The Research Toolkit

Internal Medicine Residency Program,
Department of Medicine,
Icahn School of Medicine at Mount Sinai,
New York, NY

The Research Toolkit

Internal Medicine Residency Programs
Icahn School of Medicine at Mount Sinai, New York, NY

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Chapter 1

Introduction to Scholarly Activities in Internal Medicine Residency

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The Accreditation Council for Graduate Medical Education (ACGME) is the council that accredits internal medicine residency programs and establishes training requirements. The ACGME requires that internal medicine residents are involved in scholarly activities.

The Accreditation Council for Graduate Medical Education (ACGME) requirements for scholarly activities

Excerpt from the ACGME Common Program Requirements (2022).

"Scholarship
IV.D.1. IV.D.1.a)
Medicine is both an art and a science. The physician is a humanistic scientist who cares for patients. This requires the ability to think critically, evaluate the literature, appropriately assimilate new knowledge, and practice lifelong learning. The program and faculty must create an environment that fosters the acquisition of such skills through resident participation in scholarly activities.
   Scholarly activities may include discovery, integration, application, and teaching.
The ACGME recognizes the diversity of residencies and anticipates that programs prepare physicians for a variety of roles, including clinicians, scientists, and educators. It is expected that the program's scholarship will reflect its mission(s) and aims, and the needs of the community it serves. For example, some programs may concentrate their scholarly activity on quality improvement, population health, and/or teaching, while other programs might choose to utilize more classic forms of biomedical research as the focus for scholarship.
The scholarly approach can be defined as a synthesis of teaching, learning, and research with the aim of encouraging curiosity and critical thinking based on an understanding of physiology, pathophysiology, differential diagnosis, treatments, treatment alternatives, efficiency of care, and patient safety. "

"Elements of a scholarly approach to patient care include:

- Asking meaningful questions to stimulate residents to utilize learning resources to create a differential diagnosis, a diagnostic algorithm, and treatment plan

- Challenging the evidence that the residents use to reach their medical decisions so that they understand the benefits and limits of the medical literature

- When appropriate, dissemination of scholarly learning in a peer-reviewed manner (publication or presentation)

- Improving resident learning by encouraging them to teach using a scholarly approach

  The scholarly approach to patient care begins with curiosity, is grounded in the principles of evidence-based medicine, expands the knowledge base through dissemination, and develops the habits of lifelong learning by encouraging residents to be scholarly teachers. "

Types of Scholarly Activities

These are examples of the dissemination of scholarship, adapted from the ACGME Common Program Requirements for 2022. A program's graduates must demonstrate dissemination of scholarship within or external to the program by **any** of the following methods:

- Presenting in grand rounds
- Presenting at poster sessions at regional, national and international conferences
- Leading conference presentations (journal club, morbidity and mortality, case conferences)
- Podium presentations (oral presentations) at regional, national and international conferences
- Leading workshops
- Quality improvement projects and presentations
- Grant leadership
- Non-peer-reviewed print/electronic resources for medical education
- Articles or publications (e.g. case reports, reviews, original research)
- Book chapters
- Textbooks
- Webinars
- Service on professional committees
- Serving as a journal reviewer, journal editorial board member, or editor

Icahn School of Medicine at Mount Sinai Internal Medicine Residency Scholarship

As with every aspect of residency training, residents' scholarly activities must have Mount Sinai faculty oversight. The faculty member overseeing a resident's scholarly activities is typically known as the "research mentor". (See Chapter 3, finding a mentor).

All residents have the opportunity to highlight their residency scholarly activities at the **Department of Medicine Research Day**, which is typically held in the spring each year. (See Chapter 9, for more information on the Department of Medicine Research Day).

References:

ACGME Program Requirements for Graduate Medical Education in Internal Medicine, Last Accessed April 28th 2023

Chapter 2

Getting Started

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Training Required for Research in Residency

As clinician-researchers, all residents at the Icahn School of Medicine at Mount Sinai are required to complete training in the Protection of Human Subjects. This training is completed as part of the onboarding process before they begin their PGY1 year.

For the Protection of Human Subjects research training, Mount Sinai uses the CITI Program courses (Information below on how to set up a CITI Program account).

The <u>required</u> training courses are:
- **Human Subjects Research (Basic) – for investigators**
- **Data Security and HIPAA Training**
- **HIPAA Update**
- **Rigor, Reproducibility, and Ethical Behavior in Biomedical Research**

***<u>Note:</u>** Non-CITI training completed at another institution will not be accepted at Icahn School of Medicine at Mount Sinai (ISMMS). Some CITI modules may carry over from a past institution if the modules are also used at Sinai.*

Additional Courses:
The Good Clinical Practice Training course is not required for all trainees, but may be necessary for some specific IRB-approved projects.
For more information, see <u>Good Clinical Practice (GCP)</u>.

CITI Program Information
The following information has been obtained from the <u>Mount Sinai Research Roadmap</u>.

"Set up your account
- Click <u>here</u> for step by step CITI registration instructions.
  - o   To set up your account, follow the instructions below:
  - o   Go to: <u>https://about.citiprogram.org</u>
  - o   Click "Register" on the <u>CITI Home Page</u>
  - o   Select "Icahn School of Medicine at Mount Sinai (SSO)" as your Organization Affiliation
  - o   Select "Continue" to SSO Login/Instructions

o   Use your Mount Sinai email address, your name recognized by human resources, and your Life Number (or its equivalent) to your profile. This is essential to ensure that your record of completion electronically populates into your Sinai Central profile.

- Register for required ISMMS training modules
  o   Log in to CITI Program
  o   Click the link "Add a Course or Update Learner Groups" for ISMMS
  o   Add the course(s) you need to complete and click "Submit".
      o   Human Subjects Research (Basic) – *Note: Basic Course must be taken before the Refresher even if you took the Basic course at your previous institution.*
      o   Data Security and HIPAA Training
      o   HIPAA Update
      o   Rigor, Reproducibility, and Ethical Behavior in Biomedical Research

Affiliating Your Existing CITI Account with ISMMS
To affiliate your existing CITI account with ISMMS follow the steps below:
- Log in to CITI Program. https://about.citiprogram.org
- Select "Click here to affiliate with another institution", and select "Icahn School of Medicine at Mount Sinai".
- Enter your work email account, your name as recognized by HR and your life number (or its equivalent) in the CITI profile page. This is essential to ensure your training certifications automatically populate into your Sinai Central profile.
- Add the course(s) you need to complete and click "Submit".
  o   Human Subjects Research (Basic) – *Note: Basic Course must be taken before the Refresher even if you took the Basic course at your previous institution.*
  o   Data Security and HIPAA Training
  o   HIPAA Update
  o   Rigor, Reproducibility, and Ethical Behavior in Biomedical Research "

A note about: **HIPAA Training** – The CITI HIPAA Training modules are research related and are not the same as the Annual Mandatory HIPAA Refresher training required for all Health System faculty and staff in PEAK.

The Responsible Conduct of Research

All residents at Mount Sinai must conduct their scholarly activities ethically and with responsibility. All trainees receive training in the principles of the Responsible Conduct of Research through the CITI training program on "Rigor, Reproducibility, and Ethical Behavior in Biomedical Research". See earlier in this chapter under "Training Required for Scholarly Activities in Residency" for information on how to access this training course.

The Importance of the Responsible Conduct of Research

From the National Institutes of Health, Responsible Conduct of Research Training | NIH Office of Intramural Research, last accessed April 17th 2023

"The responsible conduct of research (RCR) is essential to good science. RCR promotes the aims of scientific inquiry, fosters a research environment that enables scientists to work together toward common goals, and promotes public confidence in scientific knowledge and progress for the public good. However, there are several serious detrimental effects of research not conducted ethically and responsibly. These include, for example, data fabrication and falsification of results which undermine the pursuit of valid knowledge by misleading scientists to accept and further study false hypotheses or unreliable data. Likewise, plagiarism and harassment negatively impact the research environment by harming respect and trust among scientists. Fraudulent or socially irresponsible research undercuts the public's trust of and support for science.

The goals of RCR education and training are to:
- Develop, foster, and maintain a culture of integrity in science;
- Discourage and prevent unethical conduct;
- Empower researchers to hold themselves and others accountable to high ethical standards;
- Increase knowledge of, and sensitivity to, ethical issues surrounding the conduct of research by researchers with diverse backgrounds;
- Improve the ability to make responsible choices when faced with ethical dilemmas involving research;
- Provide an appreciation for the range of accepted scientific practices for conducting research;
- Inform scientists and research trainees about the regulations, policies, statutes, and guidelines that govern the conduct of U.S. Public Health Service-funded research and promote compliance with the same; and,
- Promote a career-long positive attitude toward research ethics and the responsible conduct of research."

Who to Ask for Help with Scholarly Activities

Every resident has a residency advisor who will help to guide them throughout their training. Residents can ask their advisors for guidance on any aspect of their training, including scholarly activities.

Once a resident has identified a research mentor, the mentor will typically guide the resident in their scholarly activities.

If your residency program has an Associate Program Director for Research then you can contact them to give you advice on any aspect of your scholarly activities.

If you are not sure if your program has an Associate Program Director for Research, ask the Chief Residents, or your residency Program Director.

References:

The Mount Sinai Research Roadmap, [Mandatory Training for Human Subject Research](#) , Last accessed April 16th, 2023

The Office of Research Integrity, Introduction to the Responsible Conduct of Research https://or i.hhs.gov/ori-introduction-responsible-conduct-research, last accessed April 28th 2023

Levy Library and Technology Resources

In this chapter, we discuss the different resources provided by the Mount Sinai Health System's digital library for residents to actively engage in research.

A) The Levy Library Resources

- How to Access Offsite: In order to access the Levy Library from offsite, simply head to the library website and use your Mount Sinai credentials to log in. (https://eresources.mssm.edu/login).

- Laptops on Loan: Residents can request up to two laptops for a maximum of 4 hours at a time, with an opportunity for renewal based on demand. In order to collect the laptop simply head to the library's front desk and remember to return it in intact condition in order to avoid a penalty fee of up to $2,000. For more information, see the following link.
Computing - Technology - Levy Library Guides at Icahn School of Medicine at Mount Sinai

- Library Classes: At any point in time, the library provides 30-60 minute free of charge classes designed to teach residents the fundamentals of conducting a research project such as literature review, selecting a journal and tools to facilitate organization (Library Events).

- Scientific Writing Help: If you're in need of assistance with scientific writing, simply book a 1:1 consultation appointment with a trained professional. This service is meant to improve your writing at any stage. Remember to request it 48 hours in advance and for maximal benefit prepare a draft in advance, to be displayed during your session (Home - ISMMS Writing Support Service - Levy Library Guides at Icahn School of Medicine at Mount Sinai).

- Systematic Review Resources: If you have ever wondered whether a research question could benefit from a systematic review, the library provides a consultation service designed to help you gain more insight into the validity of exploring your question through a meta-analysis. Head on to the link provided ahead to fill out a form and get started with your project (Levy Library Research Synthesis and Systematic Review Services: How We Can Help).

- Statistics Software and Support: The library provides teaching tools from books to short tutorials to learn how to operate the main statistical analysis softwares including SPSS and SAS, which you can also acquire at a discounted rate. If in need of a quick consultation regarding a specific question, there's a free walk-in service designed to connect you with experienced personnel via Stat-Chat. (Where can I get help with statistics and access statistics software? - Ask A Librarian).

- Ingenuity Pathway Analysis (IPA): IPA is a web-based tool that allows researchers to upload their data or search for genes, proteins or chemicals, and to build interaction networks to represent systems in biology. You can create an account using your Mount Sinai credentials.

[Databases - Bioinformatics Resources - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)

- Software for References (endnote, zotero): The library provides not only free access to reference management softwares such as endnote and zotero but also guide books and tutorials to better understand how to effectively use them. If you're still finding yourself with questions, then book a consultation with a licensed professional with the links provided ahead:

- Endnote: https://libguides.mssm.edu/endnote
- Zotero: https://libguides.mssm.edu/zotero
- Research support: https://libguides.mssm.edu/education

- Plagiarism Detection Tools (iThenticate): The library provides free access to plagiarism detection tools such as "iThenticate" which compares your work to published material. It is imperative that you always double check that your work contains non-plagiarized material before publishing ([iThenticate - Plagiarism Detection Tool - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)).

- Instructional Technology (see below): The instructional technology department provides innovative didactic strategies through animation, interactive courses and instructional technology. Their goal is to support faculty in meeting the various educational needs of learners ([Instructional Technology Group - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)).

B) Images and Figures for publications and presentations
- Instructional Technology Group: If in need of an original image or figure for your manuscript, the instructional technology group can work with you to create an illustration that can best portray your intentions ([Illustration & Animation - Instructional Technology Group - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)).

- Understanding Copyright for Images: The library provides access to open-copyright images available for educational use. Before using an image, verify whether permission has to be granted. Lastly, provide proper attribution to the original author by including in the reference: Title of the image, name of author, journal, year, volume, pages, URL and type of license. ([Finding Images for Lectures and Publications - Copyright and Fair Use: The Basics - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)).

- How to Access Copyright-Free Images: The library website has a list of sources of free of charge images to be used for lectures or publications. There are multiple different websites to choose from such as "open-i", "medpix", "wellcome images" and others. In order to access these websites head on to the link provided ahead and remember to cite them as a source: [Finding Images for Lectures and Publications - Copyright and Fair Use: The Basics - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)

Note images generated using Artificial Intelligence systems, such as Dalle-E2 are owned by the creator (i.e. if you use open source AI to generate an image it is yours to use). See an example of this system that can create images from natural language. DALL·E 2

C) Accessing Patient Data for Research - The Mount Sinai Data Warehouse: Deidentified patient data (or identified with IRB approval) from the Mount Sinai Health System can be obtained using Leaf. A Leaf account can be created by any resident. See the link for how to access, and training videos on how to use. Please also note that **Leaf is supported by grant UL1TR004419 from the National Center for Advancing Translational Sciences, National Institutes of Health**. If you publish any study using data generated using Leaf, please add this grant information (in bold font above) to the acknowledgements.
About Leaf | Mount Sinai Data Warehouse

D) Artificial Intelligence in Learning and Discovery: The Levy Library and Instructional Technology Group has launched a new guide to the world of Artificial Intelligence (AI) in education. This new guide provides information on the use of AI in medical education, research and scholarship, and how the use of AI is evolving at Mount Sinai.
https://libguides.mssm.edu/ai
See also the section in Chapter 7 in this Research Toolkit on Machine Learning in Research

Online Videos and Training Courses

Mount Sinai Education and Advancement of Knowledge (PEAK) contains a number of online training videos and courses that can help you with your research.

To log into Mount Sinai PEAK go to:
[PEAK (Portal for Education and Advancement of Knowledge) | Research Roadmap](#)
Click on the link to PEAK, and log in with your Mount Sinai credentials.

Microsoft Excel Training Videos.
[PEAK (Portal for Education and Advancement of Knowledge) | Research Roadmap](#) contains a number of pre-recorded training videos as well as a schedule for live online training videos.

· To view the selection of courses, once you log in type "Microsoft Excel" (without quotation marks) in the "Search the Catalog" Search bar.
· Alternatively, the courses can be accessed by going to "Training Catalog" in the top menu ribbon, then click on "Functional", scroll down to "Microsoft Windows & Office Productivity", click on "Office 2016" and then "Microsoft Excel"

You will see the range of upcoming and recorded courses available. The pre-recorded courses include basics of using Excel, Excel Formulas, Creating Charts, Formatting Excel, and Pivot Tables, amongst other courses.

Microsoft Word Training Videos.
[PEAK (Portal for Education and Advancement of Knowledge) | Research Roadmap](#) also contains recorded training videos to advance your skills using Microsoft Word.

· To view the selection of courses, once you log in type "Microsoft Word" (without quotation marks) in the "Search the Catalog" Search bar.
· Alternatively, the courses can be accessed by going to "Training Catalog" in the top menu ribbon, then click on "Functional", scroll down to "Microsoft Windows & Office Productivity", click on "Office 2016" and then "Microsoft Word"

Microsoft PowerPoint Training Videos.
[PEAK (Portal for Education and Advancement of Knowledge) | Research Roadmap](#) also contains recorded training videos to advance your skills using Microsoft Powerpoint.

· To view the selection of courses, once you log in type "Microsoft Powerpoint" (without quotation marks) in the "Search the Catalog" Search bar.
· Alternatively, the courses can be accessed by going to "Training Catalog" in the top menu ribbon, then click on "Functional", scroll down to "Microsoft Windows & Office Productivity", click on "Office 2016" and then "Microsoft Powerpoint"

IRB Submission Training Videos.
[PEAK (Portal for Education and Advancement of Knowledge) | Research Roadmap](#) contains IRB Training videos to help you navigate the IRB submission.

· To access the IRB training videos, "Training Catalog" in the top menu ribbon, then click on "Functional", scroll down to "Research", scroll down to IRB University. The basic

IRB submission course should be the first one on the list, named: **Institutional Review Board (IRB) 101: Basic Steps of the IRB Submission**

· If you keep scrolling down or search page for "RUTH" you will find training videos to help you navigate the RUTH submission site.

REDCap Training Videos.

Research Electronic Data Capture (REDCap) is an online tool that is HIPAA compliant and can be used for data collection.

[PEAK (Portal for Education and Advancement of Knowledge) | Research Roadmap](PEAK) contains a training video to introduce you to using REDCap.

· To view the selection of courses, once you log in type "Redcap" (without quotation marks) in the "Search the Catalog" Search bar. It will bring up the introductory video for REDCap.

Leaf Tutorial and Training Videos.

To access de-identified patient data from the Mount Sinai Datawarehouse (or identified with IRB approval), learn how to use Leaf.

Scroll down to "Leaf Support Materials" to see the list of training videos

[About Leaf | Mount Sinai Data Warehouse](#)

Biostatistics Online Courses and E-Books.

The Levy Library has a special collection of E-Books related to Biostatistics. .

https://icahn-mssm.primo.exlibrisgroup.com/discovery/collectionDiscovery?vid=01MSSM_INST:DEFAULT&collectionId=81118889940006206

There are also Free Online Courses for learning statistics**:** [Statistics Courses | Harvard University](#)

SPSS Modules, Videos, Training Workshop and E-Books.

See the Levy Library Website for SPSS Tutorials (on left of webpage) from external sources in addition to E-Books to help you use SPSS.

[SPSS Resources - Statistics & Data Science Resources - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)

- SPSS Modules from UCLA: If you like written instructions.
  - ○ [SPSS Learning Modules](#)
- SPSS Training Workshop from Central Michigan University – Videos and problem sets
  - ○ [SPSS On-Line Training Workshop](#)

SAS Modules, Training Videos and E-Books.

See the Levy Library Website for SAS Tutorials (on left of webpage) from external sources in addition to E-Books to help you use SAS.

[SAS Resources - Statistics & Data Science Resources - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)

- Free SAS E-Learning from SAS company – You will need to register, but then the beginner videos are free
  - [SAS Training in the United States -- e-Learning](#)
- SAS Modules from UCLA: Written instructions
  - [SAS Learning Modules](#)

R Modules, Videos, Courses and E-Books.
Depending on your preferred learning style, you can choose from a number of tutorials.
[Statistics & Data Science Resources - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)
- Quick-R – How to download R and R Studio with basic written instructions
  - [R Tutorial For Beginners](#)
- Datacamp – Introduction course – hands on learning.
  - [Introduction to R Programming Course](#)
- UCLA – R learning modules – Written instructions
  - [R Learning Modules](#)
- Coursera – Free online video course
  - [R Programming Course (Johns Hopkins) | Coursera](#)

Chapter 3

Mentorship and Team Based Research

Chapter Contributors
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Tips For Finding a Research Mentor During Residency

A Research Mentor will guide you through your scholarly activities, and can often also guide your career development.

Here are some tips for finding a research mentor during residency:

1. Determine your research interests:
    a. Think about the **research topics** that interest you the most.
    b. Consider the **areas** in which you would like to conduct research
    c. Determine the **skills** you have and those you would like to develop.
    d. Think about your research goals (e.g. getting to know a faculty member, gaining experience, publishing, developing skills in research, laying the foundation for a research career).

This will help you identify potential mentors who have expertise in your field of interest.

