UNIVERSITY OF MINNESOTA
Driven to Discover℠

Department of
Obstetrics and Gynecology

Fellow & New Faculty Research Handbook

Research Council

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How do I accomplish research at the University?

This handbook will outline the process by which you can take a research idea and turn it into a study that results in a published manuscript. The first step is generating an idea – which does not appear to be a problem for faculty in my experience. The difficult step is knowing how to navigate the research process and stick to a timeline in the midst of other demands. Reach out to your mentor(s) for guidance and rely on students, residents, and fellows to help complete tasks. There is a learning curve but you will be an expert soon enough!

Here is a general checklist and timeline for completing your project in an 18 month time frame assuming 1-2 hours of dedicated time per week and assistance from a student/resident/fellow for data collection. This timeline will vary quite significantly based on your particular research question and study design.

Months 1-2	☐ Generate list of possible research ideas ☐ Perform preliminary literature search to confirm numerous studies on this subject have not already been completed. Generate an annotated bibliography containing published studies relevant to the research question. Create the bibliography using a software program for managing references, such as Endnote. ☐ Identify residents or fellows interested in participating in study. Secure an agreement from a resident or fellow who is willing (and excited) to work on the project with you.
Month 3	☐ Write your hypothesis and the specific aims you will accomplish to test the hypothesis. ☐ Meet with mentor/Co-Investigators to discuss and approve the hypothesis and specific aims ☐ Meet with statistician to discuss study design. Decide on critical sample numbers that will be required to produce statistically significant results.
Month 4	☐ Write a study protocol that includes details of all the methods you will use in your study ☐ Submit your protocol to the IRB following IRB guidelines (Note, this must be done whether or not your study needs IRB approval). If you are using an animal model you will also need to submit your protocol to IACUC (Institutional Animal Care and Use Committee) following IACUC guidelines.
Month 5	☐ Create data collection tool (Excel file, REDCap database) ☐ Share tool with mentor/Co-Investigators/ statistician for feedback
Months 6-12	☐ Respond to all IRB stipulations and obtain IRB approval ☐ Collect your data (consider utilizing student/resident/fellow in this process) ☐ Select target journal(s) and review formatting requirements. Write a draft introduction and methods sections of manuscript

Month 13	☐ Review data for inconsistencies, missing data ☐ Meet with statistician to review data and discuss analysis plan
Month 14	☐ Analyze the data using a statistician or following instructions from a statistician
Month 15	☐ Complete a draft of the entire manuscript including: Intro, materials & methods, results and discussion. This should include all figures, tables, and any supplementary material. Write the draft using the formatting requirements of the journal you have chosen for submission.
Month 16	☐ Send draft to mentor, co-investigators and your statistician for review and include a deadline for when you want their comments. ☐ Re-write draft incorporating all comments from mentor/Co-Investigators/statistician
Month 17	☐ Send re-written semi-final draft to all authors for review and approval and include a deadline for comments ☐ Write a final draft
Month 18	☐ Submit final draft to journal

Study Protocol

All studies prospectively enrolling participants/patients need to have a study protocol. The purpose of a protocol is two-fold. First, the University will use the protocol to confirm the study concept and design is scientifically relevant and appropriate and second, all members of the study team will be on the same page regarding study methods and execution.

The IRB (http://www.irb.umn.edu/forms.html) and Cancer Protocol Review Committee (http://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-commitee) provide templates to help get you started.

The following components should be included in your protocol:

1. Study Synopsis
    a. A brief 1 page overview of the summary – including design, objectives, patient population, study procedure overview (maybe diagrammatic), planned enrollment and timeframe. The goal is to provide the reader with a good overview for the study, but not necessarily a free-standing representation of the protocol.
2. Study Hypotheses/Aims or Objectives
3. Background
    a. This section should discuss the problem under study and supporting background information for the proposed study with references. Not to exceed 2 - 3 pages
4. Summary and Rationale
    a. Brief summary of why this study is important to a better understanding of the problem under study – 1 paragraph is sufficient, but may be longer.
5. Study Design
    a. Overview of the study similar to the synopsis – gives the reader a concise overview and flow of study procedures (especially if complicated). Use tables or bullet points if possible.
6. Participant Selection
    a. Modify the following paragraph to fit study enrollment
        i. Study entry is open to persons (adults, children) of xx years of age regardless of gender or ethnic background. While there will be every effort to seek out and include females and minority patients, the participant population is dependent upon the (targeted disease or condition of the study) population at the University of Minnesota or where enrollment is occurring.
    b. Inclusion Criteria
    c. Exclusion Criteria
7. Participant Registration
    a. EXAMPLE - Registration will occur after the subject consent is signed and eligibility is confirmed, but before any study samples are collected. To be eligible for registration to this study, the participant must meet each criteria listed on the eligibility checklist.
    b. IF you are conducting a Cancer-related study, participants must be registered using OnCore or REDCap.
8. Study Procedures
    a. Have a separate section for each major study step if complicated or different between patients and controls – use tables or diagrams whenever possible instead of text. Add sections as needed for clarity specific to the project
    b. Clinical Data Collection / EHR review

