiology (ASNR), this hands-on training program in comparative effectiveness research (CER) will introduce you to the methodology and tools for performing CER. The training is delivered over the course of a year in a combination of online modules, web-based sessions and a 1½-day, in-person workshop.

RSNA Research Development Guides
https://www.rsna.org/research/research-development-guides

FUNDING
RSNA Education Grants
https://www.rsna.org/research/funding-opportunities/education-grants

RSNA Research Grants
https://www.rsna.org/research/funding-opportunities/research-grants

American Society of Neuroradiology (ASNR) Foundation Grants
https://foundation.asnr.org/page/awards/

APPENDIX II: Research Terminology

- **Alternative hypothesis:** The alternative hypothesis states that an association between predictor and outcome variables is present. It represents the possibility that the experimentally-observed effect is genuine. It cannot be tested directly. The classical approach is to calculate the probability that the observed effect will occur if the null hypothesis (aka random chance) is true. If this value (the "p-value") is small, then the null hypothesis is rejected in favor of the alternative hypothesis.
- **Categorical variables:** Phenomena that cannot be quantified, thereby measured by classifying into categories. Example: blood type, gender.
- **Cluster sample:** sampling technique where the entire population is divided into natural groupings, or clusters, and a random sample of these clusters is selected.
- **Continuous variable:** Rich in information; can take on infinitely many possible numerical values in a particular range, e.g., blood pressure.
- **Confidence interval (CI):** Statistic calculated from the range of the lower confidence limit and the upper confidence limit. A 95% CI indicates that if the study were replicated several times, 95% of the time the true result would fall within that confidence interval.
- **Correlation coefficient:** Measures strength and direction of the linear relationship between 2 variables.
- **Dependent variable:** Variable being measured as endpoint. Also known as the outcome variable.
- **Design:** The way in which you conceptualize your research project.
- **Discrete variable:** one that can only take specific numeric values (often whole numbers) but those numeric values have a clear quantitative interpretation (e.g., number of pregnancies).
- **Exclusion criteria:** Defines the subset of population not eligible for study participation; if too excessive, then ability to generalize becomes compromised.
- **Hypothesis:** Version of research question that summarizes all of its elements: sample, design, predictor variables, outcome variables. Establishes basis for tests of statistical significance.
- **Incidence:** The frequency or rate of new cases of disease or other outcome over a given period of time.
- **Inclusion criteria:** The main characteristics determining who will be included in the subject population for the study.
- **Independent variable:** One that comes before or is used to predict the outcome variable. Does not change. May be a qualifier, or descriptor of study population. Also known as, predictor variable.
- **Intervention:** Special predictor variable that the investigator manipulates.
- **Measurement scales:** Describe phenomena that can be analyzed statistically; continuous or ordered discrete and categorical variables. Considered with methods.
- **Methods:** Detailed tasks, steps, stages and procedures you will use to conduct the study.
- **Null hypothesis:** states that there is no association between the predictor and the outcome variable. It is the opposite of the alternative or research hypothesis. Frequently, you attempt to prove the null hypothesis is false, which makes your alternative ("research") hypothesis true.

- **Odds ratio:** Estimate of strength of association between each predictor variable and presence or absence of disease (or other outcome); frequently used in case-control studies.
- **Outcome variable:** Variable often being measured as endpoint. Also known as the dependent variable.
- **Power analysis:** Procedures and formulas that allow the researcher to determine the likelihood of achieving statistical significance with a particular sample size. Contains four variables in its calculation: level of significance set by the researcher (identified as alpha, typically alpha is given the value of .05) probability of obtaining a significant result (power desired computed as 1-beta, typically beta is given the value of 0.8) population effect size, or the hypothesized effect on the groups sample size
- **Predictor variable:** One that comes before the outcome variable. Does not change. May be a qualifier, or descriptor of study population. Also known as, independent variable.
- **Prevalence:** Statistic obtained from a cross-sectional study; proportion of variable at one point in time. E.g., the percentage of the population with diabetes at a single point in time.
- **P-value:** Measures the likelihood that the observed result is consistent with the null hypothesis, given a certain degree of random error. A p-value less than or equal to .05 is generally considered statistically significant for rejecting the null hypothesis. A p-value less than or equal to 0.001 is considered highly significant.
- **Sample size:** Number of subjects needed to observe the expected difference in outcome between study groups with a reasonable degree of precision or power.
- **Significance:** In regards to the study question - why is the question important, how will it contribute to society, what benefit will it bring, any existing research around this topic that may have left unanswered questions, or questions you wish to challenge.
    - In regards to statistics - a result is considered (statistically) significant if it is unlikely to have occurred by chance. The significance level is usually represented by the Greek symbol α (alpha).
- **Simple random sample:** Give numbers to qualifying sample population, then randomly select participants.
- **Stratified random sample:** Dividing the population into subgroups based on specific criteria, then randomly selecting from each group, or "strata". This is useful when one wishes to ensure that the study population is balanced in terms of certain characteristics (e.g., males and females).
- **Study sample:** Subset of target population available for study.
- **Target population:** Defined by clinical, demographic, geographic population; who the results will be generalized to.
- **Type I error:** Incorrectly concluding that the null hypothesis is false, when it is actually true. The probability of committing a Type I error is equivalent to ***alpha***, the significance level given to the study.
- **Type II error:** Occurs when the test fails to reject the null hypotheses as false when it is in fact false. Probability of this type of error decreases as the amount of data collected increases. The probability of committing this type of error is equivalent to ***beta***. The probability of not committing a Type II error is equivalent to ***power***.
- **Validity:** How well the measurement represents the phenomenon of interest

APPENDIX III: Types of Research Studies

DESIGN DESCRIPTION	STRENGTHS	WEAKNESSES
Prospective Cohort • Investigator defines and selects a sample from a population • Measures predictive variable(s) • Measures outcome variable(s) at follow-up some defined time later	• Powerful for defining incidence and investigating potential causes of a condition • Allows measurement of predictive variable(s) in the moment, no reliance on reconstructing patient after outcome variable(s) occurs	Often need to follow populations for long periods of time to achieve numbers sufficient for causal relationship power, therefore expensive and inefficient for general population questions – better for specific populations (ie, outcome of colon ca. surgery)
Retrospective Cohort • Identifies a population that has been assembled from past events • Collects data on predictive variable(s) as available from past records • Collects data on outcome variable(s) as collected from past or present events	• Can establish that predictor variable(s) precede outcomes • Less costly and time consuming than prospective cohort	Investigator has limited control over the sampling of population and what data was collected, thereby what data is available to serve as the predictive variable(s)
Cross - Sectional • All measurements made at once with no follow-up • Investigator selects sample from population • Measures predictor and outcome variables	• Great at describing variables and their distribution patterns • Fast, inexpensive, no subjects lost to follow-up • May generate questions for future studies	• Difficulty of establishing causal relationships • Limited in information they can produce on prognosis or natural history
Case - Controlled • Often retrospective • Sample group from a population of people with the disease (cases) • Sample group from a population at risk that is free of the disease (controls) • Measurement of predictor variable(s)	• Provides descriptive information on cases • Provides odds ratio • High yield of information with small subject size makes for efficient results and ability to generate hypotheses • Good for rare conditions	• Increased susceptibility to bias: separate sampling of cases and controls, retrospective management of predictor values • No direct way to estimate incidence or prevalence of disease or excess risk

Reference:

https://www.une.edu/sites/default/files/researchmanual.pdf