2. Look for potential mentors:
    a. Search for potential mentors in your field of interest by looking at the Mount Sinai faculty pages.
    b. Attending divisional / departmental seminars or conferences in your field of interest can help you learn about a mentor's work (note a lot of conferences are on zoom or hybrid).
    c. Ask your network – talk with senior residents and chief residents who they are working with, and about their experiences.
    d. Ask the program leadership – talk with your faculty advisor, or the Associate Program Director for Research for recommendations.

e. You can use online databases, such as [Case Hippo](#) that has previous [Department of Medicine Research Day Abstracts](#), or PubMed, to search for faculty who have written abstracts or published articles with previous residents in your area of interest.

f. Attend research events: Attend Mount Sinai poster sessions, and other events where scholarship is presented. This can help you identify potential mentors and learn more about their research.

3. <u>Reach out to potential mentors:</u>

a. If you attend a seminar or conference in person, don't be afraid to introduce yourself to a faculty member and tell them you are interested in their work, and ask if they have any projects you could be involved in.

b. If you meet an attending on a rotation that you think you would like to work with, ask them if they have any projects that you could work on.

c. Cold email potential mentors: If you find a faculty member who is conducting research that aligns with your interests, send them an email expressing your interest in their work and asking if you could be involved.

4. <u>Meet your potential mentors:</u>

a. Before the meeting, think about your research interests, the skills you have, and those that you hope to acquire, and your research goals. Be realistic about the time you have to spend on a project.

b. Prepare for the meeting: Before meeting with a potential mentor, prepare by reading their recent publications, reviewing their research interests, and developing a list of questions you would like to ask them.

5. <u>Build a good mentor-mentee relationship:</u>

a. Once you have found a mentor, focus on building a good relationship with them by communicating regularly, asking for feedback, and demonstrating your commitment to the research project.

Remember that finding a research mentor can take time and effort, so don't get discouraged if you don't find one immediately.

Be persistent and professional in your communications, keep reaching out and building your network, and be open to exploring different research opportunities.

Establishing a Good Relationship with your Mentor

"Mentor-trainee relationships begin when an experienced and an inexperienced researcher agree to work together. Each brings something to the table under such an arrangement. The experienced researcher has knowledge and skills that the inexperienced researcher needs to learn. (The mentor) may also provide support for the trainee's research and education."

"Under a productive relationship, the two work together to advance knowledge and put ideas to work. When the relationship breaks down, it is often because one of the parties is not getting from the relationship what (the trainee or mentor) expected."

"One way to avoid problems is to establish basic understandings about important issues early in the relationship.

Trainees need to know:

- **how much time they will be expected to spend on their mentor's research;**
- **the criteria that will be used for judging performance and form the basis of letters of recommendation;**
- **how responsibilities are shared or divided in the research setting;**
- **standard operating procedures, such as the way data are recorded and interpreted; and, most importantly,**
- **how credit is assigned, that is, how authorship and ownership are established.**

Clarifying these issues early in a mentor-trainee relationship can prevent problems from arising later.

The need for early understanding is not one sided. Mentors need to know that a trainee will:

- **do assigned work in a conscientious way,**
- **respect the authority of others working in the research setting,**
- **follow research regulations and research protocols, and**
- **live by agreements established for authorship and ownership.**

Mentors invest time and resources in trainees. Trainees should respect this time and use resources responsibly, keeping their mentors informed about changing research interests or other circumstances that could affect their work".

Quoted text is a slightly edited (Edits in parentheses) excerpt from **Office of Research Integrity Introduction to Responsible Conduct of Research: Chapter 7. Mentor and Trainee Responsibilities, available online at: Basic responsibilities | ORI - The Office of Research Integrity, Last Accessed April 18th, 2023**

Navigating Expectations in a Team Based Research - Setting Yourself up for Success

Resident research often requires working in teams with other co-residents, medical students, fellows, and attendings. Work on the project is often split up between team members. In the absence of a clear set of expectations, appropriately assigning authorship at the time of publication can be a source of stress and disappointment.

Here are some tips to navigate authorship questions in team-based scholarly activities:

- When joining a research project, share your goals with the faculty mentor or senior member of the team (e.g. fellow). It is important to know who is leading the project (e.g. you or someone else), and for the team to understand your goals (e.g. abstract, publication, first-author, co-author).

- Have conversations about authorship one on one with your faculty mentor, early in the research process.

- Ask if there is a system in place for determining authorship order (e.g. number of charts reviewed, data analysis, or writing expectations).

- If you are intending to take on a significant portion of the work, clarify if you will earn first authorship upon completion of this work.

- If the project has already been started by a different trainee, ask directly how you can best contribute to the project and what kind of authorship you might expect after its completion.

Potential pitfalls:

- Asking about authorship without displaying sufficient interest in the field or project.

- Taking on excess responsibility with the assumption of first authorship, then finding out that the authorship is being assigned in a different way.

- Over-committing and being unable to complete the tasks assigned.

Working in teams in research can be rewarding and challenging at all levels of training. If you feel that you are not receiving adequate credit for work completed, reach out to trusted faculty, perhaps from a different field, or the PD and APD to discuss further.

Further reading:
- NCI Field Guide for Team Science:
  https://www.cancer.gov/about-nci/organization/crs/research-initiatives/team-science-field-guide/collaboration-team-science-guide.pdf

Acknowledgements: ChatGPT contributed to an outline of some sections in Chapter.

Chapter 4

Human Subjects Research and Quality Improvement

Chapter Contributors
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Overview and history:
The majority of research performed during residency is human subjects research. This includes any data that is collected from humans, from tangible physical components such as blood or DNA samples, to opinions collected in surveys. The Belmont Report dictates that human subjects research must demonstrate the principles of respect for persons, beneficence, and justice. In order to protect the human subjects studied, many studies require Institutional Review Board (IRB) approval.

Human subjects research is federally defined by the US Department of Health and Human Services (HHS) regulations 45 CFR 46 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html, last accessed April 28th 2023).

Research versus quality improvement:
It is important to determine whether your project is **research** or **quality improvement.**

Fundamentally, research is about obtaining new information about the way things are. Quality improvement is about testing out a means of improving the current way things are.

- For **human subject research,** you will need approval or exemption by the IRB
- For **quality improvement projects**, you will need approval by the Quality Improvement Committee (QIC)

How to determine if your project is research or quality improvement:
Always discuss this question with your research mentor if it is not immediately clear.

This helpful table can start to help you differentiate:[1]

Aspect of the Project	Quality Improvement Project	Research Project
Aim	Improvement of patient-care or health-care process	Generate new knowledge
Study Design Hypothesis	Flexible hypothesis, changes as learning takes place	Fixed hypothesis
Test observability	Test is observable	Test is blinded or controlled
Bias	Accept consistent bias	Design to eliminate bias
Sample size	"Just enough" data; small sequential samples	"Just in case" data
Testing strategy	Sequential tests (Plan, Do, Study, Act cycles)	Single test
Data analysis	Run charts / Shewhart control charts to measure quality improvement metrics	Statistical tests (t-test, F-test, chi-aquare test) for significant differences (P values)
Data confidentiality	Data used only by those involved with quality improvement	Research subjects' identities are protected

Table from : Al-Surimi, K. (2018). Research versus quality improvement in healthcare. *Global Journal on Quality and Safety in Healthcare*, *1*(2), 25–27. https://doi.org/10.4103/jqsh.jqsh_16_18

Ask yourself these questions to guide your projects (quoted from the "Research versus Quality Improvement in Healthcare Editorial)[1]

"In research projects, we can be guided by asking the following:
- Do we have a clear question to be investigated and answered?
- What do we hope to accomplish by answering the question?
- What is currently known about the topic?
- What are the risks and benefits for patients involved with the study of this topic?
- What type of study design will be used (observational vs. experimental)?
- How will the data be analyzed and presented (statistical tests, *P*-values, etc.)?

In QI projects, we can ask the following:
- What is the magnitude of the quality problem based on available data?

- What types of quality tools have been used to measure and assess the problem?
- What is the measurement plan to be used during implementation of the project?
- What types of changes/interventions will be tested during the structured or validated Quality Improvement testing? (such as Plan-Do-Study-Act [PDSA], LEAN, Failure mode and effects analysis [FMEA], etc)
- Has the proposed change/intervention been used in other health-care settings or reported in the literature?
- Will the results of this project directly improve patient-care outcomes or processes?
- Is the organization's management supportive of the project and willing to dedicate employee's time and supplies to do the project?
- What is the sustainability plan for the results?"

Remember:
- You can still publish quality improvement data as long as it is approved by the QIC and contributes interesting insights to the quality improvement literature
- Consider the structured or validated Quality Improvement testing cycles (such as PDSA, LEAN, FMEA) when planning a quality improvement intervention
- The same principles of protecting patient data, including encryption, collecting the minimal amount of data required, applies to QI projects as research projects.

References:

Al-Surimi, K. (2018). Research versus quality improvement in healthcare. *Global Journal on Quality and Safety in Healthcare*, *1*(2), 25–27. https://doi.org/10.4103/jqsh.jqsh_16_18

Non-Human Subjects Research

Human subjects research is federally defined by the US Department of Health and Human Services (HHS) regulations 45 CFR 46 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html, last accessed April 28th 2023).

In some specific circumstances your research may be considered non-human subjects research, and may not require IRB approval.

The National Institutes of Health (NIH) provides a **Decision Tool** to help you and your mentor decide if your research is considered human subjects research or non-human subjects research. (https://grants.nih.gov/policy/humansubjects/hs-decision.htm, last accessed April 28th, 2023)

If you are doing non-human subjects research, you do not require IRB approval. However, if you and your mentor are unsure, do not proceed with your research and contact the Icahn School of Medicine at Mount Sinai IRB to ask: IRB@mssm.edu

Examples of non-human subjects research include:

1) All the specimens or data will come from cadavers or otherwise deceased individuals.

- If your study involves **only specimens or data from deceased individuals** and you are not proposing any other human subjects research, your research is non-human subjects research.

**If your study will involve any specimens or data from living relatives then the study may be considered human subjects research.

2) Secondary analysis of specimens or data that were **not collected specifically** for this study and **no one on your study team has access to the subject identifiers** linked to the specimens or data, your study is not considered human subjects research.

**If any identifiers are available to any member of the study team, then the research may be considered human subjects research.

3) Publicly available data that are de-identified, or analysis of data related to people that are already identifiable in the public domain are not considered human subjects research.

IRB Exemptions

What is Exempt Human Subjects Research?

       Exempt human subjects research refers to research activities that involve human subjects but are exempt from federal regulations governing the protection of human subjects, as defined by the US Department of Health and Human Services (HHS) regulations 45 CFR 46 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html, last accessed April 28th 2023).

<u>A resident or their mentor must submit an application for exempt determination to the IRB, and cannot begin their research until the IRB has made this determination.</u>

A summary of Exempt research can be found here: https://grants.nih.gov/sites/default/files/exemption_infographic_v8_508c_1-15-2020.pdf, last accessed April 28th 2023 . According to the 2018 federal regulations §46.104 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html, last accessed April 28th 2023) exempt research includes:

"(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

1. (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
2. (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
3. (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1. (i) The identifiable private information or identifiable biospecimens are publicly available;
2. (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be

ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

3. (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

4. (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or
possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

1. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

2. (ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

1. (i) If wholesome foods without additives are consumed, or

2. (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below

the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results."

How to Apply for an IRB Exemption

You will need to apply for the exempt determination from the IRB. Therefore, follow all of the steps in Submitting a Project for IRB Approval.
However, use form HRP-503e – Exempt Determination Application instead of HRP 503r
https://icahn.mssm.edu/research/pphs/researcher/forms, last accessed April 28th 2023.

Submitting a Project for IRB Approval

See the Mount Sinai PEAK Training Video for [Submitting your IRB](#).

- Pre-step 1 is (a) have a title for your project and (b) gather your team
- Step 1 in the IRB process is submitting the conflicts of interest form in the electronic Disclosure Management System (eDMS) system.

A Note on Terminology: The "PI" is the Principal Investigator - This is the faculty member in charge of the project. For IRB purposes, trainees cannot be the PI.

Note the eDMS system went live in April 2023. There have been some changes in terminology: What was previously referred to as the "Investigator Form" or "IF" is now called the "Triggering Event" or "TE". The IF number is now the TE number.

Go to:
[eDMS Platform | Icahn School of Medicine](#)

If you have not logged into eDMS previously and you cannot access your account (using your login credentials), you may need to first go to [SinaiCentral.mssm.edu](#) and go to "Activate account" to create an account. Otherwise you should be able to get into eDMS using your usual Mount Sinai login credentials.

You and all of the research team will need to have completed an Annual Disclosures Profile.

To begin a research project, you will need to complete a Trigger Event Form.

Step by step guidance on how to complete these forms can be found here: [eDMS Platform | Icahn School of Medicine](#)

Step 2: Submitting the IRB application in RUTH

Basic Study Information ❓

1. *** Title of study:**
   SGLT2 Inhibitors in Patients with Multiple Myeloma

2. *** Short title:** ❓
   SGLT2-I in MM Patients

3. *** Brief description:** ❓
   Descriptive study of safety of Sodium Glucose Cotransporter 2 inhibitors in patients with multiple myeloma.

4. *** What kind of study is this?** ❓
   Single-site study

5. *** Will an external IRB act as the IRB of record for this study?** ❓
   ○ Yes ● No

6. *** Local principal investigator:** ❓
   EMILY GALLAGHER

7. *** Attach the protocol:** ❓

	Document	Category	Date Modified	Document History
View	📄 HRP 503R 21-00853 06.30.2021.docx(0.05)	IRB Protocol	6/30/2021	History

Please upload only the Protocol here.

Reminder: Both a protocol document and a 503 application is required unless it is data or specimens only. The 503 should be uploaded on the Local Site Documents Page

- Go to RUTH (see below if you run into issues for IRB troubleshooting)
- You use the IF number (now **TE number**) that was on the Investigator Form in order to create your study
- Log in to Ruth to find the correct template
- These are updated regularly, make sure to use the most updated one - see below for an example of how to complete this form.
  - o [HRP-503e – Exempt Determination Application](#)
    - ▪ Useful for studies that may be exempt from IRB approval
  - o HRP-503R – Record Review or Specimen Analysis Form
    - ▪ Useful for Retrospective reviews

- In addition to going through the pages on the website, also go to "manage ancillary reviews" and click on FCOI.

Note once you have uploaded the documents and completed the forms only the PI can submit (the resident cannot submit). Once the documents have been completed and uploaded, ask the faculty member to review and submit.

IRB Troubleshooting

1. **Citi Training Modules for IRB**
- If your required IRB Citi training modules are completed but not showing up, you may need to log on to CITI and link your profile (most of the time, it is just missing your employee life number)

2. **Ruth Access**
- One must log on to RUTH to upload CV
- **If you don't have access**, it is likely because your Sinai email on Sinai Central is not clicked as "preferred." See below for directions:

1) Log on to https://sinaicentral.mssm.edu or https://sinaicentral.mountsinai.org
2) Click Personal Profile > Contact Info (left side of screen)
3) If your email is listed, but does not have the check activated under the **Preferred** column, click the edit Icon > Activate the check on the **Preferred** column box > Save (make sure the box is also checked under the **Visible** column)
4) If your email is not listed, add your email and check the **Preferred** *and* **Visible** box > Save

- **NOTE:** You can *only* have 1 email identified as "**Preferred**" and it *must* be a Mount Sinai Approved email to gain access to the eSuite (RUTH, eIACUC, eDMS, eSafety) applications.

5) The systems will synchronize at 4:00 **AM** (daily) - you will need to wait to login the *next* day

Sample IRB for a Retrospective Study

	Protocol Name:	Official protocol title as stated in Sinai Central and in RUTH
Mount Sinai	Principal Investigator:	PI as indicated in Sinai Central and in RUTH
	Primary Contact Name/Contact Info:	Indicate contact person and phone number
	Date Revised:	Use this for version control. Each time a change is made to this document, update this date.
	Study Number:	At initial submission for a new project, indicate the IF#. Use RUTH STUDY ID# once assigned.

HRP-503R Record Review or Specimen Analysis Application Form

⊞

HRP-503R Record Review Application Form

- *This simplified application form is intended for the submission of studies that do not involve any subject interaction (in-person or remote survey or questionnaire administration is considered subject interaction) or intervention.*
- *The HRP-503R Form is to be used for the following specific study designs only: 1) **retrospective record/data review**, 2) retrospective specimen review, 3) prospective record/data review, or 4) case-series analysis. A study can be comprised of a combination of the aforementioned research designs.*

- ***The HRP-503R is a standalone application and does not require a protocol.***

- *All other observational studies should use the standard HRP-503 Form.*
- *All exempt studies should the HRP-503e Form.*

- *NOTE: The investigator must demonstrate that the study is consistent with "sound scientific design" and that the design is sufficient to achieve the study objectives. The investigational plan, study procedures, and analysis plan must provide sufficient detail to provide the IRB with a basis for its decisions. Even though the risks of the research may be minimal, the IRB will not approve studies with insufficient information.*

- *Depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. **If the question is not applicable to the study, mark the section "N/A".** Do not delete any sections or leave them blank.*

- *Be sure to complete any supplement questions from one or another ancillary office that you receive during the RUTH application process. Please make certain that this 503R Application and responses to ancillary offices do not contradict each other and the information is*

1) Study Overview

Brief description of what your study involves

2) Number of records/cases/specimens for acquisition and review

The total number of cases to be reviewed is approximately 70. An educated guess made with the attending

3) Date Range(s) of Study

Retrospective data/specimens to be requested from the following time-period: March 1 2013 to May 31 2021 Need to specify a time period

4) Total Number of Records/Specimens/Cases to be accessed for Review

The total number of cases to be accessed for review are approximately 70.

5) Study Population

Inclusion Criteria: simple inclusion and exclusion criteria, no need for descriptions of why

Exclusion Criteria:

6) Study Procedures

Procedures are limited to retrospective review of records. important to specify for retrospective studies

List of data to be collected: requires you to have already considered what you will include in your database, make sure that this is well thought out and approved by your mentor

7) Record/ Data/Specimen Sources

How you're identifying the patients. Is it a specific attending's patients? Is it based off of an EPIC query?

Does this protocol involve any information leaving Mount Sinai?   [ ] Yes   [x] No

8) Data Elements:

Protected (Identifiable) Health Information
PHI refers to health/medical information that is accompanied by any of the listed 18 HIPAA identifiers or by a code where the key to the code that links to the identifiers is accessible to investigators. DE-IDENTIFIED DATA or anonymous (without any identifiers or codes that link back to individuals) are not considered PHI and are not subject to HIPAA regulations.

For your reference, below is a complete list of the 18 HIPAA identifiers. When a study records ANY of these data, the study involves PHI.
- Name
- Social Security Number
- Medical record number
- Address by street location
- Address by town / city / zip code
- Dates (except year), e.g., date of birth; admission / discharge date; date of procedure; date of death
- Telephone number
- Fax number
- Electronic email address
- Web URLs
- Internet protocol (IP) address
- Health plan beneficiary number
- Account number
- Certificate / license number
- Vehicle identification number and serial number, including license plate number
- Medical device identifiers and serial numbers
- Biometric identifiers (finger and voice prints)
- Full face photographic image
- Any other identifier; or combination of identifiers likely to identify the subject (e.g., Pathology Accession #)

For this study, will you be **recording** any of the 18 HIPAA identifiers with the data or using a code to link the data to any of the identifiers?

[ ] Yes   [ ] No

It is best to limit the number of identifiers, although names, MRN, and dates are usually difficult to avoid including

If "Yes", then under the HIPAA Privacy Rule provisions the data cannot be considered de-identified and authorization from the subject or a waiver of authorization must be granted by the IRB. When answering this question, consider the need for recording dates or retaining direct identifiers, such as name and/or medical record number, to link data from multiple sources, to avoid duplicating records, or for QA purposes. **NOTE: If you are recording medical record number or other identifiers, even if temporarily for QA purposes or to avoid duplicating records, then answer "Yes".[1]**

Check the identifiers that will be recorded with or linked by code to the data.
X Name
☐ Social Security Number
X Medical record number
☐ Address by street location
☐ Address by town / city / zip code
X Dates (except year), e.g., date of birth; admission / discharge date; date of procedure; date of death
☐ Telephone number
☐ Fax number
☐ Electronic email address
☐ Web URLs
☐ Internet protocol (IP) address
☐ Health plan beneficiary number
☐ Account number
☐ Certificate / license number
☐ Vehicle identification number and serial number, including license plate number
☐ Medical device identifiers and serial numbers
☐ Biometric identifiers (finger and voice prints)
☐ Full face photographic image
☐ Any other identifier; or combination of identifiers likely to identify the subject (e.g., Pathology Accession #)

Will identifiers be removed from the data and destroyed after all of the data has been collected, the study has been completed, or all regulatory and sponsor obligations have been met, consistent with regulatory and institutional research record keeping requirements?