9. Risks of Study Participation
10. Duration of Study Participation
11. Adverse Event Reporting
12. Study Data Collection and Monitoring
    a. Data Management
    b. Data and Safety Monitoring Plan (DSMP)
    c. Record Retention
13. Statistical Considerations
    a. To be written by the study statistician
14. Conduct of the Study
    a. Good Clinical Practice
        i. The study will be conducted in accordance with the appropriate regulatory requirement(s). Essential clinical documents will be maintained to demonstrate the validity of the study and the integrity of the data collected. Master files should be established at the beginning of the study, maintained for the duration of the study and retained according to the appropriate regulations.
    b. Ethical Considerations
        i. The study will be conducted in accordance with ethical principles founded in the Declaration of Helsinki. The IRB will review all appropriate study documentation in order to safeguard the rights, safety and well-being of the patients. The study will only be conducted at sites where IRB approval has been obtained. The protocol, consent, written information given to the patients, safety updates, annual progress reports, and any revisions to these documents will be provided to the IRB by the investigator.
    c. Informed Consent
        i. All potential study participants will be given a copy of the IRB-approved consent to review. The investigator or designee will explain all aspects of the study in lay language and answer all questions regarding the study. If the participant decides to participate in the study, he/she will be asked to sign and date the consent document. Patients who refuse to participate or who withdraw from the study will be treated without prejudice.
15. References

Scientific Review

Cancer-related study – Reviewed by the Cancer Center Protocol Review (CPRC) committees

- Medical Chart Review / Existing Data: application only, administratively reviewed
- Prospective study: submit application, protocol for CPRC committee review prior to IRB

*See **http://www.cancer.umn.edu/clinical-trials/cancer-protocol-review-commitee/** for applications and protocol templates*

Not-cancer related study:

- Medical Chart Review / Existing Data: no scientific review, IRB only
- Prospective study: submit protocol for review by OB/GYN research council prior to IRB

Examples of OB/GYN reviewed and approved protocols are available on the server: S:\OBGYN_Share\Research\Examples of Protocols and IRB Applications

IRB Application Process

What is the purpose of the IRB?
The IRB reviews research projects which involve human subjects to ensure that two broad standards are upheld: first, that subjects are not placed at undue risk; second, that they give un-coerced, informed consent to their participation. The IRB considers a number of basic criteria:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each prospective participant or legally authorized representative, and properly documented
- Adequate preparation is taken to protect the privacy and confidentiality of subjects
- Adequate provisions are made for the ongoing monitoring of the subjects' welfare

They will confirm that all investigators and staff included on the project, including medical students and residents, have completed the appropriate HIPAA and CITI human subjects or similar training. See the training page on the IRB website for more information.

How does the process work?
A project is first reviewed in its proposal stage, before subjects are recruited. This process may take 2-6 months depending on the complexity of the study and participant involvement.

Each approved project is reevaluated at least annually. The IRB works with investigators to modify projects to ensure adequate protection for its subjects' welfare and right of self-determination. Any changes after initial approval to the study design, surveys, consent, etc. must be approved by the IRB before being implemented.

What locations are covered by the University of Minnesota IRB?
The IRB at the University of Minnesota is charged with reviewing responsibilities for research conducted in the following areas: Minneapolis, St. Paul, Duluth, Morris, & Crookston campuses, Fairview Health Services, and Gillette Children's Specialty Hospital. If you want to conduct your research at a different location (ex. Regions Hospital), you will need to go through their IRB process. This process can be even more time-consuming and should be started early.

How do I get started?
Go to the University of Minnesota's IRB website to get started: www.irb.umn.edu. This website is very detailed and includes the Application forms for each type of project, including medical chart reviews, quality improvement projects, surveys, interventions and clinical trials.

Examples of OB/GYN approved IRB applications are available on the server:
S:\OBGYN_Share\Research\Examples of Protocols and IRB Applications

Be sure to check the version date on the forms as they are regularly updated by the IRB.

Study Design

The design of your study is the most important step as it ultimately dictates whether you can answer your research question. Spending extra time on this step will pay off in the long run.

Where to begin?

After you have decided on a topic and research question, start brainstorming a study hypothesis. The hypothesis is based on a theory you are trying to prove or disprove. Have other studies been done that had hypotheses similar to yours? If so, what were their strengths and weaknesses? Did they leave questions unanswered, or do you want to challenge the outcomes?

Study Designs:

Early studies on a topic of a question may rely on readily available data, such as a case series or secondary analysis of previously collected data. As evidence accumulates, clinical trials are often performed. The hierarchy of evidence by study design is provided in the figure below, along with a description of each type of study.

Hierarchy of Evidence in Human Studies

Case Report, Case Series:
A case report is a detailed account of a single person. Common examples are reports of a new or rare condition, a novel treatment for a condition, or a new or rare adverse effect of a treatment. When several cases are available, a case series may be compiled. Case reports or series are often the first line of evidence for new therapies, but are insufficient to establish treatment efficacy or test a hypothesis. However, they may serve an important role in describing rare occurrences or adverse events.

Cross-sectional Study:
In a cross-sectional study, a group of individuals is assessed at the same time point to determine both the exposure and outcome status. Since exposure and disease are measured at the same time-point, this type of study cannot distinguish whether or not the exposure occurred prior to the disease or if the presence of disease affected an individual's exposure level. Cross-sectional studies are useful to determine the prevalence of a disease in a population (prevalence studies).

Case-Control Study:
For a case-control study, patients who have an outcome or disease of interest and a control (comparison) group of individuals without the disease are selected for study. Controls must be sampled independently of their exposure status. Case-control studies are particularly useful when investigating rare outcomes.

Cohort Study:
Cohort studies are used to study the incidence, course, and risk factors of a disease because they are longitudinal, i.e., the same participants are followed over multiple points in time. In a cohort study, patients are gathered and then classified based on the presence or absence of an exposure. These subjects are then followed over time to determine the development of an outcome in each exposure group. Because prospective population-based cohort studies generally enroll individuals who are initially healthy at recruitment, they are well-suited to study relatively common outcomes which accrue over a reasonable follow-up period. Loss to follow-up is a major limitation, which can alter the validity of the conclusions if the loss is large, or can result in bias if the loss is associated with both the exposure and outcome.

Randomized Controlled Study:
In interventional studies, the researcher assigns the exposure (or treatment) status of each participant and then observes participants over time for the development of an outcome. A randomized controlled trial (RCT) with one treatment group and one non-treatment control group is well-known, though several other designs are also used. When participants are randomized, treated, and evaluated in a blinded fashion, these studies are generally considered to provide the most reliable evidence, as on average, all other factors that could affect disease risk (known and unknown) are randomly assigned and by chance should be equally distributed between the intervention and control groups, particularly as sample sizes are large. While RCTs are preferred, there are instances where randomization is unethical.

Meta-analysis:
A systematic review is a summary of the literature in which explicit methods are used to perform a thorough literature search and critical appraisal of studies to answer a specific clinical question. A meta-analysis is a subtype of systematic review in which statistical methods are used to combine the results of several independent trials addressing the same question. While systematic reviews and meta-analyses are considered as the highest evidence, both are subject to biases, particularly surrounding choice of study inclusion and publication bias.

Bias:

Bias refers to an unintentional non-random systematic error in the design or conduct of a study. Bias can occur at any phase in a study, from participant selection, study measurements, participant follow-up, or analysis. Some of the more common examples of bias are summarized below (adapted from Ahmed et al., 2013).

Study phase	Examples of bias	Description
Reviewing the literature	Positive-results bias, one-sided reference bias, "hot stuff" bias, online literature bias	These biases can occur when a literature review is not comprehensive (e.g., includes easily available online sources only, or the most current literature) or tends to include results that support a given hypothesis
Specifying and selecting the study sample	Selection bias	Occurs when the choice of study participants leads to bias in the study outcome. The subjects in the sample may not be representative of the population.
	Examples include healthy worker bias, membership bias, volunteer bias and non-responder bias	Persons who volunteer to participate in research (compared to non-responders) tend to be interested in health and to be healthier.
Execution of the experiment/ exposure		Involves differences in how the treatment or intervention was carried out, or how subjects were exposed to the factor of interest
	Contamination bias	Occurs when members of the "control" group inadvertently receive the intervention, thus potentially minimizing the difference in outcomes between the experiment groups
	Withdrawal bias	Participants who withdraw from a study systematically differ from those who do not; for example, participants randomized to the control or those who are more ill may drop out at greater rates than other participants
	Compliance bias	Occurs when differences in subject adherence to the treatment regimen or intervention affect study outcomes
Measurement of exposures and outcomes		Issues related to how the outcome of interest was measured
	Instrument bias	Occurs when calibration errors lead to inaccurate measurements being recorded
	Expectation bias (observation or interviewer bias)	Occurs in the absence of blinding, when observers may err in measuring data toward the expected outcome; usually favors the treatment group

Measurement of exposures and outcomes, continued	Recall or memory bias	Occurs when outcomes being measured require subjects to recall past events. People tend to recall positive events more than negative ones. Alternatively, certain subjects may be questioned more vigorously than others, thereby improving their recollections
	Obsequiousness bias	Occurs when participants alter their responses in the direction perceived to be desirable to the researchers
	Information bias	Occurs when inaccurate information about participants in a study or the outcome that is being measured leads to a biased estimate of effect
	Misclassification bias	When participants are misclassified with respect to their exposure or outcome status
	Detection bias	When one group is more likely to have information noted/recorded than the other
Data analysis		Arises from errors in analyzing the data
	Confounding bias	When the estimate of the effect of the exposure is distorted because it is mixed with the effect of a confounding (distorting) factor
	Multiple exposure bias	Failure to adjust for multiple exposures
	Post-hoc analysis bias	Includes post-hoc significance and data dredging biases. Misleading results may occur from post-hoc analyses
Interpretation of analysis		Arises from inference and speculation
	Magnitude bias	When interpreting a finding, the selection of a measurement scale may affect the interpretation
	Significance bias	The confusion of statistical significance with clinical/biological significance
	Correlation bias	Equating correlation with causation
Publishing study results	Publication bias	Bias to publish studies with positive results[i]