[X] Yes   [ ] No

9)   Statistical Considerations

---

[1]

Statistical Methods:

Very basic description of statistical methods

Sample Size and Study Power
We will use a convenience sample, namely all of the cases that are available and easily accessible, due to the small size of our focus population. As above, the date range for record review is March 1 2013 to May 31 2021. We estimate our sample size will be approximately 70 patients.

Can use power calculator to calculate the sample needed for adequate power :
https://clincalc.com/stats/samplesize.aspx

10) Consent Process and HIPAA Authorization

Either informed consent must be obtained <u>or</u> the investigator must request a waiver of informed consent and a waiver of HIPAA Authorization

For this research, will you obtain informed consent?

[ ] Yes   [X] No

For retrospective studies, you are not able to collect informed consent

Waiver of Informed Consent / Authorization

Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk. When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Partners network with password protections enabled and anti-virus software or an encrypted laptop, with access to data limited to study staff; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

Sample language for this section:

Potential confidentiality breach associated with chart-review research would have minimal impact on individuals, as the data requested pertains only to ***. Risk is minimized via methods listed in below, wherein data will be stored on a secure computer database on a password-protected computer, and HIPAA identifiers will be immediately coded to maintain confidentiality. Coded identifier and data-collection forms will be kept separately on password-protected computers. Access to data will be limited to study staff.

Explain why the research could not practicably be carried out without the waiver of consent / authorization. When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.

It is impractical to conduct this research without a waiver, owing to the anticipated large sample size, which may include an indeterminate number of deaths. In addition, the research team does not have the resources to locate individuals and consent each person. The study is retrospective and involves collection of data elements, which have been already obtained as part of clinical care.

Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization. When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.

This waiver will not adversely affect the rights and welfare of the study subjects, as the data will not impact clinical care and is only a retrospective look ***. Information resulting from this study will not have important health/medical implications for subjects. PHI will be coded, and the coded identifier and data collection form will be maintained separately. The coded identifier and the excel sheet used to collect data will be maintained on separate password-protected computers to minimize risk to the patient.

Will any *sensitive* personal information be collected?

[ ] Yes   [X] No

If "Yes", *Please check data elements below (all that apply)*
☐ HIV Status
☐ Mental Health
☐ Reproductive History (e.g., abortions)
☐ Sexual Behavior/Sexually Transmitted Diseases
☐ Substance Abuse (e.g., drug or alcohol abuse)
☐ Other potentially stigmatizing behaviors (please specify)

_____

11) Confidentiality of Data

All record/data/specimens used within this during this study will be kept confidential in accordance with Institutional research policies and HIPAA law. Research personnel will not use research data and records for any purpose other than conducting the study. In order to maintain data confidentiality, patient identifying data will be coded with the coded identifier and data collection sheet maintained separately on password protected computers.

12) Data Security

No paper record will be utilized; Patient identifying data will be coded; the coded identifier and data collection sheet will be maintained separately. Each will be stored separately as an electronic document and maintained on a password-protected computer.
Data will be stored for a period not to exceed July 1, 2024. Coded patient data will be deleted at or earlier than July 1, 2024 by way of secure file deletion.
Access to data limited to research study staff

Obtaining Quality Improvement Committee Approval

If you and your research mentor have determined that your project is a quality improvement project, you can reach out to the QI committee (QIC) for approval.

Projects are pre-screened extensively by members of the QIC prior to being officially presented at the committee.

In order to prepare for this review, make sure to have considered the questions at the beginning of the chapter [above](#).

Chapter 5

Research Project Ideas During Residency

Chapter Contributors
Hannah Goulart, Douglas Tremblay

In this chapter, we discuss the various types of research projects that you may choose to pursue during residency. We highlight the differences among the projects, and provide two different models to assist with defining your research question. Subsequent chapters in this guide will describe the various types of research projects more extensively.

<u>Goals and Expectations</u>

If you think you may be interested in participating in research during residency, there are a few goals and expectations that you should try to keep in mind before starting:

- **The why**: In thinking about potential research, it can be helpful to first establish your overall goals for the project and what you are hoping to gain from this experience
    a. Do you have a particular research question in mind? (and it's okay if not!)
    b. Are you more generally interested in participating in research to see if it's something you could see yourself doing?
    c. Are you hoping to establish or build upon a relationship with a possible mentor?
- **The how**: Once you know what your overall goal(s) is/are, you should assess the feasibility of being able to execute the project
    a. Do you have the time to work on the project?
    b. And alternatively, if you have identified a research mentor, do they have the time?
    c. Do you have the tools you need to carry out the project? – including statistical support, database management, IRB submission/approval
- **The what**: Now that you've established **the why and the how,** it's time to start thinking more about the details of your actual project and what your options are in carrying out research during residency

<u>Types of Research Projects</u>

Case Report: Involves writing up a patient vignette and including a discussion which remarks on the poignant and notable aspects of the case. These are typically less time-intensive and can be a great option for residents to write up to submit to conferences (Typically do not require IRB approval, but may require patient consent) See the PPHS website under "General Guidance "Case Reports and Case Series" [PPHS Guidance and Policies | Icahn School of Medicine](#)

Case Series: This is similar to a case report but includes multiple patient vignettes with similar presentations and/or diagnoses. See the PPHS website under "General Guidance "Case Reports and Case Series" https://icahn.mssm.edu/research/pphs/guidance

Retrospective chart review: This type of research involves reviewing a large number (usually) of patient charts, pulling data on the desired topic, and performing statistical analysis on the recorded data in order to attempt to identify potential risk factors for particular outcomes. Some important factors to consider include the generation of your research subject "list", i.e. which subjects meet the inclusion criteria to be included in your study – this can be done with the assistance of data exploration tools such as Leaf which can significantly help save time. Once you have your subject list, you will need to know what type of data you are interested in collecting, and how you are planning to collect it. Think about if there is pre-existing RedCap database ready to use or if you will have to make a new one

Narrative review: Consists of a literature search and review of the presently available research in a particular topic, summarizing what is known, discussing the remaining unknowns, and proposing a path to move literature in the particular field forward

Systematic review: Systematic reviews are more rigorous than narrative reviews and aim to reduce bias through disclosing specific search criteria which identify research studies that fit into their predefined inclusion criteria. They also have specific protocols for analyzing data from the selected studies, and can provide an interpretation of pooled results from multiple studies

Prospective research: This is typically the most time-intensive and can be in a variety of formats including observational prospective cohort studies or clinical trials. Something to keep in mind is that while novel and innovative, it can be challenging to see a project like this from start to finish in residency as they often take many years, significant effort and sometimes funding

Methodology for Assessing and Designing a Research Project

The following tools can be helpful approaches for identifying and refining your particular research question. They can help provide a framework when constructing your project to ensure that you remain in scope and highlight and answer the important questions that you hope to address with your research.

FINER: *(Hulley et al)*

F	Feasible	Will the research encompass an adequate number of subjects and utilize available technical expertise? Is the research affordable (both in time and money), and is the scope manageable?
I	Interesting	Is the research intriguing to the investigator, fellow peers and community?
N	Novel	Does the research confirm, refute or extend previous findings?
E	Ethical	Is the research amenable to a study that the institutional review board (IRB) will approve?
R	Relevant	Is the research relevant to the existing scientific knowledge or clinical/health policy? How does it contribute to the future of research in this particular field?

PICOT: (*Sackett et al)*

P	Population (patients)	What specific patient population are you interested in?
I	Intervention (if applicable)	What is your investigational intervention?
C	Comparison group	What is the main alternative to compare with the intervention?
O	Outcome of interest	What do you intend to accomplish, measure, improve or affect?
T	Time	What is the appropriate follow-up time to assess outcome?

Important side notes to keep in mind when conducting research during residency

- IRB approvals and the length of time this can take
- COI (conflict of interest) Forms on SinaiCentral – all investigators must fill this out yearly in order to be included on the IRB submission
- Ensuring CITI training is up to date every 3 years but this is what you should have to start: Human Subjects Research training for Investigator/Research Staff, HIPAA for Research Update, Data Security and HIPAA training, [+/-GCP for Clinical Trials with Investigational Drugs and Biologics] - See Chapter 2
- If you are working on a solicited review article with a hard submission deadline (see more in Chapter 6), be sure to keep your mentor in the loop regarding progress, especially if you are struggling to meet the deadline!

References

Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. 3rd ed. Lippincott Williams and Wilkins; 2007

Sackett D, Richardson WS, Rosenburg W, Haynes RB. How to practice and teach evidence based medicine. 2nd ed. Churchill Livingstone; 1997

Helpful Links

PICOT: https://libguides.mssm.edu/ebm/ebp_pico

FINER: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6691636/

Chapter 6

Overview of Research Projects

A Case Report or Case Series & How to Write

Section Contributors
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What is a case report?

A case report is a straightforward paper focused on one subject: an interesting patient. This type of writing offers an opportunity to delve deep into a disease process or medication effect which is unexpected, potentially new, and clinically intriguing. A case series reports more than one case.

The goal of your article is to provide a strong background for the case, present the patient's story in a compelling and thorough manner, and then explain why the clinical narrative should be viewed as significant. A case report can contribute to a larger body of literature, or even spark a new way of thinking about a clinical problem. Indeed, many original research ideas and discoveries in medicine have been inspired by case reports.

Before starting your case report

1. **Talk to the patient/surrogate decision maker that you are considering writing a case report about their presentation**
   a. The patient is at the center of the report, and telling them that you will be sharing their story (but not their name) is an important discussion to have early
   b. This can be a sensitive subject, but can also reinforce your therapeutic alliance with your patient if managed correctly
   c. Look to others with experience asking patients for consent to write about them, such as a faculty mentor

2. **Obtain written consent if you are even considering writing a report**
   a. As long as it's a single case and it's for educational purposes then you don't need IRB approval as of 4/2023. Check here for updated guidelines: PPHS Guidance and Policies | Icahn School of Medicine under General Guidance
   b. For a **case series you might need IRB approval.** See the same web page under General Guidance and contact the IRB, as per instructions in the link.
   c. Use the Mount Sinai consent form "Authorization for Release of PHI for Scientific Publication" on the same webpage.
   d. Make sure you include consent to use any imaging results in your conversation with patient

    e. Scan the consent form into the Media section of the patient's EPIC chart.

3. **Review the literature for similar (or nearly identical) cases**
   a. Existence of very similar case reports or series does not preclude writing your own case report/series, and might make the case(s) more interesting if it is a part of a larger pattern
   b. You also don't want to claim that this is a novel disease presentation, for example, if there is a documented account of a previous occurrence

4. **Find a mentor, likely the attending of the patient, who can edit/co-author the report**
   a. If not the general attending, perhaps an attending consultant can serve this role
   b. You can also work with a fellow if this is more feasible, but of course faculty mentorship is preferable
   c. Finally, you can include other residents or medical students involved in the patient's care to share in the responsibility and discuss ideas for the report

<u>**Preparing to publish the case report or series**</u>

1. **Pick a target journal for publishing**
   a. Here is an article which outlines some strategies for picking a journal: "How to choose the best journal for your case report" (1). Also ask your mentor and see [Chapter 8](#) [choosing a journal for your publication](#), and identifying journals with no / low article processing charges (publication fees)[Finding a Journal with No Publication Fees / Article Processing Charges](#).
   b. Make sure to read other case reports which have previously been published in this journal
   c. If your case report does not fit the appropriate subject matter or general type of report for that journal, keep on looking for a better fit
   d. Formatting and style requirements can vary widely across journals, so look at the Author Submission guidelines of any journal you are considering
   e. [Check the publishing fees (also known as Article Processing Charges](#)). Discuss the fees with your mentor <u>before</u> submitting, and ask if there is funding available to pay for the case report
   f. Note that some journals recommend or require following the [CARE case report guidelines](#)

> ***Examples***
> For formatting and style requirements, we will use **Journal of Medical Case Reports'** author guides (2, 3) as examples
> For content examples, we will use a case report about a patient who developed **Takotsubo (AKA stress-induced) cardiomyopathy** from **opioid withdrawal**

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2. **Prepare to write the report for your target journal**
   a. As we mentioned, always look at formatting and style requirements when starting to write the report – this will save you a lot of potential hassle later

       i. Note, there are often separate guidelines for overall formatting and specific style/formatting requirements

    b. The Journal of Medical Case Reports (JMCR), for example, has two separate pages for requirements:

       i. The broad overview of the necessary sections and what they should contain (2)

       ii. Specific formatting requirements for the main text and other components of the submission (3)

    c. Regardless of which journal you choose, you will always need to follow (and often document completion of) the CARE checklist (4)

       i. This checklist provides a general outline to any case report, and usually corresponds closely with journal requirements

       ii. Note that some aspects of the CARE checklist are not usually covered by journal requirements – particularly the 'Timeline' and 'Patient Perspective' components

      iii. You can complete these at the discretion of the journal to which you're submitting

Writing the report section by section

1. **Title Page: Includes the title, authors and affiliations**
   a. Title should clearly state what you're reporting and end with ": A case report" (unless the journal says otherwise)
   b. For example: "Opioid withdrawal precipitates Takotsubo cardiomyopathy: A case report"

2. **Abstract: A brief summary of the case report organized into background, case presentation, and conclusion**
   a. Summarize the below sections concisely, keeping an eye on the word/character count limits
   b. Minimize abbreviations and do not use citations, figures or tables

3. **Keywords: A few words or phrases which capture the main ideas presented in the report**
   a. Example: opioid withdrawal, takotsubo cardiomyopathy, hyperadrenergic state, opioid use disorder

4. **Background: An overview of the foundational theory and principles underlying the disease process and/or therapy**
   a. Include just enough information so the reader can understand all the most relevant medical concepts in the case report
   b. Example: include an explanation of the mechanism of opioid withdrawal, the pathophysiology of Takotsubo cardiomyopathy, and the concept of a hyperadrenergic state which connects the two conditions

5. **Case presentation: The most significant content of the report which includes the structured narrative of the patient's experience**
    a. This can be split into five main components:
        i. Demographics (Briefly)
        ii. Medical history (Briefly)
        iii. Presenting symptoms, physical exam signs, labs and imaging findings (at length)
        iv. Treatments/interventions (At length)
        v. Outcomes (At length)
    b. You can approach this like presenting an H&P and hospital course
    c. Include only relevant details of their presentation, but make sure not to spare any important facets of their story
    d. Images/figures are generally encouraged
        i. Example: an image of the echocardiogram demonstrating apical hypokinesis and left ventricular ballooning consistent with Takotsubo cardiomyopathy

6. **Discussion and conclusions: A presentation of relevant medical literature which supports the significance of your case**
    a. Example: citing an article which demonstrates the benefit of alpha-2 agonists for opioid withdrawal, supporting the theory that opioid withdrawal represents a hyperadrenergic state
    b. The discussion is also an appropriate place to review any other similar reports
    c. Finally, conclusions should demonstrate why this case is important to the field
        i. Note, your conclusions do not need to be groundbreaking, but the report should offer a consideration regarding how this might warrant future studies or changes in management

7. **Other requirements: Usually several statements required for publication/ ethical purposes**
    a. Always make sure you complete all required parts, not just the core elements above.
    b. For example, the JMCR also requires a list of abbreviations and several declarations (Ethics, consent, data availability, competing interests, funding, authors' contributions and acknowledgments)

8. **References: The list of cited works**
    a. From the beginning of writing the report, keep track of all relevant articles, preferably in a trusted reference manager tool such as Mendeley, EndNote or RefWorks (see section on The Levy Library Resources - Chapter 2)
    b. Formatting references in the correct style based on the journal's requirements is made simple if you have all articles in the same reference manager, most of which can create bibliographies for you
    c. Also ensure your in-text citation style aligns with the journal
    d. For example, JMCR requires Vancouver style citations

9. **Figures and tables: Visual aids to support and organize elements of the report**

a. Look at the journal's requirements for figure formatting
b. Often, the legend (i.e the description of the figure) will go in the main manuscript and not in the figure file itself. Make sure to crop out or black out any patient identifiers from images.
c. Tables are less often used in case reports, but if you use one make sure you know whether the journal wants the table as a separate file or embedded in the text

After the report is submitted

1. **What if your report is not accepted?**
   a. Don't panic – acceptance rates vary widely, from as low as ~10% to as high as >90% based on the journal
   b. Make sure to reformat your case report based on the requirements of the new journal: do <u>not</u> submit the same product unchanged to another journal
   c. Common reasons why case reports are rejected include a lack of novelty, unclear take home messages or teaching points - before re-submitting, check that your take home messages are clear

2. **What if your case report is accepted?**
   a. Congratulations! You've contributed to the literature
   b. Discuss with your mentor the publication fees / Article Processing Charges
   c. You will also likely need to revise your original report
      i. For this reason, never lose track of the patient's information as you may need to go back to their chart to answer an unexpected query from a reviewer

References and resources:
1. Rison RA, Shepphird JK, Kidd MR. How to choose the best journal for your case report. J Med Case Rep. 2017 Jul 22;11(1):198.
   (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5522590/)
2. JMCR case report author submission guidelines
   https://jmedicalcasereports.biomedcentral.com/submission-guidelines/preparing-your-manuscript/case-report
3. JMCR Formatting/style guide
   https://jmedicalcasereports.biomedcentral.com/submission-guidelines/preparing-your-manuscript#preparing+main+manuscript+text
4. CARE checklist https://www.care-statement.org/checklist

Additional Resource:
5. Guidelines To Writing A Clinical Case Report. Heart Views. 2017 Jul-Sep;18(3):104-105.
   (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5686928/)

A Literature Review

Section Contributors
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In this chapter, we discuss the process of writing a review article and in doing so, will describe the differences between a systematic and a narrative review. Writing a review article can be an invaluable way to learn more about a particular field of interest, as it will necessitate you to read and become familiar with the current research landscape for your particular topic. Additionally, they can allow for you to deeply assess and think about the existing gaps in knowledge, which can even promote ideas for future research studies.

First of all, what is the difference between a systematic review and a narrative review?

Systematic reviews are more rigorous and aim to reduce bias through disclosing specific search criteria which identify research studies that fit into their predefined inclusion criteria (think PICOT). They also have specific protocols for analyzing data from the selected studies, and can provide an interpretation of pooled results from multiple studies.
Narrative reviews, on the other hand, are less rigorous and provide a general overview of the available research in a particular field. While they still tend to include a large amount of references, these review articles do not disclose specific search criteria and the quality of the included studies is not always discussed.

The Process

1. **Set up for Success:** After employing either the FINER or PICOT tools (see Chapter 5) to help formulate a research question, it is important to ensure that you have the necessary tools that will enable success when writing a review article. This primarily includes having a reliable reference manager, which is particularly important to have since review articles usually include a large amount of references. EndNote is widely used and available to download on the Levy Library website. It is important to note at this step whether the review article is *solicited* vs. *unsolicited*, meaning has your mentor been invited to write a review article for a particular journal? If so, review the author instructions ahead of time to ensure you are working with the correct formatting, word count, and deadline (and if there is a hard deadline, is this realistic for you with your schedule?)

2. **Identify Keywords and Perform your PubMed Search**: Think about your research topic and identify keywords that will help find articles that will provide the background for your paper. If you are performing a systematic review, the exact process and keywords used will need to be explicitly stated in the paper. The Levy Library librarians are excellent resources to help identify keywords and refine your PubMed search – you can reach them by filling out the consultation form in *this link*. Keep track of all your sources

in a reference manager such as Endnote as mentioned above. **Note**: if working on a systematic review, be sure to utilize the *PRISMA* website, which is a resource of evidence-based guidelines to assist with the process of writing systematic reviews and meta analyses. You will also need to register your meta analysis on the PROSPERO website to help ensure that your review topic is unique.

3. **Read**: Review your selected papers, take notes and modify your search above as needed to ensure you have the sources you need to put together a thorough review. Review the references of studies that you found helpful to identify further sources that you may be able to include in your paper. Some find that creating an Excel spreadsheet to keep track of their sources is helpful, especially if sorted by topic, so that when you go to start your outline, you have the sources already organized into where they would generally fit into the paper.

4. **Develop an Outline**: The creation of an outline requires effort upfront, but will undoubtedly save you time down the road. It will help organize your thoughts and ensure that you have identified and discussed the most relevant points for your review article. Try to include cohesive thoughts in your outline as opposed to single words, as this will help when flushing the outline out into a manuscript. Distribute the outline among your co-authors so that everyone is in agreement regarding the structure of the article. If you are writing a solicited review article, the requesting journal may wish to see your outline.