Other Considerations

Measurement

Now that a study question exists, think about defining the exact outcome and how it will be measured. How you measure outcome variables depends on your question. It is strongly recommended that regardless of measurement tool used, be it a survey, pain scale, or event frequency, you ensure that the tool has been well studied for precision, accuracy and validity. Utilizing instruments or measurements that have been used in similar studies makes it easier to measure outcomes and draw conclusions.

If you are considering using a survey…

Surveys are often favored for their simplicity, though we advise caution. When possible, use standard answer sets like multiple choice, true/false or Likert scales (ex. Strongly agree, Agree, Disagree, Strongly disagree). Open-ended text cannot be analyzed without extensive knowledge of qualitative methods. If available, previously designed and validated tools are better than designing your own. If you are developing your own survey tool, have a statistician review it to ensure your data will be useful for analysis. Test a new survey on others (colleagues, friends, potential participants) first to find inconsistences. Critically review questions and responses to ensure that your tool will actually give you the information you need to assess your research question.

Study Subjects

Deciding how you will select or recruit for the study's sampling population is of great importance. Limiting bias is of course a major factor. Accessing publically available data, electronic medical records, or relying on other physicians for referrals are all viable options. A captured audience, i.e. hospitalized patients offer easy access, though may result in poor follow-up if the study is for an extended period of time and obtaining consent may be more difficult. Exclusion/Inclusion criteria should be consistent with other published studies. Also, keep in mind who you want to generalize the study to and who your target audience is. This takes you back to the question phase, i.e. what is the significance of the study, who will be effected by the results, how will the results contribute to our medical understanding or public health policy? The more exclusion criteria involved, the less the study will be generalized.

Sample Size

Sample size is important consideration when planning your study. In general, the smaller the sample size, the greater the variability in measurements, and the less likely the findings will reflect the experience of the population. For example, measurement of average height of a sample will be closer to the true average in the population if 1,000 people are measured as opposed to 10 people. In contrast, you likely wouldn't need 1,000,000 people to accurately estimate height. The purpose of calculating a sample size before conducting your study is to ensure you can address your research question appropriately while preserving resources (patients, time, and money).

Data Collection

It is important to carefully consider the data; what information you will collect and how you will collect it. Be thoughtful and deliberate. If you are doing a medical record review, it can be frustrating to go back numerous times to add additional variables. If you do a survey, you are generally unable to go back later to ask extra questions. You also do not want to waste a lot of time collecting data you will not or cannot use.

How do I get started?

- Create a template for data entry:
    - Excel spreadsheets are commonly used, though there are numerous options, including REDCap (see Data Storage section for more details).
        - NOTE: If it is a cancer-related project and you are prospectively enrolling patients, you are required to use REDCap or Oncore for patient registration.
    - Review the literature to make sure you have all relevant demographic and clinical variables for comparisons with similar studies
    - Remove any variables/items you don't intend to summarize or analyze
    - Have your statistician and co-investigators review prior to data collection

- Create a data dictionary:
    - Include the name of each variable and a definition for each. The goal would be that someone else could complete the data collection with the information provided in the data dictionary.
    - Example:

Variable Name	Question/Item	Categories/Scoring	Variable Type
id	Assigned study ID number	Range 1000-1999	Numeric
age	Age at time of surgery	Range 1-100	Numeric
surgeon	Surgeon who performed emergency appendectomy	Anderson Blake Carlson Dudd Everson	Character
considerate	Considerate of other people's feelings	0 = Not True 1 = Somewhat True 2 = Certainly True	Numeric
restless	Restless, overactive, cannot stay still for long	0 = Not True 1 = Somewhat True 2 = Certainly True	Numeric
somatic	Often complains of headaches, stomach-aches or sickness	0 = Not True 1 = Somewhat True 2 = Certainly True	Numeric

- Break up data collection and entry into smaller, manageable pieces. This will reduce the number of errors.

- Follow the tips outlined on the next page to reduce the amount of time needed to reformat the data or the number of questions from the statistician.

TIPS:

1. Name the data file with the date so that updated data sets are apparent.
2. In most cases, the best set-up is 1 row per patient/observation:

Obs_id	Age	Gender
123	52	M
124	19	
125	36	F
126		M
127	43	M
130	29	F

Good

Obs 1		Obs 2		Obs 3
id	123	id	124	etc…
Age	52	Age	19	
Gender	m	Gender		

Bad

3. Make variables names consistent and short.
4. Each observation should be given a unique identifier (obs_id).
5. Remove all identifying information not needed for the analysis.
6. Leave missing data as a blank/empty cell:

Obs_id	Age	Gender
123	52	M
124		
125	36	F
126		M
128		M
129	71	

Good

Obs_id	Age	Gender
123	52	m
124	BLANK	0
125	36	f
126	0	m
128	?	m
129	71	unknown

Bad

Note: Missing and zero are NOT the same.

7. When in doubt, separate information into more columns:

Obs_id	Procedures	Note
123	0	
124	0	
125	1	
126	1	
127	0	
128	3	
129	2	2nd procedure delayed
130	0	

Good

Obs_id	Procedures
123	0
124	0
125	1
126	1
127	0
128	3
129	2, but 2nd procedure delayed
130	0

Bad

8. Be consistent. Saint Paul ≠ St. Paul ≠ ST. PAUL

9. Don't mix numeric and character formats in one variable:

Obs_id	Age	Gender
123	52	M
124	19	
125	36	F
126		M
127	43	M
128		M
129	71	
130	29	F

Good

Obs_id	Age	Gender
123	52	m
124	< 20	0
125	36	f
126	0	m
127	40+	m
128		m
129	Over 70	?
130	29	f

Bad

10. Don't use color coding (or bold, italic, etc.) to flag certain cases unless it is just for your personal use. The statistical software is unable to read this information.

11. Don't include the measurement unit. For example: Height – enter "180" instead of "180cm".

12. When possible, use numeric variables instead of character:

Obs_id	Age	Year_in_program
123	52	1
124	19	3
125	36	2
126	-9	4

Good

Obs_id	Age	Year_in_program
123	52	First year
124	19	Third year
125	36	Second year
126	-9	Fourth year

Bad

13. Consistency is REALLY important for dates. The best format is MM/DD/YYYY (ex. 03/14/2001):

Obs_id	Age	Proc_date
123	52	5/15/1995
124	19	2/12/2001
127	43	6/29/2003
128	-9	11/6/2002
129	71	1/3/1996
130	29	6/18/2000

Good

Obs_id	Age	Proc_date
123	52	5/15/95
124	19	Feb 12, 2001
127	43	6-29-2003
128	-9	2002-11-06
129	71	Early Jan, 96
130	29	June 18, 2000

Bad

Data Analysis

This section will not go into detail on specific statistical tests as it assumes you will work with a statistician. It will cover the process of consulting with a statistician and a few key concepts.

Process for Data Analysis:

1. Look at your data yourself. Look for illogical values or missing data. If you are comfortable with Excel, calculate percentages and means as appropriate.
2. Set up a meeting with your statistician to discuss the analysis plan and issues that came up during data collection. Send the data prior to this meeting to reduce questions later.
3. Allow 2-4 weeks for data analysis. It will likely involve a few iterations.
4. When data analysis is complete, schedule a follow-up meeting with your statistician to discuss your results.
5. Include your statistician in the poster creation, oral presentation development, and manuscript writing processes. They should be given co-authorship in manuscripts and acknowledgement in poster/oral presentations.

Key Concepts:

P-values and Statistical Significance:

Statistical tests of significance (e.g., t-test) quantify the degree to which chance variability may account for the results observed in a study. The P-value is often reported with statistical tests, and represents the probability that an effect at least as extreme as that observed in a particular study could have occurred by chance alone, given that there is truly no relation between the variables (e.g. between exposure and disease).

In medical research, the arbitrarily chosen convention is that a P-value ≤ 0.05 is statistically significant. If a P-value is > 0.05, then by convention, chance cannot be excluded as an explanation for the observations and it is stated that the results are not statistically significant. A P-value outside of the significant range can indicate one of two things: there is no real difference between the sets of data, or the sample size was too small to detect a difference. Thus, the P-value is limited in that it is dependent on the magnitude of the difference between the groups as well as the sample size. Conversely, a small difference (or outcome) may be considered statistically significant if the sample size is large enough, though it may not be clinically meaningful.

Statistical significance **does not** mean:

1) Chance did not play a role in the observed findings
2) The exposure under study is responsible for the observed effect (as confounding variables may be present)
3) The observed findings have biological importance or clinical relevance.

Clinical Significance:

While a finding may be statistically significant, it may not be clinically significant. Clinical significance refers to the practical or applied value or importance of the effect of the findings – that is, whether the findings make real differences to the population being studied.

Statistically significant does not mean that is it important or interesting. Conversely, a result that is not statistically significant may turn out to be very clinically important.