5. **Start Writing**: Use the outline you created to build upon your thoughts. The typical headings included in a review article are the following:

   a. Introduction: Give readers a preview of what you will be discussing in your review. Provide an overview of your research topic and why it is relevant for the field. Explain what you are aiming to accomplish with your review article, and outline the main points that you will be discussing throughout the paper. Explain key words, if necessary. Some find the introduction easier to write after the rest of the paper is written.

   b. Background: This is likely where the majority of your references will be, and will consist of a review of the existing literature in the field. Throughout this part of the paper, you will discuss and appraise the current research landscape and begin to comment on the potential gaps in knowledge that exist, which will set you up for the discussion section that follows. As this section can be lengthy, try to organize this section in a consistent manner so that your readers can stay engaged and on track. Systematic reviews may include a meta-analysis component which can synthesize data from multiple studies into graphical representations such as forest plots.

c. Discussion/Conclusion: Now that your paper has provided the readers with an overview of your particular research topic, here is the time to propose how to move the field forward. Think about what the previous papers have accomplished, and what is still yet to be determined. This is often the section where you can really display your critical thinking and think about potential next steps for future studies.

6. **Edit and Submit**: As with all papers, prepare to go through multiple rounds of edits with input from your co-authors. Typically, the first draft is shared between the first author and the senior author until the paper is at a point where it can be distributed to the additional authors to review. It may be helpful to send a pre-submission inquiry to the editor of the journal of your interest so that you can determine if they will likely send your paper out for peer review, as this can save you time during the review process. When you are at the point of submission, ensure that your references are in the correct format that the desired journal specifies. Certain journals often have their own EndNote reference style, which you can usually download from the EndNote website. Additionally, ensure that you have asked for your co-authors' conflict of interest statements so that they can readily be included in your manuscript. Double and triple check the journal author submission guidelines to confirm that you have all the necessary sections included in your manuscript submission and that they are all in the correct order.

Helpful links

PRISMA Guidelines: http://www.prisma-statement.org

PROSPERO Registration: https://www.crd.york.ac.uk/PROSPERO/

Retrospective Studies Part 1 - Defining Your Research Question

Section Contributors
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A large amount of resident research is retrospective chart review. These projects are well-suited to resident research because they can be done whenever a resident has time to perform chart review. Major limiting factors include IRB approvals and designing a good database.

The most important element before starting a retrospective chart review is to have a clearly defined scientific question. Refer to Chapter 5 for creating a question. Be sure to perform a preliminary literature review (use the same principles outlined in A Literature Review) while creating this question in order to determine what will be novel for the field.

For example, a question can be: among patients who received a bone marrow transplant, is there a higher risk of infection? (This is your **primary research question**)

Follow-up questions may include:
- For how long after bone marrow transplant will you screen patients for infection?
- What kind of bone marrow transplants will you include in your study? Autologous? Allogeneic?
- What indication for bone marrow transplant will you include in your study? Does this matter?
- How will you measure infection? For example, will you use documentation of the word "infection"; Positive blood cultures; Hospitalization with principle reason for admission being infection? Review existing literature to see how these questions have been studied in your field already
- Is this question already answered in the literature? If so, is there a way that you can refine your question to provide novel information? For example, was the previous study generalizable to the general population or your population of interest (e.g. indication for bone marrow transplant, age of population, race / ethnicity of the population, US healthcare system or another country). When was the previous study done? (e.g. is it more than 10 years ago, or prior to significant changes in medical care)

Take time to ensure that your primary research question (and secondary research questions) are clear to you, and discuss them with your mentor before you design your data collection tool (database) based on the variables you need to collect to answer your research question.

Once your research question is defined, and you know what variables you want to collect, design a database specifically to answer your question of interest, and get IRB approval.

What is a variable?

A variable is the type of information you collect in your research.

There are different ways to think about variables.

As examples, there are:

- Demographic variables which includes age, gender, race / ethnicity;
- Lab variables such as Hb, Na, LDL cholesterol.
- Imaging or test variables such as size, right atrial pressure, oxygen saturation
- Clinical variables including height, weight, systolic blood pressure;
- Outcome variables which might include hospitalization, mortality.

Retrospective Studies Part 2– Designing Your Data Collection Tool in REDCap

> **Remember:** You cannot begin any data collection until you have IRB approval for your study.

Designing a good data collection template is critical in collecting accurate and relevant data for your study.

REDCap is a useful platform for designing, collecting and managing data collection, as it is HIPAA compliant, and multiple team members can log in from any location to contribute to the data collection.

> ***Important: July 2023, REDCap announced instituting a $100 fee /REDCap project/ year***
>
> Fees do not apply to:
>
> - Medical student projects
> - QI Projects
> - Hospital Operations projects
> - Projects that are < 90 days duration in REDCap
>
> When planning your study, discuss with your mentor whether they have funds to cover the REDCap fees.
>
> You can also use Excel but remember all patient identifiers (name, mrn) need to be changed into study ID numbers, and the "key" needs to be stored in a separate file from the data collection file. Additionally, **both files must be encrypted and password protected.**
>
> Data and surveys can be collected on Microsoft Forms, which if created through your Mount Sinai email account, and the data are not shared with a non-Mount Sinai email address (or anyone outside the study team) are HIPAA compliant.

Before you begin collecting data there are some essentials to consider:

1. **Define your research question:**
   Before designing a data collection instrument, you need to have a clear understanding of what you want to investigate

2. **Based on your research question, you need know what variables you are collecting:**

- Before creating the data collection form in RedCap, or table in Excel (or other software) **,
 plan the structure**.
- Identify the variables you want to collect based on your IRB approved protocol (you
 cannot collect variables that are not in your protocol)
- Then decide on the question or column headers, and determine the order of the
 variables being collected.

Designing your data collection template using REDCap:

1. Create a REDCap account, and ask your study team to create REDCap accounts:
   https://redcap.mountsinai.org/redcap/

   More information regarding REDCap can be found here:
   https://researchroadmap.mssm.edu/reference/systems/redcap/

2. Log in to your REDCap account and create a new project. Give your project a name and
   description.

3. Determine if a patient list can be imported, or if the data will be generated by manual
   entry.

4. From the project dashboard, click on the "Online Designer" button to access the form
   designer. Use the drag-and-drop interface to add fields to your form, choose question
   types, questions and set up branching logic.

5. **Provide clear and concise instructions** for how to complete the data collection form.
   This can help to ensure that other team members understand what information is
   required and how to input data correctly.

6. Based on the type of data you need, for **categorical data choose multiple-choice,
   yes/no** questions as much as possible. These can be generated by drop-down menus, or
   radio-buttons.

> **Tip: Avoid Free Text in Data Collection.**
> Avoiding free text in data collection can help ensure the data collection is consistent and easy
> to analyze. REDCap has a number of features that can help you avoid free text including
> dropdown fields, checkboxes, and radio buttons.

7. For **continuous variables** ensure you have added **units of measurement** and **expected
   range values** (e.g. if height is being recorded ensure the data collector is aware whether
   it is to be recorded in cm or inches and add reasonable ranges, so that the data collector
   will receive an alert if they enter 67cm). REDCap has a range validation feature.

> **Reminder: Categorical and Continuous variables.**
> **Categorical variables** are data that can be divided into distinct categories or groups (e.g. gender, race, procedure type, disease presence or absence). There can be multiple categories, and "unknown" or "other" can be categories. "Yes" and "No" are categorical.
>
> **Continuous variables** are numerical data that can be measured along a continuous scale (e.g. age, height, weight, lab values, right atrial pressure, tumor size).

8. **Avoid asking data collectors to perform calculations** (e.g. BMI, FIB-4 or other scores), as it will likely introduce errors. Ask them to collect the raw data only, calculations should be performed during the data analysis phase.

9. Make sure your **variable descriptions are clear**, so team members understand what information they are collecting.

10. Determine if the data will be collected at a single time point or multiple timepoints. Make it clear how to enter multiple timepoints in the correct locations.

11. Include "None" and "Not done" to help track missing data

12. Don't duplicate data (e.g. asking both age and DOB)

13. Determine who will enter data: your data collectors need to be named on the IRB. Give them access to edit the forms in REDCap. Note, your data collectors need to have REDCap accounts before you can add them.
    a) Ask them to log into REDCap to create an account - using their Mount Sinai credentials
    b) Once they have created accounts, you Go to "Users", find the data collector's name, go to "User Rights", and then "Edit Form Access Rights"
    c) You need to give them "View and Edit" rights at a minimum to allow data access.
    d) Do not allow the entire team full "Export Data Access Rights" during the data collection phase.
    e) Do not allow deletion of records to avoid any accidental loss of data.

14. Organize your questions in a **logical sequence** that follows the flow of the topic. For example, if the data collector is extracting data from EPIC, consider where they will find each piece of data – e.g. demographic information, medication lists, lab results, evaluation of chart data – cluster the questions based on the workflow of someone extracting the data to make data collection as efficient as possible.

15. **Train data collectors** on how to properly complete the data collection tool. This can help to ensure that all data is collected in a consistent and accurate manner.

16. **Before using the form, test it** with a small group of people who will be collecting the data to identify any potential issues with data collection workflow, or confusion in the questions, and clarify / edit based on their feedback. This will reduce errors in the data collection process.

Important Note: Residents can use REDCap for free in <u>Development Mode</u>.
This is sufficient for most projects. However, if you change the data collection tool after data collection has begun, there is a risk that previously collected data will be lost, so it is strongly recommended to design the tool and test it to make any adjustments prior to use.

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17. Start collecting the data!!

18. Monitor the data collection process by regularly checking the data quality and completeness. Follow up with team members to identify any errors in data entry or concerns regarding the process.

Retrospective Studies Part 3– Designing Your Data Collection Tool Using Excel

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Remember:

1. You cannot begin any data collection until you have IRB approval for your study.
2. All patient identifiers (name, mrn) need to be changed into study ID numbers, and the "key" (that matches the MRN to the Study ID) needs to be stored in a separate file from the data collection file. Additionally, **both files must be encrypted and password protected.**

Before you begin collecting data there are some essentials to consider:

1. **Define your research question:**
   Before designing a data collection instrument, you need to have a clear understanding of what you want to investigate

2. **Based on your research question, you need know what variables you are collecting:**
   o Before creating the data collection form in Excel (or other software) **plan the structure**.
   o Identify the variables you want to collect based on your IRB approved protocol (you cannot collect variables that are not in your protocol)

Important Note:
In Excel, each individual person should be in one row (2, 3, 4, etc) and each variable should go in a column (A, B, C etc)

The variable names go in the first row (Row 1) under columns A, B, C etc.

- Defining Variables:
  - Variable names must start with a letter.
  - Do not include special characters (#, !, ?, %, etc.) or spaces in your variable names (Use underscores- e.g. Baseline_Weight)
  - Choose readily understandable names for variables - but not too long (<= 16 characters best).
  - Document your variable names with a data dictionary and codebook
    - As you create the variable names, document what they mean so that you, your data collectors, and any statistician / collaborator can understand your data and database. The data dictionary should include

all of the variable names, data type that corresponds to the variable, a label or longer name that describes the variable including the units it is measured in, the codes for any categorical variables (if collected as codes e.g. 0, 1, 2, 3 where 0=no diabetes, 1=prediabetes, 2=diabetes, 3=unknown), and any notes for the variable. This should be a separate worksheet or document file. Codes reduce errors with typos, but Drop-down menus can also be used for categorical variables to reduce typos.
- Be sure that each variable name is unique (do not duplicate variable names).
- Do not duplicate data (e.g. collecting age and DOB)
- Use a separate column for each piece of information.
  - Don't enter data such as "120/80" for blood pressure. Enter systolic blood pressure as one variable and diastolic blood pressure as another variable.
  - Don't enter data as "A,C,D" or "BDF" if there are three possible answers to a question. Include a separate column for each answer.
- Determine if the data will be collected at a single time point or multiple timepoints. Make it clear how to enter multiple timepoints in the correct locations.
- **Avoid asking data collectors to perform calculations** (e.g. BMI, FIB-4 or other scores), as it will likely introduce errors. Ask them to collect the raw data only, calculations should be performed during the data analysis phase.

- Data Entry Convention:
  - When entering dates (especially for years prior to 1930) include a 4 digit year.
  - Two digit years can cause problems for statistical software when reading data from Excel files. The best format for dates is mm/dd/yyyy, where mm is a 2 digit month, dd is a 2 digit day and yyyy is a 4 digit year.
  - Decide on "missingness" conventions.
    - Missing data can cause many problems. To enter a missing data value either enter a blank or an "impossible" numeric code (e.g. 999999 or 0) or an easily recognizable single digit character code for character (trying to avoid mixing numeric and character data). Be sure, if you use a missing value code, that it cannot be confused with a "real" data value (e.g. don't use 0 if zero is a possible value).
    - Include "None" or "Not available" in Drop-down menus
  - Consider using **Drop-Down Menus for categorical variables** to avoid freetext errors. These are easy to create.
    - Highlight the column of cells where you would want to enter the data (highlight the entire column).
    - Click on the "Data" tab in the Excel ribbon
    - Click on "Data Validation" in the "Data Tools" group
    - In "Data Validation" dialog box, select "List" from the "Allow" drop-down menu

- ■ In the "Source field, enter the list of options you want to include in the drop-down menu, separated by commas. For example: Alive, Dead, Unknown
- ■ Click "OK" to save the data validation rule
- ■ Check the excel cells where you created the drop down menu, a small arrow will appear on the right of the cell, clicking the arrow will display the list of options you entered in the "Source" field.

- ● General Tips:
  - ○ Organize your questions in a **logical sequence** that follows the flow of the topic. For example, if the data collector is extracting data from EPIC, consider where they will find each piece of data – e.g. demographic information, medication lists, lab results, evaluation of chart data – cluster the questions based on the workflow of someone extracting the data to make data collection as efficient as possible.
  - ○ Use only one worksheet for your data.
  - ○ Do not "stack" data on the same sheets.
    - ■ For example, treated versus non-treated patients can be handled by a column variable with a dropdown menu that has a code for Treated (Y/N).
    - ■ Avoid using "special" Excel features (i.e. hidden columns, graphs on the data sheet that is your primary database, colors, italics, bold) - After data collection make copies of the primary data collection sheet for analysis.
  - ○ **Train data collectors** on how to properly complete the data collection tool. This can help to ensure that all data is collected in a consistent and accurate manner.
  - ○ **Before using the Excel Collection Sheet, test it** with a small group of people who will be collecting the data to identify any potential issues with data collection workflow, or confusion in the questions, and clarify / edit based on their feedback. This will reduce errors in the data collection process.

- ● Start collecting the data!!

- ● Monitor the data collection process by regularly checking the data quality and completeness. Follow up with team members to identify any errors in data entry or concerns regarding the process.

References:
1. https://www.unmc.edu/publichealth/centers/ccorda/exceldata.html
2. *Preparing data in Excel*. Preparing Data in Excel. (n.d.). Retrieved February 27, 2023, from https://www.unmc.edu/publichealth/centers/ccorda/exceldata.html
3. *Redcap beginners guide - University of Chicago*. (n.d.). Retrieved February 27, 2023, from https://cri.uchicago.edu/wp-content/uploads/2015/12/REDCap-Beginners-Guide.pdf

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Chapter 7:
Data Analysis and Biostatistics

Chapter Contributors:

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Data Analysis - Exporting Data from REDCap to Excel

Before you begin: If you generated your Data Collection tool in REDCap, you will need to export the data in order to analyze it. REDCap allows you to export the data in multiple formats (CSV, SPSS, SAS, R, Stata).

To export data from REDCap to Excel:

1. Log in to your REDCap project and go to the "Data Exports, Reports, and Stats" page.
2. Click on the "Custom Data Exports" tab.
3. Select the data you want to export by choosing the appropriate options in the "Data Export Tool" section. You can choose to export all data or select specific forms, fields, events, or records.
4. Choose the export file format as "Excel Format" from the dropdown list of available file formats.
5. Choose any additional export options, such as including hidden fields or redacted data. **Ensure you are not exporting any patient identifiers.**
6. Click on the "Export Data" button.
7. Your export file will be generated and you can download it by clicking on the "Download Export File" button.
8. **Save the Excel file as a password protected file**.

Once the export file has been downloaded, you can open it in Excel.

The exported data will be organized in columns, with one column for each variable, and one row for each patient (or research subject).

Data Analysis – Data Cleaning using Excel

Data cleaning is the process of identifying and correcting errors, inconsistencies, and inaccuracies in a datasets before analyzing, to ensure that it is accurate and reliable for analysis. It is an essential step in the data analysis process as it can help to eliminate errors that may affect the results of an analysis. It can be a time consuming process, so it is important to spend time on designing your data collection tool (see Chapter 6) to make this process easier.

If you identify potential data entry errors using these methods, you and your team will need to return to the raw data to verify / correct the data.

Data cleaning can be done in Excel and involves:

1. Removing duplicate data.

2. Correcting spelling and formatting errors (A good way to avoid spelling errors is to avoid freetext in REDCap, and use Drop-down menus in Excel during the data collection phase).

3. Identifying outliers.

4. Checking for missing data.

Important Definition: Data "Range" in Excel

A range of data refers to a selection of cells within an Excel worksheet. The range can consist of a single cell, multiple cells, an entire row or column, or the entire worksheet.

---

1. **How to Remove Duplicate Data in Excel.**

Note that removing duplicates in Excel permanently deletes the duplicate rows, so save a backup copy of your original data before removing duplicates to avoid accidental data loss.

a. Select the range of cells containing the data you want to remove duplicates from (typically this will only be column A, to identify accidentally duplicated patient records).

b. Go to the "Data" tab in the Excel ribbon.

c. In "Data Tools" click on "Remove Duplicates"

d. In the "Remove Duplicates" dialog box, select the columns or fields that contain the data you want to remove duplicates from. **It is important to carefully select the columns or fields to remove duplicates from to avoid unintentionally deleting important data.**

e. Click on the "OK" button to remove the duplicates.

2. **How to Identify Formatting Errors in Excel.**

Formatting errors can typically be reduced by minimizing free texting during data entry. Excel will filter data based on the selected options, displaying only the cells that match (or don't match) the selected criteria. This can help you to easily identify and correct formatting errors in the data.

    a. Select the range of cells containing the data you want to filter.

    b. Go to the "Data" tab in the Excel ribbon.

    c. In the "Sort & Filter" group, click on "Filter".

    d. In the Excel table, click on the drop-down arrow next to the column header that contains the data you want to filter.

    e. Click on any data that do not fall into predefined categories or ranges.

    f. Repeat for all variables (columns).

3. **How to Identify Outliers in Excel.**

Outliers are data points that are significantly different from other data points in the dataset. They may be correct, or may be data entry errors, and are important to identify prior to data analysis.

For example, if serum Na levels are a variable of interest, and expected ranges are 110 – 160, but one of the data collectors accidentally typed 11, you could identify this error in a number of ways in Excel.

Some straightforward ways to identify outliers using excel include:

    a. Use Conditional Formatting: Select the range of data you want to analyze, click on the "Home" tab, and select "Conditional Formatting" from the menu. From there, choose a rule, such as "Highlight Cells Rules" > "Less Than" and enter a value (e.g. 110 for the above Na example). Any values below that threshold will be highlighted as potential outliers. You can use the same method for "Greater Than" values.

    b. Create a Box-and-Whisker Plot: Use the "Insert" tab and select "Box and Whisker" from the charts menu. You'll then need to select the range of data you want to analyze and choose the options for how you want the chart to display. A box-and-whisker plot is a graphical representation of a dataset that shows the distribution of the data and identifies outliers.

4. **How to Check for Missing Data in Excel.**

You can check for missing data by using the conditional formatting to highlight any blank or missing values.

- Select the range of data you want to analyze, click on "Conditional Formatting" on the "Home" tab, and select "Highlight Cells Rules" > "Blank Cells". This will highlight any blank cells in the range.

Missing data is a well-recognized feature of research studies. It is important that you document the percent of missing data, and decide with your mentor and / or the statistician how you will deal with missing data.

Statistical Analysis - Statistics Support for Residents

A subject of stress for many residents is how to analyze their data once data collection has been completed. Before you consider consulting a statistician with your data, be certain you know:

1. What is your [primary research question](#)
2. Ensure your dataset has [been cleaned](#)
3. If your research mentor can help you with the data analysis or works with a statistician who can help

We strongly recommend that you talk with your mentor and reach out to the APD for Research, before consulting a statistician if you do not have a lot of research experience.