Data Management

De-identifying data

a. **For the latest HIPAA guidelines, view:**
http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html

b. **Identifying Information:**
Information is deemed to be de-identified if all of the following identifiers of the individual or of relatives, employers or household members of the individual are removed, and the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information. Identifying information includes the following:

- Names (including initials)
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code and their equivalent geocodes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census, (1) the geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date and date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of "age 90 or older"
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints
- Full-face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

c. Limited Dataset (for research purposes)

A limited data set is described as health information that excludes certain, listed direct identifiers (see below) but that may include city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. The direct identifiers listed in the Privacy Rule's limited data set provisions apply both to information about the individual and to information about the individual's relatives, employers, or household members. The following identifiers must be removed from health information if the data are to qualify as a limited data set:

- Names
- Postal address information, other than town or city, state, and ZIP Code
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographic images and any comparable images

Summary:

Add a study identifier/ID for each individual and create a separate file for the statistician. Make sure this identifier is included in the original dataset (with identifying information) so if question arise the statistician can send you the study ID and you can go back to the charts, etc. as needed.

DO NOT send data with names, initials, addresses, social security numbers or medical record numbers. Only send data with dates and zip codes (limited data set) if absolutely necessary for the research question(s) [example: survival analysis].

If you have any questions, ask your mentor, statistician and/or contact the IRB.

Data Storage

The University of Minnesota provides numerous options for safe storage of data that are relatively simple to learn and use. These include the Academic Health Center (AHC) servers, Google Drive (when shared using UMN email accounts), Netfiles, and REDCap.

Remember: the safest way to transfer data is to create a fully de-identified data set. Unless that is the case, DO NOT EMAIL data directly to co-investigators or your statistician.

If any identifiers exist, please use one of the following:

- AHC Servers
  - If all parties have access to the Department server, store data on the server only.
- Google Drive
  - Google Drive / Sheets can be used as an alternative to Excel if all parties with whom the document is shared have UMN email accounts (no personal Gmail accounts!)
- Netfiles
  - Netfiles is a University sponsored file storage system. It is in the process of being retired, however, it offers a safe mode of transferring data between parties within and outside of the University. It is similar to Dropbox in function.
- REDCap
  - REDCap is a secure web application designed to support data capture for research. REDCap is ideal when multiple individuals are involved in data entry/collection and/or the data being collected are complex and would benefit from the use of categories and rules/logic.
  - REDCap can be accessed through the University of Minnesota using your x500 at the following website: https://redcap.ahc.umn.edu/. You can grant permission to outside users as well.
  - If you are planning to use REDCap for your study, here is the recommended language for your protocol and IRB:
    - Data for this study will be entered into a REDCap database, which uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by the University of Minnesota Academic Health Center's Information Systems group (AHC-IS). The servers are in a physically secure location on campus and are backed up nightly, with the backups stored in accordance with the AHC-IS retention schedule of daily, weekly, and monthly tapes retained for 1 month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The AHC-IS servers provide a stable, secure, well-maintained, and high-capacity data storage environment, and both REDCap and MySQL are widely-used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the members of the study team by username and password.

Writing an Abstract

An abstract is a brief summary of your research project. Aim for a total of 250-300 words.

Components of a GOOD abstract:

Title
- Clear, intriguing title that summarizes findings

Introduction
- Set-up the problem
- 1-2 sentences that identify gaps in knowledge
- End with the hypothesis or primary objective

Methods
- Short, concise
- Must convince reader you know how to do the work
- Include key phrases (subjects randomized to, controls, confounding)

Results
- Include data (number of patients, etc.), statistical tests and p-values or confidence intervals
- Descriptive statement (only the highest dose showed…)
- *If you haven't completed your study yet, put EXPECTED RESULTS here*

Conclusion
- "We conclude that…" (Relate to hypothesis).
- 1 sentence on future research

Poster Presentations

Standard Poster Format:

- Title
- Author(s), with institutional affiliations and addresses of these institutions
- Abstract
- Introduction/Background
- Methods
- Results
- Conclusion/Discussion
- Strengths/Limitations *(optional)*
- Acknowledgements (include sources of funding including grant numbers and any people or groups that helped complete the project
- References *(optional)*

Drafting Your Poster:

- Use a layout that can be easily followed when you are not standing with your poster. It is helpful to use Background, Methods, Results, and Discussion sections in column format.
- Include overviews of the background that led you to do your study and the methods used in your study.
- Letters when enlarged should be at least ½ inch tall. Tables and figures should be clear and easily seen from a distance of 3-4 feet.
- Proofread your poster.
- Plan at least one or two rounds of revisions with your Mentor.

Printing Your Poster:

- The Department will print your poster for you.
- Allow at least 1 week to print poster before you leave for conference.

Presenting Your Poster:

- Have a one-sentence “hook” that captures the attention of a viewer that stops at your poster.
- If they stay, give an overview of your work in 3-4 minutes.
- Speak clearly and slowly; do not go into too much detail unless asked.
- Give people time to look at the poster; stand to one side but stay in the picture.
- Ask the viewer if they have any questions.