Statistical Support:

1. **The Department of Medicine at Mount Sinai supports 8 hours of free statistical support for Internal Medicine Residents.**

To access this support complete this online form:

https://docs.google.com/forms/d/e/1FAIpQLSd0Dw3jE-9fGasrU6VQYhJIbn-LAw_NxGoDidQUmIAwtXD3ng/viewform

If you have any problems with getting support through this mechanism, please email your research APD - Please provide feedback that is:

Specific - Please focus on the issue, and dates and exact interactions

Timely - Please provide feedback as close to the time of the interaction as possible

Meaningful - Please provide details

Candid - Please report your actual experiences (we want to know if there are issues)

We want to make sure this process is working for residents, so please do provide feedback (good or bad)

2. **Stat-Chat.**

If you have short, well-defined questions, Stat Chat may be the right fit. Amongst the many Levy Library support mechanisms is [Stat-Chat](#).

Analyzing your Data - Univariate Analysis

If you have no experience or training in statistical analysis, <u>speak with your mentor</u> and/or <u>reach out to the APD for Research</u> to get the <u>correct support for your data analysis</u>.

Residents frequently learn to analyze data, but if you do not have formal training in this field, it is extremely important that someone with experience is helping you learn, overseeing your progress and checking your analysis as you learn.

After <u>Data Cleaning</u>, the next step is often univariate analysis or "Descriptive Statistics".

To learn more about biostatistics in medical research and software<u>, see the available courses and workshops through Mount Sinai and other institutions.</u>

Basic Analysis:

Univariate Analysis means analyzing and describing a single variable in the dataset, without considering its relationship to other variables. (e.g. average age, percent of patients hospitalized).

What are Descriptive Statistics?

Descriptive statistics are a way to summarize your research findings. Typically **Table 1** of your publication will include descriptive statistics.

- For <u>continuous variables</u>, descriptive statistics can be used to describe:
  a) **The central tendency:**
     - The mean (average) is typically calculated for normally distributed data
     - The median (central value) for non-normally distributed data.
  b) **Variability:**
     - The standard deviation is often used for normally distributed data
     - The interquartile range is used for non-normally distributed data
- For <u>categorical variables</u>, the descriptive statistics are often presented as the frequency and percentage.

Descriptive statistics can be generated using Excel, although it is sometimes easier to use statistical software packages (e.g. SPSS, SAS, STATA, R), some of which are available on the <u>Levy Library computers</u>.

Missing Data: It is important to discuss with your mentor (and a statistician) <u>how you will deal with missing data</u> in the analysis.

Further Statistical Analysis will depend on your primary research question and study design. It is a good idea to consult with your mentor and a statistician to ensure you are using the correct methods to analyze your data. See: Statistics Support for Residents

If you would like to learn how to analyze your data, there are a number of free online courses that can help teach you more, in addition to courses for using software**, see Chapter 2.**

Machine Learning in Research

Section Contributors
John-William Sidhom

Machine learning is a powerful tool for analyzing multi-dimensional data in the field of medicine. Multi-dimensional data is data that consists of more than one variable or feature. In the context of healthcare, multi-dimensional data could include patient data such as age, gender, medical history, and test results, as well as data about the healthcare system itself, such as hospital performance metrics and drug efficacy data. Analyzing multi-dimensional data can be challenging because it requires taking into account the relationships between multiple variables and their potential interactions.

By using machine learning algorithms, healthcare professionals can identify trends and patterns in complex data sets that may not be immediately apparent to the human eye. This can help them make more informed decisions about patient care, drug development, and other important aspects of healthcare.

Machine learning can be used to analyze multi-dimensional data in a variety of medical applications, including predicting the likelihood of certain outcomes, identifying risk factors, and analyzing large amounts of data to identify trends and patterns. In order to use machine learning to analyze multi-dimensional data, it is important to have a strong understanding of the data and the specific questions you are trying to answer, as well as the appropriate machine learning algorithms and techniques for the task.

In order to begin applying methods in machine learning to analyze multi-dimensional datasets, one can follow the following steps:

1. ***Collect and prepare the data:*** The first step in using machine learning to analyze multi-dimensional medical data is to collect and prepare the data for analysis. This may involve cleaning and preprocessing the data to ensure that it is in a usable format, as well as selecting specific data points or variables/features that you want to focus on. Notably, understanding the different types of variables/features and how they are classified is important for choosing an appropriate machine learning model that can accommodate these types of variables.
   a. *Continuous variables*
   b. *Categorical variables*
   c. *Ordinal variables* are variables that can be ordered or ranked. These variables are similar to categorical variables, but the categories have a specific order or ranking. An example of an ordinal variable in the medical field is the stage of a cancer diagnosis, where "stage 1" is ranked lower than "stage 2" and "stage 3."

2. ***Choose a machine learning algorithm:*** There are many different machine learning algorithms that can be used to analyze multi-dimensional medical data, each with its own strengths and weaknesses. Some common algorithms include decision trees, random forests, and support vector machines. It is important to choose an algorithm that is well-suited to the type of data you are working with and the specific questions you are trying to answer. In the field of medicine, machine learning models are often used to perform either classification or regression tasks. Understanding the differences between these two types of tasks can be helpful for selecting the appropriate machine learning model and interpreting the results of an analysis. Classification models are well-suited for tasks that involve predicting categorical outcomes, while regression models are better suited for tasks that involve predicting continuous values.

   a. Classification tasks involve predicting which category or group an observation belongs to. For example, a classification model might be used to predict whether a patient has a certain disease based on their medical history and test results. Classification models can be binary, where the model predicts between two categories (e.g., "disease" or "no disease"), or multi-class, where the model predicts among more than two categories (e.g., "disease A," "disease B," etc.). Examples of machine learning models for classification tasks include:

      i. *Logistic regression:* Logistic regression is a type of linear model that is used for binary classification tasks, where the model predicts between two categories (e.g., "disease" or "no disease").

      ii. *Decision trees:* Decision trees are a type of model that uses a tree-like structure to make predictions. Each branch of the tree represents a decision based on a certain feature or variable, and the leaves of the tree represent the predicted class. Decision trees can be used for binary or multi-class classification tasks.

      iii. *Random forests:* Random forests are an ensemble learning method that involves training multiple decision trees and combining their predictions to make a final classification. Random forests are often more accurate than individual decision trees and are well-suited for multi-class classification tasks.

      iv. *Support vector machines (SVMs):* Support vector machines are a type of model that uses a hyperplane to separate different classes in a feature space. SVMs are effective for both binary and multi-class classification tasks and can be used with both linear and non-linear data.

      v. *Neural networks:* Neural networks are a type of machine learning model that are inspired by the structure and function of the human brain. They can be used for a wide range of classification tasks, including image classification and natural language processing.

   b. Regression tasks involve predicting a continuous value. For example, a regression model might be used to predict a patient's blood pressure based on their age, weight, and other factors. Regression models can be linear, where the relationship between the variables is assumed to be linear, or nonlinear, where

the relationship between the variables is more complex. Examples of machine learning models for regression tasks include:

      i. *Linear regression:* Linear regression is a type of model that assumes that the relationship between the variables is linear. It can be used to predict a continuous value such as blood pressure based on one or more independent variables, such as age and weight.

      ii. *Ridge regression:* Ridge regression is a type of linear regression that adds a regularization term to the model to prevent overfitting. It can be used to predict patient outcomes or other continuous values in the medical field, particularly when the number of features in the data set is large.

      iii. *Lasso regression:* Lasso regression is another type of linear regression that adds a regularization term to the model to prevent overfitting. It can be used to predict patient outcomes or other continuous values in the medical field, and can be particularly useful for identifying the most important features in the data set.

      iv. *Decision trees:* Decision trees can also be used for regression tasks in the medical field, in which case they make predictions about a continuous value such as patient survival time rather than a categorical value.

      v. *Random forests:* Random forests can also be used for regression tasks in the medical field, in which case they combine the predictions of multiple decision trees to make a final prediction. Random forests are often more accurate than individual decision trees and are well-suited for regression tasks with complex relationships between the variables.

3. **Train the model:** Once you have chosen an algorithm, the next step is to train the model on the data. This involves feeding the data into the model and adjusting the model's parameters until it is able to accurately predict the outcomes of the data.

4. **Test the model:** After the model has been trained, it is important to test its accuracy by using it to make predictions on a separate set of data. This will allow you to determine how well the model is able to generalize to new data, and make any necessary adjustments to improve its performance.

5. **Use the model to make predictions:** Once the model has been trained and tested, you can use it to make predictions on new data. This may involve using the model to predict the likelihood of certain medical outcomes or to identify trends or patterns in the data.

To implement these machine learning models, there exists a wide variety of **software packages** written across multiple programming languages. Some popular options include:

- **scikit-learn:** scikit-learn is an open-source library for machine learning in Python. It offers a wide range of machine learning algorithms and tools for preprocessing, cross-validation, and model evaluation.

- **TensorFlow:** TensorFlow is an open-source library for machine learning developed by Google. It is widely used for deep learning tasks, such as image and natural language processing.

- **Weka:** Weka is a collection of machine learning algorithms and tools for data mining and predictive modeling. It is written in Java and offers a user-friendly interface for model training and evaluation.
- **R:** R is a programming language and software environment for statistical computing and graphics. It has a large community of users and a vast array of packages for machine learning, including tools for classification, regression, clustering, and more.
- **Microsoft Azure:** Microsoft Azure is a cloud-based platform that offers machine learning tools and services for data analysis and predictive modeling.

If you would like to learn more about Machine Learning in Healthcare, see the following online course:
https://www.coursera.org/learn/fundamental-machine-learning-healthcare

See also the section in Chapter 2 on the Mount Sinai Levy Library and Instructional Technology Group Guide to Artificial Intelligence in teaching and learning (https://libguides.mssm.edu/ai) as well as other resources from the Levy Library.

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Chapter 8:

Disseminating your Research Findings

How to Write an Abstract for an Academic Conference - General Guide

Chapter Contributors
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Residents in Internal Medicine at the Icahn School of Medicine at Mount Sinai are encouraged to disseminate their scholarly work through presentations at internal and national conferences. In this section of "The Research Toolkit'', we outline the processes involved in writing an abstract for a conference, and specific guidance relating to four commonly submitted abstracts: (a) original clinical study; (b) curriculum development project, (c) quality improvement project, and (d) case report.

Common Guidance for Preparing Any Abstract for a Scientific Conference

Step 1: Talk with your faculty research mentor
- Discuss your interest in presenting your scholarly activities at a conference with your research mentor.
- Ask your mentor which conference would be the most appropriate venue for your abstract submission.
- In addition to asking your mentor for advice, other things to consider when deciding on which conference to submit your abstract are:
  o Will the work be of interest to the audience at the meeting?
  o Does the conference provide networking / collaborating opportunities?
  o Will presenting at the conference help advance your career goals?
- Discuss authorship and author order with your mentor.

> *Important notes regarding authorship:*
> *Typically the first author is the person who did most of the work on the project, the second author is usually the person who contributed the next most significantly.*
>
> *The last author is usually the supervising faculty member.*
>
> *If a statistician was involved in planning the study or analyzing the data, you should ask them if they would like to be a co-author on your abstract.*

> *The research mentor may recommend that you include other authors who contributed to various parts of the project. Ask the mentor in what order these individuals should be listed.*
>
> *Do not add an author without obtaining their permission.*
>
> *All authors must be given the opportunity to review the abstract, confirm that they accept co-authorship, and provide feedback prior to submission (see below).*

Step 2: Regulatory Approval
- Make sure you have IRB approval for any research study before starting the project, or quality committee approval for a quality improvement project.
- A case report (one case) with no patient identifiers usually does not require IRB approval. Some conferences require patient consent for case reports.
  The Mount Sinai consent form can be found here: PPHS Guidance and Policies | Icahn School of Medicine under "Authorization for Release of PHI for Scientific Publication rev.1.18"

- Scan and save the consent form in the media section of the patient's electronic medical record.
- A case series (more than one case) may require IRB approval. For more information, see "Case Reports and Case Series Guidance" under "General Guidance" https://icahn.mssm.edu/research/pphs/guidance

Step 3: Plan Ahead
- Do not wait until the last minute to start writing your abstract – you need to give your mentor and co-authors time to read and edit your abstract.
- Different co-authors will have different expertise and perspectives that will enhance the abstract.

Step 4: Read the Instructions and Rules on the Conference Website
- Every conference has different instructions, rules, and requirements.
- Well in advance of the abstract deadline, create an account, and go through the submission steps to check the requirements.
- Check:
  - The word / character limit of the titles and abstract body.
  - If the abstract should be structured or unstructured.
  - Whether tables or figures are allowed.
  - If references should be included.
  - If an author needs to be a society member, or a sponsor is needed.
  - The rules regarding previous presentations of the data, and any embargoes.
  - If there are any other requirements for submission.

Step 5: Before you Start Writing
- If you have not previously written a conference abstract, it is a good idea to look at the abstracts from previous years, which are available on the conference/ society website, to have examples of how they are composed.

Step 6: Mentor / Co-Author Review and Feedback on the Abstract Draft
- Send the draft of your abstract to your research mentor for review and editing.
- Once reviewed by your research mentor, send it to all other potential authors for review and editing / approval.
- Make sure to give your mentor and co-authors time to review the abstract and provide edits / feedback – ideally, at least two weeks before the abstract deadline.
- Ask for co-author feedback by a certain date – ideally at least a week before the abstract deadline, so there is time to incorporate their edits.
- Ask co-authors how they would like their name to appear in the abstract, and for their affiliations.
- Ask co-authors if they have any financial disclosures (read the rules of the conference you are applying to, and send the co-authors the instructions for disclosures and potential conflicts of interest) – every conference has different rules regarding disclosures.
- Ask co-authors if they have any grants / funding sources that should be included.

Original Clinical Research Study Abstract

Writing the Abstract

Even if unstructured, the abstract should follow the general IMRD format:
- ▪ Title
- ▪ **I**ntroduction / Background including the Hypothesis / Purpose;
- ▪ **M**ethods;
- ▪ **R**esults;
- ▪ **D**iscussion / Conclusions

- Title:
    - o The title should be easy to understand (avoid jargon), accurate and reflect the key purpose, or take home message of the research.

- Background / Introduction:
    - o This section should explain why you decided to do the study.
    - o Identify a knowledge gap that your study addresses.
    - o It should include a clear purpose or hypothesis.
    - o When describing an objective / aim, consider "SMART" objectives: **S**pecific, **M**easurable, **A**chievable, **R**elevant, **T**ime bound.

- Methods:
    - o This section describes what you did.
    - o State the type of study (retrospective analysis, cohort study etc), and how the individuals were identified for the study, as well as any inclusion / exclusion criteria.
    - o Include a statement of ethics (IRB) approval.
    - o Briefly describe methods of data analysis / statistical methods used.

- Results:
    - o Begin by describing the study subjects, including the number of subjects, and demographics (either mean values and standard deviation, or numbers [n] with percent).
    - o Present the key findings of the study (look back at your purpose / hypothesis to make sure your results are addressing the purpose of the study).
    - o Avoid sentences stating that groups were significantly different. Instead, include the actual numbers (mean or median, with standard deviation or interquartile range, along with p values if significantly different, or NS [non-significant] if not significantly different).
    - o If you have done more analysis, you do not need to include every piece of data. Just include the most important / relevant findings.

- o   Avoid stating that more data will be presented at the time of the conference – this is usually viewed unfavorably by abstract reviewers.
  - o   Some conferences will allow you to upload a table / figure. Only upload a table / figure if it is necessary, and enhances the abstract. Make sure any tables are clear and easy to interpret.

- Conclusions / Discussion:
  - o   This is usually approximately two sentences.
  - o   The first sentence summarizes the key findings of the study (look back at the hypothesis / purpose of the study).
  - o   The second sentence usually states the interpretation or clinical implications of the findings.

Curriculum Development Project Abstract

Writing the Abstract

Even if unstructured, the abstract should follow the general IDCRD format:
- Title
- **I**ntroduction / Background including Purpose;
- **D**evelopment / Methods;
- **C**urriculum;
- **R**esults;
- **D**iscussion.

- Title:
  o The title should be easy to understand (avoid jargon), accurate and convey the key information regarding the setting, the type of curriculum, and learners.

- Introduction / Background:
  o Explain the importance of the curriculum from a local or national perspective.
  o Describe the need or knowledge gap that the curriculum addresses at a local and / or national level. (Addressing a national need or knowledge gap increases the impact of your project).
  o Briefly report if this project was based on previous curricula.

- Development / Methods:
  o This section describes what you did.
  o Describe the process used to develop the curriculum (e.g. needs assessment, literature review, review of other curricula, and the individuals involved).
  o Describe the major decisions made (e.g. content, deliver method, instructional method).
  o If the curriculum includes innovative approaches, this section could briefly include their development.

- Curriculum:
  (*If there is no option to have a separate "Curriculum" section, include these elements in the "Results" section*).
  o Briefly describe the content of the curriculum.
  o Some conferences will allow you to upload a table / figure. Only upload a table / figure if it is necessary, and it enhances the abstract. A table or figure could be used to summarize key contents / structure of the curriculum.
  o Describe curriculum and learner evaluation strategies.

- Results:

- o Briefly describe how and when the curriculum was implemented.
- o Describe data on learner evaluation of curriculum (e.g. satisfaction scores).
- o Report any learner knowledge assessment data (e.g. pre- and post-curriculum test scores).
- o Describe any other curriculum assessment strategies.

- Discussion:
  - o This section should summarize key findings.
  - o Were any revisions made or are any planned?
  - o Include any lessons learned from the development / implementation, and suggestions for others planning a similar undertaking.

Quality Improvement Project Abstract

Writing the Abstract

Even if unstructured, the abstract should follow the general IMRD format:
- Title
- **I**ntroduction / Background including the Hypothesis / Purpose;
- **M**ethods;
- **R**esults;
- **D**iscussion / Conclusions.

- Title:
  o The title should be easy to understand (avoid jargon), accurate and reflect the key purpose, or take-home message of the quality improvement project.

- Introduction / Background:
  o This section should explain the quality improvement problem (e.g. what is the gap between current practice and preferred practice)
  o It should include a clear purpose / aim - what did you hope to achieve?
  o When describing an objective / aim, consider "SMART" factors: **S**pecific, **M**easurable, **A**chievable, **R**elevant, **T**ime bound.
  o Consider adding whether the quality problem is common in other institutions – identifying a problem that occurs outside your own institution increases the impact of your project.

- Methods:
  o This section describes what you did.
  o Include a statement that the project was approved by the Quality Improvement Committee.
  o Briefly describe: (1) the setting; (2) the participants; (3) what intervention was implemented; (4) how it was implemented; (5) how changes were tested and refined (was a PDSA [plan-do-study-act] model used?); (6) how data were analyzed, and any statistical methods used.

- Results:
  o Begin by describing the number of subjects involved in the project, and any other necessary descriptive / demographic data (either mean values and standard deviation, or numbers [n] with percent).
  o Present the key results of the project (look back at your purpose / quality problem you were trying to address to make sure your results are addressing the purpose of the project).
  o Avoid sentences stating that groups were significantly different. Instead, include the actual numbers (mean or median, with standard deviation or

interquartile range, along with p values if significantly different, or NS [non-significant] if not significantly different).

- o If you have done more analysis, you do not need to include every piece of data. Just include the most important / relevant findings.
- o Avoid stating that more data will be presented at the time of the conference – this is usually viewed unfavorably by abstract reviewers.
- o Some conferences will allow you to upload a table / figure. Only upload a table / figure if it is necessary, and enhances the abstract. Make sure any tables are clear and easy to interpret.

- Discussion / Conclusions:
  - o Briefly summarize the key results of the quality improvement project.
  - o Describe any contextual factors that may need to be considered by others considering a similar quality improvement project (e.g. how generalizable is your intervention).
  - o Include any lessons learned from the development / implementation of the project, and suggestions for others planning a similar undertaking.

A Case Report Abstract

Writing the Abstract

Even if unstructured, the abstract should follow the general format of:
- Title
- Background / Introduction including the key interesting aspect of the case;
- Case Description;
- Conclusion / Discussion.

- Title:
  o The title should be easy to understand (avoid jargon), accurate and reflect the key purpose, or take home message of the case report.

- Background / Introduction:
  o This section should briefly set the stage and explain why you decided to write the case report – e.g. the uniqueness, an unusual presentation, a specific clinical challenge.

- Case Description:
  o This section should include:
  (1) The individual – e.g. age, gender, setting (inpatient, outpatient, ER presentation), relevant history, reason for presentation, and relevant exam findings;
  (2) Results of pertinent positive and relevant negative tests (e.g. labs, radiology etc) – include units of measurement for all reported values;
  (3) Outcome of the case.
  o If patient consent was obtained, this should also be stated at the beginning of this section.
  o Some conferences will allow you to upload a table / figure. Only upload a table / figure if it is absolutely essential.
  o All patient identifiers must be removed from any images.
  <u>VERY IMPORTANT:</u> YOU MUST HAVE THE PATIENT'S WRITTEN INFORMED CONSENT TO PUBLISH ANY PATIENT PHOTOGRAPHS / IMAGES.
  The best thing to do is scan the signed consent form into the EPIC media section so it will be easily retrieved if necessary in the future.
  The consent form can be found here:
  ● Authorization for Release of PHI for Scientific Publication rev.1.18

- Conclusions / Discussion:

- o This section needs to include the teaching points / take home message from the case description.
- o Case reports are frequently rejected if there is no clear take home message or teaching point.
- o The discussion should summarize the important findings based on the facts of the case, and clearly state what is conjecture.

References:

1. [Tips for Writing Your First Conference Abstract](#), last accessed April 28th 2023.
2. Writing good abstracts. Alexandrov AV, Hennerici MG. Cerebrovasc Dis. 2007; 23(4): 256-9
3. A suggested outline for writing curriculum development journal articles: The IDCRD format. Reznich CB, Anderson WA. Teach Learn Med. 2001; 13(1): 4-8.
4. How to write an abstract that will be accepted for presentation at a national meeting. Pierson DJ. Respir Care 2004; 49(10):1206-12.
5. How to write up your quality improvement initiatives for publication. Wong BM, Sullivan GM. J Grad Med Educ 2016; 8(2):128-133.
6. Centers for Disease Control and Prevention (CDC). CDC Guideline – How to Write Smart Objectives; CDC-RFA-DP17- 1701. Atlanta, GA: CDC; 2020. [Writing SMART Objectives | cdc.gov](#), last accessed April 28th 2023.
7. ICJME Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Activities in Medical Journals, Updated December 2021. [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals | ICMJE](#), last accessed April 28th, 2023.

Poster Presentations for Academic Meetings

Presenting a poster at an academic meeting gives you many opportunities, such as associating your name with a field, developing your academic reputation, meeting people who are interested in the subject of your poster presentation, and expanding your professional network for future collaborations and job opportunities.

Before Starting To Create Your Poster
The Logistics

Read the email that you received to inform you that your abstract was accepted for a poster presentation. It contains important information that you need before you start creating your poster.

1. **Poster Dimensions and Orientation.**
   ▪ Every meeting has different requirements.
   ▪ It is important to know the dimensions of your poster (check units: inches or metric), and orientation (landscape or portrait) before you begin.
   ▪ If you use the wrong dimensions when creating your poster:
     o Your poster may not fit on the display board for in person meetings.
     o You will have to go back and rearrange everything on your poster to fit the correct template.
     o It may be rejected or distorted when you upload it to the meeting website.

2. **Presentation format.**
   ▪ Is it an E-Poster, and Printed Poster or both?
   ▪ If it is a printed poster, are there requirements regarding material (paper / fabric).
     o Note, a fabric poster can be folded and carried in a bag / suitcase.
   ▪ If it is an E-Poster, check:
     o Where you upload it;
     o The accepted file formats (e.g. .ppt, .pdf);
     o Restrictions on the size of the file.
     o Is it an asynchronous, synchronous, or blended presentation?
   ▪ If you are doing an asynchronous presentation of your poster, check:
     o If the recording is audio / video or both;
     o The maximum time length of the recording;
     o Whether you record it on your personal device and upload it, or if the conference has a specific website for the recordings;
     o The file formats and sizes accepted, if you are recording on your own device.

3. **Are there any specific elements that need to be included on the poster?**
These vary by conference, and may include:

- The poster number, which usually goes at the top of the poster beside the title;
- Author disclosures – if this is required ask co-authors for any disclosures;
- A QR code – this should be generated by the conference website.

4. Dates and Deadlines.
Make sure you know the dates of:
- The academic meeting;
- The E-Poster upload deadline - this may be 2 weeks or more before the conference date;
- Audio / video recording upload deadline, if applicable;
- Your poster display times;
- Your live presentation dates – You should be present at your poster or online at these times.

5. Allow Time for Creating, Editing, Printing, and Shipping.
When you know the dates and deadlines, allow time:
- To create an effective poster;
- For your mentor and co-authors to review and provide feedback;
- To have the poster printed and shipped to you or the conference location.

6. Where to Print Your Poster.
- Generally choose matte finishes over glossy finishes, as glossy finishes reflect light and make it hard to read your poster.
- You can get your poster printed at any of the following:
  (1) Mount Sinai Digital Media Center.
  [Digital Media Center | Icahn School of Medicine](#)
  (2) Onsite at the conference location – check the meeting website
  (3) An external poster printing company, such as:
  [Poster Nerd](#)
  [Banners and Posters Printed | The UPS Store](#)
  [Poster Printing & Custom Poster Prints | FedEx Office](#)
  [PhD Posters](#)

Important Note on Poster Printing:
Whichever printing method you use, make sure you know the turnaround time required for your poster to be printed and shipped to the location so it arrives on time.

Poster Templates and Layout

1. **Mount Sinai Poster Templates.**

Mount Sinai Poster templates (including logos) can be found under "Poster Printing" at:
[Digital Media Center | Icahn School of Medicine](#), last accessed April 18th, 2023

Poster Templates can also be found under "Templates", "Other Templates" on the Mount Sinai Brand Center (Log in using your Mount Sinai username / password).
[Mount Sinai Brand Center](#), last accessed April 19th, 2023

Important Note on Using the Mount Sinai Templates:
Do not fill in all of the sections of the Mount Sinai Poster Templates, like a form.
Use the templates for the size dimensions, color scheme and logos.

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2. **Other Templates: Traditional Poster Templates and #BetterPoster**

You do not have to use the Mount Sinai Templates when creating a poster, you can download free traditional poster templates from other sites, including:
[Scientific Poster PowerPoint Templates | PosterNerd](#), last accessed April 19th, 2023.

Recently there has been a movement to create better scientific posters with different layouts:
[Mike Morrison](#), last accessed April 28th, 2023.

- If you decide to use a less traditional poster template, make sure your mentor is in agreement, as they may not be familiar with these layouts.

Templates for these less traditional / billboard posters can be found at:
[Billboard-Style Scientfic Poster Templates | PosterNerd](#), last accessed April 19th, 2023.
[betterposter-template-landscape.pptx](#), last accessed April 19th, 2023.

💡 ***General Tips Regarding Dimensions of the Poster Template:***
- *The dimensions are listed as width x height (48 x 36 = landscape orientation, while 36 x 48 = portrait orientation)*
- *You can scale up or down a poster if you choose the correct dimension ratio:*
  - *48 x 36 template (1.3:1 ratio) can be used for 56 x 42 or 64 x 48 posters*
  - *48 x 24 template (2:1 ratio) can be used for 72 x 36 or 84 x 42 posters*
  - *36 x 24 template (1.5:1 ratio) can be used for 54 x 36 or 72 x 48 posters*

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3. **Mount Sinai Logos.**

You will find Mount Sinai Logos under the "Brand Assets" and then "Logos" tab of the [Mount Sinai Brand Center](#)

Usually you will use one of: "Icahn School of Medicine at Mount Sinai", or the "Mount Sinai" Logo. If in doubt, ask your mentor.

Important Note on Using the Mount Sinai Logos:
When using Mount Sinai logos, do not change the colors or dimensions of the Mount Sinai Logo that you take from the Brand Center or Poster Template, and only use it once on your poster (at the top, beside the title).

Making Your Poster

When you start to make your own poster, remember that it is a visual representation of your work, and does not need to contain every piece of data that you have.
A poster needs both content and visual appeal. People spend seconds glancing at posters, so first impressions count. Ideally, you want someone at the conference to notice your poster, stop, and talk with you to find out more.

1. **Look (critically) at other posters to get ideas on layout and formatting.**

If you have not previously created a poster for a scientific / medical conference, it is a good idea to look at the conference website for examples of previous poster presentations, particularly award winning posters.
However, remember that many posters presented at meetings are not well organized or easy to read. Consider the criteria in this 60-Second Poster Evaluation by George R. Hess, when evaluating the effectiveness of posters:
https://sites.google.com/ncsu.edu/effective-posters/home?pli=1, last accessed April 28th, 2023.

The Association for Medical Education in Europe (AMEE) Guide 40 contains examples of posters with critiques on various elements of the poster (see bottom of page 6 to page 10 of this link):
> Creating effective poster presentations: AMEE Guide no. 40, last accessed April 28th, 2023

2. **Your Take Home Messages:**
- Decide on one or two key points that you want your audience to take home from viewing your poster.
- Once you have decided on these key points, plan a clear story, and design **all** of the elements of your poster around your key messages.

3. **Consider The Audience:**
- Conference attendees will be at different levels of training, have different expertise, and knowledge of the subject of your scholarly activities.
- Avoid a lot of jargon and abbreviations, and adjust technical terms to the anticipated audience.

4. **Poster Organization.**
- It is important that your poster is well organized and easy to follow.
- Posters are generally organized in a similar way to your abstract.

Original Research and Quality Improvement posters are generally structured in the IMRD format:
- **I**ntroduction / Background including the Hypothesis / Purpose;
- **M**ethods;
- **R**esults;
- **D**iscussion / Conclusions

<u>Curricular Development Posters</u> generally follow the IDCRD format:

- **I**ntroduction / Background including Purpose;
- **D**evelopment / Methods;
- **C**urriculum;
- **R**esults;
- **D**iscussion.

<u>Case Report Posters</u> are generally structured as follows:

- Background / Introduction including the key interesting aspect of the case;
- Case Description;
- Conclusion / Discussion.

- See the Chapter on Writing an Abstract for a Scientific Conference of "The Research Toolkit" for more information on the contents of these sections.
- Below is general guidance for all poster types, and then specifically how to incorporate these sections into original research, quality improvement, curricular development and case report posters.

For all poster types:
- Minimize the amount of text used.
- Keep the font large, even for charts / graphics and tables.
- Do not paste your entire abstract into the poster (even if it is in the template).
- Put your contact information (email or social media handle) somewhere on the poster, either at the top with the author affiliations, or at the end (bottom left) of the poster. You can also bring business cards to a conference.

General Tip on Organizing Your Poster.
Order the poster elements so the story begins at the top left and ends on the bottom right of the poster (boxes represent areas of poster content for a traditional 3- or 4-column poster layout, the arrows represent the direction in which a viewer will read your poster).
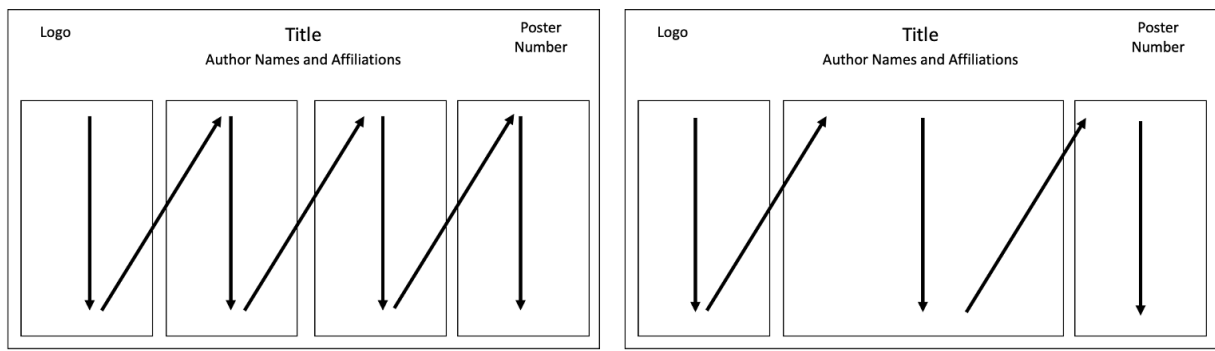
- Keep charts clear, simple, and make any text large.
- Include titles on graphs / images, and use captions to briefly explain the graph / image contents.
- Make sure pictures / photos are high-resolution so they do not become pixelated when enlarged.

Important Notes on Graphics:

Patient Photos / Images:
- Patient **consent** is required for the use of patient photos / images.
- Make sure any patient information (e.g. name, initials, address, MRN, date of scan, date of birth) is removed from the image.

Reusing Graphics from Another Publication or Online Source:
- Check the **copyright** of the image you want to use. You can often easily get permission to use an image from an academic journal for educational / academic purposes. The information on how to do this is usually on the website accompanying the journal article, and it is usually free.
- For **freely-available open-copyright images**, see the resources at the Mount Sinai Levy Library Finding Images for Lectures and Publications - Biomedical Images - Levy Library Guides at Icahn School of Medicine at Mount Sinai, last accessed April 28th, 2023.
- Always **attribute the image you use to the source**, including the Image Title, Creator, Source / website, and license.

Tips for Bringing your Poster to an In-Person Conference:

If flying, do not check-in your poster as luggage:
- Posters have a habit of getting lost when checked in.
- Keep your poster with you, and do not leave it at airport security / the airport coffee shop.

Have a hard poster carrying case or tube for paper posters:
- Do not fold your paper poster in your bag / suitcase
- Protect it from damage after all the work you put into it.
- Carrying cases can often fit a few posters, so one person can bring a few people's posters to a meeting (and a different person can bring them back).

Original Research / Quality Improvement Poster Components
Title – Largest Font (~85 pt – visible from ≥ 5 meters away) Make the title short, clear, direct and active
Authors and Affiliations – Large Font ~56 pt – visible from ≥ 2 meters away)
Introduction – Subtitle ~36pt - Provide a little background to introduce the importance of the key questions / hypothesis you will be answering. - Consider using bullet points, rather than blocks of text. - Font size at least 24 pt (visible from 1.5-2m away)
Objective / Hypothesis / Aims – Subtitle ~36pt - You can have a separate section or box to highlight the main objective / hypothesis / aims. - Clearly state the main objective, hypothesis or aims of your study / presentation. - Keep them brief, use bullet points or numbers. - Font size for text at least 24 pt (visible from 1.5-2m away)
Methods – Subtitle ~36pt - Provide a brief overview of the methods used. - Present methods as short bullet points or as a graphic. - Keep your key, take home points in mind, and only present methods related to these key points. - Font size for text at least 24pt (visible from 1.5-2m away)
Results – Subtitle ~36pt - Stay focused on the key results that address your stated objective, hypothesis, or aims. - Not every parameter needs to be included in the results. - Minimize text, consider diagrams / charts / tables that may more succinctly summarize a key aspect of your work. - Make graphics large, make labels at least font size 18pt, consider making all text horizontal (including vertical axis labels). - Put titles on all charts / tables / figures in large size font ~36pt. - You can write a short one line explanation of the key results in a chart. - You can provide non-critical information verbally to someone viewing your poster. - Font size for text at least 24pt (visible from 1.5-2m away)
Conclusions – Subtitle ~36pt Briefly summarize: - Your key findings - The key take-home messages - The implications of your findings / lessons learned / generalizability - Font size for text at least 24pt (visible from 1.5-2m away)
Acknowledgements / Funding / Disclosures – Subtitle ~36pt - Include an acknowledgement of anyone who helped but is not an author

- Add funding sources (ask your mentor if you are unsure if there was funding)   - Add any disclosures
References – Subtitle ~36pt   - Include one or two key references

Curricular Development Project Components
Title – Largest Font (~85 pt – visible from ≥ 5 meters away)   Make the title short, clear, direct and active
Authors and Affiliations – Large Font ~56 pt – visible from ≥ 2 meters away)
Introduction – Subtitle ~36pt   - Provide a little background to introduce the importance of the project, and need.   - Consider using bullet points, rather than blocks of text.   - Font size at least 24 pt (visible from 1.5-2m away)
Objective – Subtitle ~36pt   - You can have a separate section or box to clearly state the goals of the project.   - Keep them brief, use bullet points or numbers.   - Font size for text at least 24 pt (visible from 1.5-2m away)
Development / Methods – Subtitle ~36pt   - Provide a brief overview of the methods used in the development of the curriculum.   - Present methods as short bullet points or as a graphic.   - Keep your key take-home points in mind, and only present methods related to these key points.   - Font size for text at least 24pt (visible from 1.5-2m away)
Curriculum - Subtitle ~36pt   - This can be a separate section or incorporated into the results section.   - Consider using graphics / diagrams rather than blocks of text.   - If text is used, use bullet points rather than sentences.   - Font size for text at least 24pt (visible from 1.5-2m away)
Results – Subtitle ~36pt   - Stay focused on the key results that address your stated objectives   - Not every parameter needs to be included in the results.   - Minimize text, consider diagrams / charts / tables that may more succinctly summarize a key aspect of your work.   - Make graphics large, make labels at least font size 18pt, consider making all text horizontal (including vertical axis labels).   - Put titles on all charts / tables / figures in large size font ~36pt.   - You can write a short one line explanation of the key results in a chart.   - You can provide non-critical information verbally to someone viewing your poster.   - Font size for text at least 24pt (visible from 1.5-2m away)
Conclusions – Subtitle ~36pt   Briefly summarize: - Your key findings

- The key take-home messages
- The implications of your findings / lessons learned / applicability
- Font size for text at least 24pt (visible from 1.5-2m away)
Acknowledgements / Funding / Disclosures – Subtitle ~36pt
- Include an acknowledgement of anyone who helped but is not an author
- Add funding sources (ask your mentor if you are unsure if there was funding)
- Add any disclosures
References – Subtitle ~36pt
- Include one or two key references

Case Report Poster Components
Title – Largest Font (~85 pt – visible from ≥ 5 meters away) Make the title short, clear, direct and active
Authors and Affiliations – Large Font ~56 pt – visible from ≥ 2 meters away)
Introduction – Subtitle ~36pt - Provide a little background to introduce the importance of the case. - Consider using bullet points, rather than blocks of text. - Font size at least 24 pt (visible from 1.5-2m away)
Objective – Subtitle ~36pt - Clearly state the main objective in describing the case - Font size for text at least 24 pt (visible from 1.5-2m away)
Case Description – Subtitle ~36pt - Stay focused on the pertinent points of the case. - Not every parameter needs to be included in the results. - Minimize text, consider diagrams / charts / tables that may more succinctly summarize key findings – e.g. a graph for serial lab values, or a table for lab results rather than writing in a block of text. - Make graphics large, make labels at least font size 18pt, consider making all text horizontal (including vertical axis labels). - Put titles on all charts / tables / figures in large size font ~36pt. - You can write a short one line explanation of the key findings in a chart / image / graphic. - You can provide non-critical information verbally to someone viewing your poster. - Font size for text at least 24pt (visible from 1.5-2m away)
Conclusions – Subtitle ~36pt Briefly summarize: - The key teaching points / take-home messages from the case. - Font size for text at least 24pt (visible from 1.5-2m away)
Acknowledgements / Funding / Disclosures – Subtitle ~36pt - Include an acknowledgement of anyone who helped but is not an author

- Add funding sources (ask your mentor if you are unsure if there was funding)
- Add any disclosures
References – Subtitle ~36pt
- Include one or two key references

Presenting Your Poster

Presenting your poster allows you to discuss your work with potential collaborators. Giving a great poster presentation can help you build your network and even open up job opportunities.

The Presentation.
- Before presenting your poster, prepare a brief narrative to explain your poster (2 minutes), and practice.
- Briefly explain the main points of why the study was done, guide the viewer through the key elements of the poster, refer to the purpose of each chart / table or diagram before describing the results of the chart.
- You can also use the poster presentation to fill in small pieces of information that you didn't include in the poster.
- If it is asynchronous and you are recording it, check the details before you begin recording. You can <u>sometimes</u> re-do it if you don't like your first / second attempt. However, this is not always the case. Sometimes you are given <u>one chance</u> to record it on the conference website.
- Explain the take home messages, and ask the viewer for any thoughts / clarifications / questions / feedback.
- You can ask the viewer who they are, and where they are from, and if they have a particular interest in the subject of your scholarly work.

Be Prepared to Answer Questions.
- Be friendly, and don't be defensive if someone critiques your work or findings. Acknowledge weaknesses / limitations to your work, and explain why things were done as they were.
- Think about a few questions you might be asked.
- Make sure there is nothing on your poster that you do not understand (e.g. an abbreviation, specific technical or analytical method). If something was done by someone else on the project, then it is ok to say that, and you can offer to put the viewer in touch with the person who did that part of the project.
- If it is a blended virtual meeting, sometimes you may have recorded the presentation ahead of time, and the question and answer session is live on camera, or on a discussion board.