Oral Presentations

Designing Your Presentation

How a presentation is designed has a significant effect on how the information it contains is conveyed, perceived and retained. These tips are intended to help you make the most effective use of presentation technology.

A Presentation is Not a Paper

Pick out the most important and interesting findings in your research, and present that in an entertaining way. Do not overload your presentation with too much information. It is better to leave topics out and present what you do have in a calm and understandable way, than it is to pack in as much as you can and lose your audience along the way.

Slides Should Be Sparse - The 6-6-6 Rule

No more than:

- 6 bullets per slide
- 6 words per bullet
- 6 text slides in a row

In general, maximize the use of images and minimize the use of words. Do not include large tables in small font. Instead, pull out the pertinent information from a table and expand it so the audience can read and follow along with your presentation. Slides should support what you are saying, not be the whole story. Include images, animations, and text on slides that emphasize the point you are making.

Design

Use a simple design and contrasting colors to ensure your audience can read and follow your presentation. For University of Minnesota templates, go to:
https://www.ur.umn.edu/brand/logo-and-template-downloads/presentation-templates/

Final Presentation

Practice Makes Perfect

Do not just write down your presentation, and wait for the big day. Practice it over and over until it flows and is the appropriate length. It is helpful to memorize transition sentences as you move from one slide to the next. It is highly recommended that you practice your presentation in front of a few people, including your mentor, and ask for their feedback.

Tell a Story

If you can convey at least some of what you have to say in a story format, people will be much more likely to listen. Say things like, “We were interested in this topic because…. We decided to investigate further by looking at…. We found that….”

Engage the Audience

Make a conscious effort to look into the audience whenever you get the opportunity.

Manuscript Writing

Writing a paper to disseminate your research can be daunting, but rewarding. The first step is consideration of the target audience. The best way to determine this is by thinking about the study outcomes. What was measured? Who will benefit from the study? Will it impact practice management? Find research publications similar to yours and look at which journals were presenting those studies. Your faculty mentor will be able to help guide you to appropriate journals and venues for your research.

Find the journal's publication requirements: manuscript style, required sections, length, etc. Each will have particular specifications to follow. It can save time later to consider the required format ahead of time.

TIP: Use a reference manager (ex. EndNote or RefWorks) to track your references. The upfront effort will pay off in the long run as you write and edit the manuscript.

General format for manuscripts: Abstract, Introduction, Methods, Results, Discussion

Abstract: The abstract summarizes the major aspects of a paper. It should succinctly summarize the purpose of the paper, the methods used, the major results, and the author's interpretations and conclusions.

Introduction: The introduction includes information the readers needs to understand the rest of the paper. In general this section starts broad and over a few paragraphs leads to the study hypothesis/objective. These are typically 1-3 pages in length; this is highly field and journal dependent.

Methods: The purpose of the section is to make it possible for interested readers to repeat the author's study and reproduce the results. The author must describe in detail exactly what was done. Be careful not to include results in your methods section.
This section may include (as appropriate):

- Study population and recruitment
- Study design/procedures
- Measures
- Statistical Methods

Results: The results section includes the presentation of the key results of the study without interpreting their meaning (i.e. keep the discussion of the results to the discussion section). Include tables and figures as possible, however don't present findings in a table AND re-state everything in the text as well.

Discussion: This section should synthesize the whole paper. The discussion section includes the author's interpretation of results, relating them to previous studies. Do these results agree with what others have shown? If not, how does this experiment differ from others?

Include any study limitations in this section as well. What factors or sources of error might have influenced these results? How could the study be improved to gain further insight?

Finally, it is appropriate to also include what the you and your co-authors consider to be the next step on this research topic.

A great resource to consult when writing and publishing your article is the International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. 2007. Accessed online at: http://www.icmje.org/. This site includes everything you might need to consider regarding your article: publication ethics (such as authorship, sponsorship and accountability), copyright issues, and formatting.

Submission Process:
Most research articles are now submitted using online processes. Once the article has been submitted, it will be reviewed by the Editor. If deemed potentially relevant to the journal, it will be sent to reviewers. Questions, comments, revision requests will be returned or article may be denied. Author(s) have the opportunity to respond to the initial review. The revised version is then resubmitted. The author does not necessarily have to abide by the reviewer's suggestions. The editor of journal then decides whether it will be accepted for publication.

When accepted, the author will be sent "galley proofs" from the copy editor. The author is responsible for reviewing style, flow and typographical errors. Upon completion, the article is then sent back to the journal. Some journals publish articles online prior to their inclusion in the printed journal.

GENERAL TIPS
- Form a writing group to create deadlines and to hold you accountable.
- Review the literature early and often.
- Try to limit the number of projects you are working on and be strategic. Two published manuscripts are better than ten unfinished projects or five drafted papers.

Authorship Guidelines

Why Authorship Matters
Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The International Committee of Medical Journal Editors (ICMJE) has published recommendations regarding criteria for authorship:

Who Is an Author?
The ICMJE recommends that authorship be based on the following 4 criteria (ALL must be met):

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
2. Drafting the work or revising it critically for important intellectual content
3. Final approval of the version to be published
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship include acquisition of funding, technical editing/proofreading, and data collection without any contribution to experimental design or analysis.