References:
Barker E, Philips V. Creating conference posters: Structure, form and content. J Perioper Pract. 2021; 31(7-8):296-299.
Boullata JI, Mancuso CE. A "How-To'' Guide in Preparing Abstracts and Poster Presentations. Nutr Clin Pract. 2007; 22(6):641-6

Smith PEM, Fuller G, Dunstan F. Scoring posters at scientific meetings: first impressions count. J R Soc Med. 2004; 97(7): 340-1

Hess GR, Tosney KW, Liegel LH. Creating effective poster presentations: AMEE Guide no. 40. Med Teach. 2009; 3194):319-21.

Kraussman PR, Cox AS. Effective Poster Presentations. The Journal of Wildlife Management. 2018; 82(5):887–888; 2018

Miller JE. Preparing and Presenting Effective Research Posters. Health Serv Res. 2007 Feb; 42(1 Pt 1): 311–328.

Wood GJ, Morrison RS. Writing Abstracts and Developing Posters for National Meetings. J Palliat Med. 2011; 14(3): 353-359.

Further Reading:

Hess, G.R., K. Tosney, and L. Liegel. 2014. Creating Effective Poster Presentations. https://sites.google.com/ncsu.edu/effective-posters/home?pli=1, last accessed April 28th, 2023.

Oral Presentations for Academic Meetings

Top scoring abstracts at academic meetings may be chosen for oral presentations. Oral presentations are usually delivered in sessions with a specific theme, and the attendees may have a particular interest or expertise in the subject area.

Giving an oral presentation of your work helps to develop your academic reputation, meet people who are interested in the subject of your work, and expand your professional network.

Before Starting To Create Your Presentation
The Logistics

Read the email that you received to inform you that your abstract was accepted for an oral presentation. It contains important information that you need before you start creating your presentation.

1. **Duration of Presentation.**
   - Oral presentations will usually be 5-10 minutes in length, with additional time for questions from the audience.

2. **Presentation Format.**
   - Usually the presentation will be prepared on [PowerPoint](#).
   - Check the required slide size for the presentation (widescreen 16:9 or normal 4:3), and prepare your slides using the correct slide dimensions. [To change slide size in PowerPoint go to the Design Tab, and see Slide Size on the far right of the toolbar, and change it to the appropriate size].
   - Is the meeting virtual, in-person or hybrid? If it is a virtual or hybrid meeting, check if your presentation is to be pre-recorded, or delivered live.
   - If you are pre recording the presentation, check the website to see if you have to schedule an appointment to record your presentation – Do not wait until the last minute to book your recording slot, as the appointment slots will fill up rapidly.

3. **Are there any specific elements that need to be included in the presentation?**
   These vary by conference, and may include:
   - Author disclosures – if this is required ask co-authors for any disclosures;
   - A slide that says the audience can or cannot take pictures of your slides, or share them on social media.
   - Whether you should put a note on the bottom of each slide that says not to share or post on social media.
   - Any required color scheme – e.g. white or dark background on slides.

4. Dates and Deadlines.
Make sure you know the dates of:
- The academic meeting;
- Your presentation upload date (usually before the day / time of your presentation);
- Recording deadline, if you are pre-recording the presentation.
- Your live presentation dates.

5. Uploading your Presentation.
Usually you will upload your presentation the morning or day before your presentation.
- Check how the presentation is to be uploaded (e.g. on a website, or in a specific room in the conference center, or in the room where you will be delivering the talk).
- If it is not to be uploaded, make sure you have the right adaptors if you are using your own laptop, or have a copy of your presentation on a USB flash drive, or accessible in the cloud.

6. Allow Time for Creating, and Practicing.
When you know the dates and deadlines, allow time:
- To create an effective presentation;
- To practice your presentation with your mentor.

Further Reading:
See the Burroughs Wellcome Fund document on "Communicating Science - Giving Talks" - [Communicating Science: Giving Talks - Burroughs Wellcome Fund](#), last accessed April 28th 2023.

Slide Templates and Layout

1. **Mount Sinai PowerPoint Slide Templates.**

Mount Sinai PowerPoint Slide Templates can also be found under "Templates", "Other Templates" on the [Mount Sinai Brand Center](#) (Log in using your Mount Sinai username / password).
You can choose the Icahn School of Medicine at Mount Sinai Template.

2. **Mount Sinai Logos.**
You will find Mount Sinai Logos under the "Brand Assets" and then "Logos" tab of the [Mount Sinai Brand Center](#)

Usually you will use one of: "Icahn School of Medicine at Mount Sinai", or the "Mount Sinai" Logo. If in doubt, ask your mentor.

Important Note on Using the Mount Sinai Logos:
When using Mount Sinai logos, do not change the colors or dimensions of the Mount Sinai Logo that you take from the Brand Center or PowerPoint Template, and only use it once on any given slide.

Making Your Oral Presentation

When you start to make your own oral presentation, remember that you do not need to include every detail or piece of data from your study. Most people try to say too much.

1. **Your Take Home Messages:**
- Decide on one or two key points that you want your audience to take home from your presentation.
- Once you have decided on these key points, plan a clear story, and design your presentation around your key messages.

2. **Consider The Audience:**
- Conference attendees will be at different levels of training, have different expertise, and knowledge of the subject of your scholarly activities.
- Avoid a lot of jargon and abbreviations, and adjust technical terms and explanations to the anticipated audience.

3. **Organizing your Presentation**
- It is important that your presentation is well organized and easy to follow.
- Remember your slides are as visual aids for your audience to understand your message, not for the presenter to read.

- Suggested organization for an oral presentation:
  o Title slide: Presentation Title, Your Name and Qualifications (+/- mentor's name), and the date.
  o Disclosures Slide (and any other conference specific required slides)
  o Opening Slide(s):
    ▪ Briefly include the context (background) and need to do your work (tailor it to the expected audience);
    ▪ The objective / aim of your work, and hypothesis.
  o Preview slide then outlines the structure of the body of your talk.
  o Body of Talk:
    ▪ Think of your main take home messages and present the necessary methods and results to support your take home messages.
  o Review slide:
    ▪ Summarizes your findings and your take home message.
  o Conclusions Slide:
    ▪ Complications of your work / results / next steps.
  o Final Slide:
    ▪ Usually an acknowledgement slide, with your contact information (email address or social media handle).

4. **Content:**
- Make sure you understand the content of your slides, so that if someone asks you to clarify something you are able to explain it.

5. **Tips for making your slides:**
   - Keep the slides simple
   - Avoid a complicated background that might make it hard to read your slides.
   - Keep the font large (for medium sized rooms the minimum should be 28pt for text on the body of the slide, and 36pt for the slide title), even for charts / graphics and tables.
   - Use a common font type (that will be recognized by all computers, e.g. Arial), and do not change it unnecessarily between slides.

   - Minimize the amount of text; if possible use graphics instead of text.
   - Consider the 5x5 Rule: No more than 5 bullets per slide, and no more than 5 words per bullet.

   - Every slide should have a clear purpose.
   - Make slide titles active with the key message of the slide.
   - Put 1-2 references on the bottom of slides.

   - People may have difficulty discerning between green and red, so avoid using red vs green to show different groups in charts.
   - Blue and red placed side by side can appear blurred.
   - People have difficulty focusing on cobalt blue, so it is best avoided.

Important Notes on Graphics:

Patient Photos / Images:
   - Patient **consent** is required for the use of patient photos / images.
   - Make sure any patient information (e.g. name, initials, address, MRN, date of scan, date of birth) is removed from the image.

Reusing Graphics from Another Publication or Online Source:
   - Check the **copyright** of the image you want to use. You can often easily get permission to use an image from an academic journal for educational / academic purposes. The information on how to do this is usually on the website accompanying the journal article, and it is usually free.
   - For **freely-available open-copyright images**, see the resources at the Mount Sinai Levy Library [Finding Images for Lectures and Publications - Biomedical Images - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#), last accessed April 19th, 2023.
   - Always **attribute the image you use to the source**, including the Image Title, Creator, Source / website, and license.

Delivering your Presentation

Before the Presentation:
- Practice your presentation ahead of time, make sure you stick to the time.
- Practice speaking clearly and relatively slowly.
- Get feedback from your mentor / colleagues.
- When you have uploaded your talk onto the computer that will be used for the presentation, go through the slides to ensure nothing has become distorted.
- If you have any animations, make sure they are working correctly.
- Find the room where your presentation will take place, so you do not get lost or are late for your presentation.

On the Day:
- Introduce yourself to the person / people chairing the session.
- Check the presentation set up:
    o Is there a microphone at the podium or connected to you?
    o Is there a monitor in front of you where you can see your slides?
    o Is there a pointer / slide advancer, or will you use the computer mouse?
    o Is there a timer, or will the chair indicate when you have a minute left to wrap up your presentation?
- Do not read directly from the slides or from your notes.
- Make eye contact with the audience.
- Thank the audience at the end, and invite questions / comments.

Be Prepared to Answer Questions.
- Be prepared to answer questions regarding any aspect of your presentation.
- Be friendly, and don't be defensive if someone critiques your work or findings.
- Thank the audience for any questions or comments.
- Acknowledge weaknesses / limitations to your work if pointed out, and explain to the best of your ability why things were done as they were.
- If you do not know the answer to a question, you can either: (1) state that you are unsure but you will look it up or discuss it with your mentor; (2) speculate on what the answer may be, if you feel confident in discussing the field.

References:

Blome C, Sondermann H, Augustin M. Accepted standards on how to give a Medical Research Presentation: a systematic review of expert opinion papers.
GMS J Med Educ. 2017; 34(1): Doc11.

Collins J. Education Techniques for Lifelong Learning. Making a PowerPoint Presentation. Radiographics; 24(4); 1177-83.

Doumont, J., ed. English Communication for Scientists. Cambridge, MA: NPG Education, 2010. Unit 4: Giving oral Presentations. English Communication for Scientists | Learn Science at Scitable, last accessed April 28th , 2023.

Harolds JA. Tips for Giving a Memorable Presentation, Part IV: Using and Composing PowerPoint Slides. Clin Nucl Med. 2012; 37(10); 977-980.

Wellstead G, Whitehurst K, Gundogen B, Agha R. How to deliver an oral presentation. Int J Surg Oncol (N Y). 2017;2(6):e25.

Further Reading:

Kosslyn SM, Kievit RA, Russell AG, et al. Power PowerPoint® presentation flaws and failures: a psychological analysis. *Front Psychol* 2012;3:230.

How to Write and Submit a Research Manuscript

If you have never written a research manuscript, it can seem like a daunting task. If your skills on Microsoft Word could use help see the [PEAK Training Videos](#).

The purpose of writing up your scholarly work is to add something meaningful to the scientific or medical literature. In your paper, it is important to clearly explain your research question

Important Point: Don't ever plagiarize someone else's work.
> **It's ok to include someone else's ideas in your work, as long as you cite their work.**
> **If you copy something verbatim, put quotation marks around it, and cite the source.**

Before you start writing:
· Review your results with your mentor, or the research team
· Evaluate if there is any data you are missing, and if you can address it
· Have a clear understanding of the results of your study
· Discuss potential journals that would be a good fit for your research (see Chapter on Selecting a Journal for your Publication)
· Read the Author Submission Guidelines for that journal, and any specific requirements
· Discuss **author order** with your mentor – don't ever assume the order
· Check and discuss the Article Processing Fees / Publication Costs with your mentor
· If you have figures, check if color figures cost more than grayscale – discuss with your mentor
· Ask your mentor at what point do they want to see the first draft of the manuscript (sometimes they will want to review the methods, results, figures and tables before you write anything else)

When you start writing:
· <u>Start with the results and the methods</u> – these sections are the easiest to start with, as they describe what you did, how you did it, and what you found.
· While writing the methods and results sections, generate any necessary Tables or Figures.
· The first draft does not have to be perfect, it will likely be edited a number of times before it gets submitted.
· Once you have the methods and results sections completed, share with your mentor for feedback.
· Remember, the methods should have sufficient detail that someone else can replicate your work if they choose to do so, and they can analyze if you used the appropriate methods for your study.
· <u>Then write the introduction</u> – this sets the stage for how your study fits into the published literature, and why you decided to do this study. The introduction should not be an exhaustive literature review, but should include a brief background of the subject;

specific aspects of the subject that relate to your research, and the knowledge gap or question you aimed to address. Include relevant references that help explain the question you set out to answer. At this point also include the references in your references managing software (see section on Reference Managers in the Levy Library Resources Chapter).

If you find yourself stuck while writing the introduction, read the introductions of other recent papers published in the journal you plan to submit to. They don't have to be on the same topic as yours but they will give you an idea how to structure an introduction.

· <u>When adding references make sure you have read the article to be sure it supports whatever statement you are using it to support</u>**.** You can consider including the PubMed ID number (PMID) in the text at this point, rather than actually adding the reference with the reference manager.

· <u>Then write the discussion</u> –
- o One way to do this is to go back to your results section and write down the **key findings, and any unexpected findings**, think about how your results add to what is already known in the field (which should be in your introduction).
- o Think about any specific strengths (e.g. large diverse patient population), and weaknesses of your study.
- o The first paragraph of your discussion will often be a summary of the key findings (**don't repeat the results section** in the discussion).
- o Use each of your key findings or unexpected results to generate 4-5 other paragraphs, with each paragraph addressing one of these aspects, and a brief discussion of why it's interesting in the context of the published literature.
- o Include a paragraph with strengths and weaknesses of your study
- o Have a concluding paragraph which states the key take home message, why it's important, and possible future questions.

· <u>Finally, write the abstract</u> including the most important elements from the Introduction, Methods, Results, and Discussion / Conclusions.

· **Check the word limit of the journal, and make sure you are not over the limit.**
· **Send the draft to your mentor to read.**
· Expect that there will be a number of drafts and edits prior to submission. <u>Ask your mentor when they think they will get it back to you</u> (and then <u>follow up</u> with an email reminder a day or two after that deadline).

Before you submit:
· Check everyone's name is spelled correctly, and that their titles and affiliations are correct
· Ask your mentor who should be the corresponding author (this is the person who will receive all communications regarding the submission at all stages).
· Ask if any funding needs to go in the acknowledgements section.
· Ask if there are any conflicts of interest that need to be disclosed.

· Ask your mentor if they want to write the cover letter, or if you can draft it and send it to them for review and signature. (The corresponding author will usually be the letter writer). **Check the journal submission website for any specific statements that need to be in the cover letter.**

When you submit:
· Follow the journal submission website.
· You may be asked to name potential reviewers, or exclude potential reviewers – ask your mentor

If you get rejected:
· **Don't worry!!**
· If you received reviewer comments, read them and discuss with your mentor if any can be addressed before you submit elsewhere (you may get the same reviewer again at another journal, so addressing their previous critiques will be viewed favorably if they re-review)
· Reformat for the next journal according to their submission guidelines.

If you get resubmit after revisions:
· **Check the date they want the revisions returned by. If for some reason you cannot make the deadline, email the handling editor as soon as possible to ask for an extension. <u>Tell the team members the turnaround time.</u>**
· This is an opportunity, as there is a high chance if you can address the reviewers' comments your article will be accepted.
· **Make a point by point list of all of the reviewers' comments** – as Reviewer 1, comment 1, comment 2, comment 3 etc (and the same for the other reviewers). Copy and paste the reviewers' comments exactly as they are into this document.
· Go through each point and discuss with your mentor how best to address each comment, and write responses as you edit the manuscript (this will be your rebuttal letter or "response to reviewers" letter).
· **Tip: When addressing reviewers' comments, remember to thank them for their time and thoughtful comments** (Reviewers for scientific journals are usually doing it in an unpaid, voluntary way in their personal time, so appreciate the time they took to read your paper, and help you make it better).
    o Avoid getting into an argument with the reviewers. Reviewers are human so they may have missed something in your article, or didn't understand something. If it's a misunderstanding, consider rephrasing what you wrote to better explain.
    o If you cannot address a comment, state that you cannot address it, and explain why.
· Keep "Track Changes On" in word so the reviewers can easily see what you changed.
· Often journals will ask for a clean copy as well as a track changes copy of the manuscript.
· Write re resubmission cover letter

Once you get accepted:

·   Read the email for the next steps, and keep an eye on your email for further communications from the journal

·   Tell you co-authors, and congratulate the team, and thank everyone for their contribution

·   You will likely have to pay the article publishing fees at this point, if there are fees.

·   You may have to sign copyright forms.

·   **You will receive proofs** – this is your last chance to make corrections to your article, so read them carefully. **The turn-around time for proofs is typically 48 hours.** Send the proofs to all co-authors, and ask them to check names, and affiliations again. **Tell the team members the necessary turnaround time.**

Once available online, promote your article on Social Media and share with the residency program!

Choosing a Journal for Your Publication

Section Contributors
John Psonis

Choosing a journal for publication is a complicated process. It's always a good idea to consult with your colleagues and mentors for guidance regarding your specific situation. Your mentor will have a lot more experience publishing and will be able to provide insight into how to weigh different factors in the selection process and recommend the most appropriate journals for your study. Watch this video from The Levy Library ▶️ Journal Selection: Tips and Tools or continue reading below.

Typically, it is a good idea to identify a few journals that would be a good fit for your scholarly work. Work with your mentor to rank them in order of preference, so if your work gets rejected by your top choice, you can quickly reformat as needed, and resubmit to the next journal choice on your list.

Journal selection can greatly affect the reach and significance of your work. Various factors should be considered, such as the goals of your research, the journal's impact factor, the target audience, the availability of open access, the rejection rate, the time to publication and publication cost. In this chapter, we will provide a step-by-step guide on how to navigate the process. Online tools including PubsHub and Jane can help you identify appropriate journals. Access these tools through The Levy Library: [Home - Journal Selection and Identification - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)

Step 1	Identify the goals of your research
Step 2	Research potential journals
Step 3	Evaluate the scientific rigor of the journal
Step 4	Evaluate the open access options
Step 5	Evaluate the impact factor
Step 6	Consider the rejection rate and time to publication
Step 7	Evaluate the publication fees
Step 8	Consider preprint servers

Step 1: Identify the goals of your research

Consider the main question or problem you are trying to address and what you hope to achieve through your study. This will help you to define the scope and focus of your research, which will in turn help you select a journal that aligns with your goals.
If your research is focused on a specific field, you may want to prioritize a journal that specializes in that area. This will increase the chances of your work being read by experts in your field and cited by other researchers. In contrast, if your research has the potential to make a significant impact across many fields, you may want to consider submitting it to a general high-impact journal. These journals have a broad audience, which increases the visibility of your work and may lead to citations by a wider range of researchers.

Step 2: Research potential journals

Once you have identified the goals of your research, start researching potential journals. Quality journals should be indexed in major bibliographic and citation databases, such as MEDLINE, Elsevier Scopus and EMBASE, Clarivate Analytics Web of Science, Cumulative Index for Allied and Health Literature (CINAHL), and others. MEDLINE, for example, has strict scientific and editorial criteria for journals selected for indexing and MEDLINE indexing status is considered a strong indicator of quality.

When searching for potential journals, consider the following:
- The topics the journal publishes. For example, if it is clinical, target a clinical journal; if it is basic research, target a journal that publishes basic research. You can also use databases such as Master Journal List or Journal / Author Name Estimator to search for journals by topic or keyword.
- The journal's audience. Will researchers in various related fields be interested in your study? If so, a journal that covers a broad range of topics may be best. If only researchers in your field are likely to be interested in reading your study, then a more specialized journal would be more ideal. You should also consider the level of expertise of the audience, as some journals are geared towards a more general readership while others are more specialized.
- The types of articles the journal publishes. If you are looking to publish a review, case study, clinical trial, or research article, ensure that your target journal accepts these types of manuscripts.

Consider the journals that you have read. You will probably already be familiar with published studies that have a similar focus to yours. Which journal were those studies published in? The same journals are likely to be appropriate for your manuscript.
If you need more journals to consider, you can do literature searches for other published articles in your field that are similar in scope and impact on the field, and check where they were published.

Once you have listed several potential choices, review each journal's "Aims and Scope" section, even if you are familiar with the journal. The "Aims and Scope" section of a journal is written by the editor. It's a description of the type of content published by the journal and often includes information on the peer review process and open access options for that journal.

Step 3: Evaluate the scientific rigor of the journal

The scientific rigor of the studies published in the journal is a key indicator of journal quality. When considering a specific journal, you can briefly review the publications published in the last few years and assess details such as the purpose of the research, design and methodology, analysis, results, discussion. Are the tables and figures clearly marked, legible, and appropriate for the data? Are the references comprehensive and current?
Editorial quality (misspellings, grammar and punctuation errors, lack of clarity and cohesiveness) can also provide clues about the journal quality.
You can also review the protocols the journal uses to ensure scientific rigor during the peer review process (e.g. plagiarism detection tools, statistical testing to confirm data validity, tools to detect image manipulation). A reputable journal will fully disclose the peer review process (reviewer selection, criteria used, time frames etc.) and will include information on ethics (conflicts of interest, IRB approval, informed consent, human and animal subject research, confidentiality, fraud, etc.)
In addition, high quality clinical research journals require the use of standardized guidelines for reporting of research, such as CONSORT, PRISMA, STROBE, which enhance the quality and reproducibility of the research. The following link provides a simple flow chart to guide researchers in selecting the most appropriate reporting guidelines for their study: [Selecting the appropriate reporting guideline for your article | EQUATOR Network](#).
Transparency of policies for data sharing is another factor to consider when assessing scientific rigor.

[Step 4: Evaluate the open access options](#)

Open access (OA) journals make their articles freely available to the public, which can be beneficial for researchers who want to increase the visibility and impact of their work. Open access journals can help to ensure that your research is accessible to a wider audience, including those who might not have access to a traditional subscription-based journal. These journals, however, often have higher publication fees than traditional journals. There are also "hybrid" open access journals (e.g. PNAS), that allow authors to pay an "open access fee" to ensure free access to their article. Many OA journals also advertise a much more rapid publication process. Some researchers are reluctant to publish in open access journals because they may not be as well-known as some more established journals in the field. Many OA journals are newer and have not yet received their first impact factor score. You should also beware of predatory open access journals, which charge large publication fees without offering the rigorous editorial, peer review, and publishing services outlined in step 2.

Step 5: Evaluate the impact factor

The Journal of Citation Reports (JCR) Impact factor score is calculated for indexed journals in the [WoS Journal Info](), Scopus databases and PubsHub ([Home - Journal Selection and Identification - Levy Library Guides at Icahn School of Medicine at Mount Sinai]()) is based on the number of citations the average publication in the journal has garnered within a specific timeframe. High impact factor journals are generally considered to be more prestigious and have a wider readership. However, it is important to note that impact factor should not be the only factor considered when selecting a journal. Some journals with lower impact factors may still be a good fit for your research.

Step 6: Consider the rejection rate and time to publication

Rejection rate is the percentage of submissions that are rejected by a journal. Higher rejection rates may indicate that the journal is more selective and prestigious, but also suggest that it might be more difficult to get your paper published. It is important to balance the prestige and visibility of a journal with the likelihood of acceptance.
Consider the time it takes for a journal to publish articles. The average turnaround time from submission to publication is typically found on the journal's website, but you can also contact the editor. Some journals have a longer, more rigorous peer-review process and may take longer to publish articles, as is often the case with high impact factor, reputable journals. If time is of the essence, it may be beneficial to choose a journal with a shorter peer-review process. Finally, be sure to carefully review the specific guidelines and requirements (e.g format, length) the journal may have for submissions, as these can also impact the turnaround time.

[Step 7: Evaluate the publication fees]()

Some journals charge publication fees, known as article processing charges (APCs). This can be a significant expense for researchers, especially for those who are not funded. It is important to consider the cost of publication when selecting a journal. In addition, consider the value the journal provides in return for the fees they charge (reach and visibility of publication, prestige of the journal, promotion of the article, editing services).

Step 8: Consider preprint servers

You can also consider submitting your research article to a preprint server such as medRxiv or bioRxiv. These servers are not indexed in Pubmed and preprint articles are not considered official publications. These platforms allow researchers to share their work before it is peer-reviewed and published in a journal. This can be a great way to get feedback on your research and increase its visibility. In addition, "getting the results out there" as quickly as possible prior to peer review, allows researchers to build off of each other's work, accelerating innovation. Preprint articles can also be listed as references in a CV or grant proposal, enabling access to unpublished-but-nearly-complete work by prospective employers or grant reviewers.

Keep in mind that articles posted on medRxiv or bioRxiv are date-stamped. If your article is subsequently declined for review by multiple journals and then resubmitted to another journal, the editor will have access to the preprint date stamp and may infer that your manuscript has already been rejected by other journals. In addition, the preprint version of your manuscript would have likely been formatted for a particular journal, so the editor evaluating a later version may be able to identify where the manuscript was originally submitted.

Preprint servers also keep track of usage metrics (e.g. how many times the manuscript has been accessed online). Journal editors will have access to these metrics and may wonder whether they would correlate with the eventual citation rates for the final published forms of the preprints.

Be aware that submitting to more than one journal simultaneously is a breach of publishing ethics. If your paper is rejected, you can resubmit to another journal or opt to transfer your paper within the same publisher. A good editorial team should be able to advise on these matters at the time of submitting.

References

- Suiter AM, Sarli CC. Selecting a Journal for Publication: Criteria to Consider. Mo Med. 2019 Nov-Dec;116(6):461-465. PMID: 31911720
- Masten Y, Ashcraft A. Due diligence in the open-access explosion era: choosing a reputable journal for publication. FEMS Microbiol Lett. 2017 Nov 15;364(21):fnx206. PMID: 29040536
- Ioannidis JPA, Thombs BD. A user's guide to inflated and manipulated impact factors. *Eur J Clin Invest.* 2019 Sep;49(9):e13151. PMID: 31206647
- Struthers C, Harwood J, de Beyer JA, Dhiman P, Logullo P, Schlüssel M. GoodReports: developing a website to help health researchers find and use reporting guidelines. BMC Med Res Methodol. 2021 Oct 17;21(1):217. PMID: 34657590
- Fry NK, Marshall H, Mellins-Cohen T. In praise of preprints. Microb Genom. 2019 Apr;5(4):e000259. PMID: 30938670

Finding a Journal with No Publication Fees / Article Processing Charges

Section Contributors
Emily J. Gallagher

There are two resources that can help you identify journals with low / no article processing charges.

For Open Access Journals:
The Directory of Open Access Journals (DOAJ) is a resource to identify open access journals with no publication fees / article processing charges.

To find an open access journal with no charges go to

www.DOAJ.org

With "Journals" selected, type in your area of interest.
[Note that the search results are quite specific for the term typed in (e.g. "case report" yielded no results, but "case reports" identified 14 journals when tested)].

Then on the left click "Without Fees"

You can also select "English' under Languages on the left of the webpage.

As a first review, you could consider looking through the list for journals published in the United States.

Secondly, recommend checking if the journal is indexed in pubmed.
https://www.ncbi.nlm.nih.gov/pmc/journals/

Then check the "author guidelines" on the journal website to see if there are any caveats to publishing for free
(e.g. the American College of Gastroenterology ACG Case Reports journal charges $500 for publications for non-members, but is free for members. The cost of trainee membership to ACG is $25 as of June 2023).

Next, check the journal impact factor on Web of Science
WoS Journal Info

Discuss with your mentor the available journal options

For All Journals:
Go to PubsHub - note PubsHub is subscription based and needs to be accessed through The Levy Library. [Home - Journal Selection and Identification - Levy Library Guides at Icahn School of Medicine at Mount Sinai](#)

Once in PubsHub you can search on the left for the area of interest (e.g. Diabetes).

Under "Guidelines" on the left you can click yes to "Accepts Case Reports" if submitting a case report.

You can also click "No" to Submission Fees (This is not the same as Publication Fees / Article Processing Charges).

You can sort by Impact Factor, and then click on the various journals.

When you click on a specific journal, you can click on the journal website author guidelines (top left of the window that will open). Then search the journal webpage for the word "charge" or "fee" and you will quickly find if the journal charges publication fees.

Chapter 9:

The Department of Medicine Research Day and External Conferences

Chapter Contributors
Sophia Golec, Emily J. Gallagher

The Department of Medicine Research Day

Every year in the Spring the Mount Sinai Department of Medicine holds its Research Day.

It is an opportunity to bring together all of the trainees from the Department of Medicine and its Divisions to share the broad range of research activities being done.

All residents (especially graduating residents, and those who will be applying for fellowships in the Summer) are strongly encouraged to submit their research to highlight their residency scholarly activities. It is also an opportunity to learn about the research going on in the Divisions, and to meet faculty you may not typically interact with on your clinical rotations.

The 2023 Department of Medicine Research Day was held on May 15th / 16th

2023: Abstracts are available online on Case Hippo:
https://casehippo.com/spa/courses/resource/department-of-medicine-research-day-2023/event/home

2022: https://casehippo.com/spa/courses/resource/research-day-2022/event/home/posters

2021: Canceled due to SARS-CoV-2

Getting the Most out of Going to a Conference when Preparing for Fellowship Applications

There are many benefits to attending an academic conference. Not only are they opportunities to learn, but also opportunities to meet people.

If you are thinking about your fellowship application and you are going to a conference, do your best to interact with people from programs you would be interested in matching at for fellowship.

As interviews will likely continue to be virtual, connecting with people at conferences can be a way to talk less formally with faculty or fellows from programs that interest you.

The below referenced article was primarily written for scientists, but contains some excellent tips on ways to meet people at academic conferences.

" Read the agenda in advance and consider what you can get out of different types of sessions. **Poster sessions** are optimal because people are waiting for their posters to talk with you. Target posters presented by people in organizations that you would like to learn about, and perhaps work in."

"Attend special interest sessions. Large conferences can be intimidating, but smaller groups meeting around a discrete theme are usually more relaxed, so it's easier to make a connection. Join in the evening social events, and sit with people you don't know."

More details in the article, and additional ideas especially for those who are more introverted.

Reference:
Opportunities Come Through People
https://www.science.org/content/article/opportunities-come-through-people, last accessed April 18th, 2023.

Chapter 10:

Becoming a Physician-Scientist

Chapter Contributors
Fiona Desland, Kirk N. Campbell

Becoming a Physician-Scientist:

Career paths:
A physician-scientist is a clinician who has also trained in discerning the literature and designing/conducting studies that improve patient care. The scope of the research they can conduct is broad and not limited only to basic bench work – including a focus on translational, purely clinical, epidemiological, quality improvement, or health equity studies. Physician-scientists are in a unique position to directly observe patient outcomes, identify gaps for advancing patient care, and develop interventions that specifically address those needs. Therefore, in addition to delivering already evidence-based standardized care, physician-scientists also specialize in discovery and implementation of novel therapies.

Typically, physician-scientists practice in academia but can also find positions in and/or collaborate with governmental agencies, biotechnology companies, or pharmaceutical companies. Lastly, in addition to their clinical and research duties, their roles also can include standard typical administrative, educational, and mentoring duties.

> Science. 2013 Oct 16. doi: 10.1126/science.caredit.a1300227. Finding Nirvana: Paths to Becoming a Physician-Scientist.
> https://www.science.org/content/article/finding-nirvana-paths-becoming-physician-scientist

Importance of mentors and advisors:
Building long lasting relationships with mentors is important for building confidence in young physician-scientists while also furthering their careers. It's important to understand that one mentor may not be able to fulfill all your mentoring needs, and that it is okay to branch out and seek different faculty who are willing and able to provide professional, personal, or financial guidance during the different stages of your career development. These relationships set one up for success, as they provide not only intellectual and networking resources, but also often physical laboratory and/or staffing infrastructure while transitioning into independence.

The search for mentors can happen through many modes. One is via reaching out to "near peers" – i.e., senior residents, fellows, and junior faculty. This type of mentoring has the benefit of the mentor being in closer proximity in age, mindset, and career stage – easing

approachability and relatability, as well as increasing the likelihood their career advice is more relevant and applicable to the current state of the research field one wants to enter.

More practically, finding potential mentors can occur organically through working with faculty during floor rotations, electives, via preparing for JAR/SAR presentations, or attending Grand Rounds lectures. These introductions can also occur more deliberately through attending new faculty spot-light seminars or organized departmental or conference mixers.

Consult Psychol J. 2019 September; 71(3): 141–160. doi:10.1037/cpb0000124. Transformation to Academic Leadership: The Role of Mentorship and Executive Coaching

JCI Insight. 2018 Dec 6;3(23):e125651. doi: 10.1172/jci.insight.125651. Training the physician-scientist: views from program directors and aspiring young investigators

JAMA. 2006 Sep 6;296(9):1103-15. doi: 10.1001/jama.296.9.1103. Mentoring in academic medicine: a systematic review

Collaboration is key in the current research climate given all the moving parts required to design, get approval for, recruit patients or gather samples, physically run experiments, and analyze data. The ever-increasing acquisition of vast datasets also makes it impossible for "lone-ranger" investigation to occur, as no one person can fulfill all the above roles. Furthermore, the types of complex questions being asked by physician-scientists regularly require large collaborative teams (across multiple labs, institutions, and often nations) to execute studies with robust enough statistical power to actually shift the standard of care.

When looking for a team to join, one must consider not only your interest in the questions being asked, but also about the existing group dynamic.

J Investig Med. 2012 June ; 60(5): 768–775. doi:10.231/JIM.0b013e318250871d. Collaboration and Team Science: From Theory to Practice

J Clin. Invest. 2021 Jan 19;131(2):e145964. doi: 10.1172/JCI145964. Pushing the boundaries with collision collaboration: the marriage of ideas

Understanding Grant-Speak for Fellowship Interviews and Career Development

Section Contributors
Sophia Golec, Emily J. Gallagher

If you are applying for a fellowship in a highly academic program, there is a chance that you will encounter a collection of jargon you may not be familiar with.

Here is a list of confusing acronyms that you may come across, to help you understand and navigate these conversations:

Related to Grant Applications:
1. "RFA" = Request for applications – this is an announcement from a funding agency that announces and solicits grant applications related to a specific topic.
2. "FOA" = Funding Opportunity Announcement – this is a notice from a funding agency that invites grant applications within a specific subject or field.
3. "GCO" = Grants and Contracts Office - this is the department at Mount Sinai that oversees all grant applications.

The People Involved:
1. "PI" = Principal Investigator – this is the lead researcher (typically the faculty mentor, however if you submit an application for funding as a resident you will be the PI)
2. "Co-PI" = Co-Principal Investigator – this is an equal collaborator with the PI on a study.
3. "MPI" = Multiple Principal Investigators – this is when there is more than one PI on the study.
4. "Late Bloomer" = A term sometimes used to describe trainees who became interested in research during residency or fellowship years, and did not complete a PhD or MS during or before medical school.

Training Programs:
1. "MSTP" = Medical Scientist Training Program - this a dual MD-PhD granting medical school program that is funded by the National Institutes of Health (NIH).
2. "PSTP" = Postgraduate Physician Scientist Training Program - in contrast to MSTPs, PSTPs are currently not NIH funded programs. The term PSTP is frequently used to describe certain training pathways for physician-scientists, such as the combined residency and fellowship training and mentorship within the American Board of Internal Medicine (ABIM) Research Pathway; however there is no universally agreed upon definition.

Funding Agencies:
1. "NIH" = National Institutes of Health – this is the largest funding agency for research in the US.

a.   In 2023, the NIH is made up of 27 Institutes and centers that all have acronyms. See here for details https://www.nih.gov/institutes-nih/list-institutes-centers

2.   "DoD" = Department of Defense – also one of the largest research funders in the US.

3.   "Federal" = Funding from the federal government of the US – including the National Institutes of Health, the Department of Defense, the National Science Foundation, and Veterans Affairs funding.

4.   "Non-Federal" = this can be Foundation (e.g. American Cancer Society, American Diabetes Association, American Heart Association) typically non-profit societies that fund research, or for profit (e.g. pharmaceutical companies) that fund research.

Types of Research:

1.   "IIR" = Investigator Initiated Research – this is a term often used by pharmaceutical companies, where the research proposal is conceptualized, initiated, and conducted by the researcher (external to the pharmaceutical company).

2.   "IIT" = Investigator Initiated Trial – similar to IIR, except it relates specifically to a clinical trial.

Types of NIH Grants to individuals:

1.   "R01" – This is a type of Research Project Grant. This type of grant is typically awarded to faculty – for physician-scientists, an R01 is a sign of research independence.

2.   "K Award" – A K award is a Career Development Award – it is typically awarded to a senior fellow or junior faculty member. Physicians typically apply for K08, K23, or K99/R00 awards. The definition of these specific K awards unfortunately differs by NIH institute, so it is wise to discuss with the Department of Medicine physician-scientist training leadership to know what is the right fit for you.

3.   "F Award" – An F award is a Fellowship Award, an F32 can fund your research during fellowship. There are other types of F awards for graduate students.

4. "LRP" - Loan Repayment Programs - grants from the NIH that help repay loans. See: NIH Loan Repayment Programs

Institutional NIH Funded Training Awards:

1.   "T32" – This is a type of training grant that is awarded to a department or division within an institution and is used to provide salary support for trainees in the field that is covered by the scope of the grant.

2.   "R38" or "StaRR" Program – This is a type of training grant that is awarded to a department (e.g. Department of Medicine) that provides salary support and dedicated research career development for residents (and sometimes fellows) to gain meaningful experiences in research. A "K38" is the equivalent of an "F32" that is exclusively available to residents who have trained in the R38 pathway.

Writing Grants – NIH Terminology:

1. "Specific Aims" – This is a one page document that is included with any NIH grant application – It essentially is an elevator pitch of your grant idea with a brief background, hypothesis, and includes typically 2-4 (often 3) Specific Aims, in addition to possibly brief methods, and a significance / impact statement to explain how the successful completion of the aims will advance the field.

2. "Significance" – This is a description of the importance of your research question, and should also include any weakness or gaps in knowledge from prior research.

3. "Innovation" – This is a description of conceptual or technology innovation (or novelty) of the proposal.

4. "Approach" – This is a detailed description of the methods you will use to achieve your aims.

Grant Scores and Reviews

1. "Study Section" – This is a group of experts in the field who will review your grant application.

2. "Impact Scores" – During the grant review process the Study Section faculty will assign a score between 1-9 to your application. 1 is the highest score (most impactful), 9 is the lowest score (least impactful). The scores are multiplied by 10, and averaged from all reviewers. The final score an application will receive is between 10 and 90. Typically an impact score of <20 will almost certainly be funded, <30 has a high chance of being funded.

3. "Percentile score" – This score is based on the impact score, and ranking all the grants reviewed within a specific Study Section, or review area. Lower percentiles are better. Funding typically is decided upon related to the Impact Scores and Percentile.

4. "Triaged" or "Not Discussed" – These are terms that are attributed to grants that are not discussed at the Study Section meeting. They were the grants that received lower scores when they were scored by the individual grant reviewers.

5. "Summary Statement" (occasionally referred to as "Pink Sheets") – This document is the feedback provided to the PI or MPIs from the Study Section based on the reviews +/- discussion of the grant. "Pink Sheet" is a colloquial phrase used to reference a time when the reviews would arrive in the mail as a carbon paper copy.

Applying for Research Grants and Awards During Residency

Research Awards:
Research awards are given each year at the [Department of Medicine Research Day](#) for top scoring abstracts.

The most common types of external research award received by residents are travel awards, or trainee abstract awards for abstract submissions to academic conferences. When submitting your abstract to a conference, read the details regarding trainee awards and make sure to indicate what type of award you are eligible to receive.

Grants for Residents:
A small number of research grants are available to residents.

Internal (Icahn School of Medicine at Mount Sinai) research grants are occasionally available to residents and their mentors. The notifications for these opportunities are typically distributed by email. Read the instructions carefully. If you are unsure if you qualify to apply, reach out to your APD for Research, or research mentor to discuss.

As residency is typically heavily focused on clinical training, there are a limited number of external grants available to residents.
Some grants to residents are available through:
1. American Alliance of Academic Internal Medicine (AAIM) Innovation Grants:
   [Resources - AAIM](#)

2. American Hematology Society Honors Awards:
   [Medical Student, Resident, Graduate Student Awards - Hematology.org](#)

3. Department of Defense Grants:
   [I. OVERVIEW OF THE FUNDING OPPORTUNITY Peer Reviewed Cancer Research Program Career Development Award](#)
   Typically to apply for these grants, your mentor will need to be a federally funded investigator.

4. Rheumatology Research Foundation, Resident Research Preceptorship:
   [Medical Preceptorships | Rheumatology Research Foundation](#)

How to apply for an external grant:
- All external grant applications need to be submitted through the Mount Sinai Grants and Contracts Office (GCO) that requires a minimum of five working days to review the submission.
- The grant application will also need to be uploaded through InfoEd and all documents will need to be reviewed by the residency administration.

- Plan any external grant submissions well in advance with your mentor, and notify your residency program leadership and administrative team that you intend to apply.

Appendix: Feedback, Input and Suggestions

The Research Toolkit was created by residents and faculty for residents.

This is a live document, if you would like to contribute content or provide suggestions to enhance this group endeavor, please provide your input in this feedback form.
https://forms.office.com/r/sVJSDdUtKP