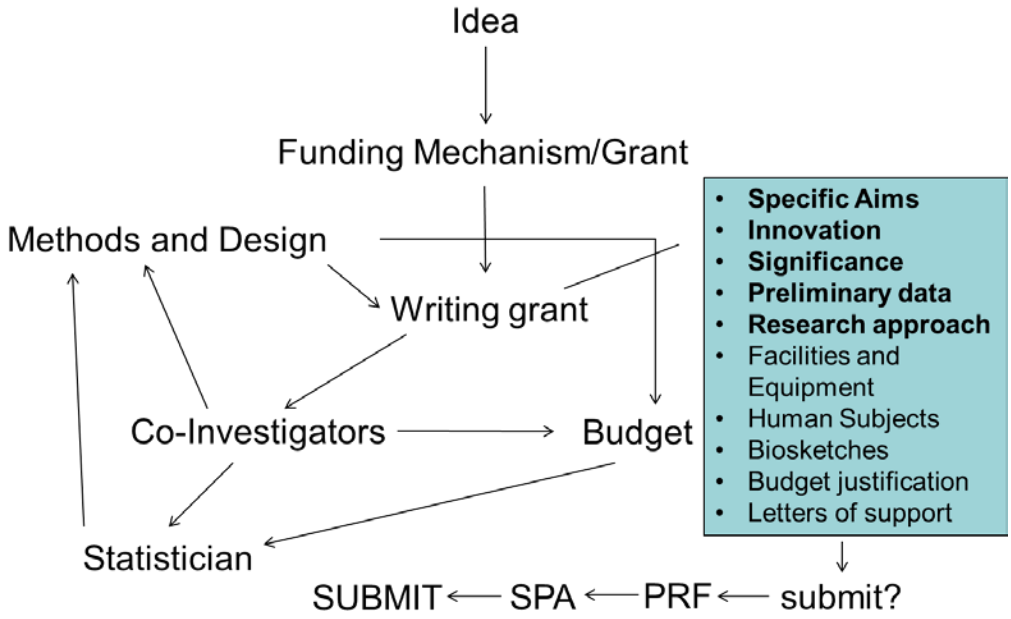
How to Determine Author Order?
Given the number of responsibilities associated with the completion of a research project, there are usually a number of contributors. Ideally conversations about authorship and order are discussed prior to starting a project with explicit details regarding responsibilities, expectations, and intentions for the project. Open communication, understanding, and revisiting of expectations are essential, and provide a basic way to identify any early development of disputes. Discussing authorship at regular intervals or at major developments in the project can help minimize the potential for the development of a disagreement later on in the project.

Typically the first author is the person who not only contributed as an author as defined above but also wrote a large proportion of the manuscript. The position of subsequent authors is usually decided by contribution, alphabetical order, or reverse seniority. In medical literature, the last author position (senior author) is reserved for the mentor, who usually provides the initial idea along with financial support for the project. The senior author sometimes takes responsibility for writing the paper, especially when the research student has not yet learned the skills of scientific writing. In this case, some faculty members still choose to put their students first and others put their own names first. A sensible policy adopted by many is to give the student a fixed period of time to write a reasonably strong draft of the paper. If the student does not deliver, the supervisor may then write the paper and put her or his own name or another faculty member who does write the paper first.

Residents/Fellows: Collecting data and providing a rough outline/draft of a paper without continued participation in the revision process DOES NOT necessarily warrant being first author.

Grant Writing

Grant writing as a Principal Investigator (PI) is a time-consuming and complicated endeavor that requires assistance from many individuals. An ideal timeline for a new grant submission is six months to allow adequate time to develop and refine the specific aims and research approach, determine an appropriate budget, complete multiple rounds of revisions with co-Investigators, and compile and write the additional required documents (see Figure below).



SPA = Sponsored Projects Administration

- Assist faculty in submitting proposals
- Ensure compliance with internal and external requirements
- Manages awarded grants
- All grants (with few exceptions) must be submitted through SPA – submit 3 days prior to official deadline

Notify your administrative staff of plans to submit a grant *ASAP*. OB/GYN contracts with the Department of Pediatrics for grant support and they require notification at least 8 weeks prior to the deadline. Your admin can help you complete their online application for support.

The University of Minnesota provides numerous resources and courses designed to help identify grant opportunities and guide you through the writing and submission process.

- http://www.research.umn.edu/advance/proposal.html#.UrMv6VMlNXt
- http://www.ctsi.umn.edu/apply-for-funding

As a new faculty member, participating as a Co-investigator on grants and working with your mentor to apply for small local grants and training grants are great first steps.

Examples of OB/GYN funded grants are available on the server:
S:\OBGYN_Share\Research\Examples of Successful Grants